COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.	SUPERIOR COURT C.A. No. 1884-cv-01808 (BLS2)
COMMONWEALTH OF MASSACHUSETTS, vs. PURDUE PHARMA, L.P., *et al.*	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT
RUSSELL J. GASDIA'S MOTION TO DISMISS THE FIRST AMENDED COMPLAINT

Dated: April 1, 2019

Juliet A. Davison (BBO# 562289)
Davison Law, LLC
280 Summer Street, 5th Fl.
Boston, MA 02210
(617) 345-9990
juliet@davisonlawllc.com

Julie B. Porter (admitted *pro hac vice*)
SALVATORE PRESCOTT & PORTER, PLLC
1010 Davis Street
Evanston, IL 60201
(312) 283-5711
porter@spplawyers.com

Counsel for Russell J. Gasdia

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes and Rules **Page(s)**

Federal

Massachusetts

Other Jurisdictions

Rules

INTRODUCTION

The Commonwealth added defendant Russell J. Gasdia to this case in December 2018. But it had no legal authority to do so. The Attorney General for the Commonwealth is empowered to bring actions under the Massachusetts Unfair and Deceptive Acts and Practices statute, and to enjoin or abate public nuisances, only when there is ongoing or imminent misconduct. Gasdia retired from Purdue over four years ago. The Commonwealth does not, and could not, allege that he is engaging in any misconduct that this Court can enjoin.

Make no mistake: Gasdia vigorously and completely denies the Commonwealth's unfounded and hyperbolic allegations, which unfairly twist the facts and fundamentally misportray an ethical man of integrity who sought only to do good and to help people. But the issue for today—when, as a matter of law, the Court must take the Commonwealth's allegations as true—is that the Commonwealth has overreached. The Attorney General, on the Commonwealth's behalf, does not have the authority to sue a long-retired employee, and the statute of limitations has also run on the claims that the Commonwealth seeks to bring. Both counts against Gasdia should be dismissed for failure to state a claim, pursuant to Massachusetts Rule of Civil Procedure 12(b)(6).[1]

BACKGROUND

A. Gasdia's sales-and-marketing role was completely over by June 2014

Gasdia worked at Purdue for 29 years. Comp. ¶ 699.[2] He started as a sales representative. *Id.* By 2007, Gasdia was Purdue's Vice President of Sales and Marketing. *Id.* at ¶ 698. Gasdia's

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[1] Gasdia also joins in full in the arguments advanced by Purdue in its March 1, 2019 Motion to Dismiss.

[2] All Complaint citations in this brief are to the First Amended Complaint filed January 31, 2019. Gasdia denies the Commonwealth's allegations. For purposes of this motion, however, he

sales-and-marketing responsibilities at Purdue were completely over by no later than June 2014, when another executive assumed the sales-and-marketing function. *Id.* at ¶ 441. The only allegation concerning Gasdia's post-June 2014 conduct is in paragraph 751, which states:

> In July 2014, in the aftermath of the Butrans launch that Richard Sackler regarded as a failure, the Sacklers removed Gasdia as Sales VP. For the rest of 2014, he continued to participate in Purdue's misconduct as Head of Strategic Initiatives. As one of the strategic initiatives, he planned a call center for which Purdue staff could telephone prescribers, including in Massachusetts, to promote opioids using the same pitches that sales reps used face to face. On December 31, 2014, Gasdia retired from Purdue.

The Commonwealth does not provide any facts at all to support its conclusory allegation that, as Head of Strategic Initiatives, Gasdia "continued to participate in Purdue's misconduct." *Id.* There are no allegations at all, nor could there be, that Gasdia's role as Head of Strategic Initiatives had anything whatsoever to do with the sales-and-marketing activities that the Commonwealth alleges were deceptive. The only alleged "strategic initiative" the Commonwealth mentions is that Gasdia "planned a call center" in September 2014. *Id.* & n.910.

Although the Commonwealth's Complaint attributes over 100 documents to Gasdia, almost all of them range from 2001 to June 2014. *Id.* (throughout Complaint). Other than two emails relating to Gasdia's formal retirement from Purdue in December 2014, *id.* at ¶¶ 699, 751 (footnotes 839, 909, 911), the ***only*** post-June 2014 document that the Commonwealth cites is the one in paragraph 751, dated September 15, 2014, referring to plans for a call center, *id.* at ¶ 751.

The Complaint does not allege—and could not allege—that Gasdia played any role in Purdue's business after December 2014. The Complaint also does not allege—and could not allege—that during his retirement, Gasdia served as a contractor, or in any other role, for Purdue.

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understands that the Court must accept them as true. *See Bridgwood v. A.J. Wood Constr., Inc.*, 480 Mass. 349, 350 (2018) (on 12(b)(6) motion, court accepts as true all facts plaintiff pleads).

Nor does, or could, the Complaint allege that Gasdia is engaged in or is about to engage in any conduct remotely related to the conduct at issue in the Complaint.

ANALYSIS

The Attorney General may, on the Commonwealth's behalf, seek judicial assistance to halt improper conduct. But the Attorney General does not have the authority to sue a long-retired employee under Section 93A or for public nuisance. Also, because Gasdia left his sales-and-marketing job in June 2014, the statute of limitations has run. The case against Gasdia should be dismissed.

1. The Commonwealth may not sue Gasdia under Chapter 93A, because he is not "using or about to use" any allegedly unlawful practice

The Commonwealth's authority to sue for Chapter 93A violations derives from G.L. c. 93A, § 4, which states in relevant part:

> Whenever the attorney general has reason to believe that any person ***is using or is about to use*** any method, act, or practice declared by section two to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the commonwealth against such person to restrain by temporary restraining order or preliminary or permanent injunction the use of such method, act or practice....

(emphasis added). The rest of Section 4 details the manner in which the Attorney General may pursue an action on the Commonwealth's behalf, and the available remedies. *Id.* But this first sentence in Section 4 is the exclusive place where the statute defines when the Attorney General may bring an action at all.

By the statute's plain language, the Attorney General is empowered to protect the Commonwealth from current or imminent misconduct—the Attorney General must "have reason to believe that any person is using or is about to use" an unlawful practice. Nothing in Section 4 authorizes the Attorney General to bring an action against a person who ***previously*** engaged in

allegedly unlawful practices, where the Attorney General has no reason to believe that such person is still engaging in or is about to engage in such practices.

Based on the statute's plain language, the Commonwealth has no authority to sue Gasdia. As alleged in the Complaint, Gasdia left the sales-and-marketing role at Purdue in June 2014 and retired altogether in December 2014. Comp. ¶¶ 441, 751. There is no allegation in the Complaint—nor could there be—that Gasdia "is using or is about to use any method, act, or practice declared by section two to be unlawful." G.L. c. 93A, § 4.

A. The statutory language clearly and unambiguously requires the Attorney General to have reason to believe that the defendant's alleged violations are current or imminent

Section 4's statutory language—"Whenever the attorney general has reason to believe that any person is using or is about to use…"—is clear and unambiguous. The phrase "is using or is about to use" makes clear that the legislature authorized the Attorney General to sue in situations where someone is engaged in, or about to engage in, misconduct. The legislature could have stopped at "is using"; the "is about to use" language shows that the legislature wanted the Attorney General's authority to be broader, so that if there was "reason to believe" that someone was about to engage in misconduct, the Attorney General did not have to wait for it to begin.

What the legislature did ***not*** add is the phrase "has used," or its equivalent. That is, the legislature did not authorize the Attorney General to bring an action for past violations, when the Attorney General had no reason to believe that the person was continuing or about to engage in prohibited practices. And because the legislature did include "is using or is about to use," those terms must be applied and enforced; any other reading would improperly render them superfluous. *See Phillips v. Equity Residential Mgmt., L.L.C.*, 478 Mass. 251, 258 (2017) (court must not interpret a statute in a way that renders any portion of it meaningless); *Commonwealth*

v. Muckle, 478 Mass. 1001, 1023-24 (2017) (finding improper a statutory interpretation that would render statutory language superfluous).

The legislature could have added "has used" language if it wanted the Attorney General to be empowered to bring cases involving past conduct. Indeed, at least 12 other states have consumer-protection statutes that explicitly bestow such authority. In those states, the attorney general may bring an action whenever he or she has reason to believe that any person "is using, ***has used,*** or is about to use" an unlawful practice. *See* Ga. Code § 10-1-397 (Georgia); I.C. § 48-606 (Idaho); 815 ILCS 505/7(a) (Illinois); K.R.S. 367.190 (Kentucky); LSA-R.S. 51:1407 (Louisiana); Miss. Code § 75-24-9 (Mississippi); MCA 32-11-402 (Montana); NRS 598.570 (Nevada); N.M.S.A. 1978 § 57-12-8 (New Mexico); Gen. Laws 1956, § 6-13.1-5 (Rhode Island); S.C. Code § 39-5-50(a) (South Carolina); SDCL § 37-24-23 (South Dakota). The fact that other states expressly added "has used" to their statutes reinforces that if Massachusetts had wanted to extend the Attorney General's authority to past practices, it could have. *See L.L. v. Commonwealth.*, 470 Mass. 169, 177 (2014) (if legislature wanted to use language from other statutes, it could have).

A review of other Chapter 93A provisions makes clear that the legislature knew how to, and did, distinguish between ongoing and imminent conduct, on one hand, and past conduct, on the other hand. For example, Section 6 of Chapter 93A empowers the Attorney General to conduct an investigation "whenever he believes a person ***has engaged in or is engaging in*** any method, act or practice declared to be unlawful by this chapter...." G.L. c. 93A, § 6(1) (emphasis added).[3] Likewise, Section 9 of Chapter 93A authorizes private civil action by a citizen "who

[3] It makes sense for the Attorney General's investigative authority to extend to what a subject has done in the past—even when the Commonwealth can sue only for continuing or imminent conduct—because looking at past activity is relevant to determining a subject's motive,

has been injured by another person's use or employment" of an unlawful practice. G.L. c. 93A, § 9(1) (emphasis added). Section 11, too, allows a suit by a person engaged in business "who suffers any loss of money or property...as a result of" another business person's unlawful practice. G.L. c. 93A, § 11. These distinctions within Chapter 93A further support a conclusion that the legislature did not authorize the Attorney General to bring actions under Section 4 for past conduct. *See Essex Reg'l Ret. Bd. v. Swallow*, 481 Mass. 241, 252 (2019) (where legislature has carefully employed a term in one place and excluded it another, it should not be implied where excluded); *Commonwealth v. Wimer*, 480 Mass. 1, 5 (2018) (it is instructive to compare language at issue to language found elsewhere in same statute).

This statutory-construction principle—that clear and unambiguous statutory language must be interpreted in accordance with its ordinary meaning—is not only well-settled, but mandatory. *See Essex*, 481 Mass. at 252 (in determining a statute's effect, court "must give the language effect consistent with its plain meaning and refrain from reading into the statute" words that the legislature did not include); *Commonwealth v. Richards*, 480 Mass. 413, 418 (2018) (where statute's language is clear and unambiguous, courts must interpret statute consistent with the language's ordinary meaning); *White v. City of Boston*, 428 Mass. 250, 253-54 (1998) (when statutory language is clear and unambiguous, courts do not have discretion to depart from it; they are "constrained" to follow the statutory language). If the statute does not authorize an action, the court may not permit it.

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opportunity, and plans to engage in possible misconduct in the future. Put differently, by investigating a person who "has engaged in" unfair trade practices, an Attorney General might identify someone who "is using or is about to use" unfair trade practices, which could prompt the Attorney General to act under Section 4.

B. The little case law that exists on this issue supports dismissal of Count One

Our research reveals hardly any case law on this issue. The lack of relevant Massachusetts case law is not surprising when one considers the manner in which the Attorney General has historically exercised authority under Section 4 of Chapter 93A. We have not identified a ***single*** case in which the Commonwealth sued a former employee in anything remotely like the circumstances here. Accepting that our research might have missed such a case, we asked the Attorney General's office if it was aware of any such cases, and the office declined to identify any.

The only Massachusetts case touching on this issue is *Lowell Gas Co. v. Attorney Gen.*, 377 Mass. 37 (1979), where the Supreme Judicial Court considered a challenge to the Attorney General's standing to sue under Section 4. In that case, the Commonwealth sued two companies, alleging that they used improper accounting procedures. *Id.* at 38-41. The companies argued that the Attorney General lacked standing to sue under Section 4 because they had terminated the complained-of practices before the complaint was filed. *Id.* at 46-47. The Court found, though, that the Commonwealth's complaints could "reasonably be read to imply that these practices were continuing." *Id.* at 47. Although the allegation that the practices were continuing resolved the matter, the Court further stated, in *dicta*, that injunctions could be obtained even where a practice is not continuing, when there is a basis to believe that the practice might be resumed. *Id.* at 47-48.

Unlike in this case, the Commonwealth in *Lowell* alleged that the unlawful practices were continuing, clearly authorizing the Attorney General to proceed under Section 4. *Lowell*, 377 Mass. at 47. Moreover, the companies were still in business and could resume the unlawful

practices. *Id.*[4] None of this can be said for Gasdia, who retired from Purdue over four years ago and has no ability—let alone plans—to resume activities that the Commonwealth complains about here.

The only other case we have found referring to this issue in Massachusetts is *In re Bartel*, 403 B.R. 173 (D. Mass. 2009). There, the Commonwealth sued a man who had been convicted of larceny. *Id.* at 174. The man objected that the Attorney General did not have standing because the Commonwealth did not allege any debt was owed to it. *Id.* The court found that the Attorney General did have standing because of its interest in the economic well-being of the Commonwealth's citizens. *Id.* at 176. The court also stated, "M.G.L. ch. 93A, § 4 clearly establishes the Attorney General's right to bring such actions. This right applies even if a company has ceased its unfair practices. *Lowell Gas Co. v Attorney General*, 377 Mass. 37, 47, 385 N.E.2d 240, 247 (1979)." It is not clear why the bankruptcy court added this reference to a company's ceasing its unfair practices (as that was not defendant's argument), but this *dicta* is unpersuasive. The only citation is to *Lowell*, which involved continuing conduct. And the issue squarely presented here was not at issue in *Bartel*.

Looking to other precedent,[5] the Federal Trade Commission Act permits the FTC to bring actions when it "has reason to believe" that a person "is violating, or is about to violate" the law.

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[4] That was true, also, in the case on which *Lowell* relied, *Goodman v. Fed. Trade Comm'n*, 244 F.2d 584 (9th Cir. 1957). There, the FTC sued Abel Goodman, alleging that he was advertising his business deceptively. *Id.* at 588. Defending against the injunction sought by FTC, Goodman argued that he was winding up his business and that a cease-and-desist order was unnecessary. *Id.* at 593. The Court rejected Goodman's argument because the evidence showed that Goodman continued to advise the business and was planning to resume the same business under a different name. *Id.*

[5] *See* G.L. c. 93A, § 2(b) ("It is the intent of the legislature that in construing paragraph (a) of this section in actions brought under sections four, nine and eleven, the courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to section

15 U.S.C. § 13(b). Acting on this authority, the FTC sued Shire ViroPharma, seeking an injunction and restitution, alleging that the company had engaged in unfair competition with respect to its drug called Vancocin. *Fed. Trade Comm'n v. Shire ViroPharma, Inc.*, 917 F.3d 147, 149 (3rd Cir. 2019). The FTC sued five years after the alleged misconduct, when the company no longer owned Vancocin. *Id.* The FTC argued that the phrase "is violating, or about to violate" was satisfied "by showing a past violation and a reasonable likelihood of recurrent future conduct." *Id.* at 150. It argued, further, that absent an injunction, there was a real danger that the company would engage in similar misconduct, because it had the incentive and opportunity to engage in such conduct in the future. *Id.* at 153. Just last month, in March 2019, the Third Circuit Court of Appeals rejected that argument, ruling that Section 13(b)'s "clear text" required a current or imminent violation:

> Section 13(b) requires that the FTC have reason to believe a wrongdoer "is violating" or "is about to violate" the law....We conclude that this language is unambiguous; it prohibits existing or impending conduct. Simply put, Section 13(b) does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant "is" committing or "is about to" commit another violation.

Id. at 157. The court therefore affirmed dismissal of the complaint for failure to state a claim upon which relief can be granted. *Id.* at 160. *See also Fed. Trade Comm'n v. Hornbeam Special Situations, LLC*, 2018 WL 6254580 (N.D. Ga. Oct. 15, 2018) (plain language of Section 13(b) requires FTC to plead facts to support its reason to believe that each defendant is violating or is about to violate the law); *Fed. Trade Comm'n v. Nat'l Urological Group, Inc.*, 2005 WL 8155166 (N.D. Ga. June 24, 2005) (finding that § 13(b) cannot be used to remedy past violations

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5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended.").

because statute limits proceedings to situations where a person is "violating or is about to violate" a law).

Gasdia's arguments here are even stronger than the company's in *Shire*. In *Shire*, the FTC tried to persuade the court that the company's incentives and opportunities to resume misconduct were close enough to support a finding that the company was "about to violate" the law. *Shire*, 917 F.3d at 160. Here, there are no such allegations; nor could there be. Gasdia retired from Purdue over four years ago, and there is no basis to suggest that he is "about to" engage in any misconduct.

Because the Commonwealth lacks authority to sue Gasdia under Section 93A, Count One against Gasdia should be dismissed.

2. Nor may the Commonwealth sue Gasdia for public nuisance, because Gasdia has long since retired from Purdue and there is no conduct to enjoin or abate

In Count Two, the Commonwealth cites its power "to bring a *parens patriae* action on behalf of the Commonwealth for abatement of a public nuisance." Comp. ¶ 903. Gasdia agrees that, in general, the Commonwealth has the power to bring such a suit. *See Attorney Gen. v. Pitcher*, 183 Mass. 513, 520 (1903) (Attorney General may proceed by information in equity without special statutory authority to obtain injunctions against public nuisances); *Attorney Gen. v. Trustees of Bos. Elevated Ry. Co.*, 319 Mass. 642, 653 (1946) (Attorney General may bring an information in equity to protect the public interest, but, in the absence of a statute, his authority is restricted to the abatement of public nuisances).

For the Commonwealth to proceed on a common-law public-nuisance claim, however, there must be an immediate need for injunctive relief: "The jurisdiction of a court of equity to abate an existing, or prevent a threatened nuisance, upon information filed by the attorney general, is limited to those public nuisances which affect or endanger the public safety or

convenience, and require immediate judicial interposition." *Attorney Gen. v. Metro. R.R. Co.*, 125 Mass. 515, 516 (1878); *see also Attorney Gen. v. Tudor Ice Co.*, 104 Mass. 239, 244 (1870) (with respect to public nuisances, Attorney General may bring suit in equity only when such nuisances "affect or endanger the public safety or convenience, and require immediate judicial interposition"). Thus, the Commonwealth can sue for common-law public nuisance only where it seeks a court's order to require a defendant to abate (meaning, remove)[6] a public nuisance, or to refrain from conduct creating a public nuisance.

The Attorney General has not brought many common-law public-nuisance suits on behalf of the Commonwealth. The cases brought typically have involved securing an injunction to stop ongoing or imminent acts creating public harm. *See Metro. R.R. Co.*, 125 Mass. at 515 (effort by Attorney General—rejected by the court—to stop railway company from laying tracks in particular area); *Attorney Gen. v. Jamaica Pond Aqueduct Corp.*, 133 Mass. 361 (1882) (seeking injunction to stop company from digging wells in a manner than reduced the water levels in Jamaica Pond and was otherwise detrimental to the public health); *Attorney Gen. v. Revere Copper Co.,* 152 Mass. 444 (1890) (information by Attorney General to restrain company from controlling water levels in pond). More typically, in the past century, the Commonwealth has brought public-nuisance cases pursuant to specific statutes, not at issue here.

Massachusetts has shown no inclination to expand the Attorney General's equitable powers. In *Commonwealth v. Stratton Fin. Co.*, 310 Mass. 469, 471 (1941), the Attorney General sought an injunction against a loan-shark business to prevent defendants from violating statutory interest laws, to declare illegal loans void, and to stop defendants from collecting on such loans.

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[6] *See Attorney Gen. v. Baldwin*, 361 Mass. 199, 207-08 (1972) (with respect to nuisances, "abate" means removal).

Although the Court acknowledged the Attorney General's jurisdiction in equity "to enjoin public nuisances," the Court found it improper for the Attorney General to seek to enforce a criminal statute by injunction. *Id.* at 472-73. *See also Pitcher*, 183 Mass. at 520 (rejecting effort by Attorney General to maintain suit in equity, absent statutory or common-law authority). The Court similarly rejected an effort to take the "novel step" of expanding what has historically been defined as a public nuisance in Massachusetts. *See Jupin v. Kask*, 447 Mass. 141, 158-59 (2006) (declining to characterize stored, unloaded firearms as a public nuisance because "they do not inherently interfere with and threaten the public safety").

The Commonwealth purports to bring a common-law public-nuisance claim against Gasdia, but the Attorney General's only authority to do so under Massachusetts law is to seek to enjoin or abate a public nuisance. Gasdia has been retired from Purdue since 2014. There is no conduct by Gasdia for this Court to enjoin. And the term "abate" does not even make sense in the context of this case; there is nothing for Gasdia to remove, let alone something that constitutes a public nuisance.

In Count Two of the Complaint, the Commonwealth states that it "intends to seek reimbursement from the defendants for its expenses abating the harms they caused." Comp. ¶ 907. The Commonwealth cites no authority for its ability to seek such reimbursement, and we are aware of none. Indeed, in *In re Acushnet River & New Bedford Harbor Proceedings re Alleged PCB Pollution*, 712 F. Supp. 994, 1003-04 (1989), a federal court took the Commonwealth to task for making essentially the same argument. There, the Commonwealth claimed that under Massachusetts law, and its powers to enjoin or abate a public nuisance in a court of equity, it could seek "reimbursement of costs incurred in abating the nuisance." *Id.* The Commonwealth cited no cases supporting that proposition, and the court's own research did not

disclose any. *Id.* There are some Massachusetts public-nuisance statutes that provide for recovery of costs to abate a nuisance. *See, e.g.,* G.L. c. 139, § 10 (in Chapter 139 action involving landlord-tenant issues, Commonwealth may recover certain costs associated with abating nuisance). But there is no such authority under state common law.

Because the Complaint identifies no basis for the Commonwealth to seek to enjoin or abate any conduct by Gasdia, Count Two against Gasdia should be dismissed.

3. The statute of limitations has run on both counts against Gasdia

Counts One and Two should be dismissed for the additional reason that, as to Gasdia, the statute of limitations has run. *See Epstein v. Seigel*, 396 Mass. 278, 279-80 (1985) (affirming Rule 12(b)(6) dismissal where facts pled in complaint showed that statute of limitations had run).

A. Gasdia ceased sales-and-marketing activities for Purdue more than four years before the complaint was filed, after the statute of limitations expired on Count One

There is a four-year statute of limitations for the Unfair and Deceptive Acts and Practices claim. *See* M.G.L. c. 260, § 5A. A cause of action accrues "when the plaintiff discovers or with reasonable diligence should have discovered that (1) he has suffered harm; (2) his harm was caused by the conduct of another; and (3) the defendant is the person who caused that harm." *Harrington v. Costello*, 467 Mass. 720, 727 (2014). "The knowledge required to trigger commencement of the statute of limitations 'is not notice of every fact which must eventually be proved in support of the claim,' but rather 'knowledge that an injury has occurred.'" *AA & D Masonry, LLC v. S. St. Bus. Park*, 93 Mass. App. Ct. 693, 699, *review denied*, 480 Mass. 1110 (2018) (citations omitted).

Here, the Complaint alleges that Purdue's drugs killed hundreds of people in Massachusetts over the past decade. Comp. ¶ 15. It says that Purdue sold more than 70 million

opioid doses in Massachusetts since 2007. *Id.* at ¶ 21. It characterizes Purdue's conduct as a "massacre." *Id.* at ¶ 22. Gasdia vigorously denies the Commonwealth's allegations in this case; but taking them as true, as he must for purposes of this motion, the Commonwealth's allegations are wholly inconsistent with a claim that it did not know it had causes of action until filing this case in 2018.

Appreciating that it has a statute-of-limitations problem, the Commonwealth includes a section in its Complaint titled "Discovery Rule and Tolling," in which it generically asserts that fraudulent concealment warrants tolling of any applicable statutes of limitation. Comp. ¶¶ 835-38. But the discovery rule does not apply in this case, because the Commonwealth knew—or, if exercising reasonable diligence, could have known—its claims and timely sued.

Although the Commonwealth puts a different gloss on its allegations and includes citations and quotes from documents it obtained in the MDL proceedings, the Commonwealth's claims are no different from claims that have been made against Purdue and its executives (and others in the opioid industry) for years. In June 2014, the City of Chicago sued Purdue and other pharmaceutical manufacturers for "deceptively marketing highly addictive prescription painkillers." *See* City of Chicago Press Release, attached as Ex. A. The City of Chicago's Complaint, attached as Ex. B, advances the same allegations that Purdue makes against the Commonwealth in this case, namely, that Purdue employed a deceptive marketing campaign to persuade prescribers and the public that opioids were less addictive and dangerous than Purdue knew them to be.

Chicago's complaint was followed by many others. Indeed, of the approximately 1,300 lawsuits that are part of the Ohio MDL proceeding, over 100 were filed in 2017. *See* Conditional Transfer Orders 1-4, attached as Ex. C-1, C-2, C-3, C-4. There are far too many cases to parse

through here, but taking as an example the very first complaint listed on the first MDL transfer order—*City of Birmingham, Ala. v. Amerisourcebergen Drug Corp., et al.*, 2:17-cv-01360-JEO (N.D. Ala.), attached as Ex. D—the City of Birmingham sued Purdue and others "to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby and to recoup monies spent because of Defendants' false, deceptive and unfair marketing…of prescription opioids." *Id.* at ¶ 1. Among other things, the Birmingham complaint alleged—just like the Commonwealth does here—that after 2007, Purdue intentionally circumvented judgments against it that prohibited it from making misrepresentations in promoting and marketing OxyContin. *Id.* at ¶ 91.

In short, the Commonwealth does not bring this case based on newly discovered information, or on information it did not know or could not have known in time to satisfy the statute of limitations. Many others sued earlier, and the discovery rule does not save the Commonwealth from its delay. *See Albrecht v. Clifford*, 436 Mass. 706, 715-16 (2002) (refusing to apply discovery rule to toll statute of limitations where plaintiff had the ability to discover claim but did not exercise reasonable diligence).

The Commonwealth first brought Gasdia into this case on December 21, 2018. Whatever its claims about Purdue or the other individual defendants, the Commonwealth cannot credibly argue that until December 2018 it did not know it could sue Gasdia. In or around April 2013, plaintiff Daniel Luberda filed a lawsuit that was removed to federal court, in the District of South Carolina, against Purdue and approximately 40 individual defendants, many of whom were Purdue executives—including Gasdia. *See Luberda v. Purdue Frederick Corp. et al.*, 4:13-cv-00897-RBH (D.S.C.) (attached as Ex. E). The complaint alleged that Gasdia and other defendants deceptively marketed OxyContin. *Id.* In an amended complaint, plaintiff alleged:

> Russell Gasdia is Vice President of Marketing and Sales for Purdue Pharma et al. Russell Gasdia was Vice President of Marketing and Sales for Purdue Pharma et al, during all times relevant. In his position of Vice President of marketing and Sales for Purdue Pharma, et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the state of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

See Am. Comp., ¶ 28, attached as Ex. F. The South Carolina complaint—just like the Commonwealth's Complaint here—highlighted the fact that Purdue and three executives pled guilty to a federal crime in 2007. *Id.* at ¶¶ 45-48. And just like here, the South Carolina complaint alleged that after pleading guilty, Purdue continued to "push a fraudulent marketing campaign." *Id.* at ¶ 49. All of the *Luberda* pleadings were readily available to the Commonwealth (and to anyone else), since 2013. To the extent that the Commonwealth is claiming that it did not know Gasdia was someone it could sue, such argument falls flat in light of the *Luberda* case. *See White v. Peabody Constr. Co.*, 386 Mass. 121, 130 (1982) (rejecting application of discovery rule where plaintiffs knew they were injured and defendants' identities were matters of public record).

Moreover, Purdue's motion to dismiss describes the Commonwealth's deep involvement with combatting the opioid crisis since 2007, including its entry into a Consent Judgment with Purdue that gave it access to internal Purdue documents. Purdue's Mem. at 15, 27-28, 42. The Commonwealth even served a Civil Investigative Demand on Purdue on March 25, 2015. *Id.* at 9 n.7. The fact that the Commonwealth knew it could—and did—serve requests for information on Purdue as early as 2015 further belies the Commonwealth's effort to rely on the discovery rule.

In the same vein, the Commonwealth alleges it sought and received a statute-of-limitations waiver from Purdue, "tolling any applicable statutes of limitation during the period

from August 3, 2016 through May 18, 2018." Comp. ¶ 839. The Commonwealth therefore must have known no later than August 2016 that it had claims that were expiring under the statute of limitations. It was the Commonwealth's choice to seek a statute waiver only from the company, and not employees, and it cannot now bring its belated claim against Gasdia.

Nor do the Commonwealth's fraudulent-concealment allegations suffice to toll the statute of limitations, because a "cause of action is not concealed from one who has knowledge of the facts that create it." *White*, 386 Mass. at 133 (citation omitted) (rejecting fraudulent-concealment argument where even though plaintiffs characterized certain conduct as effort to hide cause of action, plaintiffs knew the facts creating their claims). The Commonwealth does not and could not allege any actions by Gasdia that caused the Commonwealth not to know it had a claim. *See Harrington*, 467 Mass. at 459 (even assuming plaintiff's allegation that defendants lied was true, fraudulent-concealment argument could not toll statute of limitations, because plaintiff still knew facts giving rise to his cause of action); *AA & D Masonry*, 93 Mass. App. Ct. at 701 (rejecting fraudulent-concealment argument, because—even accepting for sake of argument that defendants engaged in concealment actions—those actions did not give rise to plaintiff's injury).

Gasdia's last involvement with sales and marketing at Purdue was in June 2014. After that, he had no role at all in any of the sales-and-marketing activities alleged in the Complaint. The Complaint's sole allegation concerning Gasdia's post-June 2014 conduct is that he participated in a September 2014 presentation about creating a call center. Comp. ¶ 751. The call-center allegation does not have anything to do with the purportedly illegal marketing practices that the Commonwealth complains of; but even if it did, Gasdia's September 2014 presentation is still outside the four-year statute of limitations. Because the statute of limitations ran in June 2018 (or September 2018 at the latest, if the Court credits the call center as related to

the Commonwealth's claims), and the Commonwealth did not sue Gasdia until December 21, 2018, Count One should be dismissed.

B. The statute of limitations on Count Two ran in June 2017, more than a year before the Commonwealth sued Gasdia

There is a three-year statute of limitations for the public-nuisance claim in Count Two. *See See* M.G.L. c. 260, § 2A. For the same reasons identified above, the statute of limitations has run on the Commonwealth's claim against Gasdia, and Count Two should be dismissed.

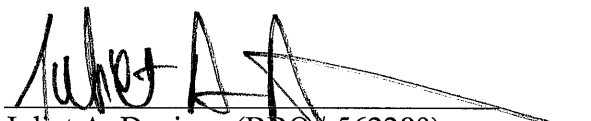
CONCLUSION

For these reasons, Defendant Russell J. Gasdia respectfully requests that Counts One and Two against him be dismissed with prejudice.

Respectfully submitted,

RUSSELL J. GASDIA,

By his attorneys,



Juliet A. Davison (BBO#562289)
Davison Law, LLC
280 Summer Street, 5th fl.
Boston, MA 02210
(617) 345-9990
juliet@davisonlawllc.com

Julie B. Porter (admitted *pro hac vice*)
SALVATORE PRESCOTT & PORTER, PLLC
1010 Davis Street
Evanston, IL 60201
(312) 283-5711

CERTIFICATE OF SERVICE

I, Juliet A. Davison, hereby certify that on April 1, 2019 I caused a copy of the Memorandum of Law in Support of Defendant Russell J. Gasdia's Motion to Dismiss to be served by email, upon counsel for all parties, as follows:

Sydenham B. Alexander III, Esq.
Gillian Feiner, Esq.
Eric M. Gold, Esq.
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
sandy.alexander@state.ma.us
gillian.feiner@state.ma.us
eric.gold@state.ma.us

Attorneys for the Commonwealth of Massachusetts

Timothy C. Blank, Esq.
Jon E. Olsson, Esq.
Dechert LLP
One International Place, 40th Fl.
100 Oliver Street
Boston, MA 02110
Timothy.blank@dechert.com
Jon.olsson@dechert.com

Attorneys for Purdue Pharma L.P. & Purdue Pharma, Inc.

Robert J. Cordy, Esq.
MCDERMOTT WILL & EMERY LLP
28 State Street
Boston, MA 02109
r.cordy@mwe.com

James R. Carroll, Esq.
Maya P. Florence, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
500 Boylston Street
Boston, MA 02116
james.carroll@skadden.com
maya.florence@skadden.com

Attorneys for Richard Sackler, Theresa Sackler, Kathe Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Beverly Sackler, David Sackler, Irene Sackler Lefcourt, Peter Boer, Paulo Costa, Cecil Pickett, Ralph Snyderman, and Judy Lewent

Attorneys for Craig Landau, John Stewart, and Mark Timney

Juliet A. Davison

Dated: April 1, 2019

EXHIBIT A

OFFICE OF THE MAYOR
CITY OF CHICAGO

FOR IMMEDIATE RELEASE
June 3, 2014

CONTACT:
Mayor's Press Office
312.744.3334
press@cityofchicago.org

CITY OF CHICAGO SUES BIG PHARMA FOR DECEPTIVELY MARKETING HIGHLY ADDICTIVE PRESCRIPTION PAINKILLERS

Drug Manufacturers Knowingly Downplayed Serious Risks, Promoted Unfounded Benefits Associated With Highly Addictive Painkillers

Mayor Rahm Emanuel today announced that the City of Chicago has filed a lawsuit in Illinois state court against five pharmaceutical manufacturers for misrepresenting the benefits of opioids, a class of highly addictive narcotic painkillers, and concealing the serious health risks associated with these drugs. This deception has led to an increase in prescription painkiller abuse, addiction and overdose that plagues communities in Chicago and in other cities across the country.

"For years, big pharma has deceived the public about the true risks and benefits of highly potent and highly addictive painkillers in order to expand their customer base and increase their bottom line. This has led to a dramatic rise in drug addiction, overdose and diversion in communities across the nation, and Chicago is not immune to this epidemic," said Mayor Emanuel. "Today, we're saying enough is enough – it's time for these companies to end these irresponsible practices and be held accountable for their deceptive actions."

The lawsuit charges that five of the nation's largest opioid manufacturers, Purdue Pharma L.P., Cephalon, Inc., Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc. and Actavis plc, knowingly and aggressively marketed these drugs as rarely addictive, while touting benefits that lacked scientific support in order to boost profits. Their efforts to increase the sale of these drugs have been successful, as the sale of opioids has quadrupled between 1999 and 2010. In fact, enough prescription painkillers were prescribed in 2010 to medicate every American adult around the clock for one month.

"We believe that these pharmaceutical manufacturers have violated a number of city ordinances and other laws in the marketing and sale of these drugs," said Chicago Corporation Counsel Stephen Patton. "The purpose of the lawsuit is simple: to stop this deceptive and unlawful marketing and hold these companies responsible for the harm their deception has caused."

In addition to the general, deceptive promotion of opioids to treat chronic pain, these drug companies specifically target their marketing to the elderly and veterans, with false promises that the opioids were unlikely to be addictive and would help improve their function and quality of life. These actions have often led to catastrophic results.

A 2008 investigation reported that 87 percent of all opioids dispensed were to patients using them to treat chronic pain on a long-term basis, even though there is no scientific evidence supporting the long-term use of these drugs for non-cancer chronic pain.

The City's Health Insurance Plan has reimbursed claims for approximately $9.5 million on these drugs since 2008. The increase in misuse and abuse of these drugs is also generating additional health care costs. For example, estimates of visits to the emergency department in Chicago due to the misuse and abuse of prescription painkillers have been steadily increasing, with a significant increase of 65 percent between 2004 and 2011. It is estimated that in Chicago in 2009, opioid misuse and abuse resulted in 1,080 trips to the emergency room.

"Caring for patients addicted to prescription painkillers was one of the most challenging parts of my clinical practice and I've seen firsthand the damage it can cause to individuals, families and entire communities," Chicago Public Health Commissioner Bechara Choucair, M.D. "Prescription drug abuse has quickly become a major health epidemic across the country, and stopping deceptive marketing tactics is essential to protecting public health."

Many patients who receive a valid prescription for an opioid painkiller become addicted to these powerful drugs. Even law abiding citizens who are prescribed these painkillers can become addicted, and some may turn to heroin because it produces the same high but is cheaper and easier to access. A recent study found that heroin use among those who misuse or abuse opioid painkillers has increased, with most reporting abuse or misuse of these drugs before starting heroin.

By dramatically increasing the market for opioids, the drug companies have also created a supply of drugs that are diverted to people to whom they are not prescribed. In fact, more than three out of four people who misuse prescription painkillers use drugs prescribed to someone else.

The City is not seeking to ban these drugs. The lawsuit seeks to end deceptive marketing so that patients and physicians are able to make informed decisions.

"These companies have misled doctors and consumers over many years, and on behalf of our residents, they need to be held accountable," said Maria Guerra Lapacek, Commissioner of the Department of Business Affairs and Consumer Protection. "This lawsuit should serve as a wake-up call not just to these pharmaceutical companies, but to every business with Chicago consumers - our City will not tolerate consumer deception."

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EXHIBIT B

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CITY OF CHICAGO,

a municipal corporation,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; and ACTAVIS PLC,

Defendants.

Case No.:
JURY TRIAL DEMANDED

COMPLAINT

Plaintiff City of Chicago, by its attorney, Stephen R. Patton, Corporation Counsel of the City of Chicago, for its Complaint against Defendants Purdue Pharma L.P., Purdue Inc., the Purdue Frederick Company, Inc., Teva Pharmaceutical Industries, Ltd., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Endo Health Solutions Inc., and Actavis plc (collectively, "Defendants"), alleges as follows:

TABLE OF CONTENTS

I. INTRODUCTION

1. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. When marketing a drug, a pharmaceutical manufacturer must tell the truth, which means ensuring that its marketing claims are supported by science and medical experience. Defendants broke these simple rules.

2. By the 1990s, Defendants had the ability to cheaply produce massive quantities of opium-like painkillers ("opioids"), but the market was small. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. They knew – and had known for years – that opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain (pain lasting three months or longer), particularly because their effectiveness waned with prolonged use and because of the substantial risk of significant side effects and addiction, especially with high-dose use.[1] They also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (e.g., hospitals), where the risk of addiction and other adverse outcomes was much less significant.

3. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[2] Like heroin, prescription opioids work by binding to receptors on the

[1] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Research & Mgmt., 247-287, (H.L. Fields and J.C. Liebeskind eds., 1994).

[2] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin),

spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death.

4. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea-change in medical and public perception that would permit the use of opioids for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches. Defendants, through a common, sophisticated, and deeply deceptive marketing campaign that continues to the present, set out to, and did, reverse the popular and medical understanding of opioids.

5. Beginning over 20 years ago, Defendants seized on anecdotal accounts of opioid use to treat chronic pain to begin a reeducation campaign about opioids. They spent millions of dollars funding, assisting, and encouraging doctors and front groups that would pioneer a new and far broader market for their potent and highly addictive drugs – the chronic pain market. Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids. They overstated the benefits of using opioids long-term to treat chronic non-cancer pain, promising improvement in patients' function and quality of life, and dismissed or minimized the serious risks and adverse outcomes of chronic opioid use, including the risk of addiction, overdose, and death. There was and is no reliable scientific evidence supporting Defendants' marketing claims, and there is a

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fentanyl (Duragesic, Fentora), heroin, methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone).

Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II.

wealth of scientific evidence to the contrary. They also deceptively marketed the drugs for indications and benefits that were prohibited by the drugs' labels.

6. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits result in the prescription of an opioid (nearly double the rate in 2000).[3] Opioids – once a niche drug – are now the most prescribed class of drugs – more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they have consumed 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.[4] Together, opioids generated $8 billion in revenue for drug companies in 2010.

7. Roughly 87% of these prescriptions are for chronic opioid therapy[5] – a prescribing practice doctors previously considered not just ineffective, but even reckless given the substantial risk of addiction chronic opioid use creates.

8. It was Defendants' marketing – and not any medical breakthrough – that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic." Prescription opioid use contributed to 16,651 overdose deaths nationally in 2010 – more than twice as many deaths as heroin and cocaine combined and surpassing motor vehicle accidents as a cause of death. For every death, more than 30 individuals are treated in the emergency room. The U.S. Department of Health estimated that in 2009 in Chicago, there were

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[3] Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51(10) Medical Care, 870-878 (2013).

[4] Laxmaiah Manchikanti et al., *Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective*, 13 Pain Physician, 401-435 (2010).

[5] Michael Von Korff, Group Health Res. Inst., "The Epidemiology of Use of Analgesics for Chronic Pain," Presentation to the FDA (2012), *available at*, http://www.fda.gov/downloads/Drugs/NewsEvents/UCM308128.pdf

40.4 emergency department visits involving adverse reactions to opioids per 100,000 people, which, for Chicago's population, translates into 1,080 trips to the emergency room.[6] But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

9. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors or from the secondary criminal market, and a pipeline of drugs that can be diverted to supply them. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[7] According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in the past year, and adolescents are abusing opioids in alarming numbers. Sixty percent of opioid abusers report that their drugs came originally from prescriptions.[8] The former president of the New Hope Recovery Center on the City's North Side stated: "Five years ago, 70 percent of the people we saw were heroin addicts. Today, 70 percent of the people we see are prescription drug users."[9]

10. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, which has imposed additional burdens on the City and local agencies that address heroin use and addiction. Chicago ranks first in the nation in heroin overdose deaths.[10] Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost

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[6] *Metro Brief Chicago: Drug-Related Emergency Dep't Visits in Metro. Areas*, U.S. Dep't of Health and Human Servs.: Substance Abuse & Mental Health Servs. Admin. (2009), http://www.samhsa.gov/data/StatesInBrief/2k9/CityReports/Chicago_IL.pdf

[7] Nathaniel Katz, *Opioids After Thousands of Years, Still Getting to Know You*, 23 The Clinical Journal of Pain, 303-306 (2007).

[8] *Id.*

[9] Monifa Thomas, *Prescription Drug Abuse Is Fastest-Growing Drug Problem in Country*, Chicago Sun-Times (Sept. 24, 2012), www.suntimes.com/2989811-417/drug-abuse-prescription-drugs-pain.html.

[10] Natalie Mooer, *Heroin: It's Cheap, It's Available and It's Dangerous Business*, WBEZ 91.5, (Dec. 14, 2013), http://www.wbez.org/news/heroin-its-cheap-its-available-and-its-dangerous-business-109304.

$10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person started on prescription opioids for a back injury, to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

11. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and the former White House drug czar, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[11]

12. To shift medical convention and unleash this epidemic, Defendants engaged in a campaign of deception that: (1) misrepresented the efficacy of opioids, (2) trivialized or obscured their serious risks and adverse outcomes, and (3) overstated their superiority, compared with other treatments. Defendants supported, encouraged, and directed employees, front groups, and doctors they identified as "Key Opinion Leaders" ("KOLs") to publicize biased and misleading studies and promotional materials and conduct thousands of medical education programs that were deceptive and lacked balance. These "educational" efforts were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic non-cancer pain outweighed their risks and that opioids could be used safely by most patients.

13. Defendants' representations regarding the benefits, risks, and relative superiority of opioids were – and are – untrue and unsupported by competent scientific evidence. In fact, even Defendants' KOLs initially were very cautious about whether opioids were safe and

[11] Transcript of Use and Abuse of Prescription Painkillers, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript.

effective to treat chronic non-cancer pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers and physicians who have sounded the alarm on the long-term use of opioids to treat chronic non-cancer pain, Defendants continue to disseminate their false and misleading marketing claims even today.

14. Defendants' marketing not only ignored contrary evidence, but also failed to acknowledge risks disclosed on their own labels and sometimes exceeded the approved indications. Defendant Cephalon, for example, marketed its opioid Fentora for chronic non-cancer pain even though it was approved only to treat cancer pain. Defendants also promised that opioids would improve patients' ability to function, even though such benefits had not been proven and were specifically disputed by the FDA.

15. Many of Defendants' strategies are modeled on promotional activities that have been deemed unlawful and for which the drug companies have paid billions of dollars in settlements and judgments. What makes this effort particularly nefarious – and dangerous – is that unlike most other prescription drugs, opioids are highly-addictive controlled substances. Defendants deceptively engaged a patient base that – physically and psychologically – could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

16. Countless Chicagoans suffer from chronic non-cancer pain, which takes an enormous toll on their health, their lives, and their families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Chicago patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payers of the chance to exercise informed judgment and subjected them to enormous suffering and costs.

17. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Fentora's label) may have allowed or did not exclude the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids; if that were the case, there would be few limits on what a drug company could say about its product.

18. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness, and indeed hijack, what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

19. Defendants' course of conduct, individually and collectively, has violated and continues to violate local, state, and common law, as laid out below.

- Chicago Municipal Code § 2-25-090, in that Defendants engaged in fraudulent, unfair, and deceptive acts and practices, including misleading advertising in their promotion of opioids to treat chronic non-cancer pain, and/or engaged in conduct that violates the Illinois Consumer Fraud and Deceptive Business Practices Act and/or the Uniform Deceptive Trade Practices Act.

- Chicago Municipal Code § 4-276-470 in that Defendants employed deception, fraud, false pretense, false promise or misrepresentation, or concealed, suppressed or omitted material facts with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise.

- Chicago Municipal Code § 1-21-010 in that Defendants knowingly made false statements of material fact to the City in violation of any statute, ordinance or regulation, or knowingly made a false statement of material fact to the city in connection with any application, report, affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit.

- Chicago Municipal Code § 1-22-020, in that Defendants knowingly presented or caused to be presented to the City false or fraudulent claims for payment or approval;

knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the City; and/or conspired to defraud the City by getting false or fraudulent claims allowed or paid.

- Chicago Municipal Code Section § 1-20-020 in that Defendants caused the City or its agents to incur costs in order to provide services reasonably related to Defendants' violation of any federal, state or local law, and/or Defendants failed to correct conditions which violate any federal, state or local law that Defendants were under a legal duty to correct.

- 720 ILCS 5/170-10.5 in that Defendants knowingly obtained, attempted to obtain, or caused to be obtained, by deception, control over the property of a self-insured entity, the City, by making a false claim or by causing a false claim to be made to the City, intending to deprive the City permanently of the use and benefit of that property.

- The common law prohibition against civil conspiracy in that Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

- The prohibition against common law fraud in that Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

- The common law prohibition on unjust enrichment in that Defendants have unjustly retained a benefit to the City's detriment, and Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

20. To redress and punish these violations, the City seeks a judgment requiring Defendants to pay restitution, damages, including multipliers of damages, disgorgement, civil penalties, punitive damages, and attorneys' fees, costs, and expenses, and any other relief to which the City may be entitled. The City also requests that the Court order Defendants to cease their unlawful promotion of opioids and to correct their misrepresentations.

II. PARTIES

A. Plaintiff

21. Plaintiff is the City of Chicago (the "City"), a municipal corporation organized and existing under the laws of the State of Illinois. The Corporation Counsel has the authority to "[a]ppear for and protect the rights and interests of the city in all actions, suits and proceedings brought by or against it or any city officer, board or department [.]" Chicago Municipal Code § 2-60-020.

B. Defendants

22. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware; Purdue, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut; and The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue is primarily engaged in the manufacture, promotion, and distribution of opioids, including OxyContin, its largest selling opioid, in both Chicago and the nation. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

24. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Pharmaceutical Industries, Ltd. acquired Cepahlon, Inc. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. (Teva Pharmaceutical Industries, Ltd. and Cephalon,

Inc. are collectively referred to herein as "Cephalon".) Cephalon is in the business of manufacturing, selling and distributing pharmaceutical drugs, including opioids Actiq and Fentora, nationally and in Chicago.

25. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain "with malignancies who had developed a tolerance to less dangerous therapies." The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon plead guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

26. Cephalon also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of sales representatives; to post payments to doctors on its web site; and to regularly certify that the company has an effective compliance program.

27. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey (Janssen Pharmaceuticals, Inc. and Johnson & Johnson are collectively referred to herein as "Janssen"). Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Chicago and nationally, including the opioids Duragesic, Nucynta, Nucynta ER, Ultracet, and Ultram. Duragesic is the largest selling opioid of the group. Sales of Janssen's opioids collectively commanded between $1.3 billion in revenue in 2009 and $1.2 billion in 2012 – a total of $4.7 billion dollars over the four-year period.

28. Defendant Endo Health Solutions Inc. ("Endo") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo develops, markets, and sells

prescription drugs, including opioids Opana, Percocet, and Percodan, in Chicago and throughout the United States. These opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana yielded revenue of $1.16 billion between 2008 and 2012, and alone accounted for 10% of Endo's total 2012 revenue.

29. Defendant Actavis plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012 and the combined company name was changed to Actavis, Inc. as of January 2013, and then Actavis plc in October 2013. Throughout the Complaint, "Actavis" collectively refers to Actavis, Inc. and Actavis plc. During the relevant time period, Actavis engaged in the business of marketing and selling opioids in Chicago and across the country, including the branded drug Kadian and generic versions of Duragesic and Opana.

III. JURISDICTION AND VENUE

30. Pursuant to the Illinois Constitution art. VI, § 9, this Court has subject matter jurisdiction over the City's claims..

31. This Court has personal jurisdiction over Defendants pursuant to 735 ILCS § 5/2-209(1) because Plaintiff is the City of Chicago, located within Illinois, and Defendants carry on a continuous and systematic part of their general business within Illinois, and have transacted substantial business in Illinois which has caused harm in Illinois.

32. Venue as to each Defendant is proper in Cook County because, pursuant to 735 ILCS § 5/2-108, part of the transactions out of which the asserted causes of action arise occurred in Cook County, Illinois.

IV. JURY DEMAND

33. Pursuant to 735 ILCS § 5/2-1105, the City demands a trial by jury.

V. FACTUAL ALLEGATIONS

A. Before Defendants' Deceptive Marketing Campaign, Opioids Were Rarely Prescribed by Physicians Because of Their Known Serious Side Effects and Substantial Risk of Addiction

34. Opioids have long been approved and accepted for the treatment of chronic cancer pain. Opioids are appropriate for this use given the severity of pain often associated with cancer and the recognition that the benefits of treating that pain outweigh the potential risk of addiction, especially for terminal patients. The same is not true for chronic non-cancer pain. Among other differences, the pathology responsible for cancer pain is distinct from these pathologies that cause chronic pain. For patients with cancer, the source of their pain is likely to be the tumor and pressure on, or erosion of nerves or bones. Chronic pain arises from multiple sources, including musculoskeletal (from joints, ligaments, or muscles), neuropathic (or nerve-related, occurring in diseases like diabetes or shingles), headache, or functional pain (arising from disease states such as irritable bowel) that respond differently—or not at all—to opioids.

35. However, over the past twenty years, fueled by aggressive marketing from the pharmaceutical industry, opioid use for the management of chronic non-cancer pain has become commonplace. As set forth below, use of opioids for long-term non-cancer pain management is based on "unsound science and blatant misinformation . . . and dangerous assumptions that opioids are highly effective and safe, and devoid of adverse events when prescribed by physicians."[12]

36. As admitted in 1994 by Dr. Russell Portenoy, a KOL who went on to tirelessly promote opioid therapy for the treatment of chronic non-cancer pain (also called chronic nonmalignant pain), the medical consensus before Defendants' "reeducation" campaign was decidedly against the use of opioids to treat chronic non-cancer pain:

> ***The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs***. This perspective has been justified by the perceived likelihood of

[12] Laxmaiah Manchikanti et al., *Opioid Epidemic in the United States*, 15(3 Suppl) Pain Physician, ES9-ES38 (July 2012).

> tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. ***Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects.*** There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.[13]

37. Dr. Portenoy left no doubt about the 1994 state of knowledge concerning the safety and efficacy of opioid therapy for long-term chronic non-cancer pain:

> At the present time, neither the medical literature nor clinical experience provides compelling evidence that long-term opioid use would be salutary for more than a very small number of patients with chronic nonmalignant pain . . .[14]

38. But the lack of any credible science supporting opioid therapy for chronic non-cancer pain did not stop Defendants from marketing opioid therapy for that use. Working with and through KOLs like Dr. Portenoy, Defendants seized on anecdotal accounts of opioid efficacy in limited populations and methodically, through numerous publications, programs, and spokespeople, overstated the benefits and understated the risks of opioids in order to create and defend a broad market for opioids that never should have and never would have come to exist absent Defendants' concerted, deliberate, and patently misleading efforts.

B. Defendants Are Obligated to Ensure that their Marketing is Truthful, Complete, and Balanced

39. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. Drug makers' claims in promotional materials must be supported by "substantial" scientific evidence and cannot be false or misleading. 21 U.S.C. § 352(a). The materials must reflect a "fair balance," accurately and

[13] Portenoy, *supra* note 1, at 247 (emphasis added).

[14] *Id*. at 278 (emphasis added).

comprehensively describing the risks and benefits of the drug, and cannot ignore or minimize a drug's risk or overstate its benefits. 21 CFR § 202.1(e)(6). Federal regulations bar affirmative claims that are untruthful, as well as the omission of material facts that make the drug-related information inaccurate. 21 CFR §§ 202.1(e)(3), 1.21(a). It is a violation of federal law for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study." 21 CFR § 99.101(a)(4).

40. Drug companies also must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience." 21 CFR § 202.1(e)(6)(ii). While the FDA must approve a drug's label — defined to include all explanatory material accompanying the label, 21 U.S.C. §§ 321 (k), (m) — it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information. *See* 21 CFR § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 CFR § 314.70(c)(2) (allowing manufacturers to make changes that "strengthen . . .a warning, precaution, or adverse reaction). In addition, while promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated, the FDA does not have to approve these materials in advance. If, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations that it deems less serious, while warning letters are reserved for violations that affect patients' safety or reflect continued violations of the law.

41. The federal regulatory framework reflects public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for making certain that prescribers have accurate and complete information so that

they can assess the risks and benefits of drugs for their patients to ensure their health and safety. The Chicago Consumer Fraud and False Claim ordinances reflect the same judgment that drug companies, like other businesses, have a duty to deal honestly with consumers, government, and other payers who purchase and use their products.

C. Defendants' Marketing of Opioids for Long-Term Use to Treat Chronic Non-Cancer Pain was False, Misleading, Imbalanced, and Unsupported by Science

42. For years, Defendants systematically violated state and local laws requiring that the promotion of pharmaceutical drugs, like other consumer products, not be false, deceptive, or misleading. Defendants manipulated and ignored scientific evidence to formulate and broadcast the misrepresentations described below, each of which was instrumental in: (1) overcoming longstanding medical and legal barriers to opioid therapy for chronic non-cancer pain; and (2) making high-dose, long-term opioid use the new "gold standard" of treatment of chronic non-cancer pain.

43. Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unbranded marketing materials—materials that generally promoted opioid use but did not name a specific opioid drug name. Upon information and belief, Defendants used these unbranded materials, which are not reviewed by the FDA, to disseminate messages that were inaccurate, were inconsistent with their branded marketing materials and the drugs' labels and package inserts, and would not pass muster with the FDA. Had they relied on branded materials, the FDA-required drug labels and package inserts would have been included to more fully describe the risks and administration of opioids.

44. Defendants marketed directly to patients to: (1) encourage them to ask doctors for opioids to relieve chronic non-cancer pain; and (2) allay their well-founded concerns that opioids were dangerous and addictive. Defendants targeted particularly vulnerable, but usually well-insured, groups of patients, such as veterans and the elderly. Defendants leveraged and funded patient organizations and communities – promoting opioids particularly for common conditions, such as headaches, arthritis, fibromyalgia, and back pain. Unlike other direct-to-

consumer marketing, Defendants, as a group, focused on unbranded advertising knowing that the creation of a new, expansive market for opioids would benefit all manufacturers.

45. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic non-cancer pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Through misleading medical education programs, treatment guidelines, and other efforts, Defendants "reeducated" general practitioners and family doctors. They knew that these doctors reach the vast majority of patients with common chronic pain complaints, but are less likely than specialists to have the time or knowledge to evaluate Defendants' deceptive messages or to closely monitor patients for signs of improvement or adverse outcomes (such as addiction).

46. Individually and collectively, Defendants developed, disseminated and promoted a series of misrepresentations aimed broadly at reversing the ultimately well-founded fears and beliefs of doctors and patients.

1. Defendants' misrepresentations regarding the benefits of opioids for chronic non-cancer pain.

47. Defendants deceptively promoted opioids as improving chronic non-cancer patients' function by allowing them to get back to "normal" and reducing their pain long-term. Defendants misrepresented the efficacy of opioids in an effort to persuade doctors and patients that their benefits outweigh their risks.

48. Although opioids may initially improve patients' function by providing pain relief in the short term, there were – and are – no controlled studies of the use of opioids beyond 16 weeks and no evidence that opioids improve patients' function long-term. Indeed, research such as a 2008 study in *Spine* has shown that pain sufferers prescribed opioids long-term suffered

addiction that made them more likely to be disabled and unable to work.[15] Despite this lack of evidence — and evidence to the contrary — Defendants consistently promoted opioids as capable of improving patients' function and quality of life.

49. The FDA has recognized that claims that opioids improve patients' function are misleading. For example, a company claimed that its opioid "Improved Overall Function," offered "Long Lasting Improvements in Physical Function," and would enable patients to be better able to engage in a list of daily activities, such as walking, standing, and climbing stairs. In a warning letter sent March 24, 2008, the FDA publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities … has not been demonstrated by substantial evidence or substantial clinical experience."

50. In marketing Kadian, Actavis made implied claims that the drug would allow chronic non-cancer pain patients to return to work, relieve "stress on your body and your mental health," and help them enjoy their lives. The FDA found that Actavis misrepresented the scientific evidence: "[W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[16]

51. Defendant Janssen also distributed a series of posters to doctors' offices that showed pictures of people dressed for a variety of active professions suggesting that doctors prescribe Ultracet because "Pain doesn't fit into their schedules." Despite the lack of scientific evidence in support of such a claim, the posters falsely implied that Ultracet was appropriate for

[15] Jeffrey Dersh et al., *Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders*, 33(20) Spine, 2219-2227 (Sept. 15, 2008).

[16] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010).

help in maintaining an active lifestyle. Several of the posters contained the tagline "Ultracet lets them perform."

52. In spite of the complete lack of scientific basis, in 2011, Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, published by the American Pain Foundation ("APF"), which asserted that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic non-cancer pain patients. To support this claim, APF cited *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, a study published in 2006 in the Canadian Medical Association Journal. However, the study concludes: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The Purdue-sponsored *Guide* failed to disclose this conclusion, as well as the fact that the study was conducted only for five weeks, and therefore could not support the long-term use of opioids, or the study's findings that opioids were actually less effective than alternative treatments.

53. Defendant Janssen — with the assistance of pain organizations APF, the American Academy of Pain Management and the American Society for Pain Management Nursing —created a national patient advocacy campaign titled *Let's Talk Pain*. The campaign consisted of a series of television segments, a website, online videos, literature and events. In 2009, one of its marquee components was a "first-of-its-kind" Web-based series, called *Let's Talk Pain,* hosted by veteran TV journalist Carol Martin. Janssen's internal planning documents recognized that *Let's Talk Pain* comprised part of an "unbranded communication plan" for its opioid Nucynta. The resource brings together medical doctors, nurses, psychologists, social workers and people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing "the psychological aspects associated with pain."

54. The *Let's Talk Pain* talk show—which is still available online—was orchestrated (through Ketchum, Inc., Janssen's public relations firm), sponsored and edited by Janssen — a

fact that was not disclosed. In the very first episode of this talk show, the following exchange, from a script edited and approved by Janssen, took place:

> **Teresa Shaffer (APF Action Network Leader)**: As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> **Dr. Al Anderson (AAPM Board of Directors)**: The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor when they are suffering from pain for a long period of time, especially moderate to severe pain. And that's the patients that we really need to use the opioids methods of treatment, because they are the ones who need to have some help with the function and they're the ones who need to have their pain controlled enough so that they can increase their quality of life.
>
> **Teresa Shaffer**: This is what has allowed me to continue to function and is what has allowed me to have somewhat of a normal life, is the opioids.[17]

There simply is no scientific evidence that opioids taken long-term improve function or quality of life for chronic non-cancer pain patients, and significant evidence that opioids impose significant risks and adverse outcomes on long-term users, none of which is disclosed in this video interview.

55. Similarly, the National Initiative on Pain Control ("NIPC"), an APF initiative [redacted] ran a facially unaffiliated website called www.painknowledge.org. NIPC billed itself as "an integrated education initiative" and promoted its expert leadership team, including "nationally respected experts in the pain management field." [redacted] Painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able

[17] Let's Talk Pain, *Episode 1: Safe Use of Opioids (PainSAFE)*, YouTube (Sept. 28, 2010), http://www.youtube.com/watch?v=zeAlVAMRgsk (0:35 to 1:09).

to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy.

56. Endo also advertised its Opana ER (or extended release) drug by depicting a professional chef and a construction worker, each with chronic lower back pain, smiling and working as a result of Opana ER.

57. Defendant Actavis trained its sales force that the "proper use" of opioids restores function, and that "many patients with chronic pain improve[] markedly when given sufficient opioids for pain control and . . . they continue[] to benefit for years without significant problems."

58. Defendants' misrepresentations about increased function are particularly misleading for specific indications for which they promoted opioids, such as migraines and lower back pain. For instance, research indicates that as many as 30% of patients who suffer from migraines have used opioids to treat their headaches.[18] Despite this, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[19] A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[20] Studies of the use of opioids long-term for chronic lower back pain similarly have been unable to demonstrate an improvement in patients' function.[21]

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[18] Dawn C. Buse, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, 52 Headache: The Journal of Head & Face Pain, 18-36 (Jan. 2012).

[19] *Id.*

[20] *Press Kits – Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment*, National Headache Foundation (May 15, 2007), http://www.headaches.org/press/NHF_Press_Kits/Press_Kits_-_Migraine_Patients_Taking_Addictive_Or_Non_Approved_FDA_Migraine_Treatments.

[21] Luis E. Chaparro, *Opioids compared to placebo or other treatments for chronic low-back pain*, 8 Cochrane Database of Systematic Reviews (2013).

59. There also is evidence that, over the long-term, opioid therapy fails to lessen, and sometimes increases, patients' pain – important facts that Defendants fail to include in their marketing literature. For example, Defendants have failed to disclose scientific evidence that establishes that many patients on chronic opioid therapy continue to experience significant pain and dysfunction.[22] Defendants also have failed to disclose research and clinical experience demonstrating that: (1) the analgesic (pain relieving) efficacy of opioids often declines over time; (2) patients on opioids long-term may develop greater sensitivity to pain ("hyperalgesia"); and (3) because they develop tolerance to the medication over time, many chronic non-cancer pain patients require ever higher doses of opioids to obtain relief and are on doses that doctors have described as "frighteningly high."[23]

60. Consistently, in their marketing, Defendants failed to disclose the lack of evidence to establish that opioids are safe and effective long-term, as well as the growing body of evidence that the risks of opioids increase and their benefits decline over time. The studies relied on by Defendants in marketing their drugs are short-term, typically for less than 12 weeks. For example, an ad that Janssen currently is running, including on its website, claims that Nucynta ER has "Efficacy you need, Tolerability you want." However, each of the studies included in the drugs approval were only conducted over a 12-week period, using a pre-seeded patient group; thus none provide support for a claim of long-term efficacy in the population at large. Indeed, Janssen also failed to disclose that it submitted a fourth study for the FDA's

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[22] Mark D. Sullivan et al., *Problems and concerns of patients receiving chronic opioid therapy for chronic non-cancer pain*, 149(2) Pain, 345-353 (2010); Jørgen Erikson et al., *Critical issues on opioids in chronic non-cancer pain*, 125(1-2) Pain, 172-179 (2006); *see also*, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, Institute of Med. Comm. on Advancing Pain Research, Care, & Educ. Board on Health Sci. Policy, (2011). K.S. Dillie et al., *Quality of life associated with daily opioid therapy in a primary care chronic pain sample*, 21(2) Journal of the Am. Bd. Of Family Med., 108-117 (Mar.-Apr., 2008).

[23] Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med., 1422-1424 (Sept. 13, 2010).

consideration that did not show pain reduction over placebo and was thus omitted from the approval.

61. As a pain specialist noted in an article titled, *Are We Making Pain Patients Worse?*, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally." Instead, at higher doses, patients are much more likely to develop dependence or addiction, experience pain deterioration due to hyperalgesia, and are three to nine times more likely to die from opioid-related causes than those on low doses.[24] Additionally, epidemiological data suggest that only a minority of patients on chronic opioid therapy benefit from the drugs and most continue to suffer significant pain and limitations on their activities. Defendants have never disclosed these facts.

2. Defendants' misrepresentations regarding the adverse outcomes and risks of opioids.

62. In an effort to persuade doctors to prescribe opioids for chronic non-cancer pain, Defendants deceptively overstated the safety and minimized the adverse outcomes, particularly the risk of addiction and abuse from using opioids long-term.

a. Risk of addiction and abuse.

63. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic non-cancer pain patients, Defendants had to overcome

[24] Tara Gomes et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain*, 171(17) Archives of Internal Med., 686-691 (Apr. 11, 2011); Kate M. Dunn et al. *Opioid prescriptions for chronic pain and overdose: a cohort study*, 152(2) Annals of Internal Med., 85-92 (Jan. 19, 2010).Most overdoses were medically serious and 12% were fatal. *Id*. *See also* J.B. Braden et al., *Emergency Department visits among recipients of chronic opioid therapy*, 170(16) Archives of Internal Med., 1425-1432 (Sept. 13, 2010) (finding that higher doses of opioids doubled the risk of adverse drug events).

doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk – condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic non-cancer pain conditions sufficient to justify that risk would have posed a nearly insurmountable challenge.

64. Remarkably, Defendants were able to do it; even though opioids are controlled substances – classified under the federal Controlled Substances Act as having "high potential for abuse" and a "risk of severe psychological and physical dependence."[25] Defendants: (1) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (2) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk – and Defendants' own FDA labels – compelled disclosure.

65. Contrary to Defendants' claims, numerous studies support that, though these patients may not presently show signs of abuse or addiction, at least 15% and as many as 40% of patients will become addicted to opioids.[26] Research has shown that opioids are even more addictive than cocaine and alcohol. One in three to five users who self-administer short-acting opioids will become addicted, versus one in eight to fifteen for users of cocaine or alcohol.[27]

(1) Minimizing the risk of addiction.

[25] 21 U.S.C. § 812(b).

[26] (*E.g.*, Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction, 1776-1782 (Oct. 2010); Joseph A. Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria*, 30(3) Journal of Addictive Diseases, 185-194 (July-Sept., 2011); *Prescription Drugs: Abuse and Addiction,* National Inst. on Drug Abuse, (Oct. 2011), http://www.drugabuse.gov/sites/default/files/rrprescription.pdf.)

[27] Mary J. Kreek et al., *Pharmacotherapy of Addictions*, 1(9) Nature Reviews: Drug Discovery, 710-726 (Sept. 2002).

66. Local pain specialists interviewed by the City indicated that sales representatives, or detailers, employed by drug companies, never talked to them about the risk of addiction from long-term use of opioids.

67. Nor did their marketing materials portray the risk of abuse or addiction. As discussed below, Defendants omitted addiction from the list of adverse outcomes they disclosed. In addition, to the extent they discussed addiction, they described it as "rare" or not an issue for pain patients, as opposed to illicit users.

68. For example, in a Janssen- sponsored publication, *Finding Relief: Pain Management for Older Adults,* published in 2009 and still available online, Janssen asserts as "Fact" that "opioids are *rarely* addictive when used properly for the management of chronic pain." (Emphasis in the original.) Numerous Janssen employees vetted and approved the content of this publication, and Janssen arranged for copies of *Finding Relief* to be distributed by its pain sales force.

69. Similarly, Endo promised on a website it funded, that "People who take opioids as prescribed usually do not become addicted."

70. Defendants' efforts to minimize the risk of addiction from taking opioids long-term are evident in the contrast between their unbranded materials, which dramatically understate or deny the risk of addiction, and branded materials, which include stronger addiction warnings taken from the drugs' labels. Defendants took advantage of the less-monitored unbranded marketing channel to disseminate their deceptive messages regarding the risk of addiction from long-term opioid use. For example (emphasis added):

[redacted]	**Living with Someone with Chronic Pain (2009)**	**Opana ER Advertisement (2011/2012/2013)**
[redacted]	unbranded patient education material created by Endo	branded Endo advertisement
[redacted]	"Most health care providers who treat people with pain agree that **most people do not develop an**	"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other

	addiction problem."	opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

71. Defendants also falsely reassured doctors and patients that, when taken properly under a doctor's supervision, opioids would not become addictive. Defendants' representations that opioid addiction can be effectively managed by competent physicians not only had the effect of increasing the number of opioid prescriptions, but deflected the responsibility from Defendants' marketing to doctors' prescribing and treatment practices.

72. Defendants deceptively downplayed the risk of addiction for chronic pain patients by defining opioid addicts as people who get the drugs illicitly and take them improperly – not patients taking drugs they were prescribed. According to Defendants, patients who take opioids prescribed to them are not addicted.

73. A 2004 Endo patient education publication, edited by KOL Dr. Russell Portenoy, and titled, *Understanding Your Pain: Taking Oral Opioid Analgesics*, which is still available online, answers the hypothetical patient question — "What should I know about opioids and addiction?" — by focusing on explaining what addiction is ("a chronic brain disease") and is not ("Taking opioids for pain relief"). It goes on to explain that, "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction."

74. On the *Let's Talk Pain* website, Janssen likewise posted the claim that taking opioids to treat pain is "just the opposite" of addiction. Similarly, Endo's *Living with Someone with Chronic Pain* brochure, published in 2007, stated that, with addiction, "[t]ypically the medicine is being use for something other than pain control."

75. More graphically, a Purdue brochure, still provided to doctors today, called *Indications of Possible Drug Abuse*; shows pictures of the stigmata of injecting or snorting

opioids – skin popping, track marks, or perforated nasal septa.[28] In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. Thus, these misrepresentations wrongly reassure doctors that as long as they did not observe those signs, they need not worry that their patients were abusing or addicted to opioids.

76. These deceptive messages gave doctors and patients a false sense of security that as long as patients are only taking opioids a doctor gives them – regardless of the dose or frequency ingested– and not manipulating them, snorting, or injecting them, they are not addicted. That is dangerously false Many opioid users who become addicted to the drugs began using them when a doctor prescribed them. Pain patients and opioid addicts are not separate universes, but overlapping circles. As one study noted, "a potential side effect from chronic use can be abuse and addiction … [I]n fact, correct use and abuse of these agents are not polar opposites – they are complex, inter-related phenomena."[29] A review of studies of urine drug monitoring for opioid patients showed that at least 11% of patients with chronic non-cancer pain were misusing opioids and at least 12% were not taking their medication as prescribed.[30]

77. Dr. Scott Fishman, another KOL whose work was long supported by opioid makers, acknowledged that data supporting the contention that addiction is rare:

> [The data] have been found to be inadequate and seriously flawed. Although we currently do not know the exact rate of addiction in patients legitimately prescribed opioids for pain or the rate of overall misuse, we know that rates are high enough that they should be considered a significant potential adverse effect.[31]

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[28] *Providing Relief, Preventing Abuse: A reference guide to controlled substance prescribing practices*, Purdue Pharma L.P. (Stamford, C.T.), 2nd ed. 2011, at 13.

[29] Wilson M. Compton & Nora D. Volkow, *Major increases in opioid analgesic abuse in the United States: concerns and strategies*, 81(2) Drug and Alcohol Dependence 103, 106 (Feb. 1, 2006).

[30] Nathaniel P. Katz et al., *Prescription Opioid Abuse: Challenges & Opportunities for Payers*, 19(4) Am. Journal of Managed Care 295, 301 (2013).

[31] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide*, 15, The Fed'n of State Med. Bds. Found., 2nd ed. (2012).

78. Relatedly, at least Endo, and potentially other Defendants, sought to minimize the risk of abuse by misrepresenting their drugs' susceptibility to tampering. In 2012, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version. The FDA denied both requests, explaining in a May 10, 2013 letter that there was no evidence the new design "would provide a reduction in oral, intranasal or intravenous abuse" and that Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse[.]" Yet, Endo advertised, and advised its sales representatives and speakers' bureau doctors, to market reformulated Opana ER as "the only oxymorphone extended release tablets that are *designed to be crush resistant*." (Emphasis added.) Endo chose its words carefully, but the misleading impression it created – that Opana is tamper-resistant and therefore less subject to abuse – was no doubt deliberate.

(2) Claiming the risk of addiction can be identified and managed.

79. Defendants continue to maintain to this day that *most* patients safely can take opioids long-term for chronic non-cancer pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants have come to admit that *some* patients *could* become addicted. But, more recently, Defendants claim that opioid addiction can be avoided if doctors use screening tools or questionnaires that identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse).[32]

80. There are three fundamental flaws in Defendants' assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that

[32] The FDA's Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics directs doctors to "assess each patients' risk of abuse." However, it does not excuse drug companies' misrepresentations that the screening tools allow them to prevent low-risk or high-risk patients from abusing or becoming addicted to opioids.

screening works to substantially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients can be given opioids safely, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients without red flags can take opioids long-term without significant danger of addiction.

81. Yet Defendants made assurances about addiction and screening anyway. For example, an Actavis advertisement for its drug, Kadian, assured that addiction "is less likely if you have never had an addiction problem," but fails to disclose that the risk of addiction for chronic non-cancer pain patients is still significant.

82. Dr. Russell Portenoy, a pro-opioid, Defendant-funded KOL, appeared on *Good Morning America*, in 2010, to discuss the use of opioids long-term to treat chronic non-cancer pain. He claimed that, "[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

83. A Cephalon-sponsored guide, *Opioid Medications and REMS: A Patient's Guide*, similarly claimed: "Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

84. Pro-opioid KOL Lynn Webster developed a basic five-question risk screening tool called the Opioid Risk Tool. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to doctors in Chicago during the relevant period.

85. An Endo-sponsored 2007 supplement to the *Journal of Family Practice* contained an article written by a Chicago doctor who was on all of Defendants' speakers' bureaus, *Pain Management Dilemmas in Primary Care: Use of Opioids*, which recommended risk screening

through the use of the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. The author claimed that even patients at high risk of addiction could be safely treated with opioids through "a maximally structured approach" including toxicology screens and pill counts.

86. In 2012, the same Chicago KOL also presented at a Purdue-sponsored continuing medical education program ("CME"), *Chronic Pain Managing and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*, in which he discussed the treatment of a high-risk chronic pain patient demonstrating signs of opioid addiction. The presentation recommended that doctors facing a similar patient, again, use risk screening tools. He also taught that doctors should consider reducing the prescription fills and switching to a different opioid as management strategies. Regardless of steps taken, the message was to continue opioid therapy.

87. Many of Defendants' misrepresentations about opioid abuse and addiction risk were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions, but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. Defendants have made a concerted effort to reach GPs through continuing medical education programs ("CMEs"), office visits, and literature specifically aimed at them, and most opioids are prescribed by primary care physicians like GPs.[33]

88. Defendants organized CMEs for GPs on prescribing opioids to chronic pain patients, but provided no guidance on recognizing opioid abuse or weaning patients off opioids. Since GPs lack specialized training in opioid treatment and are especially reliant on CMEs to equip them to manage patients on opioids, this critical learning gap makes it even less likely that, once on opioids, chronic pain patients will have the chance to get off them.

(3) Deflecting attention to "undertreated" pain.

[33] Wolters Kluwer Health, *Sharp rise in opioid drugs prescribed for non-cancer pain*, Science Daily (Sept. 16, 2013), available at http://www.sciencedaily.com/releases/2013/09/130916091218.htm.

89. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. They claimed that purportedly overblown worries about addiction caused pain to be under-treated and opioids to be over-regulated and under-prescribed. One APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, stated that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include … misconceptions about opioid addiction." The Purdue Guide further alleged that resulting regulatory constraints (like the FDA's recently mandated prescriber education program, or REMS ("Risk Evaluation and Mitigation Strategies") have a "chilling effect" on prescribing and that abuse of opioids injured and "jeopardize[d] effective pain management by impeding patient access to opioids."

90. Janssen-sponsored *Let's Talk Pain* – a multi-media patient education campaign – that warned that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program went on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients … This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

91. A Purdue website called *In the Face of Pain* complained, under the heading of "Protecting Access," that, through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed;" "restricting access to patients with pain who also have a history of substance abuse;" and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[34] This unsupported and untrue

[34] *See In the Face of Pain Fact Sheet: Providing Access to Pain Treatment*, Purdue Pharma L.P. (2013), www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf

rhetoric aimed to portray doctors who did not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

(4) Physical dependence vs. addiction.

92. In an effort to underplay the risk and impact of addiction, Defendants frequently claim that while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed by gradually tapering patients' dosage to avoid the adverse effects of withdrawal.

93. For example, in the April 2, 2010 version of its OxyContin label, Purdue states: "**Cessation of Therapy** When the patient no longer requires therapy with OxyContin, taper the dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient." The APF *Policymaker's Guide* (2011) funded by Purdue states: "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."[35] Actavis' sales-force training, for example, taught representatives to answer questions from GP's that withdrawal from Kadian could be "simply" managed. These representations are false and misleading.

94. Defendants' so-called guidance overstates the ease of withdrawing from long term use of opioids and the adverse effects that accompany their discontinuance. Withdrawal from opioids after long-term use can trigger severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms. The dependence on opioids can be so severe that withdrawal symptoms may persist for months, or even years, after a complete withdrawal from opioids.

95. Defendants also fail to disclose that long-term opioid use often causes psychological, as well as physical, dependence. Addiction is not a switch that is either off or on. Indeed, as the most recent, authoritative Diagnostic and Statistical Manual of Mental Disorders

[35] *A Policymaker's Guide to Understanding Pain & Its Mgmt.*, Am. Pain Found., Oct. 2011 at 31.

("DSM-V") acknowledges, there is a spectrum of disorders that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on that spectrum. [36]

96. This is certainly true of opioids. Anxiety over ending opioid use can trigger cravings for opioids, even after a patient is no longer physically dependent and despite the fact that he or she is not deriving benefits from the treatment. As Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, explains, opioids "hijack[] the brain's reward system," convincing users that "the drug is needed to stay alive."[37] Even absent physical dependence, a patient's fear of the unpleasant effects of discontinuing opioids can cause patients to seek the drugs.[38]

97. Thus, ending opioid therapy is not, as Defendants claim, "simply" a matter of gradually lowering a patient's dosage over time. In fact, one of the significant risks in beginning chronic opioid therapy is that, once patients become physically dependent, it will be difficult for them to ever stop using opioids. According to one study, more than half of patients who continuously use opioids for more than 90 days remain on opioids after more than five years.[39] Most patients who become physically dependent after long term use will require opioid maintenance (through methadone or buprenorphine) for years or decades. Defendants fail to disclose this significant risk to doctors and patients.

98. A publication in Purdue's current catalog of publications for providers, *Providing Relief, Preventing Abuse*, cautions against the "common error" of confusing physical dependence

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[36] For that reason, references to "addiction" in this Complaint refer to this spectrum of substance abuse disorders.

[37] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Register (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html.

[38] Jane C. Ballantyne & Cathy Stannard, *New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids*, 21(5) Pain: Clinical Updates, 1-7 (Dec. 2013).

[39] Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) Journal of Gen. Internal Med., 1450-1457 (Dec. 2011).

with addiction. It analogizes physical dependence on opioids to physical dependence on antihypertensives (blood pressure medicine) or decongestants.

99. This analogy has no basis in fact. With non-addictive drugs, like blood pressure medicine, patients may experience withdrawal symptoms, but they are rarely difficult to get over, and there is no craving for the drug. However, with long-term use of opioids, even in the absence of a formal diagnosis of addiction, patients often crave the drug long after they have discontinued use. Patients on opioids long-term will often experience symptoms that arguably may not qualify as full-blown addiction, but are certainly not mere physical dependence. Defendants' marketing failed to acknowledge the spectrum of substance abuse disorders short of full blown addiction, which also are cause for concern, and created the sense that doctors need only concern themselves with signs of addiction.

100. As with the claimed low incidence of addiction, the misrepresentation that chronic opioid therapy is easy to stop is important to Defendants' fraudulent marketing scheme. Honestly describing the difficulty of removing patients from opioids after long-term use and the complexity of patients' dependence would rebalance the risk-benefit analysis and stoke doctors' and patients' well-grounded concerns that once on opioids, severe physical and psychological dependence would make it extremely difficult for patients to ever stop their use. It might also motivate the general practitioners to whom Defendants generally marketed opioids for long-term use to refer patients requesting opioids to pain management specialists who would not so easily prescribe them. Defendants also gave GPs a false sense of confidence that they could identify addiction, distinct from physical dependence, which, again, allowed them to believe that they could continue to responsibly prescribe opioids. Defendants chose not to tell the truth so that they could sell more drugs.

(5) Pseudoaddiction.

101. Defendants needed a way to explain why so many chronic non-cancer pain patients on opioids seem to be addicted: they ask for drugs by name, they seek refills earlier than

their supplies should have run out, hoard drugs, or self-escalate their doses. Defendants, led by Purdue, managed masterfully to turn these recognized signs of addiction into a way to sell more opioids through the concept of "pseudoaddiction." Pseudoaddiction, which manifested with all of the signs of addiction, was actually the result of insufficient opioids to treat pain, and should be treated with higher or more frequent doses of the drugs. Defendants claimed that rather than addiction treatment, patients who were pseudoaddicts needed more opioids.

102. Purdue discussed pseudoaddiction in a publication called *Providing Relief, Preventing Abuse*, in which it falsely and misleadingly claimed that the concept of pseudoaddiction had "emerged in the literature" "to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." Purdue went even farther, saying that pseudoaddiction is unproblematic and may occur "occasionally even with successful opioid therapy for pain." This gave doctors confidence that signs of addiction might not be cause for concern. It also misled doctors into believing that the proper response to pain that has not been "effectively treated" through opioid prescriptions is *more* opioids. Purdue's unbranded website, Partners Against Pain.com, also hosted a pamphlet in 2005 titled, *Clinical Issues in Opioid Prescribing*, which included a list of conduct including "illicit drug use and deception" as examples of unproblematic pseudoaddiction-related behavior, not problematic addiction.

103. Defendants also managed to work the misleading concept of pseudoaddiction into medical literature. In a 1994 article, Defendant-sponsored KOL Russell Portenoy described common signs of addiction as potential signs of mere *therapeutic dependence* – which he likened to a diabetic's response to insulin – or *pseudoaddiction*.[40] Portenoy claimed that "*Pseudoaddiction* describes a specific phenomenon that has also been observed in the population with cancer pain." But his authority for this statement was limited to a single citation to an article by another KOL and later Purdue executive J. David Haddox.[41] Dr. Haddox's article did

[40] Portenoy, *supra* note 1, at 266-267.

[41] *Id*. at 267.

not concern a population study at all, but rather, simply reported the possible phenomenon in a single cancer (leukemia) patient with pneumonia and chest wall pain.[42]

104. Dr. Portenoy took the deception of pseudoaddiction one step farther, separating from a list of commonly accepted signs of drug addiction those he claimed were "probably less predictive of addiction."[43] Portenoy's "less predictive of addiction" list included:

i. Aggressive complaining about the need for more drugs;

ii. Drug hoarding during periods of reduced symptoms;

iii. Requesting specific drugs;

iv. Openly acquiring similar drugs from other medical sources;

v. Unsanctioned dose escalation or other noncompliance with therapy on one or two occasions;

vi. Unapproved use of the drug to treat other symptoms;

vii. Reporting psychic effects not intended by the clinician; and

viii. Resistance to a change in therapy associated with 'tolerable' adverse effects with expressions of anxiety related to the return of severe symptoms.

105. Portenoy cited no authority for his "less predictive of addiction" conclusion and is not himself a specialist or authority in addiction medicine. Yet his list encouraged doctors to ignore obvious signs of addiction and prescribe more opioids.

106. Similarly, in his book, *Responsible Opioid Prescribing* (2007), which was funded by Defendants Cephalon, and Purdue, and is still distributed in Chicago, Dr. Scott Fishman asserts: "It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence should be considered before a judgment is made." Thus,

[42] J. David Haddox & David E. Weissman, *Opioid pseudoaddiction – an iatrogenic syndrome*, 36(3) Pain, 363-366 (Mar. 1989).

[43] Portenoy, *supra* note 1, at 267 Table III.

according to Defendants, even patients at high risk for opioid addiction should be given the benefit of the doubt (and more opioids).

107. Defendants' used identical language to describe pseudoaddiction in their materials, evidence of their common efforts and messages (emphasis added):

Let's Talk Pain **(2009)**	***A Policymaker's Guide*** **(2011)**	***Clinical Issues in Opioid Prescribing*** **(2005)**
funded by Janssen	funded by Purdue	funded by Purdue
"A related term is pseudoaddiction, which refers to patient behaviors that may occur when **pain is under-treated** . . . Pseudoaddiction is **different from true addiction** because such behaviors can be resolved with effective pain management."	"Pseudo-addiction describes patient behaviors that may occur when **pain is undertreated** . . . Pseudo-addiction can be **distinguished from true add[i]ction** in that this behavior ceases when pain is effectively treated."	"Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when **pain is undertreated** . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be **distinguished from true addition** in that the behaviors resolve when the pain is effectively treated."

108. Despite Defendants' claims, pseudoaddiction has no scientific basis; there is no competent study documenting its existence. Based on a single cancer pain case observed by Purdue executive and KOL David Haddox, Defendants have counseled doctors to treat chronic non-cancer pain patients on opioids who seem to be addicted *with more opioids*.

109. KOL Dr. Lynn Webster recommended just this course in his book, *Avoiding Opioid Abuse While Managing Pain* (2007), a book Endo paid to distribute to general practitioners, in order to "Increase the breadth and depth of the Opana ER prescriber base[.]" Dr. Webster advised giving patients more medication when unsure whether a patient is showing signs of addiction or untreated pain; he asserted that pseudoaddiction was the cause *"in most cases and should be the clinician's first response*." Lynn R. Webster, Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007) (emphasis added). Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to

give patients more medication.… It led us down a path that caused harm. It is already something we are debunking as a concept."[44]

(1) Other adverse effects.

110. Defendants also misrepresent the risks of long-term opioid use by describing them as minor and short-term and failing to disclose the most significant risks. Defendants most frequently highlight the risk of constipation, which they advise can be addressed with laxatives or other treatments. The other side effects Defendants typically disclose are drowsiness, nausea and vomiting, mental clouding (sometimes disclosed), and itching, though Defendants promise that these symptoms will go away in a matter of days.

111. Below is a representative example of how Defendants disclose potential side effects from opioid use in unbranded material. This is taken from a 2009 patient education publication distributed by the NIPC and funded by Endo, and which was distributed in Chicago during the last four years:

[44] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee-Wisconsin Journal Sentinel (Feb. 18, 2012), http://www.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.[45] H. W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002)Nathaniel Katz & Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

112. Notably absent from this list are far more significant adverse outcomes linked to long-term opioid use, including: hyperalgesia, immunologic and hormonal dysfunction, respiratory depression, apnea, tolerance/loss of analgesic efficacy, endocrinopathies (most notably testosterone depletion, which, among other impacts, may decrease pain tolerance and the effectiveness of opioids),[45] cognitive impairment, dependence, and addiction. These adverse outcomes can result in an increase in falls and fractures in the elderly (which can shorten the lives of elderly patients), overuse, overdose, and death. Defendants also fail to disclose the risk that infants born to pregnant women using opioids will be dependent on opioids as well, suffering a condition called neonatal abstinence syndrome when they painfully withdraw from the drug after birth.[46] In addition, though the labels for opioids contain numerous warnings about use of opioids for patients who have certain conditions, are opioid naïve (new to opioids), or use other drugs, Defendants' marketing materials contain no similar cautions.

[45] H. W. Daniell, *Hypogonadism in men consuming sustained-action oral opioids*, 3(5) The Journal of Pain, 377-384 (Oct. 2002)Nathaniel Katz & Norman A. Mazer, *Impact of opioids on the endocrine system*, 25 The Clinical Journal of Pain, 170-175 (2009).

[46] The FDA now requires a boxed warning on all extended release and long acting opioids, cautioning that chronic use of those drugs by pregnant women can result in neonatal opioid withdrawal syndrome ("NOWS"), which may be life-threatening and require specialized care.

113. These omitted adverse outcomes are not, as Defendants claim, fleeting or minor. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic non-cancer pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[47] Defendants were aware of this high drop-out rate as they pushed the FDA to allow them to exclude these patients from clinical trial data, a method of research known as "enriched enrollment," which allowed drug companies to study only those patients whose negative reactions to opioids did not cause them to stop taking them.

114. Janssen's marketing campaign for Nucynta was particularly deceptive in that it promoted Nucynta's "tolerability," which is completely at odds with and misrepresents its serious side effects. In October 2009, Janssen began to run an advertisement in *Medical Economics* that proclaimed: "OPIOID EFFICACY MEETS UNEXPECTED TOLERABILITY," even though the risk of addiction and serious side effects make opioids intolerable for most patients. While the "tolerability" to which Janssen referred was a lack of GI-related side effects (*e.g.*, nausea and vomiting), a reader could only learn this after examining a bar chart representing the study's results. Thus, the all-caps claim of "unexpected tolerability" falsely implied that Nucynta could be taken without severe side effects or consequences.

115. Defendants' misleading treatment of the serious risks of opioid treatment in unbranded materials directly contradicts the disclosures they made on their own labels. The label for Purdue's OxyContin, for example, acknowledges that its use may increase the risk of serious adverse reactions "including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock[.]" Likewise, the label for Janssen's Duragesic includes the warning that "[r]espiratory depression is the chief hazard of" Duragesic, and it "has a narrow indication and should be prescribed only by healthcare professionals who are knowledgeable in the administration of potent opioids and management of chronic pain." The labels even include warnings for interactions with substances as commonly used as alcohol, as in the Nucynta ER

[47] Meredith Noble et al., *Long-term opioid management for chronic noncancer pain (Review)*, 1 Cochrane Database of Systematic Reviews, (2010).

label, which says that the drug "may be expected to have additive effects when used in conjunction with alcohol . . . [and] respiratory depression, hypotension, and profound sedation, coma or death may result." Yet, upon information and belief, these risks are not highlighted in the educational programs and marketing materials Defendants have sponsored and disseminated; materials that are much more widely read and relied on than the drug labels.

116. The table below (emphasis added) highlights the differences, described above, between how Defendants (in this instance, Janssen) disclosed side effects in unbranded materials and front group materials, versus how they disclosed side effects in their branded advertisements.

Finding Relief: Pain Management for Older Adults (2009)	**Let's Talk Pain Website (2009)**	**Nucynta IR Advertisement (2010)**
unbranded publication approved and funded by Janssen	website created and funded by Janssen	branded Janssen advertisement
"At first, the drugs can cause **upset stomach or sleepiness**. These side effects often go away as you get used to the drugs. Some other side effects, such as **constipation**, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis."	"The most common side effects of opioids include **constipation, nausea and vomiting, sedation (sleepiness), mental clouding, and itching**. Some people may also experience **dizziness** or difficulty urinating . . . The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is likely to persist."	Prescriber information in the ad states: "**Respiratory depression** is the **primary risk** of mu-opioid agonists."

117. In a 2008 warning letter, the FDA recognized that these strategies deceptively represented the side effects of opioids – in that case, Avinza. The FDA complained that one of the company's marketing materials (a file card) lists common adverse effects "including constipation, nausea, and somnolence," but omitted all of the other risks listed in the drug's package insert. According to the FDA, the file card with a page headed "Managing Side Effects"

> creates the misleading impression that the risk information contained in that section is a comprehensive presentation of the risks associated with Avinza therapy and the steps needed to

> address those risks. The fact that the File Card contains no other disclosure of drug risks reinforces this misleading impression. Furthermore, the File Card – in direct contradiction of the [Package Insert] for Avinza – implies that no serious or life-threatening risks (e.g., risk of respiratory depression, overdose, or death) can be caused by Avinza, both by disclosing only 'common adverse events' (e.g., constipation, nausea, and somnolence) and by emphasizing the drug's 'proven safety and tolerability' throughout the piece. Finally, by framing its discussion of common adverse reactions as one of 'managing' them, and by providing no disclosure to the contrary, the File Card misleadingly implies that common adverse reactions associated with the use of Avinza may ordinarily be alleviated or mitigated, and therefore do not pose a risk to patients…. Your minimization of the serious risk profile associated with your drug raises significant public health concerns.

118. In promoting their opioids, Defendants have engaged in the same marketing practices warned against by the FDA – highlighting only minor risks, emphasizing the ability to manage those risks, failing to disclose serious risks, and generally declaring the safety of their drugs. As the FDA made clear, that message is dangerously deceptive. By deliberately understating the risks of opioids, Defendants exposed patients to extremely dangerous adverse effects and deprived doctors and patients of the ability to make informed, appropriate choices about using opioids.

119. Defendants' pattern of understating the risks of chronic opioid therapies marred the CMEs and studies they funded or sponsored and left providers with the impression that opioids were much safer than they are and should be used more frequently. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded article on opioids versus another group who reviewed a non-industry-funded article. The industry-funded article did not mention opioid-related death once; the non-industry-funded article mentioned opioid-related death 26 times. A summary of the study notes that students who read the industry-funded article more frequently cited the impression that opioids were underused in chronic non-cancer pain. Those reading the non-industry-funded article, in reporting their "take-aways," mentioned the risk of death and addiction much more frequently than the other group. Neither group could accurately identify

whether the article they read was industry-funded, making clear the difficulty providers have in screening and accounting for source bias.[48]

3. Misrepresentations regarding superiority.

120. Defendants' deliberate misrepresentation of the risks of opioids is particularly evident when compared to Defendants' description of the risk of over-the-counter nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal and renal risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, but also made their omissions regarding the risks of opioids all the more striking and misleading.

121. In the Cephalon and Purdue-sponsored 2007 APF *Treatment Options*, NSAIDs are described as "life threatening," – a term never used in connection with opioids – and are said to have caused 10,000 to 20,000 deaths each year. The CDC reports that the actual number of deaths even possibly related to the use of NSAIDs in 2008, the most recent year available, is roughly 3,400, and that number includes all gastrointestinal bleeding deaths regardless of cause.[49]

122. Defendant Endo relied on this disparate treatment of risks in a "case study" it caused to be distributed to prescribers in Chicago with Opana ER's prescribing information, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. Using an example of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), the case study concluded that the patient was only able to be treated with opioids, which were described as having adverse effects that can be managed through the dosing and by rotating opioids, as needed.

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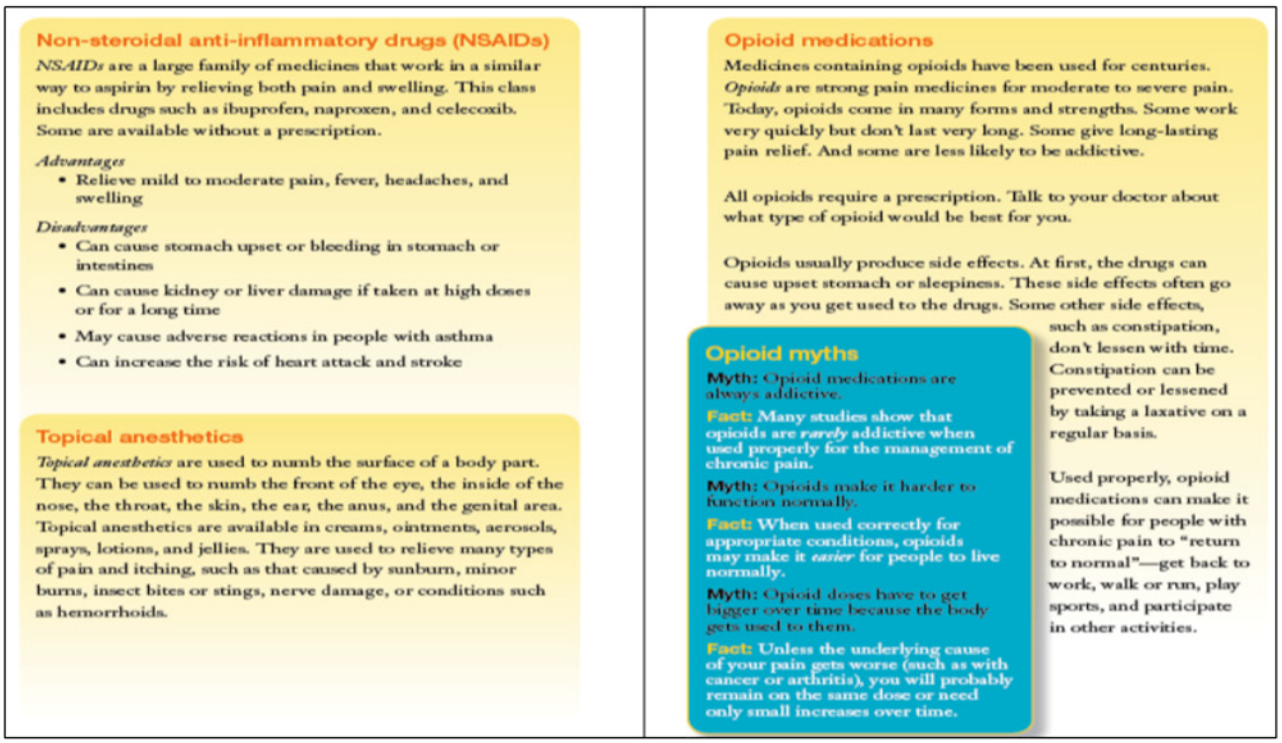
[48] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), www.pharmedout.org/Fugh-BermanPrescriptionforconflict6-25-10.pdf

[49] John Fauber, *NSAID Bleeding Risk: Smoke But No Fire*, MedPage Today (May 30, 2012), www.medpagetoday.com/Geriatrics/PainManagement/32971.

123. The Janssen-funded brochure, excerpted below, was also distributed to doctors and patients in Chicago during the relevant time period:



Non-steroidal anti-inflammatory drugs (NSAIDs)

NSAIDs are a large family of medicines that work in a similar way to aspirin by relieving both pain and swelling. This class includes drugs such as ibuprofen, naproxen, and celecoxib. Some are available without a prescription.

Advantages

- Relieve mild to moderate pain, fever, headaches, and swelling

Disadvantages

- Can cause stomach upset or bleeding in stomach or intestines
- Can cause kidney or liver damage if taken at high doses or for a long time
- May cause adverse reactions in people with asthma
- Can increase the risk of heart attack and stroke

Topical anesthetics

Topical anesthetics are used to numb the surface of a body part. They can be used to numb the front of the eye, the inside of the nose, the throat, the skin, the ear, the anus, and the genital area. Topical anesthetics are available in creams, ointments, aerosols, sprays, lotions, and jellies. They are used to relieve many types of pain and itching, such as that caused by sunburn, minor burns, insect bites or stings, nerve damage, or conditions such as hemorrhoids.

Opioid medications

Medicines containing opioids have been used for centuries. *Opioids* are strong pain medicines for moderate to severe pain. Today, opioids come in many forms and strengths. Some work very quickly but don't last very long. Some give long-lasting pain relief. And some are less likely to be addictive.

All opioids require a prescription. Talk to your doctor about what type of opioid would be best for you.

Opioids usually produce side effects. At first, the drugs can cause upset stomach or sleepiness. These side effects often go away as you get used to the drugs. Some other side effects, such as constipation, don't lessen with time. Constipation can be prevented or lessened by taking a laxative on a regular basis.

Used properly, opioid medications can make it possible for people with chronic pain to "return to normal"—get back to work, walk or run, play sports, and participate in other activities.

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

1 - *Finding Relief: Pain Management for Older Adults*, funded and distributed by defendants Janssen (2009)

The disclosed risks of NSAIDs include bleeding in the stomach or intestine, kidney or liver damage, and an increased risk of heart attack and stroke. In contrast, the side effects of opioids include an upset stomach, sleepiness, and constipation, though even these side effects often go away or can be managed. This marked difference, in a single brochure, makes evident Defendants' marketing slant.

124. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.[50]

[50] Mark Olfson et al., *Nat'l Trends in the office-based prescription of schedule II opioids*, 74(9) The Journal of Clinical Psychiatry, 932-939 (Sept. 2013).

D. Defendants, Directly and Through Their Agents and Front Organizations, Made and Caused Their Misrepresentations to Be Made and Broadly Disseminated

125. Defendants have polluted virtually every resource for information on the use of opioids to treat chronic non-cancer pain and have created a deceptively solid foundation of core materials, cited and relied upon by others, to minimize the risks and overstate the benefits of using opioids to treat chronic non-cancer pain. Both directly and indirectly – through doctors, medical education courses, seemingly independent patient advocacy groups, and professional societies like AAPM. Defendants have ensured that their messages reach and expand the market for opioids. These strategies and players are deployed according to marketing plans that Defendants developed. Defendants have identified, encouraged, and compensated high profile KOLs to give talks and advice and author books and articles. Defendants' KOLs offer and serve on the program committees that choose CMEs, and develop and promote treatment guidelines that promote chronic opioid therapy. Many of these groups and KOLs may have been misled by Defendants in the same manner as general practitioners and family doctors.

126. Directly and through public relations firms they hire, and advocacy groups and professional societies they finance and influence, Defendants have funded, drafted, edited, approved, published, and distributed websites, books, patient education brochures, videos, and other materials that carry their misrepresentations to targeted groups of doctors (such as family doctors), and patients – particularly veterans and the elderly. Defendants carry out their fraudulent promotions both individually and in concert with other industry front groups and each other, and make and disseminate these misrepresentations throughout the City.

1. Method 1: Key opinion leaders ("KOLs")

127. Defendants routinely rely on a small circle of doctors to promote the use of opioids for the treatment of chronic non-cancer pain. These doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research in order to support the broad use of opioid therapy for chronic non-cancer pain. Known by industry shorthand as "KOLs," or key opinion leaders, they have written, consulted on,

edited, and lent their names to books and articles and given speeches and CMEs supportive of chronic opioid therapy. They served on committees that developed treatment guidelines that, even while acknowledging the lack of evidence for their positions, strongly encourage the use of opioids to treat chronic non-cancer pain.

128. Using KOLs is part of Defendants' marketing strategies – and budgets. The drug companies monitored and measured the return from their investment in KOLs. Endo, for example, tracked how many doctors attended its programs and, upon information and belief, how the programs impacted the attendees' prescribing practices. Endo also tracked the takeaway messages that doctors took from their programs. Among the advantages of Opana, according to participating doctors, were the "low abuse potential" and "low incidence of side effects" – both deceptive messages.

129. Defendants' KOLs have served on the boards of the advocacy groups and professional societies that develop and offer CMEs and publish patient education materials on opioids.

130. What Defendants and the KOLs rarely disclose is the substantial sums of money Defendants have paid to the KOLs for consulting and speaking arrangements and to serve on various panels and boards; as well as through purported "research grants." Some KOLs have even gone on to become direct employees and executives of Defendants. Dr. Haddox, for example, was a KOL who, as a physician in private practice, promoted widespread opioid use for chronic non-cancer pain. He was a paid speaker and consultant for Purdue, then became a Purdue senior manager.

131. While some KOLs may initially have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected and funded doctors whose public positions were unequivocal and supportive of using opioids to treat

chronic non-cancer pain.[51] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

132. The KOLs' association with Defendants provided not only money, but also prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community. Upon information and belief, using these KOLs is a central part of Defendants' marketing plans and critical to persuading regulators and doctors – who rely heavily and more uncritically on their peers – that the benefits of chronic opioid therapy outweigh its risks. Drug companies in fact have developed sophisticated plans for the deployment of such doctors through the life-cycle of their products.

133. Dr. Russell Portenoy, Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and co-opted to further their marketing campaign. With Defendants' support, Dr. Portenoy was dubbed the "King of Pain" by TIME MAGAZINE. He co-authored *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases (1986)*, which asserted, based solely on 38 cases, that chronic opioid therapy was a safe and effective treatment for patients with intractable non-malignant pain.

134. Dr. Portenoy, thus, helped to open the door for the use of opioids to treat chronic non-cancer pain. He served on the American Pain Society/American Academy of Pain Medicine Guidelines Committee, which endorsed the use of opioids to treat chronic non-cancer pain, and the FDA Anesthetic and Life Support Drugs Advisory Committee, one of a host of FDA

[51] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used key opinion leaders in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.[52] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN Health (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/.

advisory committees that serve to provide expertise and technical assistance to assist the FDA decision-making. While he held these positions, he also was receiving research support, consulting fees, or honoraria from Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

135. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research. He is a Senior Editor of the *Pain Medicine* Journal, which published numerous articles supportive of chronic opioid therapy. He was President, and is a current board member, of AAPM, a Chicago-based front group that ardently supported chronic opioid therapy. Dr. Webster is the author of numerous CME programs, sponsored by Defendants, which contained virtually all of Defendants' misrepresentations described above. At the same time, Dr. Webster was receiving significant funding (including nearly $2 million from Cephalon).

136. Dr. Webster has been under investigation by the U.S. Drug Enforcement Administration, which raided Dr. Webster's clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a screening tool that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids.[52]

137. In a blow to Defendants' marketing campaign, Drs. Portenoy and Webster recently acknowledged shortcomings in their pro-opioid positions. Dr. Webster has admitted that the concept of pseudoaddiction – taking patients at their word and assuming they are not addicts, but just need more pain relief "–became too much of an excuse to give patients more medication . . . It is already something we are debunking as a concept."[53] Dr. Portenoy has admitted that he gave "innumerable lectures in the late 1980s and '90s" in which he asserted that

[52] Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN Health (Dec. 20, 2013), http://www.cnn.com/2013/12/20/health/pain-pillar/.

[53] Ed Silverman, *Opioids & An Overdue Senate Probe: Kolodny Explains*, Pharmalot.com (May 14, 2012), http://www.pharmalot.com/2012/05/opioids-an-overdue-senate-probe-kolodny-explains/.

fewer than 1% of patients would become addicted to opioids that "weren't true." Because the primary goal was to "destigmatize" opioids, he said, "we often left evidence behind." Dr. Portenoy also conceded that "data about the effectiveness of opioids does not exist."[54]

2. Method 2: Co-opting of chronic pain advocacy and research groups to promote opioid use.

138. A key component of Defendants' plans to promote the long-term use of opioids was co-opting pain management organizations and societies and pain patient advocacy groups. Taking a page from the tobacco industry, which had created and used front groups to proclaim tobacco was not harmful, Defendants harnessed and warped existing organizations to disseminate their deceptive messages with the expectation that these messages would circulate among and influence the conduct of prescribing physicians and other members of the medical community. These front organizations appeared to be legitimate scientific and patient advocacy organizations (and perhaps started out as such) and publicized seemingly scientific, balanced, and accurate information on opioid use. In fact, the information was false and misleading and paid for and encouraged by Defendants for the purpose of creating a vast market for the use of opioids for chronic non-cancer pain.

139. The role of these organizations in promoting opioid use and their ties to opioid makers was highlighted when, on May 8, 2012, Senators Grassley and Baucus wrote to a half-dozen of these organizations:

> There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic [of opioid use and abuse] by promoting misleading information about the drugs' safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State

[54] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), http://online.wsj.com/news/articles/SB10001424127887324478304578173342657044604

> Medical Boards, the University of Wisconsin Pain and Policy Study Group, and the Joint Commission.
>
> In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."[55] *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers play down the risks associated with opioids and exaggerate their benefits. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research.
>
> According to the *Milwaukee Journal Sentinel/MedPage Today*, a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers … helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient litigators, position statements, books and doctor education courses."[56]

140. These front groups, aided by millions of dollars in grants from Defendants and assistance from public relations firms hired by Defendants, spread the misrepresentations central to Defendants' fraudulent promotion of opioids. Indeed, Defendants influenced, if not outright controlled, the messages disseminated by many of these front groups.

a. American Pain Foundation.

141. The most prominent of Defendants' front groups was the American Pain Foundation ("APF"), which received more than [redacted] in funding from Defendants from 2007 until it closed its doors in May 2012. [redacted]

142. APF issued education guides for patients, reporters, and policymakers that promoted the benefits of opioids for chronic non-cancer pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for

[55] Charles Ornstein & Tracy Webber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), http://www.propublica.org/article/the-champion-of-painkillers.

[56] John Fauber, Follow *the Money: Pain, Policy, and Profit*, Milwaukee Journal Sentinel/MedPage Today (Feb. 19, 2012), http://www.medpagetoday.com/Neurology/PainManagement/31256.

returning veterans, described in greater detail below; promotion of opioids to treat veterans has contributed to high rates of addiction among returning soldiers. APF engaged in a significant multimedia campaign – through radio, television and the web – to educate patients about their "right" to pain treatment – namely opioids. KOLs funded by Defendants, including Drs. Perry Fine, Scott Fishman and Kathleen Foley, also served on APF's Board of Directors.

143. In 2009 and 2010, [redacted] of APF's operating budget came from industry sources. Including industry grants for specific projects, in 2009, APF received [redacted] from industry sources out of total income of [redacted]; its budget for 2010 projected receipts of [redacted] from drug companies, out of total income of [redacted]

144. But the control was even more direct than the money. [redacted]

145. [redacted] opioid "tool-kit" for the National Initiative on Pain Control [redacted] included two of Defendants' key misrepresentations:

- After starting opioid therapy, you may see the following positive improvements: - Your pain level may decrease[;] -Your level of function should improve: you may find you

are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse[;] - Your sleep may improve.

- People who take opioids as prescribed usually do not become addicted.

146. At a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the oxycontin criminal settlement," APF aggressively defended Purdue, repeatedly denying that patients prescribed opioids abuse or become addicted to the drugs. APF's board chairman, Dr. James Campbell, described addiction as a "rare problem" for chronic non-cancer pain patients and asserted that "the scientific evidence suggests that addiction to opioids by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of oxycontin and the abuse and diversion of the drug."

147. Despite APF's unequivocal pro-opioid positions, [redacted]

148. On May 8, 2012, Senators Grassley and Baucus wrote the Chairman of APF seeking information about the source of its funding and asked for a response by June 8, 2012. APF shuttered its offices and dissolved before that deadline.

b. American Academy of Pain Medicine.

149. The American Academy of Pain Medicine with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted

[redacted]

medical education programs critical to Defendants' deceptive marketing of chronic opioid therapy. Upon information and belief, AAPM received over $2.2 million in funding in the last 3 years from opioid manufacturers. AAPM created and maintained a corporate relations council, whose members paid $25,000 a year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with the AAPM's marquee event – its annual meeting in Palm Springs. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

150. Additionally, AAPM retained pro-opioid KOLs to serve on its board of directors, and advisory committees; further, allowing the organization to be used to promulgate the pro-opioid misrepresentations being pushed by the opioid manufacturers. Notably, one of AAPM's recent past presidents, Dr. Lynn Webster, was appointed to the position while he was being investigated by the DEA as a result of more than 20 deaths of chronic pain patients of Dr. Webster's clinic, who were prescribed and were taking prescription opioids. Another outspoken pro-opioid KOL, Dr. Russell Portenoy, also served as a recent past president of AAPM.

151. The AAPM and the American Pain Society issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Defendant Purdue; three years later, he became Vice President for Health Policy at Purdue. AAPM and the American Pain Society issued guidelines in 2009 and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the guidelines, including KOL Dr. Portenoy, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Upon information and belief, the 1997 consensus statement remained on AAPM's website until 2011, and was taken down only after a doctor complained.

3. Method 3: Treatment guidelines.

152. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts in, nor trained in, the treatment of chronic non-cancer pain. Treatment guidelines used in making treatment decisions are cited throughout the scientific literature and are referenced by third-party payers in determining whether they should cover treatments for specific indications.

153. As noted above, in 2009 AAPM, together with the American Pain Society ("APS"), issued their *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain*. The Guidelines represented a marked departure from previous guidelines for the promotion of opioids. The APS/AAPM guidelines promote opioids as "safe and effective" for treating chronic non-cancer pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients with and without past abuse histories. One member of the panel, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and the founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions by Defendants to the sponsoring organizations and committee members. These guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but the body of scientific evidence on opioids; the APS/AAPM guidelines have been cited 732 times in academic literature that was disseminated in Chicago during the relevant time period, are still available on the internet, and were reprinted in the *Journal of Pain*.

154. In 2009, the American Geriatric Society ("AGS") revised its guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines were distributed broadly through earmarked support from Defendants Purdue and Janssen, and included the following recommendations:

- "All patients with moderate to severe pain … should be considered for opioid therapy (low quality of evidence, strong recommendation)."
- "[Th]e risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."

These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence.

155. According to one news report, AGS received $344,000 in funding from opioid makers since 2009.[58] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock.[59]

156. In contrast, treatment guidelines that did not receive industry backing are much more reserved and endorse chronic opioid therapy only in narrow circumstances. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians, included a disclaimer that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." The American Society of Interventional Pain Physicians Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and

[58] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee Journal Sentinel/MedPage Today (May 30, 2012), http://www.medpagetoday.com/Geriatrics/PainManagement/32967.

[59] The Institute of Medicine recommends that, to ensure an unbiased result, that fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

political propaganda under the guise of improving the treatment of chronic pain." They recommend long-acting opioids in high doses only "in specific circumstances with severe intractable pain … with continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."

157. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommended against "routine use of opioids for treatment of chronic pain patients," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.

158. Industry supported guidelines, in contrast, separate the strength of the recommendation from the strength of evidence supporting the recommendation. For instance, most of the "strong" recommendations of the APS/AAPM guidelines are backed by only what the guidelines describes as weak evidence. Further, the guidelines Defendants supported fail to adequately take into account the potential adverse effects and specific label warnings that a physician should take into consideration in deciding on a treatment for any medical condition. As a result, they present a distorted picture of treatment options.

159. The separation of recommendations from the strength of supporting evidence proved useful for drug companies in promoting their opioids individually. A talk prepared by Endo pharmaceuticals in 2009 and given by a Chicago-area KOL titled, *The Role of Opana ER in the Management of Chronic Pain,* includes a slide titled, *Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain*, citing the AAPM's recommendations while omitting the guidelines' disclaimer regarding the lack of supporting evidence. Upon information and belief, the guidelines were widely referenced and promoted by the drug companies and their KOLs and front groups without disclosing the acknowledged lack of evidence to support them. This dangerously misrepresented to doctors the credibility and applicability of the pro-opioid recommendations.

4. Method 4: Continuing medical education.

160. The millions of doctors and other health care professionals[60] who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. Defendants have sponsored thousands of CME programs that promote chronic opioid therapy and support and disseminate the deceptive and biased messages described in this Complaint. Upon information and belief, Defendants' grant making to fund and sponsor CMEs has been influenced by their marketing strategies and harnessed to the goal of increasing opioid sales. Upon information and belief, Defendants are more than passive funders of these programs, which reached tens of thousands of doctors; they have influenced, if not outright controlled, the messages on topics and in the fields of practice Defendants targeted.

161. The American Medical Association has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[61]

162. Defendants have long-standing relationships with the professional associations, advocacy organizations, presenters, and CME development companies that select and develop opioid-related CMEs. These other organizations have depended upon Defendants' financial support for their activities and, in some cases, their very existence. It stands to reason that each of these organizations and the individuals running them know and believe that future financial support from Defendants depends upon producing programs that support the use of Defendants' products.

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[60] Lisa M. Schwartz & Steven Woloshin, *Medical Communication Companies and Continuing Medical Education: Clouding the Sunshine*, 310(23) The Journal of the Am. Med. Ass'n 2507, 2507 (Dec. 18, 2013).

[61] *Opinion 9.0115 – Financial Relationships with Indus. in CME*, Am. Med. Ass'n (Nov. 2011), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion90115.page.

163. Defendants are able to influence CMEs because they fund: (1) the KOLs who serve on the program committees of the professional societies that select the presentations and speakers and promote the views on which the presentations rely; (2) the KOLs who serve as speakers for the CMEs; and (3) the professional societies that host the conferences at which the presentations are given. Upon information and belief, many of these programs focus exclusively on prescribing opioids, and do not fairly present reasonable alternative treatments (except to discount them), nor do they fairly present (or present at all) the risks or benefits of chronic opioid therapy, nor how to take patients off opioids, once prescribed.

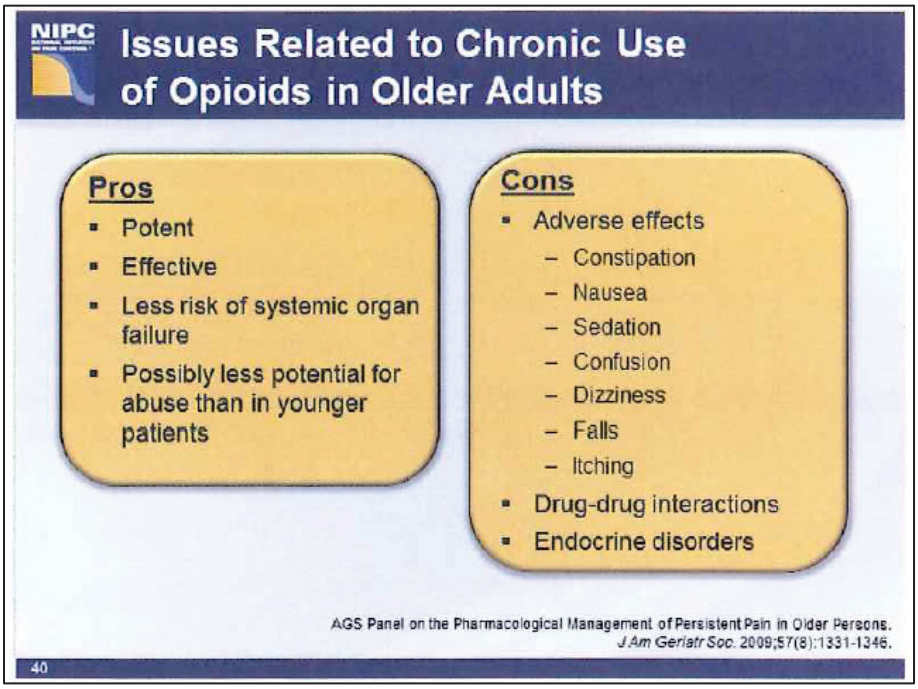
164. Defendants' sales representatives participated in conferences at which the CMEs were presented, encouraged doctors to attend the programs, and held auxiliary events that reinforced and amplified the distorted messaging of the CMEs. The CMEs themselves, however, buttressed by printed disclaimers by Defendants, were marketed to appear evidence-based and unbiased. In fact, like KOLs, the CMEs are particularly effective for disseminating Defendants' messages because doctors rely on these peer-led professional events to deepen their understanding of clinical issues.

165. *Path of the Patient, Managing Chronic Pain in Younger Adult at Risk for Abuse*, a CME program sponsored in part by Purdue and edited by KOL Dr. Perry Fine, provides one example of Defendants' use of CMEs to spread deceptive messages supportive of chronic opioid therapy. *Path of the Patient* aimed to educate primary care doctors about managing chronic non-cancer pain with opioids. The presentation is devoted entirely to opioid prescribing and, despite its title, presents *no other* potential treatments. Far from a therapy of last resort, as conventional medical thought advised, *Path of the Patient* promotes opioid therapy as the only solution, even for common chronic non-cancer pain issues such as back pain. This CME was available on-line for Chicago physicians, and others, to view during the relevant time period.

166. In a role play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills a day as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of

drug and alcohol abuse. Even given these facts, an authoritative narrator notes that, because of a condition known as pseudoaddiction, the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role play treats this patient by prescribing a high-dose, long-acting opioid.

167. An Endo-sponsored CME put on by the APF's National Initiative for Pain Control, *Persistent Pain in the Older Adult*, similarly reprises several of Defendants' misrepresentations. The program was first made available on-line, including to Chicago physicians, and others, in 2011 and continued to be available during the relevant time period. The CME describes fear of addiction, safe use, and drug-drug interactions – all factors relating to addiction, abuse, and overdose – as the most significant barriers to treating "persistent" or chronic non-cancer pain in the elderly. The presentation counsels that acetaminophen should be used only short-term and includes five slides on the FDA's restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). Citing the AGS's treatment guidelines as its sole support, the CME describes the "chronic use of opioids in older adults" as "effective" and notes "possibly less potential for abuse than in younger patients." Its listed adverse outcomes simply omit addiction, overdose, respiratory depression, or death, among others, and the slides note that tolerance to opioids more mild side effects (such as dizziness or nausea) "develops within days to weeks." The CME never discloses the heightened risks opioids pose to elderly patients (see below).



168. Dozens of CMEs that were available during the relevant time period and continue to be available to doctors in Chicago during the relevant time period also promoted the false concepts that opioids improve quality of life and physical function, that the risk of addiction to opioids is low and that doctors can identify and manage patients at higher risk of addiction. The programs train doctors to use specific risk training tools without disclosing that the tools are unproven or the lack of evidence that high-risk – or any – patients can take opioids long-term without becoming addicted.

5. Method 5: Scientific articles.

169. Defendants rely on misleading and deceptive citation of scientific articles to overstate the benefits of chronic opioid therapy and minimize its serious risks and fail to disclose contrary evidence. For instance, the Purdue-funded *Policymaker's Guide* (2011) makes the particularly callous representation that less than 1% of children prescribed opioids will become addicted. In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain. The purpose of the *Guide* was to support opioid therapy generally; it was not focused on or restricted to cancer pain patients — the only population addressed in Dr.

Foley's article, which also did not reference pediatric cancer patients or include any statistics on addiction rates. Purdue funded and distributed the Guide with this misleading citation, knowing that there was no evidence to support the general assertion that children will not become addicted to opioids, even when taken long-term. The Guide was disseminated in Chicago within the relevant time period.

170. Similarly, a 2003 scientific study funded by Purdue and co-authored by a Purdue employee concluded that OxyContin is "effective and safe for the management of [chronic diabetes-related pain] and improves QOL [quality of life]." The study asserts that there is "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse." The authors cite a single article by Porter and Jick, *Addiction Rare in Patients Treated with Narcotics*, published in the prestigious NEW ENGLAND JOURNAL OF MEDICINE. What the authors fail to disclose is that the "evidence" is actually a letter to the editor, not a peer reviewed article. Moreover, the letter describes not a study but a chart review of hospitalized patients; if medical charts failed to note that the patients exhibited documented signs of addiction while on opioids, the authors concluded that they were not addicted. Not only did the study not support the authors' assertion, but the authors' misleading citation of it created a false impression of its reliability. The Porter and Jick letter and the 2003 Purdue study have been cited 819 and 455 times, respectively, in the medical literature since 2008.

171. Practicing doctors, particularly the busy family doctors and general practitioners targeted by Defendants, do not have the time to look behind seemingly authoritative sources, particularly in scientific literature. They do – and must be able to – rely on citations to scientific literature, a fact that Defendants use to their advantage. Moreover, the misleading use of studies to give them weight or meaning they do not have is like a virus; once embedded in the literature, it takes on a life of its own. Studies that assert addiction is rare, relying either on the Foley or Porter-Jick analyses, themselves are cited for the proposition. Thus, with a few key manipulations and deceptive citations, Defendants were able to seed a scientific consensus supportive of chronic opioid therapy.

6. Method 6: Patient education.

172. Defendants reach chronic non-cancer pain patients through written publications, websites, and videos designed to present the purported "facts" about opioids in a simple, user-friendly manner. As Defendants know, these materials are accessed by both patients doing their own research and doctors, who read them when distributing them to patients. The materials Defendants produced concerning opioids include numerous fraudulent representations, overstate the benefits of chronic opioid therapy, and fail to fully disclose its risks, particularly the risks of addiction.

173. For example, Defendant Janssen funded, edited, and/or approved a patient education pamphlet produced by public relations firm Conrad & Associates. The pamphlet, *Finding Relief: Pain Management for Older Adults* (2009, also sponsored by AGS, and American Academy of Pain Medicine) is unbranded, though it was timed to coincide with and support the launch of Nucynta.

174. *Finding Relief* describes opioids as "rarely addicting when used properly for the management of chronic pain" and assures that "unless the underlying cause of your pain gets worse … you will probably remain on the same dose or only need small increases over time." As described above, these contentions are wholly lacking in scientific or clinical support. Janssen was involved in developing and approving the deceptive messages in patient education booklets such as this one.

175. Defendants created campaigns – including literature, websites, community groups, and programs – related to chronic non-cancer pain from illnesses such as lower back pain, shingles, migraines, osteoarthritis, phantom limb pain, fibromyalgia, and multiple sclerosis. These conditions affect significant numbers of people, who have formed affinity groups and on-line communities for support in seeking to address conditions that produce persistent pain and may necessitate long-term treatment. Defendants used this community-building to promote the use of opioids in the treatment of these conditions, despite the fact that there was little or no

scientific evidence supporting the use of opioids for these conditions, and little or no evidence supporting or even suggesting that the use of opioids for these conditions would provide more benefit from pain relief than harm from the many known and significant opioid treatment risks. None of these conditions reflect indications approved to appear on Defendants' drug labels, supporting the inference that Defendants did not have evidence to obtain such approval.

176. In addition to their general marketing efforts, Defendants made special efforts to market to two particularly vulnerable patient groups: the elderly and veterans. While obvious markets for chronic non-cancer pain medications, each of these patient populations has risk factors that make long-term opioid use particularly dangerous.

a. Elderly patients

177. Elderly patients taking opioids have been found to suffer elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels, occurs more frequently in elderly patients.[62] A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs.[63] Defendants' targeted marketing to the elderly and the absence of cautionary language in its promotional materials flies in the face of scientific evidence and even their own labels and creates a heightened risk of serious injury.

178. In their effort to reach elderly patients, who experience pain associated with arthritis and other aging-related conditions, Purdue partnered with AGS to produce the treatment guidelines, discussed at Paragraphs 153-154 above, and education materials focused on elderly patients. *Finding Relief: Pain Management for Older Adults*, a 2009 publication sponsored by Janssen, as noted above, repeated the same unsubstantiated, deceptive statements that opioids are

[62] Kathleen W. Saunders et al., *Relationship of opioid use and dosage levels to fractures in older chronic pain patients*, 25(4) Journal of Gen. Internal Med., 310-315 (Apr. 2010).

[63] Daniel H. Solomon et al., *The Comparative Safety of Analgesics in Older Adults with Arthritis*, 170(22) Archives of Internal Med., 1968-1976 (Dec. 13, 2010).

"rarely addictive" and increase patients' function, allowing them to get back to work or participate in recreational activities.

179. Upon information and belief, other Defendants also focused outreach efforts on the elderly. Celphalon's 2007 marketing plan for Fentora, for example, in a slide describing plans to target chronic non-cancer pain patients, laid out a multi-city tour with stops at AARP events, YMCAs, senior living facilities, and National Council on Aging chapters.

180. Defendants also promoted the notion – also without adequate scientific foundation – that the elderly are particularly unlikely to become addicted to opioids. The AGS's 2009 Guidelines, for example, described addiction rates as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study that examined overdoses among long-term opioid users found that the largest number of patients among those with serious overdoses were 65 or older.[64]

181. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

182. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed prescription drug abuse among military personnel doubled from 2002 to 2005 and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they did in 2001.[65] Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.[66] Although, upon information and belief, many of these veterans

[64] Kate M. Dunn et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85, 89 (Jan. 19, 2010).

[65] Bill Briggs, *VA Docs Defied Opiate Rules in Treating Vets, Audit Finds*, NBC News (May 15, 2014), http://www.nbcnews.com/storyline/va-hospital-scandal/va-docs-defied-opiate-rules-treating-vets-audit-finds-n106461.

[66] American-Statesman Investigative Team, *Prescription drug abuse, overdoses haunt veterans seeking relief from physical, mental pain*, Austin American-Statesman (Sept. 29, 2012),

are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving Veterans' Administration ("VA") services nationally in a single year (2005), 1,013 had died of accidental drug overdoses – double the rate of the civilian population. VA facilities outside of Chicago, which, upon information and belief, serve Chicago residents who are veterans, saw dramatic increases in their rates of prescribing opioids.

183. Opioids are particularly dangerous to veterans. According to a study published last year in the Journal of American Medicine, veterans returning from Iraq and Afghanistan prescribed opioids have higher incidence of adverse clinical outcomes, like overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.[67] Yet, according to a Veterans Affairs Office of Inspector General Report, 92.6% of veterans chronically prescribed opioid drugs were also prescribed benzodiazepines.[68] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and failed to disclose in their promotional materials the known, serious risks opioids posed to them.

184. Defendants have targeted veterans with fraudulent and unproven representations. As early as 2001, a Purdue promotional plan described spending hundreds of thousands of dollars to target the Veterans Administration and admitted that it was using "education" for what was actually marketing.[69] "Corporate initiatives and partnering efforts were very successful with

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http://www.statesman.com/news/news/prescription-drug-abuse-overdoses-haunt-veterans/nSPLW/

[67] Karen H. Seal et al., *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, 307(9) The Journal of the Am. Med. Ass'n, 940-947 (Mar. 7, 2012).

[68] Briggs, *supra* note 65.

[69] American-Statesman Investigative Team, *Critics say pharmaceutical firms spurred the increase in prescriptions for narcotic painkillers,* Austin American-Statesman (Sept. 29, 2012),

the Veterans Administration. In addition to building sales for OxyContin tablets, it also positioned Purdue as the leader in pain management education."[70]

185. *Exit Wounds*, a 2009 publication [redacted] promoted as a personal narrative by one veteran writing to others, describes opioids as "under-used" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "*increase* your level of functioning" (emphasis in original) and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards." The U.S. Federation of State Medical Boards itself received support from Defendants during the time it created and published its guidelines for prescription of opioids. Upon information and belief, *Exit Wounds* was disseminated in Chicago within the relevant time period.

186. *Exit Wounds* minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with anti-anxiety medications taken by a significant number of veterans. [redacted]

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http://www.statesman.com/news/news/local-military/critics-say-firms-spurred-painkiller-prescriptions/nSPNL/

[70] *Id.*

187. The deceptive nature of *Exit Wounds* is made obvious in comparing it to guidance on opioids published by the VA and Department of Defense ("DOD") in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses or using multiple doctors for prescriptions and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death – none of which are disclosed in *Exit Wounds*. *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the DOD, discloses that its review "revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps … include: lack of effectiveness studies on long-term benefits and harms of opioids …; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification …; lack of evidence on the utility of informed consent and opioid management plans …; and treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse." These disclosures are missing from Defendants' marketing to veterans.

E. Defendants Often Acted Together in Promoting Opioids, Opposing Regulation and Facilitating Supportive Standards to Approve Opioids

188. As laid out above, Defendants supported, assisted, encouraged and/or facilitated the same front groups and KOLs to disseminate the same deceptive messages about the use of opioids to treat chronic non-cancer pain. In fact, the similarity of their messages, language, and even their formatting (*e.g.*, the myth/fact formulation) suggests that Defendants participated in a common scheme to disseminate misleading information about opioids.

189. This inference is supported by Defendants' cooperation in other activities to promote opioids, including successful efforts to set standards for measuring and treating pain, training and regulating doctors, and approving new opioids.

190. Defendants' efforts to shift the paradigm on opioids and pain treatment began soon after their branded opioids were launched. In 2000, the Joint Commission on Accreditation

of Healthcare Organizations ("JCAHO"), in conjunction with the University of Wisconsin Pain and Studies Group, declared that pain was the "5th Vital Sign" and required all healthcare practitioners to make pain assessment and management a priority in daily practice.

191. Upon information and belief, the impetus behind the new pain standard began with June Dahl, then a professor of pharmacology at the University of Wisconsin-Madison. Dr. Dahl approached JCAHO with a proposal and helped identify pain management experts and key organizations to act as advisors to JCAHO, as well as promoters of Pain as the 5th Vital Sign. Those experts and key organizations are many of the same heavily funded KOLs and front groups that ultimately helped bring about the change in attitudes towards opioids and, subsequently, the rise in opioid prescribing. Defendant Purdue was one of two companies that paid for programs across the country to educate hospital physicians and staff about complying with the new pain standards and had exclusive rights to distribute certain education materials to JCAHO members.[71]

192. Once health practitioners were required to consider a patient's pain along with other vitals, the next step was to convince practitioners that all pain must be treated – preferably with opioids. In 2004, the Federation of State Medical Boards revised and updated its Model Policy for the Use of Controlled Substances for the Treatment of Pain. In support of those efforts, noted KOL Dr. Scott Fishman was tapped to author a companion piece, titled *Responsible Opioid Prescribing: A Physician's Guide* (2007)

193. The Guide was sponsored by Defendants Endo, and Purdue and was distributed to state medical boards, healthcare regulatory boards, medical organizations, hospitals and physicians across the country, including in Chicago. Cephalon itself paid to distribute 10,000 copies to prescribers and another 5,000 to pharmacists. The *Physician's Guide* contained many of the misrepresentations described above, notably the concept of pseudoaddiction and the claim

[71] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem,* U.S. Gen. Accounting Office (Jan. 22, 2004), www.gao.gov/htext/d04110.html.

that opioids improve function. Cephalon was so pleased with the book it wanted to permit its sales representatives to leave copies with the physicians they visited.

194. Defendants also worked together to promote opioids through the Pain Care Forum. The Forum is comprised of representatives from opioid manufacturers and distributors (including each of the Defendants); doctors and nurses in the field of pain care; health care professional organizations (*e.g.*, American Academy of Pain Management, American Pain Society, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and the American Chronic Pain Association); and other like-minded organizations (*e.g.*, Federation of State Medical Boards and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants. Upon information and belief, the Pain Care Forum was started, and continues to be run, by Defendant Purdue's in-house lobbyist Burt Rosen, previously in conjunction with APF. [redacted]

195. Upon information and belief, Defendants collaborated on a common campaign to build a market for opioids for chronic non-cancer pain, which they could share. .

F. Defendants Also Acted Individually to Deceptively Promote Their Opioids for Chronic Non-Cancer Pain.

196. In addition to participating in a shared campaign to expand the market for opioids by reaching chronic non-cancer pain patients and conditions, each Defendant acted on its own to deceptively market its specific opioids for chronic non-cancer pain and to capture a larger share of the chronic non-cancer pain market. Separately, in their branded materials and on seemingly independent websites, they each overstated the benefits and understated the risks of their drugs in the various ways described above, often causing the FDA to formally admonish them. On top of this, Cephalon engaged in additional unlawful conduct, marketing its opioid Fentora for unapproved chronic pain uses despite only recently settling a case involving almost identical activities with respect to its predecessor, Actiq. A review of the City's claims also suggests that opioids were prescribed, and potentially marketed, for off-label uses to treat depression. Purdue

also quickly began to violate a consent judgment with the federal government and the State of Illinois by continuing to misrepresent the risks and benefits of OxyContin and its other opioids.

1. Cephalon fraudulently marketed Actiq and Fentora.

197. Cephalon also engaged in a distinctive effort to market its opioids for chronic non-cancer pain despite having labels that specifically limited their use to cancer pain. As a result of its successful marketing efforts, Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs – Actiq or Fentora – is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed, causing prescriptions to be written and paid and, grievously, patients to be injured and die.

a. Cephalon launches its fraudulent marketing scheme of Actiq.

198. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate." [72]

199. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. Actiq is a rapid onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose

[72] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs,* The Wall Street Journal (Nov. 3, 2006), http://online.wsj.com/news/articles/SB116252463810112292.

for patients who are not opioid tolerant, that is, patients who have taken specific dosages of opioids for a week or longer and whose systems have acclimated to the drugs.

200. In 1995, the FDA approved Actiq "**ONLY** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." (Emphasis in FDA document.) Because of Actiq's dangers, wider, off-label uses – as the FDA label makes clear – are not permitted:

> Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is contraindicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients."
>
> Actiq is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.) Unlike other drugs, where off-label uses are permitted but cannot be promoted by the drug maker, Actiq is so potent that off-label use to opioid naïve patients is strictly forbidden.

201. Notwithstanding the drug's extreme potency and related dangers and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain – an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports related injuries, and other conditions not associated with cancer for which it was not approved, appropriate, or safe.

202. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

b. Cephalon fraudulently marketed Actiq's successor drug, Fentora.

203. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application (NDA) to the FDA for approval.

204. Like Actiq, Fentora is an extremely powerful opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth. Like Actiq, Fentora is a rapid onset opioid.

205. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already receiving and were tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

206. Fentora's inherent danger is confirmed by the unusually strong and detailed black box warning label – the most serious medication warning required by the FDA. The warning makes clear that, among other things:

> Reports of serious adverse events, including deaths in patients treated with *FENTORA* have been reported. Deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing. The substitution of *FENTORA* for any other fentanyl product may result in fatal overdosing.
>
> *FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
>
> FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine. Life-threatening respiratory depression could occur at any dose in opioid non-tolerant patients. Deaths have occurred in opioid non-tolerant patients,"
>
> . . .
>
> *FENTORA* is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

(Emphasis in original.)

c. October 1, 2006 – Cephalon launches Fentora and immediately begins deceptive marketing campaign.

207. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label.

208. Cephalon's marketing of Actiq "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally – not breakthrough cancer pain in particular – from Actiq.

209. On February 12, 2007, only five months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the rapid onset opioid market. We executed our transition strategy and the results in our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[73]

210. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities" – treating breakthrough cancer pain and:

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . . .

[73] *See Cephalon Q1 2007 Earnings Call Transcript,* Seeking Alpha (May 1, 2007, 8:48 PM EST), http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript (last visited May 27, 2014).

> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . Noting that opioids are "widely used in the treatment of . . . non-cancer patients," Roche continued:
>
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[74]

d. September 2007 – Reports of death and serious side effects lead the FDA to issue a public health warning for Fentora.

211. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora and indicating that "[t]hese deaths occurred as a result of improper patient selection *(e.g.*, use in opioid non-tolerant patients), improper dosing, and/or improper product substitution." The warning did not acknowledge Cephalon's deliberate role in the "improper patient selection."

212. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora only should be prescribed for approved conditions and that dosage guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label use. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to

[74] *Id.*

patients who have developed opioid tolerance. The Advisory reiterated that because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.

e. Cephalon sponsored CMEs used to promote the off-label use of Actiq and Fentora – 2007-2008, in spite of the FDA warnings.

213. Cephalon also used the CME programs it sponsored to promote the off-label use of their Actiq and Fentora. In 2007 and 2008, Cephalon sponsored three CMEs available to Chicago physicians that each positioned Actiq and Fentora, and only Actiq and Fentora, as "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs only use the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME would know to prescribe Actiq or Fentora.

214. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Lynn R. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid onset opioid when it cannot. The only examples of rapid onset opioids then on the market are oral transmucosal fentanyl citrate (*i.e.*, Actiq) or fentanyl effervescent buccal tablet (*i.e.*, Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients *and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well*." (Emphasis added.)

215. Similarly, *Breakthrough Pain: Improving Recognition and Management*, offered between March 31, 2008, and March 31, 2009, by Medscape, LLC completely omitted tolerance

limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like the "Optimizing Opioid Treatment" CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, *Opioid-Based Management of Persistent and Breakthrough Pain*, with Dr. Christine A. Miaskowski. They instruct their audience, "Clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommend "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including specifically in patients with chronic non-cancer pain.

216. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines that she served on Cephalon's speakers' bureau. Dr. Fine and Dr. Webster also received funding from Cephalon for consulting services, and upon information and belief, Drs. Fine and Webster continued to receive funding from other opioid manufacturers, too.

f. May 6, 2008 – The FDA rejects Cephalon's request for expanded approval of Fentora.

217. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. To support its application, Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[75] Cephalon argued for the expanded approval even though, as it acknowledged, "[t]o date, no medication has been systematically evaluated in clinical studies or

[75] *See Fentora (fentanyl buccal tablet) CII: Advisory Comm. Briefing Document,* U.S. F.D.A. Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (Apr. 4, 2008), http://wwvv.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf (last visited May 27, 2014).

approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

218. The FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[76] By a vote of 17-3, the relevant Advisory Committee – a panel of outside experts – voted against recommending approval of Cephalon's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of its already off-label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk Management Program. In December 2008, the FDA followed that up with a supplemental request, asking that the company submit a Risk Evaluation and Mitigation Strategy for Fentora as well.

g. March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora.

219. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade over Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not simply those who were opioid tolerant.

220. On March 26, 2009, the DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug. Specifically, the Warning Letter asserted that a direct-to-patient advertisement found on the internet was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is

[76] *See Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. F.D.A. Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008),, http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDA-corepresentations.ppt#289,1 (last visited May 27, 2014).

a candidate for Fentora therapy … when this is not the case." DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."** (Emphasis in original.) DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original.) DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (Emphasis in original.)

h. Cephalon continues to knowingly, deceptively, and illegally promote Fentora for off-label uses.

221. Cephalon's own market research studies confirm that its Fentora promotions were not focused on the physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

222. Yet Cephalon continued to use its general pain sales force (which numbered over 110 representatives) to promote Fentora to general pain specialists.

223. Cephalon-set sales quotas for its general pain sales force would be unattainable if they did not deceptively promote Fentora off-label. The general pain sales representatives have, from the outset, been required to adhere to call lists that include numerous pain doctors and other physicians who do not, and would not, prescribe Fentora on-label. These same call lists contain few, if any, oncologists.

224. A 2009 PowerPoint presentation by Kathy Roman, Cephalon's Associate Director of Oncology for Strategic Analysis & Planning, reported that only 4% of Fentora prescriptions were written by oncologists. Even earlier, a presentation dated July 2007, "Examining the Utilization and Opioid Tolerance of Fentora Patients, " noted that "a cancer diagnosis was found for only 19% of patients Fentora monitored in the study. Lower back pain and other pain accounted for nearly half of all Fentora patients as of the first quarter 2007."

225. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension of, and reaped the benefits of, Cephalon's generally deceptive promotion of opioids for chronic non-cancer pain.

2. Purdue's role in deceptively promoting opioids for treatment of chronic non-cancer pain.

226. Like Cephalon, Purdue also undertook its own separate campaign to deceptively market opioids. Purdue is the maker of OxyContin, which, over time, has been the most used and abused opioid. Today, with one exception, all of the drugs marketed by Purdue are opioids.

a. Purdue's marketing of OxyContin was deceptive from the start.

227. OxyContin was approved by the FDA in 1995 for "management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." Purdue immediately began promoting OxyContin as less addictive than other opioids. The drug's extended-release mechanism, according to Purdue, meant it was less likely to provide a euphoric

high and therefore was less likely to be abused, create addiction, or cause withdrawal. However, Purdue "did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications."[77] When crushed, dissolved in water, or injected, OxyContin's extended-release mechanism could be bypassed to produce a heroin-like high. In fact, OxyContin was more likely than other opioids to be abused and diverted because it had more oxycodone than other non-controlled release opioids (and oxycodone already is twice as potent as morphine).

228. Purdue's marketing persuaded primary care physicians that it was safe to prescribe OxyContin for chronic non-cancer pain. By 2003, according to the Government Accountability Office ("GAO"), general practitioners represented half of all OxyContin prescribers.[78] A GAO report noted that, between 1997 and 2002, OxyContin prescriptions for non-cancer pain increased nearly ten-fold, from 670,000 to 6.2 million, versus an increase in prescriptions for treatment of cancer pain from 250,000 to 1 million; non-cancer prescriptions represented 85% of total OxyContin prescriptions. At the same time, Purdue doubled the number of its sales representatives, who received bonuses based on sales quotas and were directed to target the most prolific opioid prescribers. Total sales bonuses in 2001 were $40 million, up from $1 million in 1996. Purdue also used speakers bureaus, which put on programs at resort locations, starter coupons to attract new patients, funded new front group websites, and, even distributed plush toys and hats, which the Drug Enforcement Administration ("DEA") says had never been done before for a controlled substance. The DEA blamed Purdue's "aggressive marketing of OxyContin" for "fuel[ing] demand for the drug and exacerbat[ing] the drug's diversion.[79]

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[78] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem, supra* note 71.

[78] *Prescription Drugs: OxyContin Abuse & Diversion & Efforts to Address the Problem, supra* note 71.

[79] *Id.*

229. In 2001, the FDA required Purdue to narrow its approved indication to "moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time" and added new warnings relating to the drug's potential for misuse and abuse. In August of that year, the FDA wrote to Purdue to make clear that all promotional materials should prominently disclose the new label information. Yet, not 18 months later, in January 2003, in response to two ads Purdue ran in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, the FDA issued a sharply worded warning letter to Purdue:

> Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk. In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use is especially egregious and alarming in its potential impact on the public health.[80]

230. The FDA's strong language seemed to have little impact on Purdue's behavior. In 2007, Purdue entered into a $635 million settlement with the federal government to resolve civil and criminal allegations relating to its marketing of OxyContin. This was a minor cost compared to the $27 billion in sales revenue generated since the introduction of OxyContin in 1996.[81] Purdue pled guilty to a single felony count of misbranding and its chief executive officer, chief

[80] Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver., and Commc'ns , U.S. F.D.A., to Michael Friedman, Executive Vice President and C.O.O., Purdue Pharma L.P. (Jan. 17, 2003), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM168946.pdf.

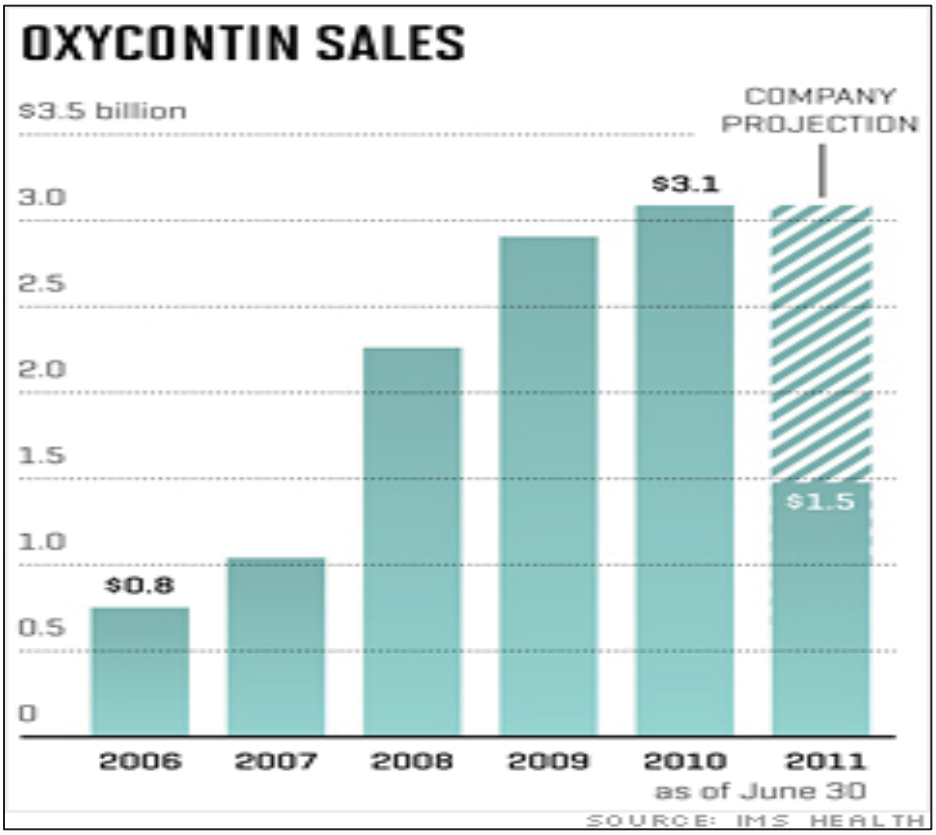
[81] Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors,* Los Angeles Times (Aug. 11, 2013), articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811.

medical officer, and general counsel individually pled guilty to misdemeanor counts. Purdue admitted in its plea that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science.

231. As part of its settlement, Purdue entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services-Office of Inspector General ("HHS-OIG"). Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the Agreement, monitor its own compliance, and report its compliance (both independently and through an independent review organization or "IRO") to HHS-OIG.

b. Purdue continued to engage in false marketing, misrepresenting OxyContin's benefits and the risk of addiction when taken long-term for chronic non-cancer pain.

232. Despite its guilty plea, Purdue continued to deceptively market opioids. And, as a result, its sales continued to grow. OxyContin yielded $3.1 billion in revenue for Purdue in 2010, up four-fold from its 2006 sales of $800 million.



233. Purdue's direct misrepresentations, and its relationship with front groups and KOLs who advanced its deceptive marketing, are described above. Upon information and belief, Purdue deployed these doctors and front groups according to marketing strategies it developed, and also funded, directed, shaped, approved, and disseminated their misrepresentations regarding the risks, benefits, and superiority of opioids' use to treat chronic non-cancer pain.

c. Purdue was aware of, and has profited from, misuse and diversion of its opioids.

234. According to the GAO, the first public news of diversion and abuse of OxyContin became known in 2000. Among them were reports of patients arriving in emergency rooms with severe withdrawal or overdoses, hundreds of deaths, and increases in drug treatment admissions for individuals on OxyContin. Since 2000, there have been countless news reports, lawsuits, and government and other data describing the rising toll of addiction, overdose, and death from OxyContin specifically and opioids generally.

235. In 2010, Purdue reformulated OxyContin, claiming that it would reduce tampering and make it less subject to abuse. The new OxyContin cannot be reduced to a powder as easily and does not dissolve; when water is added to it, it becomes gelatinous and cannot be injected.

236. While an important step, Purdue knew that even the reformulation of OxyContin did not resolve issues of abuse and addiction. A recent article in the LOS ANGELES TIMES revealed that Purdue – since 2002 – has kept a database of 1,800 doctors suspected of inappropriately prescribing its drugs, but Purdue did not alert law enforcement or medical authorities to all but a few of these doctors.[82] This database, according to the news report, was whittled down from 3,200 doctors reported as suspicious by Purdue's sales representatives (conduct that must have been so egregious that the sales representatives forewent the chance to earn commissions on the doctors' prescriptions).

237. Purdue did not use its database of problem doctors to reduce OxyContin abuse, to rein in dangerous doctors, or to stop the potentially unlawful distribution of a controlled substance. Instead, the company presented the evidence of rogue prescribing in an effort to persuade the FDA that generic drug makers should not be allowed to copy the earlier, non-tamper resistant version of OxyContin – the same OxyContin that Purdue originally promoted as less addictive – as it is too subject to abuse.

238. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in the LOS ANGELES TIMES article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." Instead, on information and belief, Purdue continued to profit from the prescriptions of these suspicious prescribers. Psychologist, researcher, and Stanford University professor Keith Humphreys noted, "[t]hose doctors are a gold mine for

[82] Glover & Girion, *supra* note 81.

Purdue. And the whole time they're taking the money, knowing that something is wrong, and not telling anyone until it gives them a market advantage to do so. That is really disgusting."[83]

G. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded and Dangerous, and Would Harm Chicago Residents.

239. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic non-cancer pain were untrue and unproven. The history of opioids, as well as research and clinical experience over the last 20 years, established that they were deeply addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to address nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.

240. Moreover, Defendants intended doctors, patients, and payers to rely on their representations. Defendants closely monitored their sales and the habits of prescribing doctors, which allowed them to see sales balloon, overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CMEs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to and also watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe, patients to use, and payers to cover their opioids for chronic pain.

[83] *Id.*

H. Defendants Fraudulently Concealed their Misrepresentations

241. At all times relevant to this Complaint, Defendants took steps to avoid detection of and fraudulently conceal their deceptive marketing and conspiratorial behavior.

242. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and relied on them to vouch for the accuracy and integrity of Defendants' untrue and unsupportable statements about opioid use for chronic non-cancer pain.

243. Upon information and belief, while Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Upon information and belief, Defendants exerted their considerable influence on these promotional and "educational" materials through their funding of and relationship with KOLs and front groups, both directly and through their public relations companies.

244. Contrary to their competitive interest in promoting their own opioid products, Defendants disseminated their deceptive messages through websites that were unbranded (did not promote a specific drug) and therefore could not easily be tied to a particular drug company sponsor. Unbranded messaging created the appearance of neutrality and gave Defendants' marketing messages the appearance of unbiased medical science. [redacted] Upon information and belief, Defendants, including Purdue and Janssen, ran similar websites that masked their own direct role in developing the content.

245. Upon information and belief, Defendants also obscured their participation by extensively using the public relations companies they hired to work with front groups to produce and disseminate deceptive materials.

246. Much of Defendants' deceptive marketing occurred at medical conferences and through CMEs that were open only to registered medical professionals. Therefore, the City would have had no access to or awareness of their content.

247. Further, in addition to hiding their own role in the deceptive conduct, Defendants manipulated their promotional materials to make it appear that they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by the City. Only in recent months have some of the KOLs whom Defendants relied upon and promoted to spread their deceptive messages acknowledged the lack of support for their positions.

248. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their marketing strategy, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the City now assert. The City was not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the City of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

I. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to the City of Chicago and Chicago Consumers.

249. Defendants' misrepresentations prompted doctors to prescribe, patients to take, and payers to cover opioids for the treatment of chronic non-cancer pain, believing that the benefits outweighed the risks and were better than alternative treatments. Defendants set out to overcome barriers to widespread prescribing of opioids – and succeeded – through a series of

deceptive messages designed to misrepresent the benefits, risks, and superiority of opioids over other treatments.

250. Defendants' deceptive marketing caused the use of opioids to explode. National trends—trends that also buffeted Chicago—reveal the alarming rates of opioid use. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids."[84] Indeed, "[o]pioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid."[85] A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010 even though the number of office visits in which patients complained of pain did not change; prescribing of non-opioid pain medications decreased over the same time.[86] For back pain alone – one of the most common chronic non-cancer pain conditions – the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady.[87] This increase corresponds with, and was caused by, Defendants' marketing push.

251. The sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as

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[84] Marie N. Stagnitti, *Statistical Brief #235: Trends in Outpatient Prescription Analgesics Utilization and Expenditures for the U.S. Civilian Noninstitutionalized Population, 1996 and 2006*, Agency for Healthcare Research and Quality, Fig. 6 (Feb. 2009), http://meps.ahrq.gov/mepsweb/data_files/publications/st235/stat235.pdf.

[85] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Archives of Internal Med. 1426, 1426 (Sept. 12, 2011).

[86] Matthew Daubresse et al., *Ambulatory Diagnosis & Treatment of Nonmalignant Pain in the U.S., 2000-2010,* 51(10) Med. Care, 870-878 (Oct. 2013).

[87] John N. Mafi et al., *Worsening Trends in the Mgmt. & Treatment of Back Pain,* 173(17) Journal of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

measured by prescriptions filled and their abuse.[88] "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[89] Opioids are involved in 40% of fatal drug overdoses – including overdoses due to illegal drugs.[90] Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.[91] According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.[92] In 2009, there were more than twice as many deaths from prescription opioid overdoses (15,597) than from cocaine (4,350) and heroin (3,278) put together.

252. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and

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[88] Theodore J. Cicero et al., *Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States*, 16(8) Pharmacoepidemiology and Drug Safety, 827-840 (Aug. 2007).

[89] Grady, *supra* note 85, at 1426.

[90] Margaret Warner et al., *NCHS Data Brief: Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999-2006*, Centers for Disease Control & Prevention, (Sept. 2009), www.cdc.gov/nchs/data/databriefs/db22.pdf.

[91] *Results from the 2011 Nat'l Survey on Drug Use & Health: Summary of Nat'l Findings*, U.S. Dep't of Health & Human Servs. (Sept. 2012), http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.pdf.

[92] *CDC Grand Rounds: Prescription Drug Overdoses, a U.S. Epidemic*, Centers for Disease Control & Prevention (Jan. 13, 2012), www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm.

795 non-medical users.[93] Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).[94]

253. Chicago's numbers are similarly dramatic. There have been over 1,000 emergency department visits for opioid overdoses, and over 1,200 emergency department visits involving patients who were illicitly using opioids.[95] For example, estimates of visits to the emergency department in Chicago due to the misuse and abuse of prescription painkillers have been steadily increasing, with a significant increase of 65 percent between 2004 and 2011.[96]

254. By May 2014, the State of Illinois had seventy-one Certified Opioid Treatment Programs, thirty-one of which are in the City of Chicago.[97] By way of contrast, Tennessee, whose opioid epidemic is among the worst in the nation, has only twelve.[98] Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction – buprenorphine and naltrexone – were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payers at $72.5 billion.[99]

255. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new

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[93] Wilson M. Compton, *Prescription Drug Abuse: It's Not What the Doctor Ordered*, Nat'l Inst. On Drug Abuse, (May 3, 2013), www.apa.org/about/gr/science/spin/2013/05/prescription-drug-abuse.pdf.

[94] *Nat'l Estimates of Drug-Related Emergency Dep't Visits, 2004-2011,* Substance Abuse & Mental Health Servs. Admin. (2011), *http://www.samhsa.gov/data/dawn/nations/Nation_2011_NMUP.xls.*

[95] *Metro Brief Chicago*, *supra* note 6.

[96] Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits. HHS Publication No. (SMA) 13-4760, DAWN Series D-39. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[97] *Opioid Treatment Program Directory,* Substance Abuse & Mental Health Servs. Admin., http://dpt2.samhsa.gov/treatment/directory.aspx

[98] *Id.*

[99] Katz, *supra* note 30.

wave of addiction, abuse, and injury. Defendants' scheme supplied both ends of the secondary market for opioids – providing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that "substantial increases in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[100] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.[101]

256. A significant black market in prescription opioids also has arisen, which has not only created and supplied additional addicts, but fueled other criminal activities. According to the Chicago field division of the Drug Enforcement Administration, "Street gangs, too, have become increasingly involved in prescription drug diversion."[102]

257. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals and, in 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids.[103] Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street." In the words of one federal Drug Enforcement Agency official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills and obtain them more easily. That is the reality we're facing."[104]

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[100] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) The Journal of the Am. Med. Ass'n, 1865-1866 (Nov. 14, 2012).

[101] Katz, *supra* note 30.("The most common source of abused [opioids] is, directly or indirectly, by prescription.").

[102] Thomas, *supra* note 9.

[103] NPR Staff, *With Rise of Painkiller Abuse, A Closer Look At Heroin*, NPR (Nov. 2, 2013), www.npr.org/2013/11/02/242594489/with-rise-of-painkiller-abuse-a-closer-look-at-heroin.

[104] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, Los Angeles Times (Feb. 3, 2014), http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204.

258. That reality holds in Chicago. Area drug treatment centers treat a significant number of patients for opioid addiction. Many of those addicted to opioids who seek treatment in Chicago treatment centers started with one prescription, liked how opioids made them feel, and stayed on them. Eventually, they became addicted, often after just a few months on opioids. Those who seek treatment often do so after a precipitating life event—either losing a job or being confronted by family—or after turning to criminal activity such as prostitution and theft to sustain their addiction. If their fates are consistent with patterns nationally some of them will overdose – some fatally, some not. Others will die prematurely from related causes – falls, traffic accidents, or assaults or from premature heart or neurological disease that hastens their death by 10 or 20 years. Those who do not relapse face a lifetime of treatment, including prolonged counseling or reliance on maintenance drugs such as methadone or buprenorphine.

259. The overprescribing of opioids for chronic non-cancer pain has given young children access to opioids, nearly all of which were prescribed for adults in their household. One study documented over 9,000 children nationally exposed to prescription opioids, with a median age of two years old. The number of exposures in young children was correlated to the number of prescriptions in the area.[105]

260. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS") also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born. They cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit

[105] . J. Elise Bailey et al., *The under recognized toll of prescription opioid abuse on young children*, 53(4) Annals of Emergency Med., 419-424 (Apr. 2009).

disorder, lack of impulse control, and a higher risk of future addiction.[106] When untreated, NAS can be life-threatening.[107] In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.[108] According to data from Tennessee, which has most closely studied the issue, 52% of mothers of NAS newborns used only drugs prescribed to them; another 20% used a mix of their own prescriptions and illicitly obtained drugs.[109]

J. Defendants' Fraudulent and Deceptive Marketing of Opioids Caused False Claims for Payment to Be Submitted to the City

261. The City provides comprehensive health care protection, including prescription drug benefits, to its employees and retirees. These benefits are provided under various health plans that the City self-insures, including a preferred provider organization ("PPO"), a health maintenance organization ("HMO"), and a plan that covers retirees who are not yet on Medicare and provides supplemental coverage to those retirees who are on Medicare. The prescription drug plan under the PPO is self-insured: the costs of prescription drugs are passed on directly to the City, which reimburses the plans for any prescription costs the plans incur. Throughout the relevant time period for this action, the PPO's prescription drug costs have been passed on directly to, and paid by, the City.

262. The HMO's prescription drug coverage has been self-insured at various times throughout the relevant time period. Before July 2006, the City paid the premiums for the HMO plans, which in turn covered the cost of prescription drugs. Between July 2006 and December 2009, the City paid the premiums for the HMO plan to Unicare, which in turn covered the cost of

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[106] *Transcript of Impact of Approved Drug Labeling – Part 15 Hearing* at 116-121, F.D.A. (Feb. 7, 2013), www.fda.gov/downloads/Drugs/NewsEvents/UCM342700.pdf.

[107] *See* Letter from Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, to Petitioner, Nat'l Advocates for Pregnant Women (Apr. 16, 2014).

[108] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome & Associated Health Care Expenditures*, 307(18) Journal of the Am. Med. Ass'n 1934, 1937 (May 9, 2012).

[109] Jonel Aleccia, *'Just flooding us': Tenn. spike in drug-dependent newborns is warning to nation*, NBC News (Oct. 11, 2013), *http://www.nbcnews.com/health/kids-health/just-flooding-us-tenn-spike-drug-dependent-newborns-warning-nation-f8C11375654.*

prescription drugs, but during that same time period, the City also had an HMO with Blue Cross/Blue Shield, which passed the costs of prescriptions drugs directly on to the City. From January 2010 to December 2011, both HMO plans were operated by Blue Cross/Blue Shield and the costs of prescriptions drugs were paid directly by the City. From January 2012 to December 2013, two HMO plans were merged into one HMO plan and the City paid premiums to the HMO plan, which in turn covered the cost of prescription drugs. Since January 1, 2014, the City's prescription drug coverage under the HMO is once again self-insured and has been directly paying the costs of prescription drugs under the HMOs.

263. The City's self-insured health plans only cover the cost of prescription drugs that are "Medically Necessary" and dispensed for a FDA-approved purpose. Prescription drugs that are not "Medically Necessary" or that are dispensed for a non-FDA-approved purpose are expressly excluded from coverage under the City's plans. Under the plans, a "Medically Necessary" prescription is that which is "customary for the treatment or diagnosis of an Illness or Injury, and is consistent with generally accepted medical standards."

264. Defendants specifically targeted doctors with their fraudulent marketing efforts in an effort to persuade doctors that opioids have real benefits and minimal risks and are superior to alternate treatments. Doctors relied in good faith on Defendants' false representations to prescribe opioids for chronic non-cancer pain, and Defendants reaped the benefits of increased opioid sales and profits.

265. In Chicago, Defendants' fraudulent marketing prompted doctors to prescribe opioids for chronic non-cancer pain to patients covered by the City's health plans. Doctors were and are bound by the provider agreements that entitle them to participate in the City's health plans. These agreements permit doctors to charge only for services that are "medically necessary," which requires that treatments be "in accordance with generally accepted standards of medical practice," and "clinically appropriate . . . and considered effective for the patient's illness, injury or disease." Generally accepted standards of medical practice is defined in the agreement as standards "based on credible scientific evidence."

266. Doctors submit claims directly to the City's health plan for the costs associated with prescribing opioids, including office visits and toxicology screens for patients prescribed opioids. In addition, prescriptions for opioids for patients covered by the City's self-insured health plans are filled by pharmacies, which submit claims for reimbursement to the City's health plan. In prescribing and filling prescriptions for chronic opioid therapy, doctors and pharmacists expressly and impliedly certify the prescriptions as "Medically Necessary," and—at least with respect to the self-insured plans (the PPO, and the various self-insured HMOs)—the health plans authorize payment from City funds.

267. But as the scientific evidence makes clear, opioid treatments for chronic non-cancer pain are not "Medically Necessary" as the City health plans define that term: Opioid treatment for chronic non-cancer pain is not a customary treatment, not consistent with generally accepted medical standards, not effective, and not based on credible scientific evidence.

268. Defendants' fraudulent marketing scheme also caused the City to pay for opioids for non-FDA approved purposes. Cephalon's Fentora, for example, was specifically marketed for non-FDA approved uses. Physicians, in turn, wrote prescriptions for Fentora for non-FDA approved uses, causing the self-insured health plans to authorize and the City to pay for those prescriptions. A review of City records reveals that opioids were prescribed for other non-FDA approved uses, including depression.

269. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by the deceptive marketing of Defendants, as laid out above; Defendants' ability to seed—through fraud—medical practice that supported the use of opioids for chronic non-cancer pain should not entitle them to profit from that fraud.

270. Defendants' fraudulent marketing scheme also caused the City to pay for opioid treatments that were worthless. Not only did chronic opioid therapy often provide no benefit in treating chronic long term pain or improving patients' function, it often worsened the pain and subjected patients to significant risks and adverse effects.

271. Since 2007, the City has paid—just in the PPO plan alone—nearly 400,000 claims submitted to it for the payment of opioid prescription fills with a total cost to the City of nearly $9,500,000. As a 2008 presentation to the FDA by the Group Health Research Institute made clear, 87% of all opioids dispensed were to chronic pain patients using opioids long-term, whereas only 13% were for acute or cancer pain patients.[110] Based on this, and upon information and belief, approximately 87% of the opioid fills that the City has paid for have been for non-"Medically Necessary" and/or non-FDA approved uses.

272. Although Defendants' collective promotion led to the total City spend on opioids, the City has spent substantial sums on each Defendant's opioids. Just from the PPO and just since 2007, the City has paid 7,949 claims, totaling $2,548,497.99 for Purdue opioids; 172,438 claims, totaling $1,553,867.3 for Actavis opioids; 2,559 claims, totaling $701,971.35 for Endo opioids; 1,564 claims, totaling $272,440.90 for Janssen opioids; and 105 claims, totaling $139,640.65 for Cephalon opioids. These figures do not reflect the cost to the City of other opioid prescriptions caused by Defendants' marketing or other costs laid out in Section I, below.

K. Defendants' Fraudulent and Deceptive Marketing of Opioids Has Caused the City to Incur Related Costs

273. In addition to paying for the costs of filling opioid prescriptions pursuant to its employee and retiree health plans, the City has suffered significant additional damages as a result of the Defendants' deceptive promotion. The City and its health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for individuals addicted to opioids, intensive care for infants born addicted to opioids, and more. In addition, Defendants have imposed upon the City costs beyond

[110] *See* Von Korff, *supra* note 5.

its health plans, providing emergency services, funding addiction treatment, and paying other costs imposed by the epidemic of opioid use and abuse in the City.

VI. COUNT ONE

CONSUMER FRAUD

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 2-25-090 AGAINST ALL DEFENDANTS

274. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

275. The Chicago Municipal Code § 2-25-090 makes it unlawful for a business to "engage in any act of consumer fraud, unfair method of competition, or deceptive practice while conducting any trade or business in the city," including "any conduct constituting an unlawful practice under the Illinois Consumer Fraud and Deceptive Business Practices Act." The Illinois Consumer Fraud and Deceptive Business Practices Act, 735 ILCS 505/2, makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ."

276. Defendants have engaged in unlawful, deceptive, and unfair business practices in violation of the Municipal Code as set forth above.

277. Defendants' practices as described in the Complaint are deceptive business practices that violate Chicago Municipal Code § 2-25-090 because the practices were and are intended to deceive consumers and occurred and continue to occur in the course of conduct involving trade and commerce in the City.

278. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 2-25-090 by making and disseminating untrue, false, and misleading statements to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

279. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 2-25-090 by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic non-cancer pain.

280. Defendant Purdue made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;
- Posting on the internet misleading statements and pamphlets concerning the risk of addiction and the misleading concept of pseudoaddiction;
- Distributing brochures to doctors that included misleading statements concerning the indicators of possible opioid abuse;
- Endorsing, directly distributed and assisted in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;
- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;
- Assisting in the dissemination of scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and
- Exclusively disseminating misleading statements in education materials to Chicago hospital doctors and staff while purportedly educating them on new pain standards created by JCAHO.

281. Defendant Endo made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, controlling, endorsing and sponsoring patient education materials and programs that contained misleading statements;

- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the ability of opioids to improve function long-term, and the efficacy of opioids long-term, in the treatment of chronic non-cancer pain;

- Facilitating the posting on the internet of misleading statements and pamphlets concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations – including over $10 million to the organization responsible for many of the most egregious misrepresentations – that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting the in the dissemination of literature written by pro-opioid KOLs that contained false, misleading and untrue statement concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the dissemination of scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life; and

- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

282. Defendant Janssen made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, controlling, endorsing and sponsoring patient education materials and programs that contained misleading statements concerning the risk of addiction;

- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the efficacy of opioids long-term in the treatment of chronic non-cancer pain;

- Facilitating the posting of misleading statements and pamphlets, concerning the risk of addiction, the misleading concept of pseudoaddiction and misleading claims that long-term treatment of opioids improves function;

- Assisting in the distribution of guidelines that contained misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeted the elderly in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain in the elderly; and

- Targeting veterans in disseminating patient education marketing materials that contained untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain.

283. Defendant Cephalon made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Creating, endorsing and sponsoring patient education materials that contained misleading statements;

- Endorsing, directly distributing and assisting in the distribution of publications that promoted the misleading concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid key opinion leader doctors who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CME programs containing untrue, false and misleading statements concerning the use of opioids approved only for cancer pain to treat chronic non-cancer pain, and which did not concern cancer pain;

- Assisting in the dissemination of scientific studies that misleadingly concluded Cephalon's opioids (approved only for cancer pain) are safe and effective for the long-term treatment of chronic non-cancer pain; and

- Targeting its marketing to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs serving chronic pain patients.

284. Defendant Actavis made and/or disseminated untrue, false and misleading statements, including, but not limited to, the following:

- Endorsing and sponsoring patient education materials that contained misleading statements;

- Instructing its sales force to make false, misleading and untrue statements to doctors concerning the ability of opioids to improve function long-term, in the treatment of chronic, non-cancer pain.

- Creating and disseminating advertisements that contained false, misleading and untrue statements concerning the risk of addiction in the long-term treatment of chronic, non-cancer pain.

- Providing significant financial support to pro-opioid key opinion leader who made untrue, false and misleading statements concerning the use of opioids to treat chronic non-cancer pain; and

- Providing significant financial support to pro-opioid pain organizations that made untrue, false and misleading statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain.

285. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and therefore likely to deceive the public. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

286. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago consumers and payers of opioid prescriptions to rely on those omissions and concealments.

287. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and Chicago payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

288. Defendants' practices as described in the Complaint are also unfair practices that violated Chicago Municipal Code § 2-25-090 because the practices offend public policy; are immoral, unethical, oppressive, or unscrupulous; or caused substantial injury to consumers.

289. Defendants' practices in deceptively exaggerating the benefits and minimizing the risks of these addictive drugs offend deep-seated public policies aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs, and preventing addiction and the sale and use of illegal drugs, among others, as described above. Defendants have sacrificed their duties to their customers and to public health in favor of blockbuster profits. They have caused and continue to cause grievous harm to consumers. The staggering rates of opioid use, abuse, and addiction resulting from Defendants' marketing efforts have caused substantial injury, including, but not limited to:

a. Upwards of 30% of all adults have used opioids, with the vast majority of the use stemming from prescribing for chronic non-cancer pain conditions. These high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.
b. Children, too, have been harmed by opioids. They have been exposed to medications prescribed to family members or others, resulting in injury, addiction, and death. Easy access to prescription opioids has made opioids a recreational drug of choice among Chicago teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and potentially lasting developmental impacts.
c. Chicagoans who have never taken opioids also have also been injured. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
d. More broadly, opioid use and misuse have driven Chicagoans' health care costs higher.

e. Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme created both ends of a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.

f. This demand also has created additional illicit markets in other opiates, particularly heroin. The low cost of heroin has led some of those who initially become addicted to prescription opioids to migrate to cheaper heroin, fueling a new heroin epidemic in the process.

g. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids have increased the demands on emergency services and law enforcement in the City.

h. All of this has caused substantial injuries to consumers – in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken families and homes.

290. Defendants' practices have also violated Chicago Municipal Code § 2-25-090 because the practices violate the Illinois Consumer Fraud and Deceptive Business Practices Act, which is incorporated into the Chicago Municipal Code § 2-25-090 by reference. The Illinois Consumer Fraud and Deceptive Business Practices Act makes unlawful, among other things, "the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act' . . ." 735 ILCS § 505/2.

291. Defendants' employed several practices proscribed by the Uniform Deceptive Trade Practices Act:

292. By, among other things, using front groups, KOLs, and others to peddle their misrepresentations, by influencing the creation of misleadingly pro-opioid treatment guidelines and CMEs, and by distorting the scientific evidence for opioid use for chronic non-cancer pain, Defendants made it appear that opioids had sponsorship and qualities that opioids do not have. In so doing, Defendants:

- "cause[d] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services." 735 ILCS § 510/2(a)(2).

- "cause[d] likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another." 735 ILCS § 510/2(a)(3).
- "represent[ed] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have." 735 ILCS § 510/2(a)(5).

293. By, among other things, deceptively characterizing the risks of NSAIDs in order to promote opioids, Defendants "disparage[d] the goods, services, or business of another by false or misleading representation of fact." 735 ILCS § 510/2(a)(8).

294. Altogether, Defendants "engage[d] in any other conduct which similarly creates a likelihood of confusion or misunderstanding." 735 ILCS § 510/2(a)(12).

295. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and/or other benefits, which they would not have received if they had not engaged in the violations of Chicago Municipal Code § 2-25-090 as described in this Complaint.

296. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count One of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 2-25-090; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' consumer fraud, unfair competition, and deceptive practices; (d) compelling Defendants to pay civil penalties up to $10,000 per violation pursuant to § 2-25-0909(f) for each day the violations occurred; (e) compelling Defendants to disgorge their ill-gotten profits; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VII. COUNT TWO

MISREPRESENTATIONS IN CONNECTION WITH SALE OR ADVERTISEMENT OF MERCHANDISE

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 4-276-470 AGAINST ALL DEFENDANTS

297. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

298. Section 4–276–470(1) of the Chicago Municipal Code states:

> It shall be unlawful for any person to act, use or employ any deception, fraud, false pretense, false promise or misrepresentation, or to conceal, suppress or omit any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale * * * or advertisement of any merchandise.

299. Defendants' practices as described in the Complaint violated Chicago Municipal Code § 4-276-470(1) because the practices were intended to deceive doctors, consumers, and other health care payers and occurred in connection with sale or advertisement of any merchandise.

300. At all times relevant to this Complaint, Defendants, directly or indirectly, violated Chicago Municipal Code § 4-276-470(1) by making and disseminating deceptions and misrepresentations to promote the sale and use of opioids to treat chronic non-cancer pain, or by causing untrue, false, and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic non-cancer pain.

301. Defendants knew at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and failed to disclose material risks and were therefore likely to deceive doctors, consumers, and other health care payers. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks of opioids.

302. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' seemingly truthful statements about opioids untrue, false, and misleading. In

omitting and concealing these material facts, Defendants intended to cause Chicago doctors, consumers, and other payers of opioid prescriptions to rely on those omissions and concealments.

303. All of this conduct, separately and collectively, was intended to deceive Chicago consumers who used or paid for opioids for chronic non-cancer pain, Chicago physicians who prescribed opioids for chronic non-cancer pain, and other payers, including the City, who purchased, or covered the purchase of, opioids for chronic non-cancer pain.

304. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of Chicago Municipal Code § 4-276-470(1) as described in this Complaint.

305. By reason of the Defendants' unlawful acts, Chicago consumers and the City have been damaged and continue to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Two of the Complaint; Chicago Municipal Code(b) compelling Defendants to pay civil penalties up to $2000 per violation pursuant to § 4-276-480 for each day the violations occurred; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

VIII. COUNT THREE

FALSE STATEMENTS TO THE CITY

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-21-010, *ET SEQ.* AGAINST ALL DEFENDANTS

306. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

307. Section 1-21-010(a) of the Chicago Municipal Code provides, in pertinent part:

> Any person who knowingly makes a false statement of material fact to the city in violation of any statute, ordinance or regulation, or who knowingly makes a false statement of material fact to the city in connection with any application, report,

> affidavit, oath, or attestation, including a statement of material fact made in connection with a bid, proposal, contract or economic disclosure statement or affidavit, is liable to the city for a civil penalty of not less than $500.00 and not more than $1,000.00, plus up to three times the amount of damages which the city sustains because of the person's violation of this section. A person who violates this section shall also be liable for the city's litigation and collection costs and attorney's fees. The penalties imposed by this section shall be in addition to any other penalty provided for in the municipal code.

308. Section 1-21-010(d) of the Chicago Municipal Code provides, in pertinent part, that:

> For the purposes of Chapter 1-21 of this Code, a person knowingly makes a false statement of material fact when that person (i) makes a statement of material fact with actual knowledge that the statement was false, or (ii) makes a statement of material fact with knowledge of facts or information that would cause a reasonable person to be aware that the statement was false when it was made, or (iii) signs, certifies, attests, submits or otherwise provides assurances, or causes any other person to sign, certify, attest, submit or otherwise provide assurances, that a statement of material fact is true or accurate in deliberate ignorance or reckless disregard of the truth or falsity of the statement. For purposes of this section, a person who fails to make a reasonable investigation to determine the accuracy, truthfulness or completeness of any material fact acts in deliberate ignorance or reckless disregard of the truth or falsity of the material fact.

309. Subsection 1-21-020 of the Chicago Municipal Code provides, in pertinent part, that:

> Any person who aids, abets, incites, compels or coerces the doing of any act prohibited by this chapter shall be liable to the city for the same penalties for the violation.

310. Defendants have incited or caused others to submit false statements of material fact to the City. Through their scheme to illegally and deceptively promote opioids in an effort to further opioids sales, Defendants aided, abetted, incited, or caused doctors, pharmacists, and/or agents of the health plans to sign, certify, attest, submit or otherwise provide assurances, expressly or impliedly, that opioids to treat chronic non-cancer pain were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain.

311. If the City had known of the false statements disseminated by Defendants in support of opioids and that doctors, pharmacists, and/or agents of the health plan were certifying and/or determining that opioids were "medically necessary" based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

312. By virtue of the above-described acts, Defendants aided, abetted, incited, and caused others to make false statements of material fact to the City in connection with claims to pay for opioids to treat chronic pain, within the meaning of Chicago Municipal Code § 1-21-010 and 1-21-020.

313. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Three of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-010 and/or 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $1,000 for each false statement made to the City that the Defendants aided, abetted, incited, or caused; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

IX. COUNT FOUR

FALSE CLAIMS

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-22-020 AGAINST ALL DEFENDANTS

314. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

315. Section 1-22-020 of the Chicago Municipal Code is violated when any person "(1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) 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 city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid."

316. Section 1-22-010 of the Chicago Municipal Code defines a claim as "any request or demand, whether under a contract or otherwise, for money or property which is made by a city contractor, grantee, or other recipient if the city is the source of any portion of the money or property which is requested or demanded, or if the city will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded."

317. Defendants, through their 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 a false statement to get a false or fraudulent claim for payment or approval by the City.

318. Defendants knew, or by the exercise of reasonable care should have known, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, or misleading and were made for the purpose of getting the City's health plans and other insurers to reimburse or pay for opioids. In addition, Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic non-cancer pain.

319. The Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic non-cancer pain that were presented to the City's health plans for payment. The City

only covers the cost of prescription drugs that are "medically necessary." Opioids, however, are not "medically necessary" to treat chronic non-cancer pain. Yet doctors, pharmacists, and/or other agents of the health plans, expressly or impliedly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the City were for uses that were not approved by the FDA and therefore, were not medically necessary.

320. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic non-cancer pain, which were dispensed as a consequence of Defendants' fraud.

321. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, and/or the health plans were certifying and/or determining that opioids were medically necessary, the City would have refused to authorize payment for opioid prescriptions.

322. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic non-cancer pain were paid by the City.

323. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City to approve and pay such false and fraudulent claims.

324. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

325. Defendants' fraudulent marketing scheme also caused the City to pay false claims in that the scheme also caused the City to pay for opioids that were worthless. As described

above, opioids provide no benefit to many patients treated with them long-term for chronic pain; in many cases, it worsened the pain and subjected patients to significant risks and adverse effects.

326. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

327. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

328. Each Defendant is responsible for the claims submitted and the amount the City spent on each Defendant's opioids.

329. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on non-medically necessary opioids to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Four of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired as a result of Defendants' false statements; (d) compelling Defendants to pay civil penalties up to $10,000 for each false or fraudulent claim the Defendants caused to be presented to an official or employee of the City for payment or approval; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including

attorneys' fees; and (g) awarding the City such other, further, and different relief as this Honorable Court may deem just.

X. COUNT FIVE

CONSPIRACY TO DEFRAUD BY GETTING FALSE OR FRAUDULENT CLAIMS PAID OR APPROVED BY THE CITY

VIOLATIONS OF CHICAGO MUNICIPAL CODE § 1-22-020 AGAINST ALL DEFENDANTS

330. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

331. Section 1-22-020 of the Chicago Municipal Code is violated when any person "(1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval; (2) 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 city; [or] (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid."

332. Defendants conspired to defraud the City by getting a false or fraudulent claims allowed or paid, by acting in concert in a comprehensive scheme to defraud the City while illegally and deceptively promoting opioids in an effort to further opioids sales.

333. Defendants knowingly and voluntarily engaged in a concerted scheme to promote the widespread use of opioids for the treatment of chronic non-cancer pain directly through their own publications and employees, and indirectly, through seemingly independent thought-leaders, advocacy groups, and professional societies, by making, funding, suggesting, editing, approving, and distributing untrue, false, and misleading statements and representations to doctors and patients. The concerted scheme was entered into for the purpose of getting insurers, including the City's health plans, to reimburse or pay for opioids.

334. Defendants' common scheme was carried out through their common funding of the same front groups, CMEs and KOLs, their common advocacy through and participation in the Pain Care Forum, their coordinated marketing messages, and other steps.

335. Because of the Defendants' scheme, doctors wrote prescriptions for opioids to treat chronic non-cancer pain that were submitted to the City's health plans for payment, which only covers the cost of "medically necessary" prescriptions and those that are prescribed for FDA-approved uses. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain. Yet doctors, pharmacists, and/or other agents of the health plans explicitly or implicitly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the City were for uses that were not approved by the FDA and therefore were not medically necessary.

336. Defendants knew or should have known that, as a natural consequence of their actions, governments such as the City would necessarily be paying for long-term prescriptions of opioids to treat chronic non-cancer pain, which were dispensed as a consequence of Defendants' fraud.

337. Defendants' misrepresentations were material because if the City had known of the false statements disseminated by Defendants in support of opioids and that doctors, pharmacies, and/or the health plans were certifying and/or determining that opioids were medically necessary based on those false statements, the City would have refused to authorize payment for opioid prescriptions.

338. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of long-term prescriptions of opioids to treat chronic non-cancer pain were paid by the City.

339. By virtue of the above-described acts, Defendants conspired to defraud the City by getting a false or fraudulent claim allowed or paid.

340. Alternatively, to the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Defendants' deceptive marketing.

341. Defendants' fraudulent marketing scheme also caused the City to pay false claims in that the scheme also caused the City to pay for opioids that were worthless. As described above, opioids provide no benefit to many patients treated with them long-term for chronic pain; in many cases, it worsened the pain and subjected patients to significant risks and adverse effects.

342. The City, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

343. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

344. Each Defendant is responsible for the claims submitted and the amount the City spent on each Defendant's opioids.

345. Because Defendants acted concurrently and/or collaboratively in carrying out a common fraudulent scheme—causing others to submit false claims for opioids which were paid by the City—Defendants are jointly and severally liable for the City's total spend on non-medically necessary opioids to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Five of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the Chicago Municipal Code § 1-21-020; (c) compelling Defendants to pay restitution of any money acquired by Defendants' false statements; (d) compelling Defendants to

pay civil penalties up to $10,000 for each instance Defendants made or used false records and statements and caused false statements and records to be used to get a false or fraudulent claim paid or approved by the City; (e) compelling Defendants to pay three times the amount of damages sustained by the City for each violation of this section; (f) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (f) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XI. COUNT SIX

RECOVERY OF CITY COSTS OF PROVIDING SERVICES VIOLATIONS OF THE CHICAGO MUNICIPAL CODE § 1-20-020 AGAINST ALL DEFENDANTS

346. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

347. Section 1-20-020 of the Chicago Municipal Code provides, in pertinent part:

> Any person who causes the city or its agents to incur costs in order to provide services reasonably related to such person's violation of any federal, state or local law, or such person's failure to correct conditions which violate any federal, state or local law when such person was under a legal duty to do so, shall be liable to the city for those costs. This liability shall be collectible in the same manner as any other personal liability.

348. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

(1) violating Chicago Municipal Code § 2-25-090;

(2) violating Chicago Municipal Code § 4-276-470;

(3) violating Chicago Municipal Code § 1-21-010;

(4) violating Chicago Municipal Code § 1-22-020;

(5) violating Chicago Municipal Code § 1-20-020;

(6) violating 720 ILCS § 5/17-10.5;

(7) committing common law fraud; and

(8) committing common law unjust enrichment.

349. The City has incurred costs reasonably related to Defendants' violations of federal, state, or local laws.

350. The City has incurred the costs of paying for opioids prescribed for chronic non-cancer pain and related costs through its health plans, and these costs are reasonably related to Defendants' unlawful scheme.

351. The City's health plans have paid costs that include, but are not limited to, the costs immediately associated with prescribing opioids, such as doctors' visits and toxicology screens to monitor patients' drug-taking, as well as other costs imposed by long-term opioid use, abuse, and addiction, such as hospitalizations for opioid overdoses, drug treatment for individuals addicted to opioids, intensive care for infants born addicted to opioids, and more. In addition, Defendants have imposed upon the City costs beyond its health plans, such as providing emergency services, funding addiction treatment, and paying other costs imposed by the epidemic of opioid use and abuse in the City.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Six of the Complaint; (b) compelling Defendants to pay the costs the City incurred that were reasonably related to the Defendants' violations of federal, state, or local law; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XII. COUNT SEVEN

INSURANCE FRAUD VIOLATIONS OF 720 ILCS 5/17-10.5 AGAINST ALL DEFENDANTS

352. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

353. 720 ILCS § 5/17-10.5(a)(1) provides in pertinent part:

> (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false

> claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

354. 720 ILCS § 5/17-10.5(e)(1) provides in pertinent part:

> Civil damages for insurance fraud. A person who knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of any insurance company by the making of a false claim or by causing a false claim to be made on a policy of insurance issued by an insurance company, or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property, shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self- insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained, twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

355. Through their illegal and deceptive promotion of opioids, Defendants knowingly caused false claims to be made to the City's health plans, which are self-insured, and knowingly obtained or caused to be obtained through deception the property of the City in payments for those false claims.

356. The Defendants' scheme caused doctors to write prescriptions for opioids to treat chronic non-cancer pain that were presented to the City's health plans, which cover City employees and retirees, for payment.

357. Further, the City only covers the cost of services, tests, and prescription drugs that are "medically necessary" and prescribed for an FDA-approved use. Opioids, however, are not "medically necessary" to treat chronic non-cancer pain.

358. Doctors, pharmacists, or other agents of the health plans, explicitly or implicitly certified to the City that such prescriptions were "medically necessary" because they were influenced by the false and misleading statements disseminated by the Defendants about the risks, benefits, and superiority of opioids for chronic non-cancer pain. Moreover, many of the prescriptions written by physicians and/or authorized by the health plans, and submitted to the

City were for uses that were not approved by the FDA and therefore, were not medically necessary.

359. The misrepresentations were material because if the City had known of the false statements disseminated by Defendants and that doctors, pharmacies, and/or the health plans certified and/or determined that opioids were medically necessary based on those false statements, the City would have refused to authorize payment for opioid prescriptions. The City is a self-insured entity and directly covers the cost of prescription drugs for City employees and retirees.

360. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made false claims with the intent to induce the City to approve and pay such false and fraudulent claims.

361. By reason of Defendants' insurance fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription to be filled, costing nearly $9,500,000 and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Seven of the Complaint; (b) compelling Defendants to pay three times any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; and (d) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIII. COUNT EIGHT

CIVIL CONSPIRACY
VIOLATIONS OF THE COMMON LAW PROHIBITION AGAINST CIVIL CONSPIRACY
AGAINST ALL DEFENDANTS

362. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

363. Defendants knowingly and voluntarily participated in a common scheme to commit unlawful acts or lawful acts in an unlawful manner.

364. Defendants' common scheme was carried out through their common funding of the same front groups, CMEs and KOLs, their common advocacy through and participation in the Pain Care Forum, their coordinated marketing messages, and other steps.

365. The defendants participated in unlawful acts or lawful acts in an unlawful manner by, among other unlawful conduct:

(1) violating Chicago Municipal Code § 2-25-090;

(2) violating Chicago Municipal Code § 4-276-470;

(3) violating Chicago Municipal Code § 1-21-010;

(4) violating Chicago Municipal Code § 1-22-020;

(5) violating Chicago Municipal Code § 1-20-020;

(6) violating 720 ILCS § 5/17-10.5;

(7) committing common law fraud; and

(8) committing common law unjust enrichment.

366. By reason of the Defendants' unlawful acts, the City has been damaged and continues to be damaged by paying for the costs of opioid prescriptions for chronic non-cancer pain and suffered additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Eight of the Complaint; (b) compelling Defendants to pay the City's direct and consequential damages; and

(c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XIV. COUNT NINE

COMMON LAW FRAUD AGAINST ALL DEFENDANTS

367. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

368. Defendants made false statements of material fact that they knew were false to induce the City to act; the City relied on Defendants' false statements, relied on others who relied on Defendants' false statements, or both; and was damaged as a result.

369. Defendants repeatedly failed to disclose material facts about the risks of opioids. Such material omissions, which are deceptive and misleading in their own right, render even Defendants' and seemingly truthful statements about opioids untrue, false, and misleading. In omitting and concealing these material facts, Defendants intended to cause Chicago consumers and payers of opioid prescriptions to rely on those omissions and concealments.

370. Defendants engaged in this scheme because they intended prescription drug payers, including the City, to rely on its statements about the safety and efficacy of opioids and rely on its omissions about the risks of opioids.

371. The City relied on Defendants' statements or relied on others who relied on Defendants' statements about the risks, benefits, and superiority of opioids for the treatment of chronic non-cancer pain when it paid for prescriptions for opioids to treat chronic non-cancer pain. Had the City known about the false statements disseminated by Defendants in support of opioids for chronic non-cancer pain, the City would have refused to authorize payment for such opioid prescriptions.

372. By reason of the Defendants' fraud, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Since 2007, the City has paid for nearly 400,000 claims for opioid prescription fills, costing nearly $9,500,000, and suffered

additional damages for the costs of providing and using opioids long-term.to treat chronic non-cancer pain.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Nine of the Complaint; (b) compelling Defendants to pay restitution of any money acquired as a result of Defendants' fraud; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees; (d) compelling Defendants to pay punitive damages because their false representations were wantonly and designedly made; and (e) awarding the City such other, further, and different relief as this Honorable Court may deem just.

XV. COUNT TEN

UNJUST ENRICHMENT

VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT AGAINST ALL DEFENDANTS

373. The City realleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Count.

374. Defendants have unjustly retained a benefit to the City's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

375. By illegally and deceptively promoting opioids, Defendants have unjustly enriched themselves at the City's expense. The City has made payments for opioid prescriptions and treatments, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the City lacks a remedy provided by law.

376. By reason of the Defendants' unlawful acts, the City has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, PLAINTIFF, CITY OF CHICAGO, respectfully requests that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count Ten of the

Complaint; (b) compelling Defendants to disgorge all unjust enrichment to the City; and (c) awarding the City such other, further, and different relief as this Honorable Court may deem just.

DATED: June _____, 2014.

Respectfully submitted,

STEPHEN R. PATTON
Corporation Counsel, City of Chicago

BY: _____

Attorney No. 90909
MICHAEL DOLESH
Senior Counsel
City of Chicago, Department of Law
Constitutional & Commercial Litigation Division
30 N. LaSalle St., Suite 1230
Chicago, IL 60602
Michael.Dolesh@cityofchicago.org
Phone: (312) 744-9028
Fax: (312) 742-3925

FIONA A. BURKE
Senior Counsel
City of Chicago, Department of Law
Aviation, Environmental, Regulatory & Contracts Division
30 N. LaSalle St., Suite 1400
Chicago, IL 60602
Fiona.Burke@cityofchicago.org
Phone: (312) 744-6929
Fax: (312) 742-3832

COHEN MILSTEIN SELLERS & TOLL PLLC
Linda Singer
lsinger@cohenmilstein.com
Pro hac to be submitted
Jeanne Markey
jmarkey@cohenmilstein.com
Pro hac to be submitted
Eric Harrington
eharrington@cohenmilstein.com
Pro hac to be submitted
1100 New York Ave NW, Suite 500 East
Washington, DC 20005
Telephone: (202) 408-4600
Facsimile: (202) 408-4699

EXHIBIT C1

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

TRANSFER ORDER

Before the Panel:[*] Plaintiffs in 46 actions move under 28 U.S.C. § 1407 to centralize pretrial proceedings in the Southern District of Ohio or the Southern District of Illinois, but plaintiffs do not oppose centralization in the Southern District of West Virginia. These cases concern the alleged improper marketing of and inappropriate distribution of various prescription opiate medications into cities, states and towns across the country. Plaintiffs' motion includes the 64 actions listed on Schedule A,[1] which are pending in nine districts. Since plaintiffs filed this motion, the parties have notified the Panel of 115 potentially related actions.[2]

Responding plaintiffs' positions on centralization vary considerably. Plaintiffs in over 40 actions or potential tag-along actions support centralization. Plaintiffs in fifteen actions or potential tag-along actions oppose centralization altogether or oppose transfer of their action. In addition to opposing transfer, the State of West Virginia suggests that we delay transferring its case until the Southern District of West Virginia court decides its motion to remand to state court. Third party payor plaintiffs in an Eastern District of Pennsylvania potential tag-along action (*Philadelphia Teachers Health and Welfare Fund*) oppose centralization of third party payor actions. Western District of Washington plaintiff City of Everett opposes centralization and, alternatively, requests exclusion of its case. Northern District of Illinois tag-along plaintiff City of Chicago asks the Panel to defer transfer of its action until document discovery is completed.

Defendants' positions on centralization also vary considerably. The "Big Three" distributor defendants,[3] which reportedly distribute over 80% of the drugs at issue and are defendants in most cases,

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[*] Judges Lewis A. Kaplan and Ellen Segal Huvelle did not participate in the decision of this matter.

[1] Two actions included on plaintiffs' motion to centralize were remanded to state court during the pendency of the motion.

[2] These actions, and any other related actions, are potential tag-along actions. *See* Panel Rules 1.1(h), 7.1 and 7.2.

[3] AmerisourceBergen Drug Corp., AmerisourceBergen Corp., McKesson Corp., Cardinal Health 110, LLC, Cardinal Health, Inc., Cardinal Health 105, Inc., Cardinal Health 108, LLC, Cardinal Health 112, LLC, Cardinal Health 414, LLC, and Cardinal Health subsidiary The Harvard Drug

support centralization in the Southern District of West Virginia. These defendants request that the Panel either delay issuing its transfer order or delay transfer of their cases until their motions to dismiss are decided. Defendant distributor Miami-Luken also supports centralization in the Southern District of West Virginia. Multiple manufacturer defendants[4] support centralization in the Southern District of New York or the Northern District of Illinois; defendant Malinckrodt, LLC, takes no position on centralization but supports the same districts. Teva defendants[5] suggest centralization in the Eastern District of Pennsylvania or the manufacturers' preferred districts. Physician defendants[6] in three Ohio actions, who are alleged to be "key opinion leaders" paid by manufacturing defendants, do not oppose centralization in the Southern District of Ohio.

Defendants in several Southern District of West Virginia cases oppose centralization. These defendants include several smaller distributor defendants or "closed" distributors that supply only their own stores.[7] Many of these defendants specifically request exclusion of the claims against them from the MDL. Also, manufacturer Pfizer, Inc., opposes centralization and requests that we exclude any claims against it from this MDL.[8]

The responding parties suggest a wide range of potential transferee districts, including: the Southern District of West Virginia, the Southern District of Illinois, the Northern District of Illinois, the Eastern District of Missouri (in a brief submitted after the Panel's hearing), the District of New Jersey, the

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Group, L.L.C.

[4] Actavis LLC, Actavis Pharma, Inc., Allergan PLC, Allergan Finance, LLC, Allergan plc f/k/a Actavis plc, Actavis Pharma Inc. f/k/a Watson Pharma Inc., Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., and Allergan PLC f/k/a Actavis PLS, Cephalon, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc., Purdue Frederick Company Inc., Purdue Pharma Inc., Purdue Pharma L.P., Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.

[5] Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals U.S.A, Inc., Cephalon, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc.

[6] Scott Fishman, M.D., Perry Fine, M.D., Lynn Webster, M.D., and Russell Portenoy, M.D.

[7] JM Smith Corp.; CVS Indiana, LLC and Omnicare Distribution Center, LLC; TopRx; Kroger Limited Partnership I, Kroger Limited Partnership II, SAJ Distributors (a Walgreens distributor for two months in 2012), Walgreen Eastern Co., Inc., and Rite Aid of Maryland, Inc.; Masters Pharmaceuticals and KeySource Medical; WalMart Stores East, LP.

[8] Pfizer specifically requests that we exclude any potential future claims against it because of its minimal involvement in the opioid market. At oral argument, counsel stated that Pfizer was not named as a defendant in any pending case. In the absence of a case before us, the Panel will not address Pfizer's argument.

Southern District of New York, the Southern District of Ohio, the Northern District of Ohio, the Eastern District of Pennsylvania, the Eastern District of Texas, the Western District of Washington and the Eastern District of Wisconsin.

After considering the argument of counsel, we find that the actions in this litigation involve common questions of fact, and that centralization in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Plaintiffs in the actions before us are cities, counties and states that allege that: (1) manufacturers of prescription opioid medications overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians, and/or (2) distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates. All actions involve common factual questions about, *inter alia*, the manufacturing and distributor defendants' knowledge of and conduct regarding the alleged diversion of these prescription opiates, as well as the manufacturers' alleged improper marketing of such drugs. Both manufacturers and distributors are under an obligation under the Controlled Substances Act and similar state laws to prevent diversion of opiates and other controlled substances into illicit channels. Plaintiffs assert that defendants have failed to adhere to those standards, which caused the diversion of opiates into their communities. Plaintiffs variously bring claims for violation of RICO statutes, consumer protection laws, state analogues to the Controlled Substances Act, as well as common law claims such as public nuisance, negligence, negligent misrepresentation, fraud and unjust enrichment.

The parties opposing transfer stress the uniqueness of the claims they bring (or the claims that are brought against them), and they argue that centralization of so many diverse claims against manufacturers and distributors will lead to inefficiencies that could slow the progress of all cases. While we appreciate these arguments, we are not persuaded by them. All of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation, and discovery likely will be voluminous. Although individualized factual issues may arise in each action, such issues do not – especially at this early stage of litigation – negate the efficiencies to be gained by centralization. The transferee judge might find it useful, for example, to establish different tracks for the different types of parties or claims. The alternative of allowing the various cases to proceed independently across myriad districts raises a significant risk of inconsistent rulings and inefficient pretrial proceedings. In our opinion, centralization will substantially reduce the risk of duplicative discovery, minimize the possibility of inconsistent pretrial obligations, and prevent conflicting rulings on pretrial motions. Centralization will also allow a single transferee judge to coordinate with numerous cases pending in state courts. Finally, we deny the requests to delay transfer pending rulings on various pretrial motions (*e.g.*, motions to dismiss or to remand to state court) or until the completion of document discovery in *City of Chicago*.

Although all of the cases on the motion before us involve claims brought by political subdivisions, we have been notified of potential tag-along actions brought by individuals, consumers, hospitals and third party payors. As reflected in our questions at oral argument, this litigation might evolve to include

additional categories of plaintiffs and defendants, as well as different types of claims. We will address whether to include specific actions or claims through the conditional transfer order process.[9]

As this litigation progresses, it may become apparent that certain types of actions or claims could be more efficiently handled in the actions' respective transferor courts. Should the transferee judge deem remand of any claims or actions appropriate (or, relatedly, the subsequent exclusion of similar types of claims or actions from the centralized proceedings), then he may accomplish this by filing a suggestion of remand to the Panel. *See* Panel Rule 10.1. As always, we trust such matters to the sound judgment of the transferee judge.

Most parties acknowledge that any number of the proposed transferee districts would be suitable for this litigation that is nationwide in scope. We are persuaded that the Northern District of Ohio is the appropriate transferee district for this litigation. Ohio has a strong factual connection to this litigation, given that it has experienced a significant rise in the number of opioid-related overdoses in the past several years and expended significant sums in dealing with the effects of the opioid epidemic. The Northern District of Ohio presents a geographically central and accessible forum that is relatively close to defendants' various headquarters in New York, Connecticut, New Jersey and Pennsylvania. Indeed, one of the Big Three distributor defendants, Cardinal Health, is based in Ohio. Judge Dan A. Polster is an experienced transferee judge who presides over several opiate cases. Judge Polster's previous MDL experience, particularly MDL No. 1909 – *In re: Gadolinium Contrast Dyes Products Liability Litigation*, which involved several hundred cases, has provided him valuable insight into the management of complex, multidistrict litigation. We have no doubt that Judge Polster will steer this litigation on a prudent course.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside of the Northern District of Ohio are transferred to the Northern District of Ohio and, with the consent of that court, assigned to the Honorable Dan A. Polster for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Sarah S. Vance
Chair

Charles R. Breyer
R. David Proctor
Marjorie O. Rendell
Catherine D. Perry

[9] Eastern District of Pennsylvania *Philadelphia Teachers Health and Welfare Fund* third party payor plaintiff opposed centralization of such claims, stating that it intends to file a motion for centralization of third party payor claims. We will address that motion, if it is filed, in due course.

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

SCHEDULE A

Northern District of Alabama

CITY OF BIRMINGHAM v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-01360

Eastern District of California

COUNTY OF SAN JOAQUIN, ET AL. v. PURDUE PHARMA, L.P., ET AL., C.A. No. 2:17-01485

Southern District of Illinois

PEOPLE OF THE STATE OF ILLINOIS, ET AL. v. PURDUE PHARMA LP, ET AL., C.A. No. 3:17-00616
PEOPLE OF THE STATE OF ILLINOIS, ET AL. v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00856
PEOPLE OF STATE OF ILLINOIS, ET AL. v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00876

Eastern District of Kentucky

BOONE COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00157
PENDLETON COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00161
CAMPBELL COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00167
ANDERSON COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00070
FRANKLIN COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00071
SHELBY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00072
HENRY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00073
BOYLE COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00367
FLEMING COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00368

Eastern District of Kentucky (cont.)

GARRARD COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00369
LINCOLN COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00370
MADISON COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00371
NICHOLAS COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00373
BELL COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00246
HARLAN COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00247
KNOX COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00248
LESLIE COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00249
WHITLEY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00250
CLAY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00255

Western District of Kentucky

THE FISCAL COURT OF CUMBERLAND COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 1:17-00163
LOUISVILLE/JEFFERSON COUNTY METRO GOVERNMENT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00508
THE FISCAL COURT OF SPENCER COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00557
THE FISCAL COURT OF UNION COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 4:17-00120
THE FISCAL COURT OF CARLISLE COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00136

Northern District of Ohio

CITY OF LORAIN v. PURDUE PHARMA L.P., ET AL., C.A. No. 1:17-01639
CITY OF PARMA v. PURDUE PHARMA L.P., ET AL., C.A. No. 1:17-01872

Southern District of Ohio

CLERMONT COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00662
BELMONT COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00663
BROWN COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00664
VINTON COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN CORPORATION, ET AL., C.A. No. 2:17-00665
JACKSON COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00680
SCIOTO COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00682
PIKE COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00696
ROSS COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00704
CITY OF CINCINNATI v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00713
CITY OF PORTSMOUTH v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00723
GALLIA COUNTY BOARD OF COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00768
HOCKING COUNTY BOARD OF COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00769
LAWRENCE COUNTY BOARD OF COMMISSIONERS v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00770
DAYTON v. PURDUE PHARMA LP, ET AL., C.A. No. 3:17-00229

Western District of Washington

CITY OF EVERETT v. PURDUE PHARMA LP, ET AL., C.A. No. 2:17-00209
CITY OF TACOMA v. PURDUE PHARMA, L.P., ET AL., C.A. No. 3:17-05737

Southern District of West Virginia

THE COUNTY COMMISSION OF MCDOWELL COUNTY v. MCKESSON CORPORATION, ET AL., C.A. No. 1:17-00946
HONAKER v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 1:17-03364
THE COUNTY COMMISSION OF MERCER COUNTY v. WEST VIRGINIA BOARD OF PHARMACY, C.A. No. 1:17-03716

Southern District of West Virginia (cont.)

KANAWHA COUNTY COMMISSION v. RITE AID OF MARYLAND, INC., ET AL., C.A. No. 2:17-01666
FAYETTE COUNTY COMMISSION v. CARDINAL HEALTH, INC., ET AL., C.A. No. 2:17-01957
BOONE COUNTY COMMISSION v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-02028
LOGAN COUNTY COMMISSION v. CARDINAL HEALTH, INC., ET AL., C.A. No. 2:17-02296
THE COUNTY COMMISSION OF LINCOLN COUNTY v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 2:17-03366
LIVINGGOOD v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 2:17-03369
SPARKS v. WEST VIRGINIA BOARD OF PHARMACY, C.A. No. 2:17-03372
CARLTON, ET AL. v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 2:17-03532
STATE OF WEST VIRGINIA, ET AL. v. MCKESSON CORPORATION, C.A. No. 2:17-03555
BARKER v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 2:17-03715
THE CITY OF HUNTINGTON v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-01362
CABELL COUNTY COMMISSION v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-01665
WAYNE COUNTY COMMISSION v. RITE AID OF MARYLAND, INC., ET AL., C.A. No. 3:17-01962
WYOMING COUNTY COMMISSION v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-02311

EXHIBIT C2

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO −2)

On December 5, 2017, the Panel transferred 62 civil action(s) to the United States District Court for the Northern District of Ohio for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* _F.Supp.3d_ (J.P.M.L. 2017). Since that time, no additional action(s) have been transferred to the Northern District of Ohio. With the consent of that court, all such actions have been assigned to the Honorable Dan A. Polster.

It appears that the action(s) on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of Ohio and assigned to Judge Polster.

Pursuant to Rule 7.1 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, the action(s) on the attached schedule are transferred under 28 U.S.C. § 1407 to the Northern District of Ohio for the reasons stated in the order of December 5, 2017, and, with the consent of that court, assigned to the Honorable Dan A. Polster.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of Ohio. The transmittal of this order to said Clerk shall be stayed 7 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 7−day period, the stay will be continued until further order of the Panel.

Inasmuch as no objection is pending at this time, the stay is lifted.

Dec 20, 2017

CLERK'S OFFICE
UNITED STATES
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

SCHEDULE CTO−2 − TAG−ALONG ACTIONS

DIST	DIV.	C.A.NO.	CASE CAPTION
ALABAMA SOUTHERN			
~~ALS~~	~~1~~	~~17−00521~~	~~The Estate of Bruce Brockel, Deceased, by and through Donna Brockel, as Personal Representative v. Purdue Pharma L.P. et al~~ Opposed 12/19/17
KENTUCKY EASTERN			
KYE	5	17−00473	Clark County Fiscal Court v. Amerisourcebergen Drug Corporation et al
KYE	5	17−00474	Scott County Fiscal Court v. Amerisourcebergen Drug Corporation et al
KYE	5	17−00475	Woodford County Fiscal Court v. Amerisourcebergen Drug Corporation et al
~~KYE~~	~~7~~	~~17−00186~~	~~Floyd, The County of v. Purdue Pharma L.P. et al~~ Opposed 12/19/
LOUISIANA WESTERN			
LAW	1	17−01586	Hilton v. Purdue Pharma L P et al
LAW	2	17−01585	Mancuso v. Purdue Pharma L P et al
LAW	6	17−01583	Garber v. Purdue Pharma L P et al
MASSACHUSETTS			
MA	3	17−12342	Teamsters Health Service and Insurance Plan Local 404 v. PURDUE PHARMA, LP et al
MISSISSIPPI SOUTHERN			
MSS	5	17−00145	Southwest Mississippi Regional Medical Center et al v. Amerisourcebergen Drug Corporation et al
WISCONSIN WESTERN			
~~WIW~~	~~3~~	~~17−00914~~	~~St. Croix Chippewa Indians of Wisconsin v. McKesson Corporation et al~~ Opposed 12/19/17

EXHIBIT C3

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO −3)

On December 5, 2017, the Panel transferred 62 civil action(s) to the United States District Court for the Northern District of Ohio for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* _F.Supp.3d_ (J.P.M.L. 2017). Since that time, 124 additional action(s) have been transferred to the Northern District of Ohio. With the consent of that court, all such actions have been assigned to the Honorable Dan A. Polster.

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This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of Ohio. The transmittal of this order to said Clerk shall be stayed 7 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 7−day period, the stay will be continued until further order of the Panel.

Inasmuch as no objection is pending at this time, the stay is lifted.

Jan 10, 2018

CLERK'S OFFICE
UNITED STATES
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

SCHEDULE CTO−3 − TAG−ALONG ACTIONS

DIST	DIV.	C.A.NO.	CASE CAPTION
ALABAMA MIDDLE			
ALM	1	17−00838	Houston County, Alabama v. Purdue Pharma L.P. et al
ALM	2	17−00836	City of Greenville, Alabama v. Purdue Pharma L.P. et al
ALM	2	17−00840	City of Opp, Alabama v. Amerisourcebergen Drug Corporation et al
ALABAMA NORTHERN			
ALN	3	17−02086	The Town of Cherokee Alabama et al v. Purdue Pharma LP et al
FLORIDA SOUTHERN			
FLS	9	17−81384	City of Delray Beach v. Purdue Pharma L.P. et al
GEORGIA NORTHERN			
~~GAN~~	~~1~~	~~17−04757~~	~~The County of Fulton v. Purdue Pharma, LP et al~~ **Opposed 1/4/18**
ILLINOIS CENTRAL			
ILC	3	17−03293	People of the State of Illinois et al v. AmerisourceBergen Drug Corporation et al
ILLINOIS SOUTHERN			
ILS	3	17−01338	People of the State of Illinois et al v. Amerisourcebergen Drug Corporation et al
ILS	3	17−01340	People of the State of Illinois et al v. Amerisourcebergen Drug Corporation et al
ILS	3	17−01342	People of the State of Illinois et al v. Amerisourcebergen Drug Corporation et al
INDIANA SOUTHERN			
INS	1	17−04591	CITY OF NEW CASTLE v. PURDUE PHARMA L.P. et al

KANSAS			
KS	6	17−01313	Sedgwick County Board of Commissioners v. Amerisourcebergen Drug Corporation et al
KENTUCKY EASTERN			
KYE	0	17−00130	Rowan County Fiscal Court v. Amerisourcebergen Drug Corporation et al
KENTUCKY WESTERN			
KYW	1	17−00196	The Fiscal Court of Allen County v. AmerisourceBergen Drug Corporation et al
KYW	3	17−00727	The Fiscal Court of Bullitt County v. AmerisourceBergen Drug Corporation et al
KYW	4	17−00157	The Fiscal Court of Hopkins County v. AmerisourceBergen Drug Corporation et al
LOUISIANA MIDDLE			
~~LAM~~	~~3~~	~~17−01766~~	~~Louisiana Health Service & Indemnity Company d/b/a Blue Cross and Blue Shield of Louisiana et al v. Purdue Pharma, LP et al~~ **Opposed 1/10/18**
MASSACHUSETTS			
MA	3	17−30175	City of Greenfield, v. Amerisourcebergen Drug Corporation et al
MISSISSIPPI NORTHERN			
MSN	4	17−00189	Sunflower County, Mississippi v. Purdue Pharma, L.P. et al
MSN	4	17−00190	Humphreys County, Mississippi v. Purdue Pharma, L.P. et al
MSN	4	17−00191	Washington County, Mississippi v. Purdue Pharma, L.P. et al
MISSISSIPPI SOUTHERN			
MSS	2	17−00199	Lawrence County, Mississippi v. Amerisourcebergen Drug Corporation et al
MSS	2	17−00200	Jefferson Davis County, Mississippi v. Amerisourcebergen Drug Corporation et al
MSS	3	17−01012	Rush Health Systems, Inc. v. McKesson Corporation et al
MSS	5	17−00150	Claiborne County, Mississippi v. Purdue Pharma, L.P. et al
MISSOURI WESTERN			
MOW	5	17−06141	

			Buchanan County, Missouri v. AmerisourceBergen Drug Corporation et al
MONTANA			
MT	4	17−00130	County of Cascade v. Purdue Pharma et al
NEW JERSEY			
~~NJ~~	~~2~~	~~17−13433~~	~~CITY OF PATERSON v. PURDUE PHARMA L.P. et al~~ **Opposed 1/10/18**
NORTH CAROLINA EASTERN			
NCE	7	17−00241	New Hanover County v. AmerisourceBergen Drug Corporation et al
NORTH CAROLINA MIDDLE			
NCM	1	17−01085	YADKIN COUNTY, NORTH CAROLINA v. AMERISOURCEBERGEN DRUG CORPORATION et al
NCM	1	17−01114	ROCKINGHAM COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION et al
OHIO SOUTHERN			
OHS	2	17−01064	Darke County Board of County Commissioners v. Amerisourcebergen Drug Corporation et al
OHS	2	17−01097	Logan County Board of County Commissioners v. Amerisourcebergen Drug Corporation et al
OHS	2	17−01102	The City of Columbus v. PURDUE PHARMA L.P. et al
OHS	2	17−01105	Coshocton County Board of County Commissioners v. Amerisourcebergen Drug Corporation et al
OREGON			
Opposed 1/10/18 ~~OR~~	~~3~~	~~17−02010~~	~~County of Multnomah v. Purdue Pharma, LP et al~~
PUERTO RICO			
PR	3	17−02364	Municipality of Guayanilla v. Purdue Pharma L.P. et al
PR	3	17−02371	Municipality of Loiza, Puerto Rico v. Purdue Pharma L.P. et al
TENNESSEE MIDDLE			
TNM	2	17−00078	Smith County, Tennessee v. Purdue Pharma L.P. et al
TEXAS EASTERN			
TXE	4	17−00845	County Of Hopkins v. Endo Health Solutions Inc. et al

TEXAS SOUTHERN

TXS	4	17−03756	County of Montgomery v Purdue Pharma LP

EXHIBIT C4

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO −4)

On December 5, 2017, the Panel transferred 62 civil action(s) to the United States District Court for the Northern District of Ohio for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* _F.Supp.3d_ (J.P.M.L. 2017). Since that time, 124 additional action(s) have been transferred to the Northern District of Ohio. With the consent of that court, all such actions have been assigned to the Honorable Dan A. Polster.

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Inasmuch as no objection is pending at this time, the stay is lifted.

Jan 17, 2018

CLERK'S OFFICE
UNITED STATES
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION MDL No. 2804

SCHEDULE CTO−4 − TAG−ALONG ACTIONS

DIST	DIV.	C.A.NO.	CASE CAPTION
ALABAMA SOUTHERN			
ALS	1	17−00564	City of Mobile, Alabama v. Amerisourcebergen Drug Corporation et al
CONNECTICUT			
CT	3	17−02092	Teamsters Local 493 Health Services and Insurance Plan v. Purdue Pharma L.P. et al
CT	3	17−02093	Teamsters Local 671 Health Services and Insurance Plan v. Purdue Pharma, LP et al
CT	3	17−02094	Teamsters Local 677 Health Services & Insurance Fund
CT	3	17−02095	IBEW Local 90 Benefits Plan v. Purdue Pharma, LP et al
INDIANA SOUTHERN			
INS	1	17−04651	TOWN OF SHERIDAN v. AMERISOURCEBERGEN DRUG CORPORATION et al
LOUISIANA EASTERN			
LAE	2	17−17722	Seal v. Purdue Pharma LP et al
LOUISIANA MIDDLE			
LAM	3	17−01815	Bossier Parish v. Amerisourcebergen Drug Corporation et al
MICHIGAN EASTERN			
MIE	1	17−14076	Saginaw, County of v. Purdue Pharma L.P. et al
MIE	2	17−14074	Genesee, County of v. Purdue Pharma L.P. et al
MIE	4	17−14075	City of Detroit, Michigan, A Municipal Corporation v. Purdue Pharma L.P. et al
MIE	4	17−14077	Macomb, County of v. Purdue Pharma L.P. et al
MICHIGAN WESTERN			

MIW	1	17−01114	Lansing, City of v. Purdue Pharma L.P. et al
MIW	1	17−01115	Grand Traverse, County of v. Purdue Pharma L.P. et al
MIW	2	17−00206	Chippewa, County of v. Purdue Pharma L.P. et al
MIW	2	17−00207	Delta, County of v. Purdue Pharma L.P. et al
MIW	2	17−00208	Escanaba, City of v. Purdue Pharma L.P. et al
MINNESOTA			
MN	0	17−05491	Leech Lake Band of Ojibwe, The v. Purdue Pharma L.P. et al
MISSISSIPPI SOUTHERN			
MSS	2	17−00202	Marion County, Mississippi v. Amerisourcebergen Drug Corporation et al
NEW HAMPSHIRE			
NH	1	17−00730	Nashua, NH, City of v. Purdue Pharma, L.P. et al
NEW JERSEY			
NJ	3	17−13462	THE TOWNSHIP OF BLOOMFIELD, NEW JERSEY v. PURDUE PHARMA, L.P. et al
NEW YORK SOUTHERN			
NYS	1	17−09877	Laborers 17 Health Benefit Fund v. Purdue Pharma, L.P. et al
NORTH CAROLINA MIDDLE			
NCM	1	17−01159	SURRY COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION et al
OHIO SOUTHERN			
OHS	2	17−01117	Clinton County Board of Commissioners v. Purdue Pharma L.P. et al
OHS	2	17−01126	Morrow County Board of County Commissioners v. Amerisourcebergen Drug Corporation et al
OHS	2	17−01132	Champaign County Board of County Commissioners v. AmerisourceBergen Drug Corporation et al
PUERTO RICO			
PR	3	17−02380	Municipality of Sabana Grande et al v. Purdue Pharma L.P. et al
TENNESSEE MIDDLE			
TNM	3	17−01605	Metropolitan Government of Nashville and Davidson County Tennessee v. Purdue Pharma L.P. et al

TEXAS EASTERN

TXE	6	17−00699	County of Smith v. Purdue Pharma L.P. et al
TXE	9	17−00213	Polk County v. Purdue Pharma L.P. et al

TEXAS NORTHERN

TXN	1	17−00196	Nolan County
TXN	1	17−00197	Mitchell County v. Purdue Pharma LP
TXN	7	17−00173	County of Wichita, Texas v. Purdue Pharma L.P. et al

EXHIBIT D

THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

CITY OF BIRMINGHAM, ALABAMA, a municipal corporation;

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC and MALLINCKRODT LLC.

Defendants.

CASE NO.: 2-17-cv-01360-JEO

FIRST AMENDED COMPLAINT

Complaint for Public Nuisance, Drug Related Nuisance, Violations of Racketeer Influenced and Corrupt Organizations Act (RICO) 18 U.S.C. § 1961 *et seq*., Violations of 18 U.S.C. § 1962 *et seq*., Negligence and Negligent Misrepresentation, Civil Conspiracy, Fraud and Fraudulent Misrepresentation.

JURY TRIAL DEMANDED AND ENDORSED HEREON

TABLE OF CONTENTS

Plaintiff, THE CITY OF BIRMINGHAM, ALABAMA, brings this Amended Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt plc; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges as follows:

I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby and to recoup monies spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

3. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[3] See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, which turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

II. PARTIES

A. PLAINTIFF.

6. Plaintiff THE CITY OF BIRMINGHAM, ALABAMA ("Birmingham" or "Plaintiff") is a municipal corporation organized under the laws of the State of Alabama and is authorized to bring the causes of action brought herein. ALA. CODE § 11-40-1 ("All municipal organizations now existing in the State of Alabama . . . shall sue and be sued … . Such municipal corporations shall be invested with the full powers, duties, and authority granted in this title."). Plaintiff is responsible for the public health, safety and welfare of its citizens.

7. Plaintiff is specifically authorized to seek common law public nuisance remedies available under Alabama law. *See* ALA. CODE §§ 6-5-122 ("All municipalities in the State of Alabama may commence an action in the name of the city to abate or enjoin any public nuisance injurious to the health, morals, comfort, or welfare of the community or any portion thereof."); 11-47-118; ("Municipalities may maintain a civil action to enjoin and abate any public nuisance, injurious to the health, morals, comfort or welfare of the community or any portion thereof.");

11-47-117 ("All cities and towns of this state shall have the power to prevent injury or annoyances from anything dangerous or offensive or unwholesome and to cause all nuisances to be abated and assess the cost of abating the same against the person creating or maintaining the same.").

8. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis and are a public nuisance and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

9. The distribution and diversion of opioids into Alabama ("the State") and into the City of Birmingham and its surrounding areas (collectively, "Plaintiff's Community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

10. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. The Plaintiff has suffered and continues to directly suffer these damages.

11. Plaintiff also seeks the means to abate the epidemic Defendants' wrongful and/or unlawful conduct has created.

12. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein, including, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

B. DEFENDANTS.

1. Manufacturer Defendants.

13. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

14. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA, INC. is a New York corporation with its principal place of business in Stamford, Connecticut and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

15. Purdue manufactures, promotes, sells and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006

sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

16. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

17. Cephalon, Inc. manufactures, promotes, sells and distributes opioids, such as Actiq and Fentora, in the United States. The FDA has approved Actiq only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[4] The FDA has approved Fentora only 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."[5] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.[6]

18. Teva Ltd., Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for

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[4] *Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII* (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.

[5] *Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.

[6] Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that Teva USA submitted the guide and directs physicians to contact Teva USA to report adverse events.

19. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[7] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including, *inter alia*, sales of Fentora®.[8] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries, Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; and Cephalon, Inc. are referred to as "Cephalon."

20. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of

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[7] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 21, 2017).

[8] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco and J&J are referred to as "Janssen."

21. Janssen manufactures, promotes, sells and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

22. ENDO HEALTH SOLUTIONS, INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC. is a wholly owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are referred to as "Endo."

23. Endo develops, markets and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013 and accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, such as oxycodone, oxymorphone, hydromorphone and hydrocodone products, in the United States, by itself and through its subsidiary, QUALITEST PHARMACEUTICALS, INC.

24. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Allergan PLC owns each of these defendants and uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan PLC; Actavis PLC; Actavis, Inc.; Actavis LLC; Actavis Pharma, Inc.; Watson

Pharmaceuticals, Inc.; Watson Pharma, Inc. and Watson Laboratories, Inc. are referred to as "Actavis."

25. Actavis manufactures, promotes, sells and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

26. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

27. Mallinckrodt manufactures, markets and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.[9]

2. Distributor Defendants.

28. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor

[9] Press Release, U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations,* July 11, 2017, https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders, last accessed October 26, 2017.

Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

29. McKESSON CORPORATION ("McKesson") at all relevant times operated as a licensed pharmacy wholesaler in Alabama. McKesson is a Delaware corporation. McKesson has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Alabama, including in McCalla, Alabama.

30. CARDINAL HEALTH, INC. ("Cardinal") at all relevant times operated as a licensed pharmacy wholesaler in Alabama. Cardinal's principal office located in Dublin, Ohio. Cardinal operates distribution centers in Alabama, including in Birmingham, Alabama.

31. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") at all relevant times operated as a licensed pharmacy wholesaler in Alabama. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen operates distribution centers in Alabama, including in Pelham, Alabama.

32. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[10] nor the wholesale distributors[11] will voluntarily disclose the data necessary to identify with specificity the transactions that will form the evidentiary basis for the claims asserted herein.

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[10] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[11] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

33. Consequently, Plaintiff has named the three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation) that dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Drug Corporation predecessors). The DEA has investigated and/or fined each for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct that resulted in the diversion of prescription opioids into our community, and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the "Big 3" herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

III. JURISDICTION & VENUE

34. This Complaint was filed as an original action in this District.

35. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*. ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

36. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a) because the Plaintiff is a "citizens" of this State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

37. This Court has personal jurisdiction over Defendants because they conduct business in the State, they purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license and they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

38. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g.*, *Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.,* 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

39. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim for relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC.

1. The National Opioid Epidemic.

40. Increasing abuse and diversion of prescription drugs, including opioid medications, have characterized the past two decades in the United States.[12]

41. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[13]

42. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention declared prescription painkiller overdoses to be at epidemic levels. The News Release noted:

> a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
>
> b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
>
> c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
>
> d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the

[12] *See* Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

[13] Katherine M. Keyes *et al*., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.[14]

43. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.[15]

44. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.[16]

45. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[17]

46. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin

[14] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

[15] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[16] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Provisional Counts of Drug Overdose Deaths*, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

[17] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[18]

47. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,*** specifically among persons who report past-year dependence or abuse. The increased availability of heroin combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[19]

48. The societal costs of prescription drug abuse are "huge."[20]

49. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[21]

50. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[22] The

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[18] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

[19] *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

[20] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

[21] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP*. 2016;65, doi:10.15585/mmwr.mm655051e1).

[22] Opioid Crisis, NIH.

economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.[23]

51. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[24]

52. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[25]

53. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken for candy.[26]

54. In 2016, the President of the United States declared an opioid and heroin epidemic.[27]

55. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[28] Meanwhile, the manufacturers and distributors

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[23] *Id*. (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

[24] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

[25] *See* Volkow & McLellan, *supra* note 1.

[26] Julie Turkewitz, *'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

[27] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[28] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.

of prescription opioids extract billions of dollars of revenue from the addicted American public while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

56. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to cause the national, state and local opioid epidemic.

2. Alabama's Opioid Epidemic.

57. The national opioid crisis has especially ravaged Alabama.

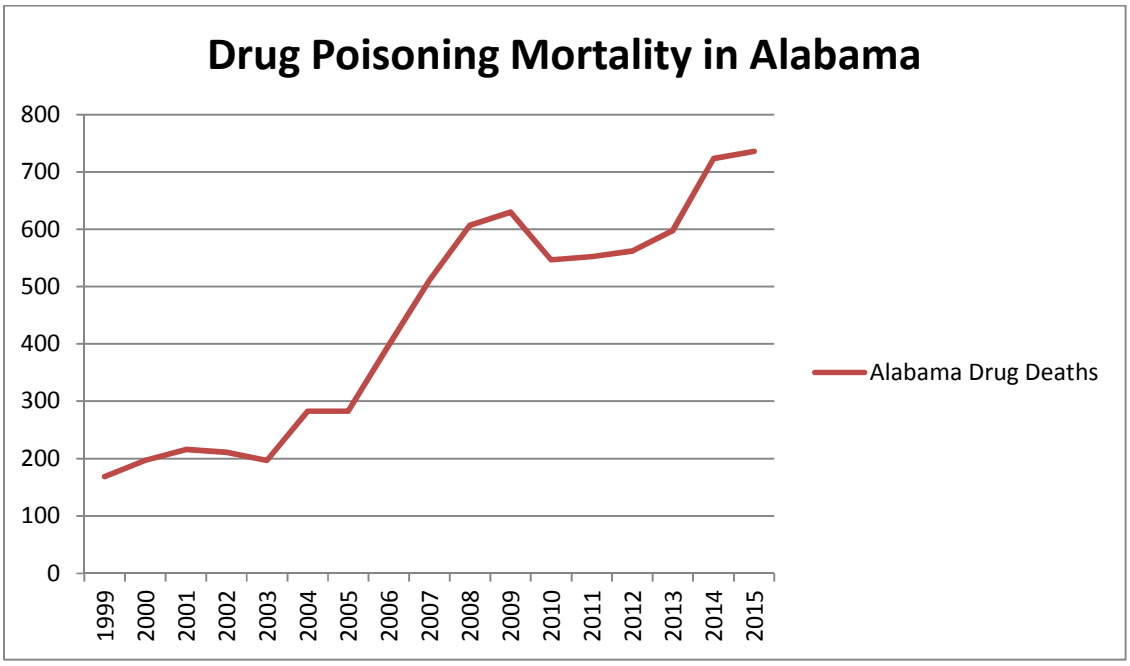
58. Alabama has the ***highest opioid prescription rate in the nation***, at a rate of 142.9 prescriptions per 100 persons (U.S. median rate: 82.5). Alabama is second in the nation for benzodiazepine prescriptions, at a rate of 61.9 per 100 persons (U.S. median rate: 37.6).[29] Over 6.5 million opioid prescriptions were filled in Alabama in 2015, supplying over 437 million pills, which equates to a total days' supply of 127,159,152 – or 348,381 years' worth.[30]

59. Overdose mortalities in Alabama have increased sharply in recent years:[31]

[29] *See* Leonard J. Paulozzi, M.D., *et al., Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills.

[30] George C. Smith, Jr., M.D., *ALBME Efforts to Combat Opioid Overuse,* Alabama Board of Medical Examiners (March 10, 2017), http://www.alabamapublichealth.gov/pharmacy/assets/presentation_smith_2017.pdf, last visited October 11, 2017

[31] U.S. Centers for Disease Control and Prevention, National Center for Health Statistics' Drug Poisoning Mortality dataset, accessible at: https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/ (last visited October 11, 2017).



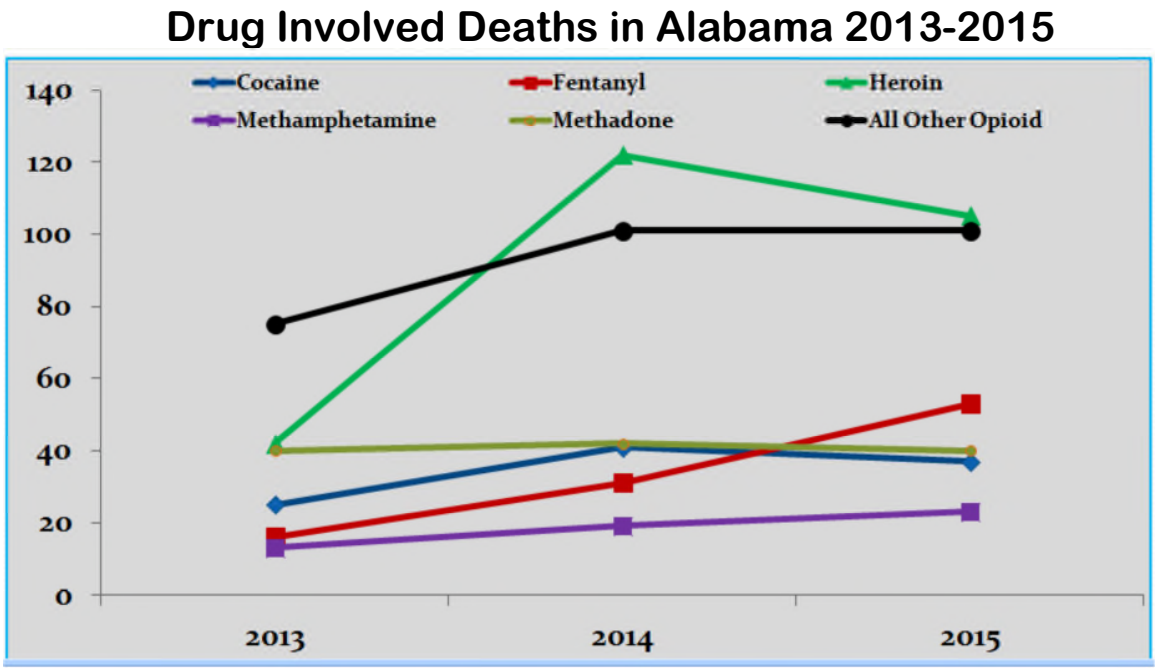
60. From 2013 to 2014 alone, Alabama saw a 20 percent increase in overdose fatalities.[32] In 2014, there were 723 Alabama overdose deaths, up from 598 Alabama overdose deaths in 2013.[33]

61. These deaths are overwhelmingly caused by opioids:[34]

[32] Centers for Disease Control and Prevention, Drug Overdose Death Data at https://www.cdc.gov/drugoverdose/data/statedeaths.html, last visited July 29, 2017.

[33] *Id*.

[34] X.J. Shen, Ph.D., Director, Division of Statistical Analysis, Alabama Department of Public Health, Center for Health Statistics, *Data-Driven Prevention Initiative (DDPI) for Heroin and Opioid Abuse/Overdose* (April 28, 2017). Available at http://www.alabamapublichealth.gov/pharmacy/assets/ddpi_opioidoverdose.pdf, last accessed October 11, 2017.



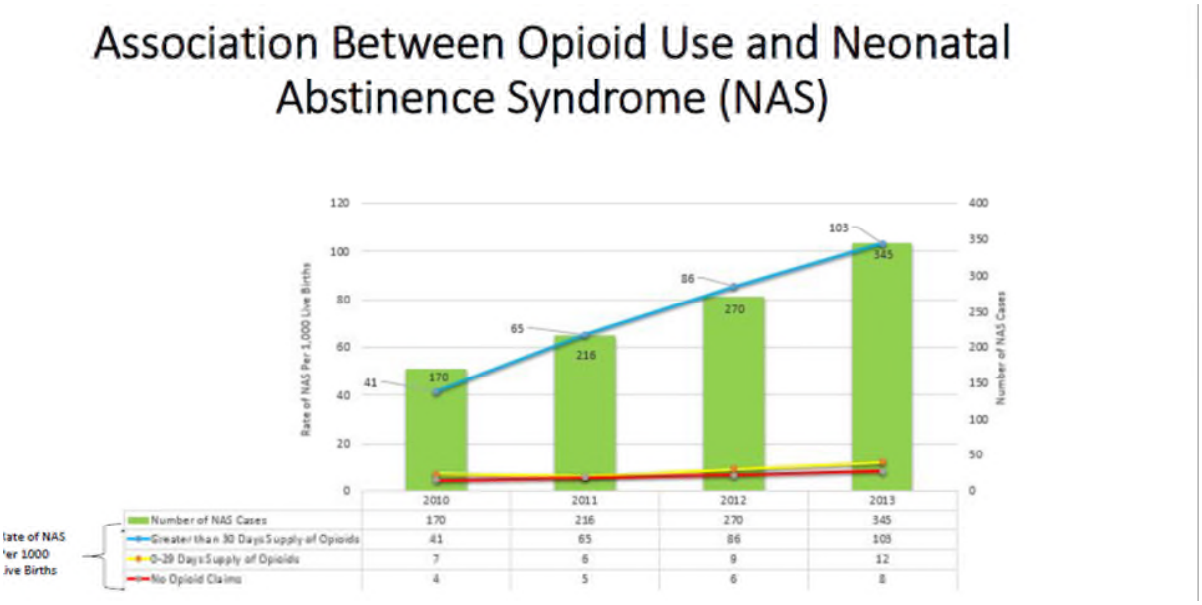
62. The percentage of Alabama children in foster care because of parental drug abuse has risen from 11.5% in 2006 to 37% in 2016.[35] Children with parents addicted to drugs tend to stay in foster care longer and often enter the system having experienced significant trauma, which makes their care more expensive.[36]

63. Alabama and neighboring states have now become ground zero for an explosion of cases in newborns with Neonatal Abstinence Syndrome ("NAS"), a collection of symptoms babies experience in withdrawing from opioid medications taken by the mother. "The region that includes Alabama, Mississippi, Tennessee and Kentucky has the highest rate in the country, with

[35] Mary Sell, *Parental drug use putting more children in foster care,* Decatur Daily, Montgomery Bureau, January 29, 2017, at http://www.decaturdaily.com/news/local/parental-drug-use-putting-more-children-in-foster-care/article_957642a9-e3d5-52a3-b8d9-d881be352aab.html, last visited October 11, 2017, citing Alabama Department of Human Resources.

[36] Trista Thurston, *Drug addiction drives spike in Ohio foster care,* Newark Advocate (Mar. 23, 2017), available at http://www.newarkadvocate.com/story/news/crime/high-in-ohio/2017/03/23/drug-addiction-drives-spike-ohio-foster-care/99545804/, last visited July 12, 2017.

NAS occurring in 16.2 out of every 1,000 hospital births in 2012."[37] Furthermore, "The number of cases of NAS covered by Medicaid in Alabama more than doubled from 170 cases in 2010 to 345 in 2013."[38] NAS is closely associated with opioid use:[39]



64. Alabama has the second-highest rate of nonmedical use of prescription pain relievers in the nation, covering one out of every nineteen Alabamans aged 12 or older.[40] Alabama is also second in the nation for Blue Cross Blue Shield patients diagnosed with opioid use disorders.[41]

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[37] Amy Yurkanin, *A grim and growing trend: Alabama sees increased cases of drug-dependent newborns* (Sep. 29, 2015), available at http://www.al.com/news/index.ssf/2015/09/a_grim_and_growing_trend_alaba.html, last visited October 11, 2017.

[38] *Id*.

[39] Casey Wylie, Quality Analytics, Alabama Medicaid Agency, *Neonatal Abstinence Syndrome (NAS) Adverse Fetal Outcomes in Mothers with Prescribed Opioid Medications Compared to Mothers With No Prescribed Opioid Medications Data-Driven Prevention Initiative (DDPI) for Heroin and Opioid Abuse/Overdose* (December 10, 2014). Available at http://www.alabamapublichealth.gov/perinatal/assets/NASPresentationforSCPH.pdf, last accessed October 11, 2017.

[40] Rachel N. Lipari, Ph.D., et al., *State and Substate Estimates of Nonmedical Use of Prescription Pain Relievers*, National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration, Jul. 13, 2017, at: https://www.samhsa.gov/data/sites/default/files/report_3187/ShortReport-3187.html, visited Oct. 11, 2017.

[41] Amy Yurkanin, *Blue Cross report finds alarming trends in Alabama opioid prescriptions*, AL.com, Jul. 1, 2017, at: http://www.al.com/news/index.ssf/2017/07/blue_cross_report_finds_alarmi.html, visited Oct. 11, 2017.

3. The Opioid Epidemic in Plaintiff's Community.

65. The opioid epidemic is particularly devastating in Plaintiff's Community.

66. Jefferson County, Alabama, where the City of Birmingham is situated, had an opioid prescription rate of 116.7 prescriptions per 100 persons in 2016. From 2010 to 2016, the average rate of prescriptions per 100 persons was an unbelievable 132.3.[42]

67. This high rate of prescriptions only scratches the surface of the full extent of the problem in Birmingham and Jefferson County. Based on the amount prescribed, Jefferson County had over 1,000 morphine milligram equivalents of opioids prescribed ***per capita***[43] in 2015. Over 90% of people in Jefferson County who need addiction treatment do not receive it.[44]

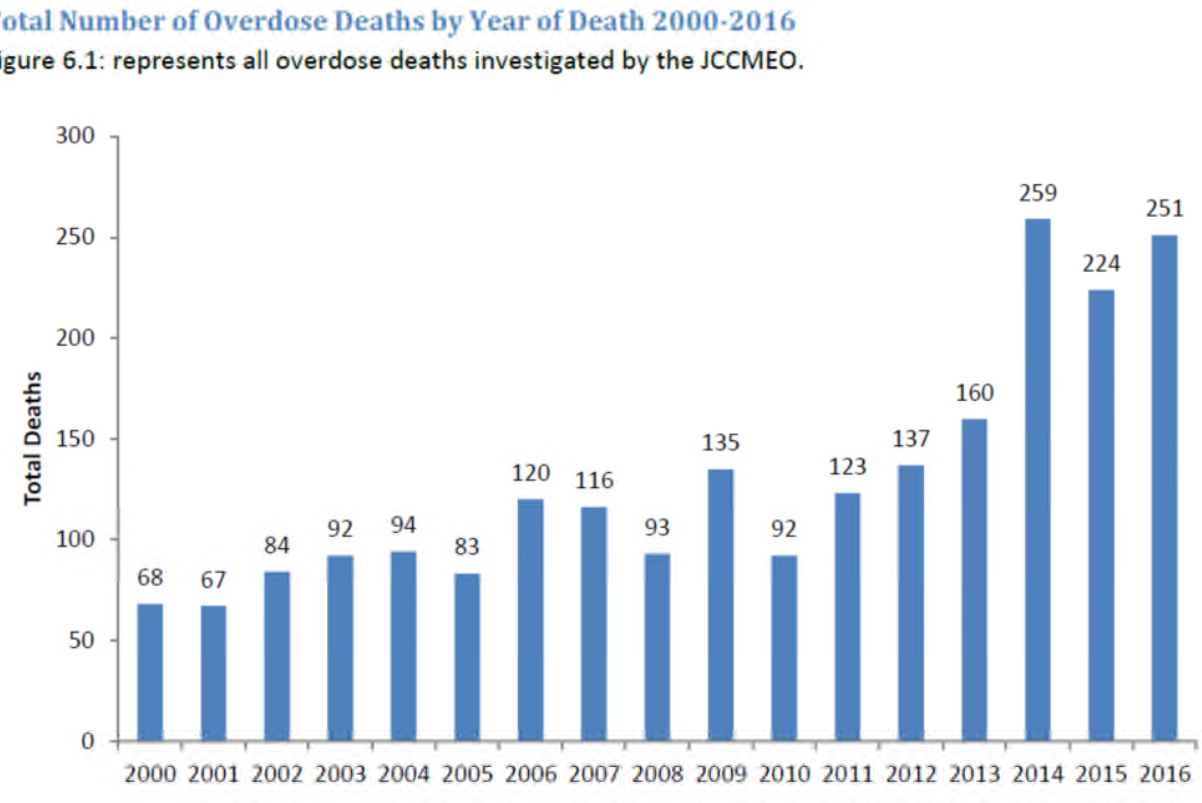
[42] U.S. Prescribing Rate Maps, Centers for Disease Control and Prevention (2017), https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (last visited Oct 13, 2017).

[43] Alabama Opioid Epidemic, amfAR, http://opioid.amfar.org/AL (last visited Oct 13, 2017).

[44] amfAR, *supra*

68. As a result, Jefferson County's drug overdose death rate has more than tripled since 2000:[45]

Drug Overdose Deaths in Jefferson County, Alabama



69. This may not even fully encompass the issue – amfAR's Opioid & Health Indicators gives a rate of 24.8 drug-related deaths per 100,000 Jefferson County residents for 2015. amfAR's data also shows that more than one in twenty County residents over age 12 reported non-medical use of pain relievers in 2016, and around half of those reported drug dependence.[46]

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[45] Jefferson County Coroner/Medical Examiner's Office, Jefferson County, Alabama 2016 Annual Report, accessible at: http://www.jccal.org/Sites/Jefferson_County/Documents/Coroner_Medical%20Examiner%20Office/2016%20Annual%20Report.pdf (last visited October 16, 2017).

[46] amfAR, *supra*

70. The City of Birmingham, and its surrounding community in particular, is now in the midst of an opioid epidemic. In 2016, drug deaths were the most common cause of accidental death in Jefferson County, where the City of Birmingham is located, accounting for 54.8% of the deaths.[47] There was a 12.0% increase in the total drug deaths in 2016, from 224 drug deaths in 2015 to 251 drug deaths in 2016.[48]

B. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE AND UNFAIR MARKETING OF OPIOIDS.

71. The opioid epidemic did not happen by accident.

72. Before the 1990s, generally accepted standards of medical practice dictated that patients should only use opioids short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

73. Each Manufacturer Defendant has conducted and has continued to conduct a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent and continues to

[47] Jefferson County Coroner/Medical Examiner's Office, Jefferson County, Alabama 2016 Annual Report, accessible at: http://www.jccal.org/Sites/Jefferson_County/Documents/Coroner_Medical%20Examiner%20Office/2016%20Annual%20Report.pdf (last visited October 16, 2017).

[48] *Id*.

spend millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

74. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that doctors should treat the signs of addiction with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that it is easy to manage opioid dependence and withdrawal; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

75. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

76. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[49] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon

[49] *See* Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on*

General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[50] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply) and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

77. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

78. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties whom they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

79. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, corporate headquarters fund and oversee "core message" on a national basis. This comprehensive approach ensures that the

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$10bn Opioid Habit, Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[50] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

Manufacturer Defendants accurately and consistently deliver their messages across marketing channels – including detailing visits, speaker events and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

80. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants required their sales representatives and physician speakers to stick to prescribed talking points, sales messages and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

i. Direct Marketing.

81. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

82. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads called "Pain vignettes" for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for

each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

83. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

84. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

85. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to

reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[51]

ii. Indirect Marketing.

86. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

87. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff's Community through unbranded advertising – *e.g.*, advertising that promotes opioid use generally but does not name a specific opioid. Independent third parties ostensibly created and disseminated this advertising. However, by funding, directing, reviewing, editing and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages these third parties disseminated and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as the Manufacturer Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, they similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

88. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded

[51] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

89. The Manufacturer Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

90. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLs and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences, seminars and scientific articles. Thus, working individually and collectively and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most

circumstances for long-term use – was untrue and that the compassionate treatment of pain required opioids.

91. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions included contributing to the creation of misleading publications and prescribing guidelines, which lack reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

92. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

93. Defendants utilized many KOLs, including many of the same ones.

94. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, Janssen

and Purdue (among others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

95. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[52]

96. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[53] Portenoy candidly stated: "Did I teach about pain management,

[52] Good Morning America (ABC television broadcast Aug. 30, 2010).

[53] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[54]

97. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

98. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the DEA closed the investigation without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

99. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on or are linked to websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk

[54] *Id*.

Tool into their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

100. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff's Community.[55]

101. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that doctors should see addictive behaviors not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[56] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[57]

102. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these

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[55] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

[56] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

[57] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

"Front Groups" generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

103. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

104. Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and Pain & Policy Studies Group ("PPSG").[58]

105. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012,

[58] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

primarily from Endo and Purdue. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff's Community.

106. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of a total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo and others to avoid using its line of credit.

107. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing and thus the profitability of its sponsors. Upon information and belief, the Manufacturer Defendants often called upon it to provide "patient representatives" for the promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the

basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

108. Plaintiff is informed and believes that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

109. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[59]

110. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

111. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational

[59] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

112. Upon information and belief, Endo internally views AAPM as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. The AAPM even elected Dr. Webster president while he was under a DEA investigation.

113. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

114. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, the AAPM only removed it from the website after a doctor complained.[60]

[60] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

115. AAPM and APS issued their own treatment guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[61] Doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants, have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis and Purdue discussed treatment guidelines with doctors during individual sales visits.

116. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[62] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still

[61] Roger Chou *et al*., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

[62] *Id*.

available online and were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants' financial support to members of the panel.

117. The Manufacturer Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF comprises representatives from opioid manufacturers (including Cephalon, Endo, Janssen and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

2. The Manufacturer Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

i. The Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

118. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC have conclusively debunked. These misrepresentations – described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted and because doctors could identify and manage those at greatest risk for addiction; (2) patients who displayed signs of addiction probably were not addicted, and, in any event, doctors could easily wean them from the drugs;

(3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations; they continue to make them today.

119. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of long-term opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

120. Some illustrative examples of the Manufacturer Defendants' false, deceptive and unfair claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure, *Managing Chronic Back Pain*, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.[63]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that

[63] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed, edited, approved and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[64]

h. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen and Cephalon in the State and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction, misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations and routinely did not correct the misrepresentations noted above.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[65]

121. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an

[64] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[65] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

alternative term for opioid addiction], [and] overdose . . .)."[66] The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[67]

122. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[68]

123. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers

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[66] Deborah Dowell *et al*., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[67] *Id*. at 2, 25.

[68] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

meeting the clinical criteria for an opioid use disorder."[69] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this State.

124. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented to doctors and patients that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (*i.e.* pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

125. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive and unfair statements regarding pseudoaddiction include:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids and hoarding are all signs of pseudoaddiction, rather than true addiction.[70] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[71]

b. Janssen sponsored, funded and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain

[69] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc. (*Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

[70] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

[71] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a roleplay, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

126. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

127. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to

their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue, upon information and belief, sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

128. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."[72]

129. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that doctors can easily address opioid dependence by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.[73]

[72] *Id*. at 11.

[73] *Id*. at 26.

130. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.[74]

131. A fifth category of false, deceptive and unfair statements the Manufacturer Defendants made to sell more drugs is that patients could increase opioid dosages indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.[75] This publication is still available online.

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

[74] APF, *Policymaker's Guide*, *supra* note 48, at 32.

[75] APF, *Treatment Options*, *supra* note 47, at 12.

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[76]

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as "disadvantages" of other pain medicines, but omitted any discussion of risks of increased opioid dosages.

f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary" and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.[77]

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[78]

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[79]

132. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline

[76] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

[77] APF, *Policymaker's Guide*, *supra* note 48, at 32.

[78] The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Aug. 21, 2017).

[79] Brief of APF, *supra* note 49, at 9.

clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[80] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[81] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."[82] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[83]

133. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

134. The Manufacturer Defendants made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed Endo had designed it to be crush-resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[84] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for

[80] 2016 CDC Guideline, *supra* note 50, at 22–23.

[81] *Id*. at 23–24.

[82] *Id*. at 21.

[83] *Id*. at 16.

[84] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

injection."[85] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[86] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Endo remove Opana ER from the market.

ii. The Manufacturer Defendants embarked upon a campaign of false, deceptive and unfair assurances grossly overstating the benefits of the opioid drugs.

135. To convince doctors and patients that they should use opioids to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[87] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

136. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health" and help patients enjoy their lives.

b. Endo distributed advertisements that claimed the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

[85] *Id*. at 6.

[86] *Id*. at 6 n.21.

[87] *Id*. at 15.

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters for display in doctors' offices of presumed patients in active professions. The caption read: "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. *Responsible Opioid Prescribing* (2007), which Cephalon, Endo and Purdue sponsored and distributed, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve."[88] This publication is still available online.

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[89] Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored

[88] APF, *Treatment Options*, *supra* note 47.

[89] *E.g.*, NIPC, *Persistent Pain and the Older Patient* (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20Invite.pdf.

website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health" and "[o]verall health-related quality of life for chronic pain."[90] The Policymaker's Guide was originally published in 2011.

l. Purdue's, Cephalon's, Endo's and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

137. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

138. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[91] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

139. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by

[90] APF, *Policymaker's Guide*, *supra* note 48, at 29.

[91] Letter from Thomas Abrams to Doug Boothe, *supra* note 32.

the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[92] Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when the tablet releases less medicine. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

140. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours.

[92] 2016 CDC Guideline, *supra* note 50, at 12.

Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

141. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

> OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.[93]

142. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain, even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for nor has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007, emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used

[93] Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at *4 (footnote omitted).

for any other conditions, such as migraines, post-operative pain or pain due to injury.[94] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant,* meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."[95]

143. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved and is not appropriate or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

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[94] *See* U.S. Food & Drug Admin., *Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.

[95] *Id*.

144. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

145. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.[96]

146. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion and inappropriate prescribing; paid bonuses to sales representatives for detailing

[96] Harriet Ryan *et al*., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

3. The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

147. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

148. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients, even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance and a smaller window between safe and unsafe dosages.[97] The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id*. at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

[97] 2016 CDC Guideline, *supra* note 50, at 13.

4. The Manufacturer Defendants Made Materially Deceptive Statements and Concealed Material Facts.

149. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts in the course of manufacturing, marketing and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

150. Defendant Purdue made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to doctors, patients and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff, while purportedly educating them on new pain standards;

q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and

r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials, advertisements and CMEs they knew would reach these same prescribers.

151. Defendant Endo made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

152. Defendant Janssen made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites, over which Janssen exercised final editorial control and approval, stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites, over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

153. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

154. Defendant Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

5. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

155. The Manufacturer Defendants, both individually and collectively, made, promoted and profited from their misrepresentations about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience, establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data and reports of adverse events, including reports of addiction, hospitalization and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

156. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy

and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence and meetings with KOLs, Front Groups and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which the NIPC runs, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

157. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could the Plaintiff or Plaintiff's Community have detected it. Thus, the Manufacturer Defendants successfully concealed from the medical

community, patients and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

C. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS.

158. The Distributor Defendants owe a duty under both federal law and Alabama law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community, as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

159. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

160. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

161. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

162. The opioid epidemic in the State, including, *inter alia,* in Plaintiff's Community, remains an immediate ***hazard to public health and safety***.

163. The opioid epidemic in Plaintiff's Community is a temporary and continuous ***public nuisance*** and remains unabated.

164. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Wholesale Drug Distributors Have a Duty Under State and Federal Law to Guard Against and Report Unlawful Diversion and to Report and Prevent Suspicious Orders.

165. Opioids are a controlled substance, and Alabama law categorizes them as having a "high potential for abuse." See ALA. CODE §20-2-24(1)(a). These "Schedule II" drugs are controlled substances with a "high potential for abuse," 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C).

166. Alabama law required each Defendant to first be registered with and permitted by the Alabama State Board of Pharmacy. ALA. CODE §§ 20-2-51 and 34-23-32; and ALA. ADMIN. CODE §§ 680-X-2-.25, 680-X-3-.01 and 680-X-3-.05.

167. Alabama's Pharmacy Board Regulations predicate such registration for both manufacturers and distributors upon, *inter alia*, "[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and "[p]ast experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion." ALA. CODE § 20-2-52(a)(1) and (4).

168. Alabama Pharmacy Board Regulations also require manufacturers and distributors of controlled substances doing business in Alabama to "submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days." ALA. ADMIN. CODE § 680-X-3-.05. *See also* ALA. ADMIN. CODE § 680-X-2-.23e (requiring wholesale distributors to forward all "records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual

volumes purchased by pharmacies. . . to the Board of Pharmacy.") *See also* ALA. CODE §20-2-56 ("Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy"); ALA. CODE § 20-2-71(a)(3) ("It is unlawful for any person: . . . To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under this chapter"); and ALA. CODE § 20-2-72 (a)(4) ("It is unlawful for any person: . . . To furnish false or fraudulent material information in or omit any material information from any application, report, or other document required to be kept or filed under [the Alabama Uniform Controlled Substances Act] or any record required to be kept by [the Alabama Uniform Controlled Substances Act]; . . .).

169. Furthermore, Alabama law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations. *See* ALA. CODE § 20-2-52(d) (each manufacturer and distributor, was required to "compl[y] with the provisions of the federal law respecting registration . . . ."); ALA. ADMIN. CODE 680-X-2-.23(k) ("Wholesale drug distributors shall operate in compliance with applicable Federal, State and Municipal laws and regulations."); and ALA. CODE § 20-2-56 ("Persons registered to manufacture, distribute, or dispense controlled substances under [Article 3 of the Alabama Uniform Controlled Substances Act] shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with any additional rules issued by the State Board of Medical Examiners, the State Board of Health, or the State Board of Pharmacy.").

170. The federal Controlled Substance Act further required each Distributor Defendant to register with the DEA. *See* 21 U.S.C. § 823(b), (e) and 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Alabama law adopts and incorporates those requirements, as set out above. *See, e.g.*, ALA. CODE § 20-2-52(d).

171. Each Distributor Defendant has an affirmative duty under federal and Alabama law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). Alabama law adopts and incorporates those requirements, as set out above.

172. The Alabama Legislature has found that "the diversion, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitutes a serious threat to the health and welfare of the citizens of the State of Alabama." ALA. CODE § 20-2-210. *See also* ALA. ADMIN. CODE 680-X-2-.23(k) ("It shall be a violation of these rules for a wholesale drug distributor to . . . operate in such a manner as to endanger the public health."). The Legislature has further termed this diversion constitutes a "drug crisis in the State of Alabama which is plaguing our neighborhoods." ALA. CODE § 6-5-155.

173. Federal regulations, incorporated by Alabama law, impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] 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." 21 C.F.R. § 1301.74(b).

174. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the distributor should report the order as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

175. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders that were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc*., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, distributors must report all flagged orders. *Id*.

176. The law regulates these prescription drugs for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate**

channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[98]

177. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[99]

178. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[100]

179. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[101]

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[98] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[99] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

[100] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[101] *See* Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

180. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, ***in addition*** to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[102] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[103] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[104]

181. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[105] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[106] The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

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[102] Rannazzisi Letter, *supra* note 83, at 2.

[103] *Id*. at 1.

[104] *Id*. at 2.

[105] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

[106] *Id*.

> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.[107]

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to

[107] *Id.*

report suspicious orders and "some criteria to use when determining whether an order is suspicious."[108]

182. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."[109]

183. The Distributor Defendants knew they were required to monitor, detect and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or the distributor otherwise characterizes it as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[110]

184. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

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[108] *Id*.

[109] *See* Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *2.

[110] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

185. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

186. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

187. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

188. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

189. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

190. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

2. The Distributor Defendants Breached Their Duties.

191. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[111]

192. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community is excessive for the medical need of the

[111] *See* Rannazzisi Decl. ¶ 10, filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[112]

193. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community or that the Distributor Defendants knew were likely to be diverted to Plaintiff's Community to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.

194. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

195. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

196. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific and industrial channels.

197. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

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[112] *Masters Pharmaceuticals, Inc*., 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

198. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[113]

199. The federal and state laws at issue here are public safety laws.

200. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under State law.

201. The Distributor Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

202. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law, which require Distributor Defendants to legally acquire and maintain a license to distribute prescription opiates.

203. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

204. The Distributor Defendants' repeated shipments of suspicious orders over an extended period of time, in violation of public safety statutes and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

[113] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

3. The Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with their Legal Duties.

205. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

206. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association the Distributor Defendants run, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows**:**

> a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[114]
>
> b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[115]
>
> c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[116]

[114] Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4–5.

[115] *Id*. at *8 (citations and quotation marks omitted).

[116] *Id*. at *14.

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[117]

e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[118]

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[119]

207. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[120]

208. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that, in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Masters Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled

[117] *Id.* at *22.

[118] *Id.* at *24–25.

[119] *Id.* at 26.

[120] *See* Brief of HDMA, *supra* note 19, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

suspicious orders. *Id*. at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above) that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

209. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[121] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[122] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers", including the McKesson

[121] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

[122] *Id*. at 4.

Distribution Center located in "Washington Courthouse, Ohio."[123] Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.[124]

210. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[125] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[126] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[127] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[128]

211. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

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[123] *Id*.

[124] *Id*. at 6.

[125] *Id*. at 4.

[126] *Id*.

[127] *Id*.; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.

[128] *See* 2017 Settlement Agreement and Release, *supra* note 112, at 6.

212. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[129] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[130] These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas

[129] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[130] *Id*.

Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA, which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"); Valencia, California ("Valencia Facility"); and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuan, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

213. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the

DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act", which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before the DEA can issue a suspension order.[131]

214. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

215. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[132] Given the sales volumes and the company's history of violations, this executive was either not telling the truth or, if Cardinal Health had such a system, it ignored the results.

216. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is

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[131] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

[132] Lenny Bernstein *et al*., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

"deeply passionate about curbing the opioid epidemic in our country."[133] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

217. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

218. Meanwhile, the opioid epidemic rages unabated in the Nation, the State and Plaintiff's Community.

219. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers, and when the DEA suspends one facility, they simply ship from another facility.

220. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Distributor Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

221. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

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[133] Scott Higham *et al*., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

D. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT AND PREVENT SUSPICIOUS ORDERS.

222. The same legal duties to prevent diversion and to monitor, report and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal and Alabama law.

223. Under Alabama and federal law, the Manufacturing Defendants were required to comply with substantially the same licensing and permitting requirements as the Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

224. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances like prescription opioids. *See* 21 U.S.C. § 823(a). A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . . . .

21 USCA § 823(a)(1) (emphasis added).

225. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. 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.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Manufacture Defendants breached these duties.

226. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

227. Federal statutes and regulations – and Alabama law incorporating those requirements – are clear: just like opioid distributors, the law requires opioid manufacturers to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(1).

228. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for

failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[134]

229. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands[.]"[135]

230. Among the allegations the settlement resolved, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[136]

231. The Memorandum of Agreement Mallinckrodt entered into ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain

[134] *See* Press Release, U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

[135] *Id*.

[136] *Id*.

effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[137]

232. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C,F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:
>
> i. conduct adequate due diligence of its customers;
> ii. detect and report to the DEA orders of unusual size and frequency;
> iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
> 1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
> 2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and
> 3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;
> iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and
> v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[138]

[137] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

[138] 2017 Mallinckrodt MOA at p. 2-3.

233. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[139]

234. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[140]

235. The same duties federal law imposed on Mallinckrodt were imposed upon all Manufacturer Defendants.

236. The same business practices Mallinckrodt utilized regarding "charge backs" and receipt and review of data from opioid distributors as to orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

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[139] *Id*. at 3-4.

[140] *Id*. at p.5.

237. Through, *inter alia*, the charge-back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

238. The Manufacturer Defendants failed to monitor, report and halt suspicious orders of opioids as required by federal law.

239. The Manufacturer Defendants' failures to monitor, report and halt suspicious orders of opioids were intentional and unlawful.

240. The Manufacturer Defendants have misrepresented their compliance with federal law.

241. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

242. Plaintiff's racketeering allegations below allege in greater detail the wrongful actions and omissions of the Manufacturer Defendants, which have caused the diversion of opioids and have been a substantial contributing factor to and/or proximate cause of the opioid crisis.

243. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

E. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.

244. As the Manufacturer Defendants' efforts to expand the market for opioids have increased, so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization and death among the people of the State and the

Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's Community, fueling the epidemic.

245. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[141]

246. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[142]

247. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[143]

248. The increased abuse of prescription painkillers, along with growing sales, has contributed to a large number of overdoses and deaths.[144]

249. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects: substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opiates.

250. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff's Community and areas from which such opioids are being diverted into Plaintiff's Community has resulted in the Defendant-caused opioid epidemic including heroin addiction, abuse and death.

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[141] *See* Dart *et al*., *supra* note 11.

[142] *See* Volkow & McLellan, *supra* note 1.

[143] *See* Califf *et al*., *supra* note 3.

[144] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* note 13.

251. Prescription opioid abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

252. Heroin abuse, addiction, morbidity and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

253. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of and/or substantial factors leading to the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

254. The unlawful diversion of prescription opioids is a direct and proximate cause of and/or substantial factor leading to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms the Plaintiff and Plaintiff's Community have incurred.

255. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

256. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

257. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

258. To eliminate the hazard to public health and safety and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[145]

259. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying opioid-addicted individuals early and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[146]

260. These community-based problems require community-based solutions that "budgetary constraints at the state and Federal levels" have limited.[147]

261. Having profited enormously through the aggressive sale, misleading promotion and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

F. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct.

262. Plaintiff contends it continues to suffer harm from Defendants' unlawful actions.

263. Defendants' continued tortious and unlawful conduct causes a repeated or continuous injury. The damages have not occurred all at once, but have continued to occur and increase as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity have not ceased. The public nuisance remains unabated.

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[145] *See* Rudd et al., *supra* note 20, at 1145.

[146] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

[147] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

2. Equitable Estoppel.

264. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and continuing to generate profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff and Plaintiff's Community, that they are working to curb the opioid epidemic.

265. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[148]

266. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[149]

267. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[150]

[148] Bernstein et al., *supra* note 117.

[149] Higham et al., *supra* note 118.

[150] Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *3-4, *25.

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

Through the above statements made on their behalf by their trade associations and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

268. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

269. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer

Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks and promoting sales. Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community deceived the medical community, consumers, the State and Plaintiff's Community.

270. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

271. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

3. Fraudulent Concealment.

272. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowing and fraudulent concealment of the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's Community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

273. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon

discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

274. In light of their statements to the media, in legal filings and in settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

275. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on their part.

V. LEGAL CAUSES OF ACTION

COUNT I
PUBLIC NUISANCE
(Against All Defendants)

276. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

277. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of and/or a substantial factor leading to Plaintiff's injury. *See* Restatement Second, Torts § 821B.

278. Under Alabama Law, a nuisance "is anything that works hurt, inconvenience, or damage to another." ALA. CODE § 6-5-120 (1975). "A public nuisance is one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals." ALA. CODE § 6-5-121 (1975).

279. Plaintiff has standing to bring claims for nuisance due to the opioid epidemic affecting and causing harm in its community.

280. Plaintiff also specifically has standing to pursue an action against Defendants for public nuisance under Alabama law. *See, e.g.*, ALA. CODE § 6-5-122 (1975) ("[a]ll municipalities in the State of Alabama may commence an action in the name of the city to abate or enjoin any public nuisance injurious to the health, morals, comfort, or welfare of the community or any portion thereof.")

281. By causing dangerously addictive drugs to flood the community and be diverted for illicit purposes, in contravention of federal and State law, each Defendant has injuriously affected rights common to the general public, specifically including the rights of the people of the Plaintiff's Community to public health, public safety, public peace, public comfort and public convenience. The public nuisance caused by the diversion of dangerous drugs has caused substantial annoyance, inconvenience and injury to the public.

282. By selling dangerously addictive opioid drugs diverted from a legitimate medical, scientific or industrial purpose, Defendants have committed a course of conduct that injuriously affects the safety, health and morals of the people of the Plaintiff's Community.

283. By failing to maintain a closed system that guards against diversion of dangerously addictive drugs for illicit purposes, Defendants injuriously affected public rights, including the right to public health, public safety, public peace and public comfort of the people of the Plaintiff's Community.

284. Plaintiff alleges that Defendants' wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

285. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

286. The residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

287. Defendants intentionally, unlawfully and recklessly manufacture, market, distribute and sell prescription opioids that Defendants know or reasonably should know will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse; an elevated level of crime, death and injuries to the residents of Plaintiff's Community; a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community; and direct costs to Plaintiff's Community.

288. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Community and its residents.

289. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders and/or stop shipment of suspicious orders.

290. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort, convenience and ability to be free from disturbance and reasonable apprehension of danger to person or property.

291. Defendants' conduct in illegally distributing and selling prescription opioids or causing such opioids to be distributed and sold where Defendants know or reasonably should know such opioids will be diverted, possessed and/or used illegally in Plaintiff's Community is of a continuing nature.

292. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

293. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

294. Statute and regulation proscribe Defendants' distribution of opioids while failing to maintain effective controls against diversion.

295. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

296. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

297. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

298. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

299. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling and distributing prescription drugs, including opioids, which Defendants specifically know to be dangerous under federal law. *See*, *e.g.*, 21 U.S.C. § 812 (b)(2).

300. Defendants' conduct in marketing, distributing and selling prescription opioids Defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise significantly and unreasonably interfere with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

301. It is, or should be, reasonably foreseeable to Defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community and will otherwise significantly and unreasonably interfere with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

302. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse and addiction are prevalent and where diverted opioids tend to be used frequently.

303. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

304. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, but for Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse and addiction that now exists would have been averted.

305. The presence of diverted prescription opioids in Plaintiff's Community and the consequence of prescription opioids having been diverted in Plaintiff's Community proximately results in and/or substantially contributes to the creation of significant costs to the Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police force and treat the victims of opioid abuse and addiction.

306. Stemming the flow of illegally distributed prescription opioids and abating the nuisance caused by the illegal flow of opioids will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

307. Defendants' conduct is a direct and proximate cause of and/or a substantial contributing factor to opioid addiction and abuse in Plaintiff's Community and costs borne by Plaintiff's Community and the Plaintiff, as well as a significant and unreasonable interference with public health, safety and welfare and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

308. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

309. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community; however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

310. Defendants knew prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting and refusing shipment of suspicious orders, that the opioids would be diverted and create an opioid abuse nuisance in Plaintiff's Community.

311. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

312. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

313. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance that the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

314. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiff here seeks recovery for its own harm.

315. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, *inter alia*, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

316. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing and persistent actions and omissions and interference with a right common to the public.

317. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages and punitive damages from the Defendants for the creation of a public nuisance, attorneys' fees and costs, and pre- and post-judgment interest.

318. Defendants' intentional and unlawful actions and omissions, as well as their unreasonable interference with a right common to the public are of a continuing nature.

319. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's Community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which

are specifically known to Defendants to be dangerous because, *inter alia,* federal and state law define these drugs as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

320. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties and the Manufacturer Defendants' fraudulent marketing activities have caused harm to the entire community that includes, but is not limited to, the following:

a. The high rates of use have led and continue to lead to unnecessary opioid abuse, addiction, overdose, injuries and deaths.

b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those residents of Plaintiff's Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids and the loss of companionship, wages or other support from family members who have used, abused, become addicted to, overdosed on or been killed by opioids.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to

more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement and financial resources of the Plaintiff's Community.

j. Defendants' interference with the comfortable enjoyment of life in the Plaintiff's Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm Defendants' actions inflicted.

321. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because their damages include, *inter alia,* health services and law enforcement expenditures, as described in this Complaint.

322. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

323. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia,* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT II
DRUG-RELATED NUISANCE
ALABAMA CODE § 6-5-155, *et seq*.
(Against All Defendants)

324. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows:

325. Alabama law defines a "Drug-Related Nuisance" as "[t]he use, sale, distribution, possession, storage, transportation, or manufacture of any controlled substances in violation of the controlled substance acts, or similar act of the United States or any other state." ALA. CODE § 6-5-155.1

326. For purposes of the Drug-Related Nuisance statute, "controlled substance acts" are defined as "[t]he provisions of Sections 20-2-1 et seq., known as the "Alabama Uniform Controlled Substance Act," and Sections 13A-12-201 et seq., known as "The Drug Predator Control Act of 1987," and Sections 13A-12-210 et seq., known as "The Drug Crimes Amendments Act of 1987." ALA. CODE § 6-5-155.1

327. The Alabama Uniform Controlled Substance Act, the US Controlled Substances Act and regulations promulgated by the Alabama State Board of Pharmacy proscribe Defendants' manufacture and distribution of opioids while failing to maintain effective controls against diversion. *See, e.g.*, 21 CFR § 1301.74(b); 21 U.S.C. § 823(a)(1), (b)(1); ALA. CODE §§ 20-2-56 and 57; ALA. ADMIN. CODE §680-X-3-.05. This manufacture and distribution in violation of the controlled substance acts or similar act of the United States constitutes a Drug-Related Nuisance.

328. "Wherever there is reason to believe that a drug-related nuisance exists, … the attorney for the county or municipality, … may file an action . . . to abate, enjoin, and prevent the drug-related nuisance." ALA. CODE § 6-5-155.2. Any person residing in the county where the nuisance exists may also bring such action. *Id*.

329. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Birmingham will be diverted, leading to abuse, addiction, crime and public health and safety costs.

330. As a result of the Drug-Related Nuisance caused by Defendants, the Plaintiff has suffered numerous adverse impacts, including, *inter alia*, an increase in the number of ambulance and police calls related to the use of opioids and/or to violence stemming from drug-related activity. In addition, the staggering rates of prescription opioid abuse and heroin use resulting from Defendants' abdication of their gate-keeping duties have caused harm to the entire community, as set out in previous allegations, which are incorporated herein.

331. The notice provisions of ALA. CODE § 6-5-155.3 are inapplicable here, as the Drug-Related Nuisance is not confined to any single property, but rather, the Drug-Related Nuisance is situated throughout the Plaintiff's Community. Thus, the Plaintiff is in the position of notifying themselves of the nuisance, the existence of which the Plaintiff is keenly aware.

332. Plaintiff requests, pursuant to ALA. CODE § 6-5-155.7, that the Court order the maximum per day civil penalty for each day the nuisance exists.

333. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

334. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, abatement, compensatory damages and punitive damages, from the Defendants for the creation of a drug-related nuisance, attorneys' fees and costs, and pre- and post-judgment interest, as well as any and all civil remedies specifically enumerated in ALA. CODE § 6-5-156.3.

COUNT III
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1961, *et seq.*
(Against All Defendants)

335. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

336. Plaintiff brings this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

337. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

338. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

339. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id*.

340. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq*. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

341. Congress specifically intended the closed system created by the CSA, including the establishment of quotas, to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling "the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[151]

342. Finding it impossible to legally achieve their ever-increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of

[151] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

suspicious orders and to notify the DEA of suspicious orders.[152] As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. [153] In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed them to generate obscene profits.

343. An association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants hatched Defendants' illegal scheme, and each of them executed it in perfect harmony. In particular, each of the RICO Defendants were associated with and conducted or participated in the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), the purpose of which was to engage in the unlawful sales of opioids, while deceiving the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c), and 18 U.S.C. § 1964(c) entitles Plaintiff to treble damages for its injuries.

[152] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

[153] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

344. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[154] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

345. On information and belief, each of the RICO Defendants is a member, participant and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

346. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. Additionally, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

347. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

[154] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

A. THE OPIOID DIVERSION ENTERPRISE

348. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[155] The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals.[156] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[157] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[158] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[159] Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[160] All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting

[155] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[156] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

[157] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[158] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

[159] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[160] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).

requirements that are designed to identify or prevent diversion.[161] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[162] The result is the scourge of addiction that has occurred.

349. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and inform the DEA of any suspicious orders.[163] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[164]

350. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances] and requiring order forms for all transfers of these drugs."[165] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

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[161] *Id*.

[162] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[163] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

[164] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

[165] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[166]

351. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA or (2) in excess of a quota assigned to it by the DEA.[167]

352. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

353. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone and oxycodone increased 13-fold, 4-fold and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to

[166] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[167] *Id*. (citing 21 U.S.C. 842(b)).

medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[168] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[169]

354. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. However, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

355. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) was characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and requests that the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

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[168] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):e52-9.

[169] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

356. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations[170] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believes that the Pain Care Forum and its members poured millions of dollars into lobbying efforts in this region while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

357. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids and the identification, investigation and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales.

[170] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

However, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

358. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across state lines, such as manufacture, sale, distribution and shipment of prescription opioids throughout the country and this jurisdiction and the corresponding payment and/or receipt of money from the sale of the same.

359. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

360. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in and are members of the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and

roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

361. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum and the HDA and through their contractual relationships.

362. The Pain Care Forum ("PCF") is a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when reporters discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

363. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[171] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[172]

364. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[173] In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen

[171] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added).

[172] *Id*.

[173] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

Pharmaceuticals), Actavis (*i.e.*, Allergan) and Teva (the parent company of Cephalon).[174] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. However, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[175] Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

365. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. Additionally, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

366. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies, sole purpose of which was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

367. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the

[174] *Id*. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[175] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.[176] Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

368. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners" and "make connections."[177] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

369. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.[178] A "senior company executive" must sign the manufacturer membership application, and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA

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[176] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

[177] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

[178] Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

application also requests that the manufacturer identify its current distribution information and its most recent year-end net sales through any HDA distributors, including, but not limited to, Defendants AmerisourceBergen, Cardinal Health and McKesson.[179]

370. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[180]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.[181]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[182]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[183]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability,

[179] *Id*.

[180] Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and-committees

[181] *Id*.

[182] *Id*.

[183] *Id*.

distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.[184]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[185]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[186]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[187]

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[188]

371. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

372. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[189] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the

[184] *Id*.

[185] *Id*.

[186] *Id*.

[187] *Id*.

[188] *Id*.

[189] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.

healthcare distribution industry."[190] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[191]

373. Third, the RICO Defendants maintained their interpersonal relationships by working together, exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

374. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[192] As reported in the Washington Post, identified by Senator McCaskill and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[193] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship

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[190] *Id*.

[191] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

[192] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.

[193] *Id*.

notices, and invoices.[194] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

375. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that Manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

376. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants were in communication and cooperation.

377. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum – the members of which include the Manufacturers and

[194] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

the Distributors' trade association – has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[195] Additionally, from 2006 to 2016, the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[196] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[197]

378. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

379. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market and to halt such unlawful sales so as to increase production quotas and generate unlawful profits, as follows:

380. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

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[195] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (accessed September 19, 2017), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

[196] *Id*.

[197] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

381. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

382. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

383. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

384. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

385. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[198]

[198] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

386. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Additionally, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

387. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids the RICO Defendants had not properly investigated or reported.

388. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[199] On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances they sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

[199] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

389. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[200] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.[201]

390. Defendants' scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

391. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

392. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious

[200] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[201] *Id*.

orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[202]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

[202] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

393. The scheme the RICO Defendants devised and implemented amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY.

394. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343) and (18 U.S.C. § 1961(D)) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud.

395. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

396. The RICO Defendants committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each

other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the internet to transmit mailings and wires in interstate or foreign commerce.

397. The RICO Defendants used, directed the use of and/or caused to be used thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

398. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

399. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market and sell the prescription opioids by means of false pretenses, misrepresentations, promises and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by

wire for the purpose of executing the unlawful scheme to design, manufacture, market and sell the prescription opioids by means of false pretenses, misrepresentations, promises and omissions.

400. The RICO Defendants' use of the mail and wires includes, but is not limited to, Manufacturers, Distributors or third parties that were foreseeably caused to conduct the transmission, delivery or shipment of the following as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas and procurement quotas;

f. Defendants' records and reports that 21 U.S.C. § 827 required Defendants to submit to the DEA;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

401. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

402. Purdue manufactures multiple forms of prescription opioids, including, but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

403. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

404. Cephalon manufactures multiple forms of prescription opioids, including, but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

405. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.

406. Janssen manufactures a prescription opioid known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

407. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

408. Endo manufactures multiple forms of prescription opioids, including, but not limited to: Opana/Opana ER, Percodan, Percocet and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in the State.

409. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

410. Actavis manufactures multiple forms of prescription opioids, including, but not limited to: Kadian and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

411. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.

412. Mallinckrodt manufactures multiple forms of prescription opioids, including, but not limited to: Exalgo and Roxicodone.

413. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

414. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

415. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing

diversion of prescription opioids and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

416. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales and to transmit payments and rebates/chargebacks.

417. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with each other and various other affiliates, regional offices, regulators, distributors and other third-party entities in furtherance of the scheme.

418. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants intended their scheme and common course of conduct to increase or maintain high production quotas for their prescription opioids from which they could profit.

419. Defendants have deliberately hid many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities, and these cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

420. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other

persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share and /or minimize the losses for the RICO Defendants.

421. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

422. The RICO Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of tens of millions of doses of prescription opioids into the illicit market.

423. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

424. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

425. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenue from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events.

426. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants, while Plaintiff was left with substantial injury to their business through the damage that the prescription opioid epidemic caused. The RICO Defendants committed or caused to be committed the predicate acts through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

427. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

428. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

429. RICO Defendants have hidden many of the precise dates of the criminal actions at issue here, and these cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

430. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly

neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

431. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

432. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

433. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances, and Their Crimes Are Punishable as Felonies.

434. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

435. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or

filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

436. Each of the RICO Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

437. The CSA and the Code of Federal Regulations required the RICO Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

438. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders and/or omitted material information from reports, records and other documents they were required to file with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

439. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[203]

[203] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017),

440. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as they relate to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles, yet failed to alert the DEA.[204] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[205] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[206]

441. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt, arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[207] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying

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http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/.

[204] Harriet Ryan, *et al*., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

[205] *Id*.

[206] *Id*.

[207] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.[208]

442. Plaintiff is informed and believes that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. The sheer volume of enforcement actions available in the public record against the Distributor Defendants supports this conclusion.[209] For example:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA, which provided that

[208] *Id*.

[209] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"); Valencia, California ("Valencia Facility"); and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Livonia, Michigan; Methuan, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

443. These actions against the Distributor Defendants confirm that the Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

444. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

445. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

446. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

447. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

448. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

449. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

450. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

451. Defendants' racketeering activities proximately caused Plaintiff's injuries and those of her citizens. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

452. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries and those of her citizens.

453. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

454. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia,* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT IV
RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT
18 U.S.C. 1962(d), *et seq.*
(Against All Defendants)

455. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

456. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d), it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

457. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE.

458. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Opioid Diversion Enterprise."

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

459. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Conduct of the Opioid Diversion Enterprise."

C. PATTERN OF RACKETEERING ACTIVITY.

460. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Pattern of Racketeering Activity."

D. DAMAGES.

461. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in their business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

462. The RICO Defendants' racketeering activities proximately caused Plaintiff's injuries and those of her citizens. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

463. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries and those of her citizens.

464. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

465. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT V
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION
(Against All Defendants)

466. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

467. Plaintiff seeks economic damages that were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

468. Under State law, to establish actionable negligence, one must show, in addition to the existence of a duty, a breach of that duty and injury resulting proximately therefrom and/or that was substantially caused thereby. All such essential elements exist here.

469. In Alabama, the "key factor" for determining whether a duty should be imposed as a matter of law is the "foreseeability" of the harm that might result if care is not exercised. *See, e.g.*, *Taylor v. Smith*, 892 So. 2d 887, 892 (Ala. 2004) (quoting *Key v. Compass Bank, Inc.*, 826 So. 2d 159, 170 (Ala. Civ. App. 2001) (in turn quoting *Patrick v. Union State Bank*, 681 So. 2d 1364, 1368 (Ala. 1996). Each Defendant owed a duty to the Plaintiff and to the public health and safety in the Plaintiff's Community because the injury was foreseeable and, in fact, foreseen by the Defendants. If a course of action creates a foreseeable risk of injury, the individual engaged in that course of action has a duty to protect others from such injury. Each Defendant owed a duty to the Plaintiff and to the public in the Plaintiff's Community, because the injury was foreseeable and, in fact, foreseen by the Defendants.

470. In Alabama, a legal duty to "exercise care . . . arises where the parties are bound by contract, . . . or where the obligations are expressly or impliedly imposed by statute, municipal ordinance, or by administrative rules or regulations, or by judicial decisions." *King v. National Spa & Pool Institute*, 570 So. 2d 612, 614 (Ala. 1990) (citations and internal quotation marks omitted).

471. Further, as Section 302B of the Restatement of Torts provides: "An act or an omission may be negligent if the actor realizes or should realize that it involves an unreasonable risk of harm to another through the conduct of the other or a third person which is intended to cause harm, even though such conduct is criminal."

472. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs to the State and Plaintiff's Community.

473. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling and distributing highly dangerous opioid drugs in the State and Plaintiff's Community.

474. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and impose significant costs upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

475. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

476. Moreover, law enforcement repeatedly warned Defendants of the unlawfulness and consequences of their actions and omissions.

477. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

478. As described above in allegations expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

479. As described elsewhere in the Complaint in allegations expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

480. As described elsewhere in the Complaint in allegations expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

481. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and their lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

482. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

483. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive and/or fraudulent.

484. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

485. As described above in allegations expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bear a causal connection with and/or proximately resulted in the damages sought herein.

486. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific or industrial channels. However, Defendants breached their duties to monitor for, report and halt suspicious orders; breached their duties to prevent diversion; and, further, misrepresented what their duties were and their compliance with their legal duties.

487. The Defendants failed to disclose the material facts that, *inter alia*, they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids.

488. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed and sold had characteristics, uses or benefits that they do not have. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when the Manufacturer Defendants knew, or should have known, such representations were untrue, false and misleading.

489. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value and in fact caused addiction and overdose deaths.

490. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

491. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under State law.

492. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' actions and omissions.

493. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia,* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VI
CIVIL CONSPIRACY
(Against All Defendants)

494. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here and further allege as follows.

495. As set forth herein, Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and Plaintiff's Community.

496. As set forth herein, Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's Community.

497. As set forth herein, Defendants engaged in a civil conspiracy to unlawfully divert opioids and create opioid dependence and abuse in the State and Plaintiff's Community.

498. Distributor and Manufacturer Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report and prevent suspicious orders of opioids.

499. The Manufacturer Defendants further unlawfully marketed opioids in the State and Plaintiff's Community in furtherance of that conspiracy.

500. Defendants acted tortiously in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

501. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing and/or have occurred within the last year.

502. Plaintiff alleges Defendants' conspiracy and acts in furtherance in greater detail earlier in the Complaint, including, without limitation, in Plaintiff's racketeering allegations. Such allegations are incorporated herein.

503. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

504. Defendants acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

505. Defendants' conspiracy and Defendants' actions and omissions in furtherance thereof proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

506. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' civil conspiracy.

507. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia,* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VII
FRAUD AND FRAUDULENT MISREPRESENTATION
(Against All Defendants)

508. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

509. Defendants violated their general duty not to actively deceive, have made knowingly false statements and have omitted and/or concealed information that made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

510. As alleged herein, Defendants made false statements as to their compliance with state and federal law regarding their duties to prevent diversion and their duties to monitor, report and halt suspicious orders and/or concealed their noncompliance with these requirements.

511. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic, non-cancer pain.

512. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false

representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's Community, the public and persons on whom Plaintiff relied.

513. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community and the physicians who prescribed opioids for persons in Plaintiff's Community; were made with the intent to deceive; and did in fact deceive these persons, Plaintiff and Plaintiff's Community.

514. Plaintiff, Plaintiff's Community and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

515. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. This reliance proximately caused Plaintiff's injuries.

516. Defendants' fraudulent conduct was a direct and proximate cause of the injuries Plaintiff alleges herein.

517. Plaintiff seeks economic losses (direct, incidental or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment.

518. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia,* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

PUNITIVE DAMAGES

519. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

520. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiff with fraud, oppression and/or malice and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal and state statutes and common law.

521. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as punishment and a deterrence.

522. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

523. Entering Judgment in favor of the Plaintiff in a final order against each of the Defendants;

524. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;

525. Order that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

526. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

527. Awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorneys' fees and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;

528. Awarding the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchase, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic.

529. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

530. Granting the Plaintiff

1. The costs of investigation, reasonable attorneys' fees, and all other costs and expenses;

2. Pre-judgment and post-judgment interest; and

3. All other relief as provided by law and/or as the Court deems appropriate and just.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: November 1, 2017

/s/ Peter J. Mougey

Peter J. Mougey (AL Bar No. ASB-2825-U72P)
Page A. Poerschke (AL Bar No. ASB-9647-D61P)
Laura S. Dunning (AL Bar No. ASB-1540-U50S)
Archie C. Lamb, Jr. (AL Bar No. ASB-1488-A52A)
James M. "Mike" Papantonio (*Pro Hac Vice*)
Jeffrey Gaddy (*Pro Hac Vice*)
Neil E. "Ned" McWilliams, Jr. (*Pro Hac Vice*)
LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
850.435.7068 (office)
850.436.6068 (fax)
pmougey@levinlaw.com
ppoerschke@levinlaw.com
ldunning@levinlaw.com
alamb@levinlaw.com
mpapantonio@levinlaw.com
jgaddy@levinlaw.com
nmcwilliams@levinlaw.com

Paul T. Farrell, Jr. (*Pro Hac Vice*)
GREENE, KETCHUM, FARRELL, BAILEY & TWEEL, LLP
419 - 11th Street (25701)/ P.O. Box 2389
Huntington, West Virginia 25724-2389
Phone: 800.479.0053 or 304.525.9115
Fax: 304.529.3284
Email: paul@greeneketchum.com

Russell W. Budd (*Pro Hac Vice*)
J. Burton LeBlanc (*Pro Hac Vice*)
Laura J. Baughman (*Pro Hac Vice*)
S. Ann Saucer (*Pro Hac Vice*)
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, Suite 1100
Dallas, TX 75219
Tel.: 214-521-3605
Fax: 214-520-1181
rbudd@baronbudd.com
bleblanc@baronbudd.com
lbaughman@baronbudd.com
asaucer@baronbudd.com

James C. Peterson (*Pro Hac Vice*)
R. Edison Hill (*Pro Hac Vice*)
HILL, PETERSON, CARPER, BEE & DEITZLER, PLLC
NorthGate Business Park
500 Tracy Way
Charleston, WV 25311
304-345-5667
304-345-1519 fax
jcpeterson@hpcdb.com
rehill@hpcbd.com

Barry W. Walker (AL Bar No. ASB-4526-E52B)
WALKER LAW, LLC
115 Richard Arrington Jr Blvd N
Birmingham, AL 35203
Phone: 205-252-2770
Fax: 205-252-2119
Email: Barry@bwwlawllc.com

Roland K. Tellis (*Pro Hac Vice*)
Mark P. Pifko (*Pro Hac Vice*)
BARON & BUDD, P.C.
15910 Ventura Boulevard, Suite 1600
Los Angeles, CA 91436
Tel.: 818-839-2333
Fax: 818-986-9698
rtellis@baronbudd.com
mpifko@baronbudd.com

Michael J. Fuller, Jr., (*Pro Hac Vice*)
Amy Quezon (*Pro Hac Vice*)
MCHUGH FULLER LAW GROUP, PLLC
97 Elias Whiddon Rd.
Hattiesburg, MS 39402
Telephone: 601-261-2220
Facsimile: 601-261-2481
mike@mchughfuller.com
amy@mchughfuller.com

CERTIFICATE OF SERVICE

I certify that on the 1st day of November, 2017, I electronically filed the foregoing **FIRST AMENDED COMPLAINT** using the CM/ECF system which will send notification of such filing to CM/ECF participants.

*/s/ Peter J. Mougey*_____

Peter J. Mougey (AL Bar No. ASB-2825-U72P)
LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502-5996
850.435.7068 (office)
850.436.6068 (fax)
pmougey@levinlaw.com

EXHIBIT E

EXHIBIT A

Entity Served:
PURDUE PHARMA, L.P.

Title of Action:
DANIEL C. LUBERDA BY HIS APPOINTED AGENT DANIEL L. LUBERDA v. PURDUE FREDERICK CORP.

Document(s) Type(s):
Summons/Complaint

Nature of Action:
Personal Injury

Court:
Horry County Court Of Common Pleas

Case Number:
2013-CP-26-1221

Jurisdiction Served:
New York

Date Served:
03/11/2013

Answer or Appearance Due:
30

Originally Served On:
CSC

How Served:
CERTIFIEDMAIL

Plaintiff's Attorney:
Carla F. Grabert-Lowenstein

P.O. Box 50097
Myrtle Beach, SC 29579

- U.S. District Court South Carolina
- U.S. Fourth Circuit Court of Appeals
- U.S. Supreme Court

The Law Offices of
CARLA FAYE GRABERT-LOWENSTEIN
Attorney At Law
314 Main Street
Conway, SC 29526
Office (843) 488-0912 Cell (843) 855-2547
Fax (843) 488-0916
cfgl@earthlink.net

Bar Licensed
- South Carolina No. 76886
- District of Columbia No. 86441
- California No. 123113

March 5, 2013

Purdue Pharma, L.P.
c/o Corporation Service Company
80 State Street
Albany, New York 12207-2543

RE: Daniel C. Luberda, by his personal agent Daniel L. Luberda v. Purdue Frederick Corp., Purdue Pharma, L.P., et al

Dear Sir or Madam:

I am hereby serving the enclosed Summons and Complaint on you as the Registered Agent for Purdue Pharma L.P., via Certified Mail this date. Please sign the enclosed Acceptance of Service and send back to me in the enclosed, self-addressed, stamped envelope.

Please inform your client that if they are willing to accept service for all listed defendants, we are willing to give them 60 days to answer the Complaint.

Sincerely,

Carla F. Grabert-Lowenstein
Attorney at Law
CFGL/sp

STATE OF SOUTH CAROLINA COUNTY OF HORRY Daniel C. Luberda by his appointed agent Daniel L. Luberda, Plaintiff(s) vs. Purdue Frederick Corp., Purdue Pharma L.P., The Purdue Pharma Company, Purdue Pharmaceutical Products L.P., Purdue Pharma Technologies Inc., Purdue Pharma of North Carolina Limited Partnership, Purdue Pharmaceutical Laboratories Limited Partnership, Purdue Products L.P., Purdue Pharmaceuticals Limited Partnership, Michael Friedman, Howard Udell, Paul Goldenheim, M.D. Danielle Nelson, Edward B. Mahony, Stuart D. Baker, John N. Stewart, David A. Long, James Dolan, Michael Danahy, Robin Abrams, Richard W. Silbert, Larry A. Pickett Jr., Craig Landau M.D., Robert F. Kaiko, Burt Weinstein, Kathleen M. Schady, PH.D, F. Mark Geraci, Don Kyle, Diana Lenkowsky, Burt Rosen, David Haddox, Phillip C. Strassburger, Russell Gasdia, David Lundie, William Malin, Tom Baumgartner M.D., Dennis A. Merlo, Alan Must; Dr. Alan Spanos; J. David Haddox, M.D., Scott Fishman, M.D., Lynn Webster, MD, Russell Portenoy, M.D., Perry Fine, M.D., Curtis Wright, M.D., Raymond Sackler, M.D., Richard Sackler Defendant(s).	IN THE COURT OF COMMON PLEAS FOR THE FIFTEENTH JUDICIAL CIRCUIT CASE NO: 2013-CP-26-1221 **ACCEPTANCE OF SERVICE**

Pursuant to Rule 4(j) SCRCP, I certify that I, on behalf of Corporation Service Company, certify that I received a copy of the following: Civil Action Coversheet, Summons, Complaint

and Verification in this action at the following location this _____ day of March, 2013:

80 State Street
Albany, New York 12207-2543

CORPORATION SERVICE COMPANY
as Registered Agent for Purdue Pharma, L.P.

By:_____

As its:_____

Sworn to and subscribed before me
this ____ day of March, 2013

_____
Notary Public for the State of New York
My Commission Expires:_____

STATE OF SOUTH CAROLINA)
) IN THE COURT OF COMMON PLEAS
COUNTY OF HORRY)
)
DANIEL C. LUBERDA by his personal agent) CIVIL ACTION COVERSHEET
DANIEL L. LUBERDA
Plaintiff(s))
) 2013-CP - 26- 1221
vs.)
)
Purdue Frederick Corp., Purdue Pharma L.P., et al)
Defendant(s))

Submitted By: Carla F. Grabert-Lowenstein
SC Bar #: 76886
Telephone #: 843-488-0912
Fax #: 843-488-0916
Other:
E-mail: cfgl@earthlink.net

Address: 314 Main Street
Conway, SC 29526

NOTE: The coversheet and information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is required for the use of the Clerk of Court for the purpose of docketing. It must be filled out completely, signed, and dated. A copy of this coversheet must be served on the defendant(s) along with the Summons and Complaint.

DOCKETING INFORMATION (*Check all that apply*)

***If Action is Judgment/Settlement do not complete*

- [x] **JURY TRIAL** demanded in complaint. [ ] **NON-JURY TRIAL** demanded in complaint.
- [x] This case is subject to **ARBITRATION** pursuant to the Court Annexed Alternative Dispute Resolution Rules.
- [x] This case is subject to **MEDIATION** pursuant to the Court Annexed Alternative Dispute Resolution Rules.
- [ ] This case is exempt from ADR. (Proof of ADR/Exemption Attached)

NATURE OF ACTION (*Check One Box Below*)

Contracts
- [ ] Constructions (100)
- [ ] Debt Collection (110)
- [ ] Employment (120)
- [ ] General (130)
- [ ] Breach of Contract (140)
- [ ] Other (199)

Torts - Professional Malpractice
- [ ] Dental Malpractice (200)
- [ ] Legal Malpractice (210)
- [ ] Medical Malpractice (220)

Previous Notice of Intent Case # 20____-CP-_____-_____

- [ ] Notice/ File Med Mal (230)
- [ ] Other (299)

Torts – Personal Injury
- [ ] Assault/Slander/Libel (300)
- [ ] Conversion (310)
- [ ] Motor Vehicle Accident (320)
- [ ] Premises Liability (330)
- [ ] Products Liability (340)
- [ ] Personal Injury (350)
- [ ] Wrongful Death (360)
- [ ] Other (399)

Real Property
- [ ] Claim & Delivery (400)
- [ ] Condemnation (410)
- [ ] Foreclosure (420)
- [ ] Mechanic's Lien (430)
- [ ] Partition (440)
- [ ] Possession (450)
- [ ] Building Code Violation (460)
- [ ] Other (499)

Inmate Petitions
- [ ] PCR (500)
- [ ] Mandamus (520)
- [ ] Habeas Corpus (530)
- [ ] Other (599)

Administrative Law/Relief
- [ ] Reinstate Drv. License (800)
- [ ] Judicial Review (810)
- [ ] Relief (820)
- [ ] Permanent Injunction (830)
- [ ] Forfeiture-Petition (840)
- [ ] Forfeiture—Consent Order (850)
- [ ] Other (899)

Judgments/Settlements
- [ ] Death Settlement (700)
- [ ] Foreign Judgment (710)
- [ ] Magistrate's Judgment (720)
- [ ] Minor Settlement (730)
- [ ] Transcript Judgment (740)
- [ ] Lis Pendens (750)
- [ ] Transfer of Structured Settlement Payment Rights Application (760)
- [ ] Confession of Judgment (770)
- [ ] Petition for Workers Compensation Settlement Approval (780)
- [ ] Other (799)

Appeals
- [ ] Arbitration (900)
- [ ] Magistrate-Civil (910)
- [ ] Magistrate-Criminal (920)
- [ ] Municipal (930)
- [ ] Probate Court (940)
- [ ] SCDOT (950)
- [ ] Worker's Comp (960)
- [ ] Zoning Board (970)
- [ ] Public Service Comm. (990)
- [ ] Employment Security Comm (991)
- [ ] Other (999)

Special/Complex /Other
- [ ] Environmental (600)
- [ ] Automobile Arb. (610)
- [ ] Medical (620)
- [ ] Other (699)
- [x] Pharmaceuticals (630)
- [ ] Unfair Trade Practices (640)
- [ ] Out-of State Depositions (650)
- [ ] Motion to Quash Subpoena in an Out-of-County Action (660)
- [ ] Sexual Predator (510)

Submitting Party Signature: Carla F. Grabert-Lowenstein **Date:** 2-27-13

Note: Frivolous civil proceedings may be subject to sanctions pursuant to SCRCP, Rule 11, and the South Carolina Frivolous Civil Proceedings Sanctions Act, S.C. Code Ann. §15-36-10 et. seq.

FOR MANDATED ADR COUNTIES ONLY

Allendale, Anderson, Beaufort, Clarendon, Colleton, Florence, Greenville, Hampton, Horry, Jasper, Lee, Lexington, Pickens (Family Court Only), Richland, Sumter, Union, Williamsburg, and York

SUPREME COURT RULES REQUIRE THE SUBMISSION OF ALL CIVIL CASES TO AN ALTERNATIVE DISPUTE RESOLUTION PROCESS, UNLESS OTHERWISE EXEMPT.

You are required to take the following action(s):

1. The parties shall select a neutral and file a "Proof of ADR" form on or by the 210th day of the filing of this action. If the parties have not selected a neutral within 210 days, the Clerk of Court shall then appoint a primary and secondary mediator from the current roster on a rotating basis from among those mediators agreeing to accept cases in the county in which the action has been filed.

2. The initial ADR conference must be held within 300 days after the filing of the action.

3. Pre-suit medical malpractice mediations required by S.C. Code §15-79-125 shall be held not later than 120 days after all defendants are served with the "Notice of Intent to File Suit" or as the court directs. (Medical malpractice mediation is mandatory statewide.)

4. Cases are exempt from ADR only upon the following grounds:

    a. Special proceeding, or actions seeking extraordinary relief such as mandamus, habeas corpus, or prohibition;

    b. Requests for temporary relief;

    c. Appeals

    d. Post Conviction relief matters;

    e. Contempt of Court proceedings;

    f. Forfeiture proceedings brought by governmental entities;

    g. Mortgage foreclosures; and

    h. Cases that have been previously subjected to an ADR conference, unless otherwise required by Rule 3 or by statute.

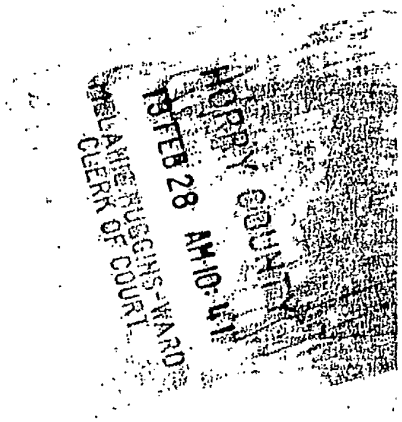
5. In cases not subject to ADR, the Chief Judge for Administrative Purposes, upon the motion of the court or of any party, may order a case to mediation.

6. Motion of a party to be exempt from payment of neutral fees due to indigency should be filed with the Court within ten (10) days after the ADR conference has been concluded.

Please Note: **You must comply with the Supreme Court Rules regarding ADR. Failure to do so may affect your case or may result in sanctions.**

STATE OF SOUTH CAROLINA)
)
COUNTY OF HORRY)
)
Daniel C. Luberda by his appointed)
agent Daniel L. Luberda,)
)
Plaintiff(s))
vs.)
)
)
Purdue Frederick Corp., Purdue)
Pharma L.P., The Purdue Pharma)
Company, Purdue Pharmaceutical)
Products L.P., Purdue Pharma)
Technologies Inc., Purdue Pharma)
of North Carolina Limited)
Partnership, Purdue Pharmaceutical)
Laboratories Limited)
Partnership, Purdue Products L.P.,)
Purdue Pharmaceuticals Limited)
Partnership, Michael Friedman,)
Howard Udell, Paul Goldenheim, M.D.)
Danielle Nelson, Edward B. Mahony,)
Stuart D. Baker, John N. Stewart,)
David A. Long, James Dolan,)
Michael Danahy, Robin Abrams,)
Richard W. Silbert, Larry A.)
Pickett Jr., Craig Landau M.D.,)
Robert F. Kaiko, Burt Weinstein,)
Kathleen M. Schady, PH.D, F. Mark)
Geraci, Don Kyle, Diana Lenkowsky,)
Burt Rosen, David Haddox, Phillip C.)
Strassburger, Russell Gasdia, David)
Lundie, William Malin, Tom)
Baumgartner M.D., Dennis A. Merlo,)
Alan Must; Dr. Alan Spanos;)
J. David Haddox, M.D., Scott)
Fishman, M.D., Lynn Webster, MD,)
Russell Portenoy, M.D., Perry Fine,)
M.D., Curtis Wright, M.D., Raymond)
Sackler, M.D., Richard Sackler)
)
Defendant(s).)
_____)

IN THE COURT OF COMMON PLEAS
FOR THE FIFTEENTH JUDICIAL CIRCUIT
CASE NO: 2013-CP-_____



SUMMONS

TO THE DEFENDANTS ABOVE-NAMED:

YOU ARE HEREBY SUMMONED and notified that an action has been filed against you in this court. Within thirty (30) days of the day you receive this Summons and Complaint, you must respond in writing to this Complaint by filing an Answer with this court. You must also serve a copy of your Answer to this Complaint upon the Plaintiff or the Plaintiff's attorney at the address shown below. If you fail to answer the Complaint, judgment by default could be rendered against you for the relief requested in the Complaint.

Dated this 27 day of February, 2013

Carla F. Grabert-Lowenstein
Attorney for Plaintiff
314 Main Street
Conway, SC 29526
(843) 488-0912

STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	FOR THE FIFTEENTH JUDICIAL CIRCUIT
COUNTY OF HORRY)	CASE NO: 2013-CP-_____
)	
Daniel C. Luberda by his appointed)	
agent Daniel L. Luberda,)	
)	
Plaintiff(s))	
vs.)	**COMPLAINT**
)	
Purdue Frederick Corp., Purdue)	
Pharma L.P., The Purdue Pharma)	
Company, Purdue Pharmaceutical)	
Products L.P., Purdue Pharma)	
Technologies Inc., Purdue Pharma)	
of North Carolina Limited)	
Partnership, Purdue Pharmaceutical)	
Laboratories Limited)	
Partnership, Purdue Products L.P.,)	
Purdue Pharmaceuticals Limited)	
Partnership, Michael Friedman,)	
Howard Udell, Paul Goldenheim, M.D.)	
Danielle Nelson, Edward B. Mahony,)	
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David A. Long, James Dolan,)	
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Strassburger, Russell Gasdia, David)	
Lundie, William Malin, Tom)	
Baumgartner M.D., Dennis A. Merlo,)	
Alan Must; Dr. Alan Spanos;)	
J. David Haddox, M.D., Scott)	
Fishman, M.D., Lynn Webster, MD,)	
Russell Portenoy, M.D., Perry Fine,)	
M.D., Curtis Wright, M.D., Raymond)	
Sackler, M.D., Richard Sackler)	
)	
Defendant(s).)	
_____)	

NOW COMES THE PLAINTIFFS, by and through undersigned counsel of record,

Carla Faye Grabert-Lowenstein, and alleges that the items in this complaint are true and accurate to the best of their knowledge:

PARTIES

1. Purdue Frederick, a State of New York corporation doing business as Purdue Fredrick, headquartered in Connecticut, at all times relevant to the Complaint. Purdue Fredrick and other related and associated entities were engaged in the pharmaceutical manufacturing business throughout the United States.
2. Purdue Pharma LP is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE.
3. The Purdue Pharma Company is a GENERAL PARTNERSHIP that is domiciled in the State of DELAWARE.
4. Purdue Pharmaceutical Products LP is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE.
5. Purdue Pharma Technologies Inc., is a CORPORATION incorporated in the State of DELAWARE, and does business in South Carolina, specifically, Horry County and,
6. Purdue Pharma of North Carolina Limited Partnership is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE, and conducts business in South Carolina, specifically, Horry County.
7. Purdue Pharmaceutical Laboratories Limited Partnership is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE, and does business in South Carolina,

specifically, Horry County.

8. Purdue Products LP is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE and does business in South Carolina, specifically Horry County.

9. Purdue Pharmaceuticals Limited Partnership, aka Purdue Pharmaceuticals L.P., is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE, and does business in South Carolina, including, Horry County.

10. South Carolina State Courts do have in persona jurisdiction over the Defendant(s).

11. Purdue Frederick and its other enmities conducted business in the State of South Carolina specifically selling their pharmaceutical products and sold in the State of South Carolina.

12. Raymond R. Sackler is co-founder and owner of Purdue Pharmaceutical L.P.

13. Michael Friedman is the former President for Purdue Pharma et al.

14. Howard Udell is an Assistant Corporate Secretary and former Chief Counsel for Purdue Pharma et al.

15. Paul Goldenheim, M.D. is the former medical director for Purdue Pharma et al.

16. Danielle Nelson is an Assistant Corporate Secretary for Purdue Pharma et al.

17. Edward B. Mahony is an Executive Vice President, Chief Financial Officer, and Treasurer for Purdue Pharma et al.

18. Stuart D. Baker is an Executive Vice President and Secretary for Purdue Pharma et al.

19. John N. Stewart is the President and CEO for Purdue Pharma et al.

20. David A. Long is the Vice President for Purdue Pharma. et al

21. James Dolan is the Senor Vice President of Licensing and Business for Purdue Pharma et al.

22. Michael Danahy is the Tax Officer for Purdue Pharma et al.

23. Robin Abrams is a Vice President Associate General Counsel for Purdue Pharma et al.

24. Richard W. Silbert is Vice President Associate General Counsel for Purdue Pharma et al.

25. Larry A. Pickett Jr. is the Vice President Chief Information Officer for Purdue Pharma et al.

26. Craig Landau, M.D. is the Vice President Chief Medical Officer for Purdue Pharma et al.

27. Robert F. Kaiko is the Vice President of Clinical Research for Purdue Pharma et al.

28. Burt Weinstein is Vice President of Corporate Compliance for Purdue Pharma et al.

29. Kathleen M. Schady Ph.D is Vice President of Corporate Quality for Purdue Pharma et al.

30. F. Mark Geraci is Vice President of Corporate Security for Purdue Pharma et al.

31. Don Kyle is Vice President of Discovery for Purdue Pharma et al.

32. Diana Lenkowsky is the Vice President of Facilities and Administration for Purdue Pharma et al.

33. Burt Rosen is Vice President of Federal Court Affairs for Purdue Pharma et al.

34. David Haddox is Vice President of Health Policy for Purdue Pharma et al.

35. Phillip C. Strassburger is Vice President of Intellectual Property for Purdue Pharma et al.

36. Russell Gasdia is Vice President of Marketing and Sales for Purdue Pharma et al.

37. David Lundie is Vice President of Manufacturing and Supply Chain for Purdue Pharma et al.

38. William Malin is Vice President of Project Marketing for Purdue Pharma et al.

39. Todd Baumgartner, M.D., is Vice President of Regulatory Affairs for Purdue Pharma et al.

40. Dennis A. Merlo is Vice President of Sales Operations for Purdue Pharma et al.

41. Alan Must is Vice President of State Government Relations for Purdue Pharma et al.

42. James Heins, Senior Director of Public Affairs Purdue Pharma;

43. Robin Hogan, former Vice President of Communications of Purdue Pharma and corporate spokesperson.

44. Curtis Wright, M.D., employed by Purdue Pharma during the relevant time period after being part of approval process for OxyContin at the United States Food and Drug Administration ("FDA")

JURISDICTION AND VENUE

45. All of the alleged acts occurred within Horry County South Carolina.

At all times relevant Defendants conducted business within the borders of Horry, County South Carolina. Plaintiffs resided in Horry County South Carolina during the relevant time period. As Defendants continue to conduct business in Horry County South Carolina, and plaintiffs, continue to reside in Horry County this court has jurisdiction and is the proper venue for all causes of action.

FACTUAL BACKGROUND

46. Oxycontin is an opioid analgesic drug, sold in tablet form, which is a controlled-release oral form of Oxycodone hydrochloride; Oxycontin is a Schedule II drug.

47. At all times described herein, the Defendants named in cause of action were in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing pharmaceutical products, including Oxycontin.

48. The Defendants named in this cause of action advertised and marketed Oxycontin to physicians and to the public throughout the United States, including South Carolina. This marketing included oral representations and written labeling, including package inserts and/or brochures and/or other writings; and included advertising and marketing through various media and website publications.

49. The Defendants named in this cause of action, through its market representatives, advertised and marketed Oxycontin directly to Daniel C. Luberda.

50. At the time that the Defendants named in this cause of action marketed Oxycontin to Daniel C. Luberda, the Defendants knew that Oxycontin was a highly-addictive drug, even when taken as directed, and that it had other defects.

51. The Defendants named in this cause of action, in the course of the commerce of Oxycontin and with intent that Plaintiff rely on the deception, did commit deceptive acts or practices in one or more of the following respects:

a. The Defendants named in this cause of action told doctors and the public at large that Oxycontin was the new wonder drug; that it was the standard of care for treatment of chronic pain; and/or

b. The Defendants named in this cause of action told doctors and the public at large that Oxycontin was safe and effective and non-addictive; and/or

c. The Defendants named in this cause of action told doctors and the public at large that it would be medical malpractice *not* to prescribe Oxycontin to patients with chronic pain; and/or

d. The Defendants named in this cause of action told doctors and the public at large that the Defendants would sue doctors who failed to prescribe Oxycontin to treat chronic pain; and/or

e. Oxycontin poses no serious risks of physical dependence and addiction; and/or

f. Oxycontin has been safely and effectively used to treat arthritis patients and car accident victims, facts represented in a segment on the website called "Pain Management Success Stories"; and/or

g. True addiction, described by this website as meaning using a drug to get "high", very rarely occurs when opioids are being used under medical supervision to relieve pain.

52. The Defendants named in this cause of action, pleaded guilty on May 10, 2007 to the felony of deceptive practices or acts in the misbranding of Oxycontin with intent to defraud or mislead, and agreed to a statement of facts which admitted conduct that included the deceptive practices and acts in the marketing of Oxycontin that were used to market Oxycontin to Daniel C. Luberda; and on or about July 20, 2007, the Defendant named in this Count was sentenced for these deceptive practices and acts, and paid fines (or agreed to pay fines) in excess of $600,000,000.00; see Excerpt from the "Plea

Agreement" and the "Agreed Statement of Facts", attached hereto and incorporated herein by reference.

53. Howard Udell, Michael Friedman, and Dr. Paul Goldenheim all plead guilty in United States Federal District Court to charges of misleading doctors and patients by marketing Oxycontin as less likely to be abused than other narcotics.

54. Defendant(s) admitted to misleading the public about Oxycontin risk of addiction.

55. Defendants Udell, Friedman and Goldenheim as a result of their conviction were further prohibited from participation in the Medicare and Medicad and other federal health care programs for fifteen years by the United States Department of Health and Human Services.

56. Notwithstanding the federal conviction on like prior bad acts Defendant(s) continued to push a fraudulent marketing campaign that promoted Oxycontin as less addictive, less subject to abuse and less likely to cause withdrawal, when they in fact knew such information was not true.

57. Defendant(s) marketed Oxycontin as a safe, effective, and non-habit forming, painkiller.

58. Defendant(s) shorted the recommended time between doses from every twelve (12) hours (as recommended by the FDA) to every eight (8) hours to increase the amount needed to fill a prescription increasing sales.

59. On or about August 7, 2004 Daniel C. Luberda was involved in an automobile accident that resulted in a very serious injury to his right foot, elbow and shoulder.

60. Daniel C. Luberda was prescribed Oxycontin for the pain by Dr. Thomas J. Chambers, M.D. who was not informed in anyway by Defendant(s) of the addictive nature of the drug.

61. Prior to August 7, 2004 Daniel C. Luberda had never used OxyContin.

62. The Plaintiff, Daniel C. Luberda, did rely on the above detailed deceptions and took Oxycontin for his own chronic pain. By October of 2004 Daniel C. Luberda became involuntarily addicted to Oxycontin; and while suffering involuntary addiction, and to satisfy the addiction, Daniel C. Luberda took Oxycontin that was not prescribed for him for his own use, and did use this Oxycontin to satisfy his own involuntary addiction.

63. Daniel C. Luberda suffered serious physical and psychological withdrawal symptoms when he was not able to obtain Oxycontin.

64. Once his own money ran out Daniel C. Luberda began burglarizing houses to steal property that could be sold in exchange for Oxycontin.

65. The cost of the Oxycontin addiction started at $60.00 per day, and gradually increased to the $400-$500 range, to satisfy Daniel C. Luberda's withdrawal symptoms.

66. Ultimately, the addiction to Oxycontin drove Daniel C. Luberda to the point where he robbed two (2) banks, leading to his arrest on December 21, 2010 and his five (5) year sentence of incarceration at a Federal prison commencing on August 19, 2011.

67. Daniel C. Luberda was never advised of or warned, in any way whatsoever about the addictive nature of Oxycontin or the potential outcome of his use of the drug.

68. As a result of his addiction to Oxycontin, which began when it was legally prescribed by a medical doctor, in accordance with the recommendations of Defendant(s), Daniel C. Luberda has suffered financial losses, physical and mental harm, as well as, the deprivation of his freedom.

FIRST CAUSE OF ACTION

NEGLIGENCE

69. Plaintiff alleges, re-affirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 68 and further states that Defendants acted in a manner constituting negligence in that:

a. Defendants owed Plaintiff a duty to properly warn of the potential for and/or risk of addiction associate with their product.

b. Defendants breached this duty by failing to properly warn of the potential for and/or risk of addiction in the manner in which they labeled, marketed and misbranded their product.

c. Defendants' breach was the direct and proximate cause of the injuries and damages sustained by Plaintiff.

70. Further, that each Defendant named in this cause of action is jointly and severably liable for the above detailed negligence.

SECOND CAUSE OF ACTION

GROSS NEGLIGENCE

71. Plaintiff alleges, re-affirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 70 and further states that Defendants acted in a manner constituting gross negligence in that:

    a. Defendants owed Plaintiff a duty to properly warn of the potential for and/or risk of addiction associate with their product.

    b. Defendants intentionally breached this duty by deceiving medical professionals and patients as to the potential for and/or risk of addiction through the manner in which they labeled, marketed and misbranded their product.

    c. Defendants' breach was the direct and proximate cause of the injuries and damages sustained by Plaintiff.

72. Further, that each Defendant named in this cause of action is jointly and severably liable for the above detailed gross negligence.

THIRD CAUSE OF ACTION

COMMON LAW FRAUD

73. Plaintiff alleges, reaffirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 72 and further states that Defendants acted in a manner common law fraud in that:

    a. Defendants deceived and/or misrepresented to Plaintiff as to the potential for

misrepresentation as promulgated in the labeling, marketing, and misbranding of their product.

c. Plaintiff did in fact rely on said deceptions and/or misrepresentations.

d. Defendants' deceptions and/or misrepresentations were the direct and proximate cause of the injuries and damages sustained by Plaintiff.

74. Further, that each Defendant named in this cause of action is jointly and severably liable.

FOURTH CAUSE OF ACTION

VIOLATION OF SECTION 39-23-8- OF THE SOUTH CAROLINA CODE OF LAWS

75. Plaintiffs alleges, re-affirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 74 and further state; the defendants marketing a misbranded drug, specifically OxyContin, into the commerce of South Carolina. The actions of allowing the misbranded Oxy-Cotin into the commerce of South Carolina was the direct and proximate cause of plaintiffs injuries.

PRAYER FOR RELIEF

Plaintiff hereby demands a jury trial.

76. Plaintiff is entitled to and also prays for the following relief:

77. Over $300,000.00 in damages for the money paid to obtain Oxycontin.

78. Relief for emotional and physical pain and suffering attributed to the Oxycontin addiction and the actions resulting there from.

79. For prejudgment interest on all damages to the extent allowed by law.

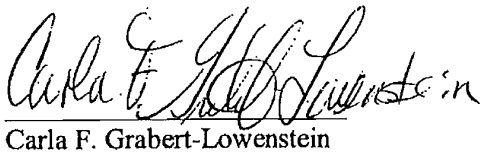
80. For an order declaring the conduct of defendants violates the statutes alleged.

81. Plaintiffs request unspecified punitive damages as allowed by law.

82. Plaintiffs request attorney's fees and costs to the extent allowed by law.

83. Plaintiffs request any further relief as the court may deem just and proper

Respectfully submitted,



Carla F. Grabert-Lowenstein
Attorney for Plaintiff
314 Main Street
Conway, SC 29526
(843) 488-0912

February 25, 2013
Conway, South Carolina

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
v.) **Case No.** 1:07CR29
)
MICHAEL FRIEDMAN)

PLEA AGREEMENT

My counsel and I have entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P.)" The terms and conditions of this agreement are as follows:

1. CHARGE(S) TO WHICH I AM PLEADING GUILTY AND WAIVER OF RIGHTS

I will enter a plea of guilty to Count Two of the attached Information, charging me with the strict liability misdemeanor offense of misbranding a drug in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1). The maximum statutory penalty for Count Two is a fine of $100,000.00, pursuant to 18 U.S.C. § 3571(b)(5), and/or imprisonment for a term of one year, plus a period of supervised release. I understand that fees may be imposed to pay for incarceration or supervised release and that there will be a $25 special assessment, pursuant to 18 U.S.C. § 3013(a)(1)(A)(iii). I further understand that any term of probation may be revoked if I violate its terms and conditions.

My attorney has informed me of the nature of the charge(s) and the elements of the charge(s) that must be proved by the United States beyond a reasonable doubt before I could be found guilty as charged.

I acknowledge that I have had all of my rights explained to me and I expressly recognize that I have the following constitutional rights and, that by voluntarily pleading guilty, I knowingly waive and give up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses in my own behalf.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

Defendant's Initials: MF

I am pleading guilty as described above because I am in fact guilty and because I believe it is in my best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for my plea of guilty. I agree that the Court can accept the Agreed Statement of Facts as the factual basis for my guilty plea.

I understand that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the following Guidelines' section should apply, exclusively, to my conduct:

2N2.1 6 Base Offense Level

Pursuant to Fed. R. Crim. P. 11(c)(1)(C), the parties agree to ask the Court to impose a non-incarcerative sentence. The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence I will be free to withdraw this guilty plea. In that event, this Agreement will be null and void and nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict me or any other entity or individual on any charge.

The parties agree and stipulate that restitution is not applicable to my conviction.

If the Court were to impose a sentence that includes probation, I do not believe that any non-standard conditions of probation are appropriate. The United States agrees to take no position as to any non-standard conditions of probation.

3. DISGORGEMENT

Prior to the entry of my guilty plea, I will transfer $19,000,000.00 (nineteen million dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund. If the Court rejects this Plea Agreement and, as a result, I withdraw my plea, the $19,000,000.00 (nineteen million dollars) will be returned to me.

4. MANDATORY ASSESSMENT AND FINE

I understand that there is a mandatory assessment of $25.00 per misdemeanor count of conviction. The parties agree and stipulate that a fine of $5,000.00, at the upper end of the guidelines' range, is appropriate for this case. I agree that I will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $5,025.00 within seven days of entering my plea of guilty.

5. **ADDITIONAL OBLIGATIONS**

Unless the Court rejects this Plea Agreement and, as a result, I withdraw my plea, I agree to: (1) accept responsibility for my conduct; (2) fully comply with all terms of probation, if a term of probation is imposed; (3) not attempt to withdraw my guilty plea; (4) not deny that I committed the crime to which I have pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this agreement (if a presentence report is ordered by the Court).

I consent to public disclosure of all resolution documents related to this case.

I will not make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts. Should the United States Attorney's Office for the Western District of Virginia notify me of a public statement that contradicts a statement of fact contained in the Agreed Statement of Facts, I may avoid noncompliance with my obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, I may avail myself of any legal or factual arguments available to me in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. **ADMISSIBILITY OF STATEMENTS**

I understand that any statements I make or made on my behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against me in this or any other related criminal proceeding. I knowingly waive any right I may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, I do not waive my right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, I withdraw my plea, I will not be bound by the waivers set forth in this section of the Plea Agreement.

7. **WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT**

If the Court accepts this Plea Agreement, I agree that I will not appeal the conviction or sentence imposed. I am knowingly and voluntarily waiving any right to appeal and am voluntarily willing to rely on the Court in sentencing me pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). I agree not to collaterally attack the judgment and/or sentence imposed in this case and waive my right to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and

any part of the sentence imposed upon me by the Court. I agree and understand that if I file any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in my case, the United States will be free to take whatever actions it wishes based on this failure to comply with my obligations under the Plea Agreement.

8. **REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION**

I understand that if: (1) I attempt to withdraw my plea (in the absence of the Court refusing to accept the Plea Agreement) or fail to comply with any provision of this agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's Plea Agreement prior to the imposition of judgment; (3) my conviction is set aside, for any reason; and/or (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this agreement, including, but not limited to, those obligations set forth in the section of this agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this agreement, I will still be bound by my obligations under this agreement. I hereby waive my right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consent to the filing of an information against me concerning any charges filed pursuant to this section of the Plea Agreement. I hereby waive any statute of limitations argument as to any such charges.

9. **INFORMATION ACCESS WAIVER**

I knowingly and voluntarily agree to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §552a.

10. **DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT**

The United States Attorney's Office will inform me when my personal financial records and/or other records or items obtained from my accountant or any documents otherwise relating to my personal finances are available for removal. I expressly agree that, within 30 days of being informed by the United States Attorney's Office that such records are available for removal, I will remove, at my cost, all such records from the premises designated by the United States Attorney's

Office. In addition, by signing this Plea Agreement, I hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation (other than those described above), and will execute any documents necessary to comply with this provision.

11. COMPLETION OF PROSECUTION

I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

I understand that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against me, and I agree that I will not raise this Plea Agreement or my guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

I have discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against me with my attorney and am fully satisfied with my attorney and my attorney's advice. At this time, I have no dissatisfaction or complaint with my attorney's representation. I agree to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint I may have with my attorney's representation.

14. WAIVER OF CERTAIN DEFENSES

By signing this Plea Agreement, I waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of March 29, 2006. This waiver is binding on me only as to charges brought by the United States. This waiver expires once judgment is entered, except as set forth in the section of the Plea Agreement entitled "REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION."

15. EFFECT OF MY SIGNATURE

I understand that my signature on this Plea Agreement constitutes a binding offer by me to enter into this Plea Agreement. I understand that the United States has not accepted my offer until it signs the Plea Agreement.

16. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the attached Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court accepts this Plea Agreement and sentences me to a non-incarcerative sentence, I understand that I will have no right to withdraw my guilty plea. In addition, I understand that I will not have any right to withdraw my plea if I violate my conditions of probation (if any term of probation is imposed) and, as a result, I am sentenced to incarceration.

If the Court orders a presentence report, I understand that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

I understand that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case. I understand that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

I willingly stipulate that the Agreed Statement of Facts provides the Court with a sufficient factual basis to support my plea of guilty.

I understand that this Plea Agreement does not apply to any crimes or charges not addressed in this agreement. I understand that if I should testify falsely in this or in a related proceeding I may be prosecuted for perjury and statements I may have given authorities pursuant to this Plea Agreement may be used against me in such a proceeding.

I have not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for my plea of guilty. I understand that my attorney will be free to argue any mitigating factors on my behalf; to the extent that they are not inconsistent with the terms of this Plea Agreement. I understand that I will have an opportunity to personally address the Court prior to sentence being imposed.

This writing sets forth the entire understanding between the parties and constitutes the complete Plea Agreement between the United States of America and me, and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. This Plea Agreement supersedes all prior understandings, promises, agreements, or conditions, if any, between the United States and me.

I have consulted with my attorney and fully understand all my rights with respect to the offenses charged in the Information. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement and I voluntarily agree to it. Being aware of all of the possible consequences of my plea, I have independently decided to enter this plea of my own free will, and am affirming that agreement on this date and by my signature below.

Date: 5/7/07

Michael Friedman, Defendant

I have fully explained to my client all rights available to my client with respect to the offenses charged in the Information. I have carefully reviewed every part of this Plea Agreement and attached Agreed Statement of Facts with my client. To my knowledge, my client's decision to enter into this Plea Agreement is an informed and voluntary one.

Date: 5/8/07

Mark F. Pomerantz
Counsel for Defendant

Date: May 9, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

RELEASE BY THE COMMONWEALTH OF VIRGINIA

For purposes of this release, PURDUE shall be defined in the same manner as in the Non-Prosecution Agreement between the United States and PURDUE entered in 2007 and filed as an attachment to the Plea Agreement of The Purdue Frederick Company, Inc.

The Virginia Medicaid Fraud Control Unit with the Virginia Attorney General's Office actively participated in a prolonged investigation of PURDUE by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation. The investigation has resulted in a negotiated resolution that includes plea agreements between the United States and the Purdue Frederick Company, Inc., and certain individuals. By the terms of those plea agreements, the Program Income Fund of the Virginia Medicaid Fraud Control Unit will receive $39,800,000.00 and a $20,000,000.00 trust will be established to fund the Virginia Prescription Monitoring Program.

In accordance with the Constitution of Virginia and pursuant to the authority conferred upon the Governor of Virginia and the Attorney General of Virginia by the Code of Virginia, the Governor of Virginia and the Attorney General of Virginia hereby agree that so long as (1) PURDUE complies with all of its obligations as set forth in the Non-Prosecution Agreement and the documents referenced therein and (2) Michael Friedman, Howard R. Udell, and Paul D. Goldenheim comply with all of their obligations in their plea agreements prior to the imposition of judgment, there will be no further civil or criminal action by the Governor or by the Attorney General's Office, including the Virginia Medicaid Fraud Control Unit, on behalf of the Commonwealth of Virginia against PURDUE, its current and former directors, officers, employees, co-promoters, owners (including trustees and trust beneficiaries of such owners), successors and assigns; any of PURDUE'S related and associated entities (as listed on Attachment A to the Plea Agreement of The Purdue Frederick Company, Inc.), and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), successors and assigns, and trusts for the benefit of the families of the current and former directors of PURDUE, including the trustees and trust beneficiaries of such trusts, for any violations of law, occurring on or before the date the guilty pleas are entered, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

This release shall not limit the Commonwealth's ability to settle pending matters related to Virginia's consumer protection laws or to otherwise participate in the multi-state portion of any amounts obtained as a result of these Plea Agreements. The Commonwealth agrees and understands that any of the money paid pursuant to these Plea Agreements will be returned if, and only if, the Court refuses to accept the Plea Agreements with the agreed-upon sentences and, as a result, the defendants withdraw their guilty pleas. If this occurs, the Commonwealth understands that it is free to assert any and all claims against the defendants.

This Release shall be made an attachment to the plea agreements referenced herein.

Executed this 7th of May, 2007.

Timothy M. Kaine
Governor of Virginia

Robert F. McDonnell
Attorney General of Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
v.) Case No. 1:07CR29
)
PAUL D. GOLDENHEIM)

PLEA AGREEMENT

My counsel and I have entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P.)" The terms and conditions of this agreement are as follows:

1. CHARGE(S) TO WHICH I AM PLEADING GUILTY AND WAIVER OF RIGHTS

I will enter a plea of guilty to Count Two of the attached Information, charging me with the strict liability misdemeanor offense of misbranding a drug in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1). The maximum statutory penalty for Count Two is a fine of $100,000.00, pursuant to 18 U.S.C. § 3571(b)(5), and/or imprisonment for a term of one year, plus a period of supervised release. I understand that fees may be imposed to pay for incarceration or supervised release and that there will be a $25 special assessment, pursuant to 18 U.S.C. § 3013(a)(1)(A)(iii). I further understand that any term of probation may be revoked if I violate its terms and conditions.

My attorney has informed me of the nature of the charge(s) and the elements of the charge(s) that must be proved by the United States beyond a reasonable doubt before I could be found guilty as charged.

I acknowledge that I have had all of my rights explained to me and I expressly recognize that I have the following constitutional rights and, that by voluntarily pleading guilty, I knowingly waive and give up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses in my own behalf.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

I am pleading guilty as described above because I am in fact guilty and because I believe it is in my best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for my plea of guilty. I agree that the Court can accept the Agreed Statement of Facts as the factual basis for my guilty plea.

I understand that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the following Guidelines' section should apply, exclusively, to my conduct:

2N2.1 6 Base Offense Level

Pursuant to Fed. R. Crim. P. 11(c)(1)(C), the parties agree to ask the Court to impose a non-incarcerative sentence. The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence I will be free to withdraw this guilty plea. In that event, this Agreement will be null and void and nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict me or any other entity or individual on any charge.

The parties agree and stipulate that restitution is not applicable to my conviction.

If the Court were to impose a sentence that includes probation, I do not believe that any non-standard conditions of probation are appropriate. The United States agrees to take no position as to any non-standard conditions of probation.

3. DISGORGEMENT

Prior to the entry of my guilty plea, I will transfer $7,500,000.00 (seven million five hundred thousand dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund. If the Court rejects this Plea Agreement and, as a result, I withdraw my plea, the $7,500,000.00 (seven million five hundred thousand dollars) will be returned to me.

4. MANDATORY ASSESSMENT AND FINE

I understand that there is a mandatory assessment of $25.00 per misdemeanor count of conviction. The parties agree and stipulate that a fine of $5,000.00, at the upper end of the guidelines' range, is appropriate for this case. I agree that I will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $5,025.00 within seven days of entering my plea of guilty.

5. **ADDITIONAL OBLIGATIONS**

Unless the Court rejects this Plea Agreement and, as a result, I withdraw my plea, I agree to: (1) accept responsibility for my conduct; (2) fully comply with all terms of probation, if a term of probation is imposed; (3) not attempt to withdraw my guilty plea; (4) not deny that I committed the crime to which I have pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this agreement (if a presentence report is ordered by the Court).

I consent to public disclosure of all resolution documents related to this case.

I will not make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts. Should the United States Attorney's Office for the Western District of Virginia notify me of a public statement that contradicts a statement of fact contained in the Agreed Statement of Facts, I may avoid noncompliance with my obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, I may avail myself of any legal or factual arguments available to me in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. **ADMISSIBILITY OF STATEMENTS**

I understand that any statements I make or made on my behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against me in this or any other related criminal proceeding. I knowingly waive any right I may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, I do not waive my right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, I withdraw my plea, I will not be bound by the waivers set forth in this section of the Plea Agreement.

7. **WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT**

If the Court accepts this Plea Agreement, I agree that I will not appeal the conviction or sentence imposed. I am knowingly and voluntarily waiving any right to appeal and am voluntarily willing to rely on the Court in sentencing me pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). I agree not to collaterally attack the judgment and/or sentence imposed in this case and waive my right to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and

any part of the sentence imposed upon me by the Court. I agree and understand that if I file any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in my case, the United States will be free to take whatever actions it wishes based on this failure to comply with my obligations under the Plea Agreement.

8. **REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION**

I understand that if: (1) I attempt to withdraw my plea (in the absence of the Court refusing to accept the Plea Agreement) or fail to comply with any provision of this agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's Plea Agreement prior to the imposition of judgment; (3) my conviction is set aside, for any reason; and/or (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this agreement, including, but not limited to, those obligations set forth in the section of this agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this agreement, I will still be bound by my obligations under this agreement. I hereby waive my right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consent to the filing of an information against me concerning any charges filed pursuant to this section of the Plea Agreement. I hereby waive any statute of limitations argument as to any such charges.

9. **INFORMATION ACCESS WAIVER**

I knowingly and voluntarily agree to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §552a.

10. **DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT**

The United States Attorney's Office will inform me when my personal financial records and/or other records or items obtained from my accountant or any documents otherwise relating to my personal finances are available for removal. I expressly agree that, within 30 days of being informed by the United States Attorney's Office that such records are available for removal, I will remove, at my cost, all such records from the premises designated by the United States Attorney's

Office. In addition, by signing this Plea Agreement, I hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation (other than those described above), and will execute any documents necessary to comply with this provision.

11. COMPLETION OF PROSECUTION

I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

I understand that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against me, and I agree that I will not raise this Plea Agreement or my guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

I have discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against me with my attorney and am fully satisfied with my attorney and my attorney's advice. At this time, I have no dissatisfaction or complaint with my attorney's representation. I agree to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint I may have with my attorney's representation.

14. WAIVER OF CERTAIN DEFENSES

By signing this Plea Agreement, I waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of March 29, 2006. This waiver is binding on me only as to charges brought by the United States. This waiver expires once judgment is entered, except as set forth in the section of the Plea Agreement entitled "REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION."

15. EFFECT OF MY SIGNATURE

I understand that my signature on this Plea Agreement constitutes a binding offer by me to

enter into this Plea Agreement. I understand that the United States has not accepted my offer until it signs the Plea Agreement.

16. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the attached Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court accepts this Plea Agreement and sentences me to a non-incarcerative sentence, I understand that I will have no right to withdraw my guilty plea. In addition, I understand that I will not have any right to withdraw my plea if I violate my conditions of probation (if any term of probation is imposed) and, as a result, I am sentenced to incarceration.

If the Court orders a presentence report, I understand that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

I understand that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case. I understand that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

I willingly stipulate that the Agreed Statement of Facts provides the Court with a sufficient factual basis to support my plea of guilty.

I understand that this Plea Agreement does not apply to any crimes or charges not addressed in this agreement. I understand that if I should testify falsely in this or in a related proceeding I may be prosecuted for perjury and statements I may have given authorities pursuant to this Plea Agreement may be used against me in such a proceeding.

I have not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for my plea of guilty. I understand that my attorney will be free to argue any mitigating factors on my behalf, to the extent that they are not inconsistent with the terms of this Plea Agreement. I understand that I will have an opportunity to personally address the Court prior to sentence being imposed.

This writing sets forth the entire understanding between the parties and constitutes the complete Plea Agreement between the United States of America and me, and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. This Plea Agreement supersedes all prior understandings, promises, agreements, or conditions, if any, between the United States and me.

I have consulted with my attorney and fully understand all my rights with respect to the offenses charged in the Information. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement and I voluntarily agree to it. Being

aware of all of the possible consequences of my plea, I have independently decided to enter this plea of my own free will, and am affirming that agreement on this date and by my signature below.

Date: May 8, 2007

Paul D. Goldenheim, Defendant

I have fully explained to my client all rights available to my client with respect to the offenses charged in the Information. I have carefully reviewed every part of this Plea Agreement and attached Agreed Statement of Facts with my client. To my knowledge, my client's decision to enter into this Plea Agreement is an informed and voluntary one.

Date: May 8, 2007

Andrew Good
Counsel for Defendant

Date: May 10, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

RELEASE BY THE COMMONWEALTH OF VIRGINIA

For purposes of this release, PURDUE shall be defined in the same manner as in the Non-Prosecution Agreement between the United States and PURDUE entered in 2007 and filed as an attachment to the Plea Agreement of The Purdue Frederick Company, Inc.

The Virginia Medicaid Fraud Control Unit with the Virginia Attorney General's Office actively participated in a prolonged investigation of PURDUE by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation. The investigation has resulted in a negotiated resolution that includes plea agreements between the United States and the Purdue Frederick Company, Inc., and certain individuals. By the terms of those plea agreements, the Program Income Fund of the Virginia Medicaid Fraud Control Unit will receive $39,800,000.00 and a $20,000,000.00 trust will be established to fund the Virginia Prescription Monitoring Program.

In accordance with the Constitution of Virginia and pursuant to the authority conferred upon the Governor of Virginia and the Attorney General of Virginia by the Code of Virginia, the Governor of Virginia and the Attorney General of Virginia hereby agree that so long as (1) PURDUE complies with all of its obligations as set forth in the Non-Prosecution Agreement and the documents referenced therein and (2) Michael Friedman, Howard R. Udell, and Paul D. Goldenheim comply with all of their obligations in their plea agreements prior to the imposition of judgment, there will be no further civil or criminal action by the Governor or by the Attorney General's Office, including the Virginia Medicaid Fraud Control Unit, on behalf of the Commonwealth of Virginia against PURDUE, its current and former directors, officers, employees, co-promoters, owners (including trustees and trust beneficiaries of such owners), successors and assigns; any of PURDUE'S related and associated entities (as listed on Attachment A to the Plea Agreement of The Purdue Frederick Company, Inc.), and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), successors and assigns, and trusts for the benefit of the families of the current and former directors of PURDUE, including the trustees and trust beneficiaries of such trusts, for any violations of law, occurring on or before the date the guilty pleas are entered, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

This release shall not limit the Commonwealth's ability to settle pending matters related to Virginia's consumer protection laws or to otherwise participate in the multi-state portion of any amounts obtained as a result of these Plea Agreements. The Commonwealth agrees and understands that any of the money paid pursuant to these Plea Agreements will be returned if, and only if, the Court refuses to accept the Plea Agreements with the agreed-upon sentences and, as a result, the defendants withdraw their guilty pleas. If this occurs, the Commonwealth understands that it is free to assert any and all claims against the defendants.

This Release shall be made an attachment to the plea agreements referenced herein.

Executed this 7th of May, 2007.

Timothy M. Kaine
Governor of Virginia

Robert F. McDonnell
Attorney General of Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
v.) Case No. 1:07CR29
)
THE PURDUE FREDERICK COMPANY, INC.)

PLEA AGREEMENT

THE PURDUE FREDERICK COMPANY, INC. ("PURDUE") has entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P."). The terms and conditions of this agreement are as follows:

1. CHARGE TO WHICH PURDUE IS PLEADING GUILTY AND WAIVER OF RIGHTS

PURDUE will enter a plea of guilty to Count One of an Information, charging it with the felony of misbranding a drug, with the intent to defraud or mislead, in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2). The maximum statutory penalty is a fine of $500,000.00 or twice the gross gain or loss, pursuant to Title 18, United States Code, Sections 3571(c)(3) and 3571(d), plus a period of probation of up to five years, pursuant to Title 18, United States Code, Section 3561(c)(1). In addition, PURDUE's assets may be subject to forfeiture. PURDUE understands that fees may be imposed to pay for probation and that there will be a $400 special assessment, pursuant to Title 18, United States Code, Section 3013(a)(2)(B). PURDUE's attorney has informed it of the nature of the charge and the elements of the charge that must be proved by the United States beyond a reasonable doubt before PURDUE could be found guilty as charged.

PURDUE hereby waives its right to be proceeded against by indictment and consents to the filing of an Information charging it with a violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

PURDUE acknowledges that PURDUE has had all of its rights explained to it. PURDUE expressly recognizes that, as a corporation, PURDUE may have the following constitutional rights and, that by voluntarily pleading guilty, PURDUE knowingly waives and gives up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.

The right to confront and cross-examine witnesses.
The right to present evidence and witnesses.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

PURDUE is pleading guilty as described above because PURDUE is in fact guilty and because PURDUE believes it is in its best interest to do so and not because of any threats or promises, other than the terms of the Plea Agreement, described herein, in exchange for its plea of guilty. PURDUE agrees that all of the matters set forth in the Information are true and correct.

PURDUE understands that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the 2006 United States Sentencing Guidelines ("U.S.S.G.") Manual should be used and the following sentencing guidelines sections apply, exclusively.

The Offense Level is computed as follows:

6	§ 2B1.1(a)(2)	Base offense level (cross reference from §2N2.1(b)(1)).
+2	§ 2B1.1(b)(2)(A)(ii)	The offense was committed through mass-marketing.
+2	§ 2B1.1(b)(9)(C)	The offense involved sophisticated means.
10	Total	
12	§ 2B1.1(b)(9)	If the resulting offense level is less than level 12; increase to level 12.

Total Offense Level is 12

The Culpability Score is computed as follows:

5	§ 8C2.5(a)	Start with 5 points.
+4	§ 8C2.5(b)(2)(A)(ii)	The organization had 1,000 or more employees.
-1	§ 8C2.5(g)(3)	The organization accepted responsibility for its criminal conduct.

Total Culpability Score is 8.

The Base Fine for an Offense Level of 12 is $40,000.00 (§ 8C2.4(d)).

The Minimum Multiplier for a Culpability Score of 8 is 1.60 (§ 8C2.6).
The Maximum Multiplier for a Culpability Score of 8 is 3.20 (§ 8C2.6).

The Guideline Fine Range is $64,000.00 to $128,000.00 ((1.60 x $40,000.00) to (3.20 x $40,000.00)) (§ 8C2.7).

The United States asserts that an upward departure to a statutory maximum fine of $500,000.00 is appropriate because, pursuant to § 5K2.0(a)(1)(A), there exists an aggravating circumstance of a kind, or to a degree, not adequately taken into consideration by the Sentencing Commission in formulating the guidelines. PURDUE does not oppose the Court ordering the statutory maximum fine of $500,000.00.

The parties agree and stipulate that determining the pecuniary gain or loss would unduly complicate or prolong the sentencing process and, in accordance with U.S.S.G. § 8C2.4(c) and 18 U.S.C. § 3571(d), should not be used for the determination of the fine.

The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence, this Plea Agreement will be null and void, and PURDUE will be free to withdraw this guilty plea. In the event the Court refuses to accept the Plea Agreement with the agreed-upon sentence and PURDUE withdraws this guilty plea, nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict PURDUE or any other entity or individual on any charge.

The parties have not agreed to any matters concerning the length and terms of probation. Accordingly, the Court may impose whatever length and terms of probation, if any, that it determines is appropriate.

3. FINANCIAL OBLIGATIONS

PURDUE agrees and understands that any of the money paid pursuant to this Plea Agreement will be returned if, and only if, the Court refuses to accept the Plea Agreement with the agreed-upon sentence and, as a result, PURDUE withdraws its guilty plea.

For the remaining portions of this "FINANCIAL OBLIGATIONS" section, "PURDUE" means "THE PURDUE FREDERICK COMPANY, INC. or Purdue Pharma L.P.")

a. Immediate Payments

Prior to the entry of PURDUE's guilty plea, PURDUE will make the following disbursements:

(1) $3,087,277.60 (three million eighty-seven thousand two hundred seventy-seven dollars and sixty cents) to the Federal and State Medicaid programs for improperly calculated Medicaid rebates for the years 1998 and 1999;

(2) $500,000.00 (five hundred thousand dollars) to the Clerk, U.S. District Court, Abingdon, Virginia, as payment of the maximum statutory fine;

(3) $20,000,000.00 (twenty million dollars) will be paid into an account to be held in trust ("Trust Account") solely for the operation of the Virginia Prescription Monitoring Program ("PMP") or its successors. The Trust Account funds should be prudently invested to ensure an adequate return. Money may be drawn from the Trust Account solely for the purpose of funding the PMP (including, but not limited to, operating and maintaining the PMP and providing training and educational programs concerning the use of the PMP.) The maximum amount to be drawn from the account each year shall be the lesser of (a) sufficient funds to fund Virginia's Prescription Monitoring Program or (b) the Yearly Expenditure Cap. The Yearly Expenditure Cap will be $1,000,000.00 (one million dollars) for the first year and will increase by 4% per year. If, prior to December 31, 2057, there is a calendar year during which Virginia does not have a PMP or its rough equivalent, the remaining money in the Trust Account shall be paid to the United States Treasury. The money in the Trust Account may not be used for any purpose other than funding the PMP, prior to December 31, 2057. As of December 31, 2057, if the PMP and its successors no longer exist, the money remaining in the account may be used for any purpose, for the benefit of the Commonwealth of Virginia;

(4) $5,300,000.00 (five million three hundred thousand dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund; and

(5) $151,100,000.00 (one hundred fifty-one million one hundred thousand dollars) as directed by the United States Attorney's Office as partial payment of a total forfeiture of $276,100,000.00 (two hundred seventy six million one hundred thousand dollars).

b. Civil Settlement Payments

PURDUE will pay a total of $160,000,000.00 (one hundred sixty million dollars) to the United States and the States to settle civil governmental claims, as set forth below:

(1) PURDUE shall pay $100,615,797.25 (one hundred million six hundred fifteen thousand seven hundred ninety-seven dollars and twenty-five cents) to the United States plus interest at the rate of 4.75% per annum ($13,093.84 per day) on $100,615,797.25 from the

date of the plea by The Purdue Frederick Company, Inc. and continuing until and including the day before complete payment is made pursuant to the Civil Settlement Agreement (attached as Attachment D) between the United States and PURDUE; and $59,384,202.75 (fifty-nine million three hundred eighty-four thousand two hundred two dollars and seventy-five cents) to the States as set forth in Section 3(b)(2) below. These payments shall satisfy Purdue's obligation to make restitution under this Plea Agreement;

(2) The $59,384,202.75 paid to the States shall be placed in a dedicated interest bearing account. Each state that elects to participate in this settlement shall, upon execution of the Form State Release (attached as Attachment L) (or an alternative release agreed to by PURDUE and the state), receive its proportionate share as determined by the Medicaid Fraud Control Unit Negotiating Team, plus interest in accordance with the Form State Release, in a timely manner in accordance with the schedule as provided in the Form State Release. Any money remaining in the dedicated interest bearing account after PURDUE has fully paid all of its obligations shall be returned to PURDUE; and

(3) The parties agree and stipulate, pursuant to 18 U.S.C. § 3663(a)(1)(B)(ii), that no other restitution should be ordered.

c. Subsequent Forfeiture Payments

On or before the six month anniversary of the entry of its guilty plea, PURDUE will deposit $90,000,000.00 (ninety million dollars) as directed by the United States Attorney's Office as payment toward a total forfeiture of $276,100,000.00 (two hundred seventy six million one hundred thousand dollars).

On or before the twelve month anniversary of the entry of its guilty plea, PURDUE will deposit $35,000,000.00 (thirty-five million dollars) as directed by the United States Attorney's Office as final payment of a total forfeiture of $276,100,000.00 (two hundred seventy six million one hundred thousand dollars).

d. Compensation and Settlement

Based on the agreement in principle reached between PURDUE and the United States on October 25, 2006, PURDUE set aside a total of $130,000,000.00 (one hundred thirty million dollars), some or all of which will have been paid by the date of the entry of the guilty plea, for compensation and settlement of private civil liabilities related to OxyContin. Any of the $130,000,000.00 (one hundred thirty million dollars) remaining unpaid two years after the entry of

PURDUE's guilty plea will be paid to the United States Treasury. Two years after the entry of PURDUE's guilty plea or at the time the entire $130,000,000.00 has been appropriately expended (if the moneys have been expended in less than two years), PURDUE's attorney shall provide to the Court and the United States Attorney's Office an accounting of the moneys paid and will certify that all payments have been made to resolve PURDUE's private civil liabilities related to OxyContin.

e. Forfeiture

To accomplish the forfeiture, which will be paid as set forth above, PURDUE agrees to the filing of a civil forfeiture complaint, pursuant to 18 U.S.C. § 981(a)(1)(A), in the Western District of Virginia and agrees to forfeit $276,100,000.00 in cash in settlement of the forfeiture complaint ("settlement sum"). PURDUE agrees to sign, concurrent with the signing of this Plea Agreement, a settlement agreement acknowledging that the settlement sum represents proceeds of a violation of 18 U.S.C. § 1957 and/or are forfeitable in lieu of certain property that would be otherwise subject to forfeiture pursuant to 19 U.S.C. § 1613(c). PURDUE agrees to forfeit all interest in these funds and to take whatever steps are necessary to pass clear title of this sum to the United States. These steps include but are not limited to making the sum available to the United States, as directed by the United States. PURDUE agrees not to file a claim in any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets. PURDUE understands and agrees that forfeiture of this property is proportionate to the degree and nature of the offense, and does not raise any of the concerns raised in *United States v. Austin*, 113 S.Ct. 2801 (1993). To the extent that such concerns are raised, PURDUE freely and knowingly waives any and all right it may have to raise a defense of "excessive fines" under the Eighth Amendment to this forfeiture. PURDUE further understands and agrees that this forfeiture is separate and distinct from, and is not in the nature of, or in lieu of, any monetary penalty that may be imposed by the court.

f. Monitoring Costs

PURDUE agrees to expend not less than $5,012,722.40 (five million twelve thousand seven hundred twenty-two dollars and forty cents) in monitoring costs over the next seventy-two months for the purpose of ensuring that Purdue Pharma L.P. complies with its Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services Office of Inspector General ("OIG") and does not engage in any further criminal activity. On an annual basis, beginning on the first anniversary of PURDUE's guilty plea, PURDUE's attorney shall provide to the United States Attorney's Office an accounting of the moneys paid and will certify that all payments set forth therein have been paid as part of a monitoring program as set forth by the CIA between Purdue Pharma L.P. and the OIG or otherwise to prevent future criminal activity by Purdue Pharma L.P. Any of the $5,012,722.40 (five million twelve thousand seven hundred twenty-two dollars and forty cents) remaining unspent seventy-two months after the entry of PURDUE's guilty plea will be paid to the United States Treasury.

g. **Security**

Prior to pleading guilty, Purdue agrees to provide a lien to the United States against sufficient company assets to secure the $125,000,000.00 in deferred payments.

4. **MANDATORY ASSESSMENT**

PURDUE understands that there is a mandatory assessment of $400.00 per felony count of conviction. PURDUE agrees that it will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $400.00 within seven days of entering its plea of guilty.

5. **ADDITIONAL OBLIGATIONS**

Unless the Court rejects this Plea Agreement and, as a result, PURDUE withdraws its plea, PURDUE agrees to: (1) accept responsibility for its conduct; (2) fully comply with all terms of probation, if probation is imposed; (3) not attempt to withdraw its guilty plea; (4) not deny that it committed the crime to which it has pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this Plea Agreement (if a presentence report is ordered by the Court); and (6) comply with its obligations under the Civil Settlement Agreement (attached as Attachment D).

PURDUE consents to public disclosure of all resolution documents related to this case.

Neither PURDUE nor any of its associated entities (as set forth in Attachment A), will, through its present or future directors, officers, employees, agents, or attorneys, make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts (attached as Attachment B). Should the United States Attorney's Office for the Western District of Virginia notify PURDUE of a public statement by any such person that in whole or in part contradicts a statement of fact contained in the Agreed Statement of Facts, PURDUE may avoid noncompliance with its obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, any PURDUE entity may avail itself of any legal or factual arguments available to it in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. **ADMISSIBILITY OF STATEMENTS**

PURDUE understands that any statements made on its behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against

it in this or any other related criminal proceeding. PURDUE knowingly waives any right it may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, PURDUE does not waive its right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, PURDUE withdraws its plea, PURDUE will not be bound by the waivers set forth in this section of the Plea Agreement.

7. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, PURDUE agrees that PURDUE will not appeal the conviction or sentence imposed. PURDUE is knowingly and voluntarily waiving any right to appeal and is voluntarily willing to rely on the Court in sentencing it, pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C).

PURDUE agrees not to collaterally attack the judgment and/or sentence imposed in this case and waives its right, if any, to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and any part of the sentence imposed upon it by the Court. PURDUE agrees and understands that if PURDUE, or anyone acting on PURDUE's behalf, files any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in its case, the United States will be free to take whatever actions it wishes based on this failure of PURDUE to comply with its obligations under the Plea Agreement.

8. REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION

PURDUE understands that if: (1) PURDUE attempts to withdraw its plea (in the absence of the Court refusing to accept the Plea Agreement) or fails to comply with any provision of this Plea Agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's plea agreement prior to the imposition of judgment; (3) PURDUE's conviction is set aside, for any reason; (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment; and/or (5) PURDUE fails to comply with its obligations under the Civil Settlement Agreement (attached as Attachment D) the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this Plea Agreement, including, but not limited to, those obligations set forth in the section of this Plea Agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this Plea Agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this Plea Agreement, PURDUE will still be bound by its obligations under this Plea Agreement. PURDUE hereby waives its right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consents to the filing of an information against it concerning any charges filed pursuant to this section of the Plea Agreement. PURDUE hereby waives any statute of limitations argument as to any such charges.

9. INFORMATION ACCESS WAIVER

PURDUE and any related entity knowingly and voluntarily agrees to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

10. DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT

By signing this Plea Agreement, PURDUE and any related entities hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation, with the exception of the company's original files. However, PURDUE expressly agrees that, within 30 days of being informed by the United States Attorney's Office that records and/or other items obtained from PURDUE or entities/individuals who were employed by PURDUE or entities/individuals who were agents of PURDUE are available for removal, it will remove, at its cost, all such records and/or other items from the premises designated by the United States Attorney's Office.

11. COMPLETION OF PROSECUTION

PURDUE understands that except as provided for in this Plea Agreement and the Non-Prosecution Agreement (attached as Attachment C), so long as PURDUE complies with all of its obligations under the Plea Agreement, and all entities set forth in the Non-Prosecution Agreement comply with their obligations therein, there will be no further criminal prosecution or forfeiture action by the United States for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement, against the following, or any property owned by any of the following: PURDUE, its current and former directors, officers, employees, co-promoters, owners (including trustees and trust beneficiaries of such owners), successors and assigns; any of PURDUE'S related and associated entities (as listed on Attachment A); and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), successors and assigns, and trusts for the benefit of the families of the current and former directors of PURDUE, including the trustees and trust beneficiaries of such trusts.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

PURDUE understands that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against PURDUE, and PURDUE agrees that it will not raise this Plea Agreement or its guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

PURDUE has discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against it with its attorney and is fully satisfied with its attorney and its attorney's advice. At this time, PURDUE has no dissatisfaction or complaint with its attorney's representation. PURDUE agrees to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint PURDUE may have with its attorney's representation.

14. EFFECT OF PURDUE'S SIGNATURE

PURDUE understands that its Authorized Corporate Officer's signature on this Plea Agreement constitutes a binding offer by it to enter into this Plea Agreement. PURDUE understands that the United States has not accepted PURDUE's offer until the authorized representative of the United States has signed the Plea Agreement.

15. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court orders a presentence report, PURDUE understands that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

PURDUE understands that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case.

PURDUE understands that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address

the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

PURDUE willingly stipulates that there is a sufficient factual basis for the Court to accept the plea.

PURDUE understands that this Plea Agreement does not apply to any crimes or charges not addressed in this Plea Agreement.

PURDUE has not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for its plea of guilty. PURDUE understands that its attorney will be free to argue any mitigating factors on its behalf; to the extent they are not inconsistent with the terms of this Plea Agreement. PURDUE understands that PURDUE will have an opportunity to have a representative address the Court prior to sentence being imposed.

This writing and the Agreed Statement of Facts (attached as Attachment B), Non-Prosecution Agreement (attached as Attachment C), Civil Settlement Agreement (attached as Attachment D), Corporate Integrity Agreement (attached as Attachment E), Stipulation for Compromise Settlement (attached as Attachment G), and Agreed Order of Forfeiture (attached as Attachment H) are the complete and only agreements between the United States and PURDUE, Purdue Pharma L.P. and its related and associated entities concerning resolution of this matter. Also attached to this agreement are the Virginia Release (attached as Attachment L) and the Form State Release (attached as Attachment M). In addition, PURDUE has no objection to the filing of the Information (Attachment F), Verified Complaint for Forfeiture *In Rem* (attached as Attachment I), and the Notice of Compliance (attached as Attachment J) and the Court's entry of a Warrant of Arrest *In Rem* (attached as Attachment K). The agreements and documents listed in this paragraph set forth the entire understanding between the parties and constitutes the complete agreement between the United States Attorney for the Western District of Virginia and PURDUE, Purdue Pharma L.P. and its related and associated entities and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. These agreements supersede all prior understandings, promises, agreements, or conditions, if any, between the United States and PURDUE, Purdue Pharma L.P. and its related and associated entities.

PURDUE has consulted with its attorney and fully understands its rights with respect to the offenses charged in the charging document(s). Further, PURDUE has consulted with its attorney and fully understands its rights. PURDUE has read this Plea Agreement and carefully reviewed every part of it with its attorney. PURDUE understands this Plea Agreement and PURDUE voluntarily agrees to it. Being aware of all of the possible consequences of its plea, PURDUE has independently decided to enter this plea of its own free will and is affirming that agreement on this date by the signature of its Authorized Corporate Officer below.

The Authorized Corporate Officer, by her signature below, hereby certifies to the following:

(1) She has read the entire Plea Agreement and documents referenced herein and discussed them with PURDUE's owners;

(2) PURDUE understands all the terms of the Plea Agreement and those terms correctly reflect the results of plea negotiations;

(3) PURDUE is fully satisfied with PURDUE's attorneys' representation during all phases of this case;

(4) PURDUE is freely and voluntarily pleading guilty in this case;.
(5) PURDUE is pleading guilty as set forth in this Plea Agreement because it is guilty of the crimes to which it is entering its plea; and
(6) PURDUE understands that it is waiving its right to appeal the judgment and conviction in this case.

PURDUE acknowledges its acceptance of this Plea Agreement by the signature of its counsel and Authorized Corporate Officer. A copy of a certification by PURDUE's Board of Directors authorizing the Authorized Corporate Officer to execute this Plea Agreement and all other documents to resolve this matter on behalf of PURDUE is attached.

Date: May 7, 2007

Robin E. Abrams

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

I have discussed with and fully explained to the Board of Directors of PURDUE the facts and circumstances of the case; all rights with respect to the offense charged in the Information; possible defenses to the offense charged in the Information; all rights with respect to the Sentencing Guidelines; and all of the consequences of entering into this Plea Agreement and entering a guilty plea. I have reviewed the entire Plea Agreement and documents referenced herein with my client, through its Authorized Corporate Officer. In my judgment, PURDUE understands the terms and conditions of the Plea Agreement, and I believe PURDUE's decision to enter into the Plea Agreement is knowing and voluntary. PURDUE's execution of and entry into the Plea Agreement is done with my consent.

Date: May 8, 2007

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

Date: May 9, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

THE PURDUE FREDERICK COMPANY INC.

Vice President's Certificate

The undersigned, Robin E. Abrams, the Vice President of The Purdue Frederick Company Inc., a New York corporation (the "Corporation"), DOES HEREBY CERTIFY that attached hereto as Schedule 1 is a true, correct and complete copy of the resolutions approved by the Written Consent of the Sole Director of the Corporation dated May 4, 2007 authorizing the Corporation to execute and deliver on behalf of the Corporation that certain Plea Agreement between the United States of America and the Corporation, together with other documents listed therein with respect to settling that certain investigation by the United States Attorney's Office for the Western District of Virginia, which resolutions have not been amended or rescinded as of the date hereof.

IN WITNESS WHEREOF, the undersigned has executed this Certificate this May 4, 2007.

Robin E. Abrams
Vice President

SCHEDULE 1

RESOLVED, that the Agreed Statement of Facts between the United States of America and the Corporation (the "Agreed Statement of Facts") in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Settlement Agreement among the United States of America, acting through the Civil Division of the Department of Justice and the United States Attorney's Office for the Western District of Virginia, the Office of the Inspector General of the United States Department of Health and Human Services, the United States Office of Personnel Management, the United States Department of Defense TRICARE Management Activity, the United States Department of Labor Office of Workers' Compensation Programs, the Corporation and Purdue Pharma L.P., a Delaware limited partnership (the "Civil Settlement Agreement"), in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Plea Agreement between the United States of America and the Corporation (the "Plea Agreement") in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Stipulation for Compromise Settlement between the United States of America and the Corporation (the "Stipulation for Compromise Settlement") in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that the Agreed Order of Forfeiture between the United States of America and the Corporation (the "Agreed Order of Forfeiture"; the Agreed Statement of Facts, the Civil Settlement Agreement, the Plea Agreement, the Stipulation for Compromise Settlement, and the Agreed Order of Forfeiture are hereinafter collectively referred to as the "Settlement Documents"), in the form presented to the Director of the Corporation be and the same hereby is approved; and further

RESOLVED, that Robin E. Abrams as the Vice President of the Corporation, be and she hereby is authorized and directed to execute and deliver in the name and on behalf of the Corporation the Settlement Documents, each in the form or substantially in the form presented to the Director of the Corporation, with such changes, additions and modifications thereto as she shall approve, such approval to be conclusively evidenced by her execution and delivery thereof; and further

RESOLVED, that Robin E. Abrams as the Vice President of the Corporation, be and she hereby is authorized and directed to make, execute and deliver, or cause to be made, executed and delivered, all such agreements, documents, instruments and other papers, and to do or cause to be done on behalf of the Corporation all such acts, as she may deem necessary or appropriate to carry out the purposes and intent of the foregoing resolutions, including, but not limited to, appearing on behalf of the Corporation in the United States District Court for the Western district of Virginia, Abingdon Division, in order to make any statement or statements on behalf of the Corporation she deems appropriate in connection with the judgment to be pronounced against the Corporation in accordance with the Settlement Documents.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
v.) Case No. 1:07CR29
)
HOWARD R. UDELL)

PLEA AGREEMENT

My counsel and I have entered into a Plea Agreement with the United States of America, by counsel, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure ("Fed. R. Crim. P.)" The terms and conditions of this agreement are as follows:

1. CHARGE(S) TO WHICH I AM PLEADING GUILTY AND WAIVER OF RIGHTS

I will enter a plea of guilty to Count Two of the attached Information, charging me with the strict liability misdemeanor offense of misbranding a drug in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1). The maximum statutory penalty for Count Two is a fine of $100,000.00, pursuant to 18 U.S.C. § 3571(b)(5), and/or imprisonment for a term of one year, plus a period of supervised release. I understand that fees may be imposed to pay for incarceration or supervised release and that there will be a $25 special assessment, pursuant to 18 U.S.C. § 3013(a)(1)(A)(iii). I further understand that any term of probation may be revoked if I violate its terms and conditions.

My attorney has informed me of the nature of the charge(s) and the elements of the charge(s) that must be proved by the United States beyond a reasonable doubt before I could be found guilty as charged.

I acknowledge that I have had all of my rights explained to me and I expressly recognize that I have the following constitutional rights and, that by voluntarily pleading guilty, I knowingly waive and give up these valuable constitutional rights:

The right to plead not guilty and persist in that plea.
The right to a speedy and public jury trial.
The right to assistance of counsel at that trial and in any subsequent appeal.
The right to remain silent at trial.
The right to testify at trial.
The right to confront and cross-examine witnesses.
The right to present evidence and witnesses in my own behalf.
The right to compulsory process of the court.
The right to compel the attendance of witnesses at trial.
The right to be presumed innocent.
The right to a unanimous guilty verdict.
The right to appeal a guilty verdict.

I am pleading guilty as described above because I am in fact guilty and because I believe it is in my best interest to do so and not because of any threats or promises, other than the terms of this Plea Agreement, described herein, in exchange for my plea of guilty. I agree that the Court can accept the Agreed Statement of Facts as the factual basis for my guilty plea.

I understand that the plea is being entered in accordance with Fed. R. Crim. P. 11(c)(1)(C).

2. SENTENCING PROVISIONS

The parties agree and stipulate that the following Guidelines' section should apply, exclusively, to my conduct:

2N2.1	6	Base Offense Level

Pursuant to Fed. R. Crim. P. 11(c)(1)(C), the parties agree to ask the Court to impose a non-incarcerative sentence. The parties agree that if the Court refuses to accept the Plea Agreement with the agreed-upon sentence I will be free to withdraw this guilty plea. In that event, this Agreement will be null and void and nothing in this Plea Agreement shall be deemed a waiver of the provisions of Federal Rule of Evidence ("Fed. R. Evid.") 410 and the United States will move to dismiss the Information without prejudice to the United States' right to indict me or any other entity or individual on any charge.

The parties agree and stipulate that restitution is not applicable to my conviction.

If the Court were to impose a sentence that includes probation, I do not believe that any non-standard conditions of probation are appropriate. The United States agrees to take no position as to any non-standard conditions of probation.

3. DISGORGEMENT

Prior to the entry of my guilty plea, I will transfer $8,000,000.00 (eight million dollars) to the Virginia Medicaid Fraud Control Unit's Program Income Fund. If the Court rejects this Plea Agreement and, as a result, I withdraw my plea, the $8,000,000.00 (eight million dollars) will be returned to me.

4. MANDATORY ASSESSMENT AND FINE

I understand that there is a mandatory assessment of $25.00 per misdemeanor count of conviction. The parties agree and stipulate that a fine of $5,000.00, at the upper end of the guidelines' range, is appropriate for this case. I agree that I will submit to the U.S. Clerk's Office, a certified check, money order, or attorney's trust check, made payable to the "Clerk, U.S. District Court" in the amount of $5,025.00 within seven days of entering my plea of guilty.

5. ADDITIONAL OBLIGATIONS

Unless the Court rejects this Plea Agreement and, as a result, I withdraw my plea, I agree to: (1) accept responsibility for my conduct; (2) fully comply with all terms of probation, if a term of probation is imposed; (3) not attempt to withdraw my guilty plea; (4) not deny that I committed the crime to which I have pled guilty; and (5) not make or adopt any arguments or objections to the presentence investigation report that are inconsistent with this agreement (if a presentence report is ordered by the Court).

I consent to public disclosure of all resolution documents related to this case.

I will not make any public statements, including statements or positions in litigation in which any United States department or agency is a party, contradicting any statement of fact set forth in the Agreed Statement of Facts. Should the United States Attorney's Office for the Western District of Virginia notify me of a public statement that contradicts a statement of fact contained in the Agreed Statement of Facts, I may avoid noncompliance with my obligations under this Plea Agreement by publicly repudiating such statement within two business days after such notification. Notwithstanding the above, I may avail myself of any legal or factual arguments available to me in defending litigation brought by a party other than the United States or in any investigation or proceeding brought by a state entity or by the United States Congress. This paragraph is not intended to apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative or civil case initiated by any governmental or private party against such individual.

6. ADMISSIBILITY OF STATEMENTS

I understand that any statements I make or made on my behalf (including, but not limited to, this Plea Agreement and its admission of guilt) during or in preparation for any guilty plea hearing, sentencing hearing, or other hearing and any statements made, in any setting, may be used against me in this or any other related criminal proceeding. I knowingly waive any right I may have under the Constitution, any statute, rule or other source of law to have such statements, or evidence derived from such statements, suppressed or excluded from being admitted into evidence in this or any other related criminal proceeding. With the exception of the situations set forth above, I do not waive my right to argue against admissibility under any ground permitted under federal or state rules of evidence in any other proceeding.

If the Court rejects the Plea Agreement, and, as a result, I withdraw my plea, I will not be bound by the waivers set forth in this section of the Plea Agreement.

7. WAIVER OF RIGHT TO APPEAL AND COLLATERALLY ATTACK THE JUDGMENT AND SENTENCE IMPOSED BY THE COURT

If the Court accepts this Plea Agreement, I agree that I will not appeal the conviction or sentence imposed. I am knowingly and voluntarily waiving any right to appeal and am voluntarily willing to rely on the Court in sentencing me pursuant to the terms of Fed. R. Crim. P. 11(c)(1)(C). I agree not to collaterally attack the judgment and/or sentence imposed in this case and waive my right to collaterally attack, pursuant to Title 28, United States Code, Section 2255, the judgment and

any part of the sentence imposed upon me by the Court. I agree and understand that if I file any court document (including but not limited to a notice of appeal) seeking to disturb, in any way, the judgment and/or sentence imposed in my case, the United States will be free to take whatever actions it wishes based on this failure to comply with my obligations under the Plea Agreement.

8. **REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION**

I understand that if: (1) I attempt to withdraw my plea (in the absence of the Court refusing to accept the Plea Agreement) or fail to comply with any provision of this agreement, at any time; (2) any defendant in this case does not fulfill the defendant's obligations under the defendant's Plea Agreement prior to the imposition of judgment; (3) my conviction is set aside, for any reason; and/or (4) any entity related to any defendant fails to execute all required paperwork or fails to fulfill its obligations to effectuate the resolution of this entire investigation prior to the imposition of judgment, the United States may, at its election, pursue any or all of the following remedies: (a) declare this Plea Agreement void; (b) file, by indictment or information, any charges which were filed and/or could have been filed concerning the matters involved in the instant investigation; (c) refuse to abide by any stipulations and/or recommendations contained in this Plea Agreement; (d) not be bound by any obligation of the United States set forth in this agreement, including, but not limited to, those obligations set forth in the section of this agreement entitled "COMPLETION OF PROSECUTION;" and (e) take any other action provided for under this agreement or by statute, regulation or court rule.

The remedies set forth above are cumulative and not mutually exclusive. If the United States pursues any of its permissible remedies as set forth in this agreement, I will still be bound by my obligations under this agreement. I hereby waive my right under Fed. R. Crim. P. 7 to be proceeded against by indictment and consent to the filing of an information against me concerning any charges filed pursuant to this section of the Plea Agreement. I hereby waive any statute of limitations argument as to any such charges.

9. **INFORMATION ACCESS WAIVER**

I knowingly and voluntarily agree to waive all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §552a.

10. **DESTRUCTION OF ITEMS OBTAINED BY LAW ENFORCEMENT**

The United States Attorney's Office will inform me when my personal financial records and/or other records or items obtained from my accountant or any documents otherwise relating to my personal finances are available for removal. I expressly agree that, within 30 days of being informed by the United States Attorney's Office that such records are available for removal, I will remove, at my cost, all such records from the premises designated by the United States Attorney's

Office. In addition, by signing this Plea Agreement, I hereby consent to the destruction of all items obtained by law enforcement agents during the course of the investigation (other than those described above), and will execute any documents necessary to comply with this provision.

11. COMPLETION OF PROSECUTION

I understand that except as provided for in this agreement, so long as I comply with all of my obligations under the agreement, there will be no further criminal prosecution or forfeiture action by the United States against me, for any violations of law, occurring before May 10, 2007, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

Nothing in this Plea Agreement affects the administrative, civil, criminal, or other tax liability of any entity or individual and this Plea Agreement does not bind the Internal Revenue Service of the Department of Treasury, the Tax Division of the United States Department of Justice, or any other government agency with respect to the resolution of any tax issue.

I understand that nothing in this Plea Agreement precludes any private party from pursuing any civil remedy against me, and I agree that I will not raise this Plea Agreement or my guilty plea as a defense to any such civil action.

12. LIMITATION OF AGREEMENT

This Plea Agreement is limited to the United States of America and does not bind any state or local authorities.

13. EFFECTIVE REPRESENTATION

I have discussed the terms of the foregoing Plea Agreement and all matters pertaining to the charges against me with my attorney and am fully satisfied with my attorney and my attorney's advice. At this time, I have no dissatisfaction or complaint with my attorney's representation. I agree to make known to the Court no later than at the time of sentencing any dissatisfaction or complaint I may have with my attorney's representation.

14. WAIVER OF CERTAIN DEFENSES

By signing this Plea Agreement, I waive any defenses regarding pre-indictment delay, statute of limitations, or Speedy Trial Act with respect to any and all criminal charges that could have been timely brought or pursued as of March 29, 2006. This waiver is binding on me only as to charges brought by the United States. This waiver expires once judgment is entered, except as set forth in the section of the Plea Agreement entitled "REMEDIES FOR FAILURE TO COMPLY WITH ANY PROVISION OF THE PLEA AGREEMENT OR OVERALL RESOLUTION."

15. EFFECT OF MY SIGNATURE

I understand that my signature on this Plea Agreement constitutes a binding offer by me to

enter into this Plea Agreement. I understand that the United States has not accepted my offer until it signs the Plea Agreement.

16. GENERAL UNDERSTANDINGS

The parties jointly submit that this Plea Agreement and the attached Agreed Statement of Facts provide sufficient information concerning PURDUE and the crimes charged in this case to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. The parties agree to request that the Court impose sentence at the date of the arraignment and plea pursuant to the provisions of Fed. Rule Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1(a)(2), if the Court determines that a presentence report is not necessary.

If the Court accepts this Plea Agreement and sentences me to a non-incarcerative sentence, I understand that I will have no right to withdraw my guilty plea. In addition, I understand that I will not have any right to withdraw my plea if I violate my conditions of probation (if any term of probation is imposed) and, as a result, I am sentenced to incarceration.

If the Court orders a presentence report, I understand that a thorough presentence investigation will be conducted and sentencing recommendations independent of the United States Attorney's Office will be made by the presentence preparer.

I understand that the prosecution will be free to allocute or describe the nature of this offense and the evidence in this case. I understand that the United States retains the right, notwithstanding any provision in this Plea Agreement, to inform the Probation Office and the Court of all relevant facts, to address the Court with respect to the nature and seriousness of the offense(s), to respond to any questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, if a report is prepared, and to respond to any statements made to the Court by or on behalf of the defendant.

I willingly stipulate that the Agreed Statement of Facts provides the Court with a sufficient factual basis to support my plea of guilty.

I understand that this Plea Agreement does not apply to any crimes or charges not addressed in this agreement. I understand that if I should testify falsely in this or in a related proceeding I may be prosecuted for perjury and statements I may have given authorities pursuant to this Plea Agreement may be used against me in such a proceeding.

I have not been coerced, threatened, or promised anything other than the terms of this Plea Agreement, described above, in exchange for my plea of guilty. I understand that my attorney will be free to argue any mitigating factors on my behalf; to the extent that they are not inconsistent with the terms of this Plea Agreement. I understand that I will have an opportunity to personally address the Court prior to sentence being imposed.

This writing sets forth the entire understanding between the parties and constitutes the complete Plea Agreement between the United States of America and me, and no other additional terms or agreements shall be entered except and unless those other terms or agreements are in writing and signed by the parties. This Plea Agreement supersedes all prior understandings, promises, agreements, or conditions, if any, between the United States and me.

I have consulted with my attorney and fully understand all my rights with respect to the offenses charged in the Information. I have read this Plea Agreement and carefully reviewed every part of it with my attorney. I understand this Plea Agreement and I voluntarily agree to it. Being

aware of all of the possible consequences of my plea, I have independently decided to enter this plea of my own free will, and am affirming that agreement on this date and by my signature below.

Date: 5/7/07

Howard R. Udell, Defendant

I have fully explained to my client all rights available to my client with respect to the offenses charged in the Information. I have carefully reviewed every part of this Plea Agreement and attached Agreed Statement of Facts with my client. To my knowledge, my client's decision to enter into this Plea Agreement is an informed and voluntary one.

Date: 5/8/07

Mary Jo White
Counsel for Defendant

Date: May 9, 2007

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

RELEASE BY THE COMMONWEALTH OF VIRGINIA

For purposes of this release, PURDUE shall be defined in the same manner as in the Non-Prosecution Agreement between the United States and PURDUE entered in 2007 and filed as an attachment to the Plea Agreement of The Purdue Frederick Company, Inc.

The Virginia Medicaid Fraud Control Unit with the Virginia Attorney General's Office actively participated in a prolonged investigation of PURDUE by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation. The investigation has resulted in a negotiated resolution that includes plea agreements between the United States and the Purdue Frederick Company, Inc., and certain individuals. By the terms of those plea agreements, the Program Income Fund of the Virginia Medicaid Fraud Control Unit will receive $39,800,000.00 and a $20,000,000.00 trust will be established to fund the Virginia Prescription Monitoring Program.

In accordance with the Constitution of Virginia and pursuant to the authority conferred upon the Governor of Virginia and the Attorney General of Virginia by the Code of Virginia, the Governor of Virginia and the Attorney General of Virginia hereby agree that so long as (1) PURDUE complies with all of its obligations as set forth in the Non-Prosecution Agreement and the documents referenced therein and (2) Michael Friedman, Howard R. Udell, and Paul D. Goldenheim comply with all of their obligations in their plea agreements prior to the imposition of judgment, there will be no further civil or criminal action by the Governor or by the Attorney General's Office, including the Virginia Medicaid Fraud Control Unit, on behalf of the Commonwealth of Virginia against PURDUE, its current and former directors, officers, employees, co-promoters, owners (including trustees and trust beneficiaries of such owners), successors and assigns; any of PURDUE'S related and associated entities (as listed on Attachment A to the Plea Agreement of The Purdue Frederick Company, Inc.), and such related and associated entities' current and former directors, officers, employees, owners (including trustees and trust beneficiaries of such owners), successors and assigns, and trusts for the benefit of the families of the current and former directors of PURDUE, including the trustees and trust beneficiaries of such trusts, for any violations of law, occurring on or before the date the guilty pleas are entered, pertaining to OxyContin that was the subject matter of the investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation that led to this agreement.

This release shall not limit the Commonwealth's ability to settle pending matters related to Virginia's consumer protection laws or to otherwise participate in the multi-state portion of any amounts obtained as a result of these Plea Agreements. The Commonwealth agrees and understands that any of the money paid pursuant to these Plea Agreements will be returned if, and only if, the Court refuses to accept the Plea Agreements with the agreed-upon sentences and, as a result, the defendants withdraw their guilty pleas. If this occurs, the Commonwealth understands that it is free to assert any and all claims against the defendants.

This Release shall be made an attachment to the plea agreements referenced herein.

Executed this 7th of May, 2007.

Timothy M. Kaine
Governor of Virginia

Robert F. McDonnell
Attorney General of Virginia

STATE OF SOUTH CAROLINA COUNTY OF HORRY DANIEL C. LUBERDA by his appointed agent DANIEL L. LUBERDA Plaintiff, vs. Purdue Frederick Corp., Purdue Pharma L.P., The Purdue Pharma Company, Purdue Pharmaceutical Products L.P., Purdue Pharma Technologies Inc., Purdue Pharma of North Carolina Limited Partnership, Purdue Pharmaceutical Laboratories Limited Partnership, Purdue Products L.P., Purdue Pharmaceuticals Limited Partnership, Michael Friedman, Howard Udell, Paul Goldenheim, M.D. Danielle Nelson, Edward B. Mahony, Stuart D. Baker, John N. Stewart, David A. Long, James Dolan, Michael Danahy, Robin Abrams, Richard W. Silbert, Larry A. Pickett Jr., Craig Landau M.D., Robert F. Kaiko, Burt Weinstein, Kathleen M. Schady, PH.D, F. Mark Geraci, Don Kyle, Diana Lenkowsky, Burt Rosen, David Haddox, Phillip C. Strassburger, Russell Gasdia, David Lundie, William Malin, Tom Baumgartner M.D., Dennis A. Merlo, Alan Must; Dr. Alan Spanos; J. David Haddox, M.D., Scott Fishman, M.D., Lynn Webster, MD, Russell Portenoy, M.D., Perry Fine, M.D., Curtis Wright, M.D., Raymond Sackler, M.D., Richard Sackler Defendant(s).	IN THE COURT OF COMMON PLEAS FOR THE FIFTEENTH JUDICIAL CIRCUIT Docket No.: 2013-CP-26-_____ **VERIFICATION**

PERSONALLY appeared before me, DANIEL L. LUBERDA, appointed agent for Daniel C. Luberda, who being first duly sworn, says that they have read the foregoing ***Summons and Complaint*** and knows the contents thereof; that the same is true to his own knowledge, except as to the matters therein stated to be alleged on information and belief; and to those matters he believes to be true.

Daniel L. Luberda

DANIEL L. LUBERDA
Agent for Daniel C. Luberda

SWORN to and before me this
26th day of February, 2013.

Susan L. Platt

Notary Public for South Carolina
My Commission Expires: June 18, 2017

The Law Office of
Carla F. Grabert– Lowenstein
314 Main Street
Conway, SC 29526

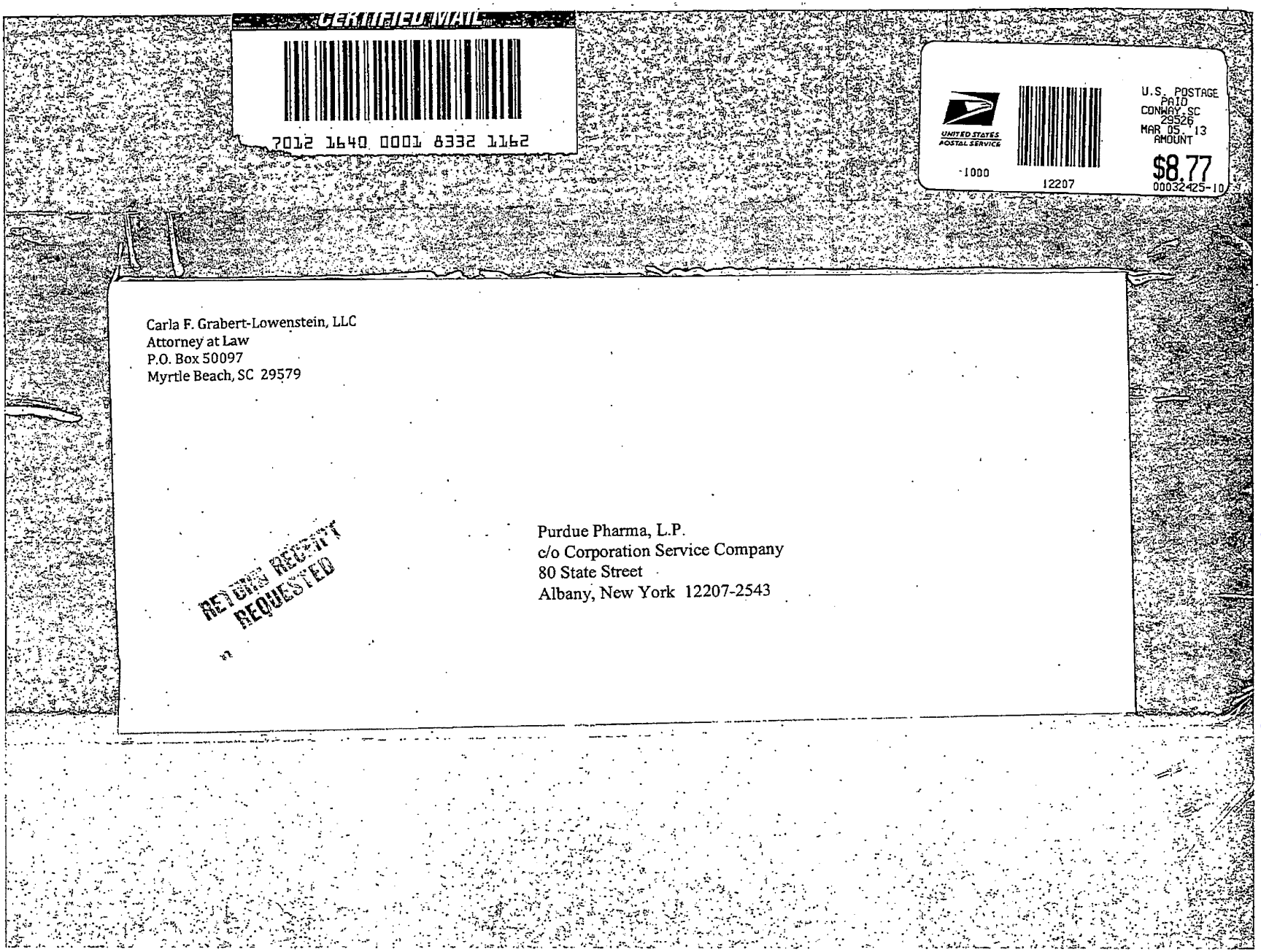


EXHIBIT F

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF SOUTH CAROLINA

FLORENCE DIVISION

Daniel C. Luberda by his appointed agent Daniel L. Luberda, Plaintiff(s) vs. Purdue Frederick Corp., Purdue Pharma L.P., The Purdue Pharma Company, Purdue Pharmaceutical Products L.P., Purdue Pharma Technologies Inc., Purdue Pharma of North Carolina Limited Partnership, Purdue Pharmaceutical Laboratories Limited Partnership, Purdue Products L.P., Purdue Pharmaceuticals Limited Partnership, Michael Friedman, Howard Udell, Paul Goldenheim, M.D. Danielle Nelson, Edward B. Mahony, Stuart D. Baker, John N. Stewart, David A. Long, James Dolan, Robin Abrams, Richard S. Silbert Craig Landau, M.D., Robert F. Kaiko, Bert Weinstein, Phillip C. Strassberger Russell Gasdia, William Malin, Alan Spanos, M.D., J. David Haddox, DDS, M.D., Scott Fishman, M.D., Lynn Webster, MD, Russell Portenoy, M.D., Perry Fine, M.D., Curtis Wright, M.D., James Heins, Charles Robin Hogen. Defendant(s).	Civil Action No. 4:13-cv-00897-TLW **AMENDED COMPLAINT**

NOW COMES THE PLAINTIFFS, by and through undersigned counsel of record, Carla Faye Grabert-Lowenstein, and alleges that the items in this complaint are true and accurate to the best of their knowledge:

PARTIES

1. Purdue Frederick, a State of New York corporation doing business as Purdue Frederick, headquartered in Connecticut, and was at all times relevant to the Complaint. Purdue Frederick and other related and associated entities were engaged in the pharmaceutical manufacturing business throughout the United States.
2. Purdue Pharma LP is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE.
3. The Purdue Pharma Company is a GENERAL PARTNERSHIP that is domiciled in the State of DELAWARE.
4. Purdue Pharmaceutical Products LP is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE.
5. Purdue Pharma Technologies Inc., is a CORPORATION incorporated in the State of DELAWARE, and does business in South Carolina, specifically, Horry County.
6. Purdue Pharma of North Carolina Limited Partnership is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE, and conducts business in South Carolina, specifically, Horry County.
7. Purdue Pharmaceutical Laboratories Limited Partnership is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE, and does business in South Carolina, specifically, Horry County.

8. Purdue Products LP is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE and does business in South Carolina, specifically Horry County.

9. Purdue Pharmaceuticals Limited Partnership, aka Purdue Pharmaceuticals L.P., is a LIMITED PARTNERSHIP incorporated in the State of DELAWARE, and does business in South Carolina, including, Horry County.

10. South Carolina State Courts do have in persona jurisdiction over the Defendant(s).

11. Purdue Frederick and its other entities conducted business in the State of South Carolina specifically selling their pharmaceutical products and sold in the State of South Carolina.

12. Michael Friedman is the former President and CEO for Purdue Pharma et al, and was President and CEO during all times relevant. As President and CEO of Purdue Pharma et al, he participated in the decision making process which led to mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

13. Howard Udell was Assistant Corporate Secretary and former Chief Legal Counsel for Purdue Pharma et al, during all times relevant. As Assistant Corporate Secretary and former Chief Counsel for Purdue Pharma, he participated in the

decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties; throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

14. Paul Goldenheim, M.D. is the former medical director for Purdue Pharma, et al, and was the medical director at all times relevant. As medical director for Purdue Pharma, et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin..

15. Danielle Nelson is an Assistant Corporate Secretary for Purdue Pharma et al. Danielle Nelson was Assistant Corporate Secretary for Purdue Pharma et al during all times relevant. As Assistant Corporate Secretary for Purdue Pharma et al, she participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally she knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

16. Edward B. Mahony is an Executive Vice President, Chief Financial Officer, and Treasurer for Purdue Pharma et al. Edward B. Mahony was Executive Vice President, Chief Financial Officer during all times relevant. As Executive Vice President and Chief Financial Officer and Treasureer for Purdue Pharma et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

17. Stuart D. Baker is an Executive Vice President and Secretary for Purdue Pharma et al. Stuart D. Baker was Executive Vice President and Secretary for Purdue Pharma. In his position as Executive Vice President and Secretary for Purdue Pharma et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

18. John N. Stewart is the President and CEO for Purdue Pharma et al. John N. Steward was President and CEO for Purdue Pharma during all times relevant. As President and CEO for Purdue Pharma et al, he participated in the decision making

process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

19. David A. Long is the Vice President for Purdue Pharma. et al. David A. Long has been Vice President of Purdue Pharma during all times relevant. As Vice President for Purdue Pharma et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

20. James Dolan is the Senior Vice President of Licensing and Business for Purdue Pharma et al. James Dolan has been Senior Vice President for Licensing and Business for Purdue Pharma during all times relevant. he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

21. Robin Abrams is a Vice President and Associate General Counsel for Purdue

Pharma et al. Robin Abrams has been Vice President and Associate General Counsel for Purdue Pharma during all times relevant. As Vice President and Associate General Counsel form Purdue Pharma et al, she participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties; throughout the United States including the State of South Carolina. Additionally she knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

22. Richard W. Silbert is Vice President Associate General Counsel for Purdue Pharma et al. Richard W. Silbert was Vice President Associate General Counsel for Purdue Pharma et al, during all times relevant. In his position as Vice President for Purdue Pharma, et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

23. Craig Landau, M.D. is Chief Medical Officer and Vice President for R & D Innovation, Clinical and Medical Affairs for Purdue Pharma et al. Dr. Landau was the Chief Medical Officer and Vice President for R&D Innovation, Clinical and Medical Affairs for Purdue Pharma, et al, during all relevant times. In his position

as Chief Medical Officer and and Vice President for R & D Innovation, Clinical and Medical Affairs for Purdue Pharma et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

24. Robert F. Kaiko was Vice President of Purdue Pharma, et al, during all times relevant. In his position as the Vice President of Clinical Research for Purdue Pharma et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

25. Bert Weinstein is Vice President of Corporate Compliance for Purdue Pharma et al. Bert Weinstein was Vice President of Corporate Compliance during all times relevant. In his position as Vice President of Corporate Compliance he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the

addictive nature of OxyContin.

26. J. David Haddox, DDS, M.D. is Vice President of Health Policy for Purdue Pharma et al. Dr. Haddox was Vice President of Health Policy for Purdue Pharma during all times relevant. In his position of Vice President for Health Policy for Purdue Pharma, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties; throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

27. Phillip C. Strassburger is Vice President and General Counsel for Purdue Pharma, et al. Phillip C. Strassburger was Vice President and General Counsel for Purdue Pharma, et al, during all times relevant. In his position as Vice President and General Counsel for Purdue Pharma, et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

28. Russell Gasdia is Vice President of Marketing and Sales for Purdue Pharma et al. Russell Gasdia was Vice President of Marketing and Sales for Purdue Pharma et al, during all times relevant. In his position of Vice President of marketing and

Sales for Purdue Pharma, et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

29. William Malin is Vice President of Project Marketing for Purdue Pharma et al. William Malin was Vice President of Project Marketing for Purdue Pharma et al during all times relevant. As Vice President of Project Marketing for Purdue Pharma, et al, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

30. James Heins is Senior Director of Public Affairs for Purdue Pharma. James Heins was director of Public Affairs for Purdue Pharma during all times relevant. In his position as Senior Director of Public Affairs for Purdue Pharma, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties; throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the

addictive nature of OxyContin.

31. Charles Robin Hogen, is the former Vice President of Communications of Purdue Pharma and corporate spokesperson and was during all relevant periods of time. As Vice President of Communications and corporate spokesperson, he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

32. Curtis Wright, M.D., was employed by Purdue Pharma during the relevant time period after being part of approval process for OxyContin at the United States Food and Drug Administration ("FDA"); While employed at Purdue Pharma he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

33. Dr. Lynn Webster was involved in the American Pain Foundation and American Academy of Pain Medicine during all relevant times. These organizations received funding from Purdue Pharma during all relevant times. Dr. Lynn Webster, used his

association with the aforementioned organizations to misrepresent the addictive nature of OxyContin; During all times relevant, he participated in the decision making process to mislabel OxyContin to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the above mentioned misrepresentations would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

34. Dr. Scott Fishman was involved in the American Pain Foundation and American Academy of Pain Medicine during all relevant times. These organizations were funded by defendant Purdue Pharma. Dr. Fishman, used his association with the aforementioned organizations, to misrepresent the addictive nature of OxyContin. Dr. Fishman also received grants for his work with Purdue Pharma. During times relevant he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the misrepresentations and mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

35. Dr. Russell Porteney was involved in the American Pain Foundation and the American Academy of Pain Medicine during all relevant times. These organizations were funded by defendant Purdue Pharma during all relevant times.

Defendant, Dr. Russell Portenoy, used his association with the aforementioned organizations, to misrepresent addictive nature of OxyContin. During times relevant he participated in the decision making process that led to the mislabeling of OxyContin as to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the misrepresentations and mislabling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

36. Dr. Perry Fine was involved in the American Pain Foundation and the American Academy of Pain Medicine during all relevant times. These organizations received funding payments from Purdue Pharma during all relevant times. During all relevant times Dr. Perry Fine used his association with the aforementioned organizations, to misrepresent as to the addictive nature of OxyContin. During times relevant During times relevant he participated in the decision making process to mislabel OxyContin to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the misrepresentation and mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin.

37. Alan Spanos, M.D. was a paid promotional speaker for Purdue Pharma during all relevant periods of time and misled the American public and prescribing doctors as to the addictive nature of OxyContin. He participated in the decision making

process to mislabel OxyContin to its addictive nature and properties, throughout the United States including the State of South Carolina. Additionally he knew or should have known the misrepresentations and mislabeling would mislead prescribing physicians and patients as to the addictive nature of OxyContin. as to the addictive nature of OxyContin.

JURISDICTION AND VENUE

38. All of the alleged acts occurred within Horry County South Carolina.

At all times relevant Defendants conducted business within the borders of Horry, County South Carolina. Plaintiffs resided in Horry County South Carolina during the relevant time period. As Defendants continue to conduct business in Horry County South Carolina, and plaintiffs, continue to reside in Horry County this court has jurisdiction and is the proper venue for all causes of action.

FACTUAL BACKGROUND

39. OxyContin is an opioid analgesic drug, sold in tablet form, which is a controlled-release oral form of Oxycodone hydrochloride; OxyContin is a Schedule II drug.

40. At all times described herein, the Defendants named in cause of action were in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing pharmaceutical products, including OxyContin.

41. The Defendants named in this cause of action advertised and marketed OxyContin to physicians and to the public throughout the United States, including South Carolina. This marketing included oral representations and written labeling, including package inserts and/or brochures and/or other writings; and included advertising and marketing through various media and website publications.

42. The Defendants named in this cause of action, through its market representatives, advertised and marketed OxyContin directly to Daniel C. Luberda.

43. At the time that the Defendants named in this cause of action marketed OxyContin to Daniel C. Luberda, the Defendants knew that OxyContin was a highly-addictive drug, even when taken as directed, and that it had other defects.

44. The Defendants named in this cause of action, in the course of the commerce of OxyContin and with intent that Plaintiff rely on the deception, did commit deceptive acts or practices in one or more of the following respects:

a. The Defendants named in this cause of action told doctors and the public at large that OxyContin was the new wonder drug; that it was the standard of care for treatment of chronic pain; and/or

b. The Defendants named in this cause of action told doctors and the public at large that OxyContin was safe and effective and non-addictive; and/or

c. The Defendants named in this cause of action told doctors and the public at large that it would be medical malpractice *not* to prescribe OxyContin to patients with chronic pain; and/or

d. The Defendants named in this cause of action told doctors and the public at large that the Defendants would sue doctors who failed to prescribe OxyContin to treat chronic pain; and/or

e. OxyContin poses no serious risks of physical dependence and addiction; and/or

f. OxyContin has been safely and effectively used to treat arthritis patients and car accident victims, facts represented in a segment on the website called "Pain Management Success Stories"; and/or

g. True addiction, described by this website as meaning using a drug to get "high", very rarely occurs when opioids are being used under medical supervision to relieve pain.

45. The Defendants named in this cause of action, pleaded guilty on May 10, 2007 to the felony of deceptive practices or acts in the misbranding of OxyContin with intent to defraud or mislead, and agreed to a statement of facts which admitted conduct that included the deceptive practices and acts in the marketing of OxyContin that were used to market OxyContin to Daniel C. Luberda; and on or about July 20, 2007, the Defendant named in this Count was sentenced for these deceptive practices and acts, and paid fines (or agreed to pay fines) in excess of $600,000,000.00; see Excerpt from the "Plea Agreement" and the "Agreed Statement of Facts", attached hereto and incorporated herein by reference.

46. Howard Udell, Michael Friedman, and Dr. Paul Goldenheim all plead guilty in United States Federal District Court to charges of misleading doctors and patients by marketing OxyContin as less likely to be abused than other narcotics.

47. Defendant(s) admitted to misleading the public about OxyContin risk of addiction.

48. Defendants Udell, Friedman and Goldenheim as a result of their conviction were further prohibited from participation in the Medicare and Medicad and other federal health care programs for fifteen years by the United States Department of Health and Human Services.

49. Notwithstanding the federal conviction on like prior bad acts Defendant(s) continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse and less likely to cause withdrawal, when they in fact knew such information was not true.

50. Defendant(s) marketed OxyContin as a safe, effective, and non-habit forming, painkiller.

51. Defendant(s) shorted the recommended time between doses from every twelve (12) hours (as recommended by the FDA) to every eight (8) hours to increase the amount needed to fill a prescription increasing sales.

52. On or about August 7, 2004 Daniel C. Luberda was involved in an automobile accident that resulted in a very serious injury to his right foot, elbow and shoulder.

53. Daniel C. Luberda was prescribed OxyContin for the pain by Dr. Thomas J. Chambers, M.D. who was not informed in anyway by Defendant(s) of the addictive nature of the drug.

54. Prior to August 7, 2004 Daniel C. Luberda had never used OxyContin.

55. The Plaintiff, Daniel C. Luberda, did rely on the above detailed deceptions and took OxyContin for his own chronic pain. By October of 2004 Daniel C. Luberda became involuntarily addicted to OxyContin; and while suffering involuntary addiction, and to satisfy the addiction, Daniel C. Luberda took OxyContin that was not prescribed for him for his own use, and did use this OxyContin to satisfy his own involuntary addiction.

56. Daniel C. Luberda suffered serious physical and psychological withdrawal symptoms when he was not able to obtain OxyContin.

57. Once his own money ran out Daniel C. Luberda began burglarizing houses to steal property that could be sold in exchange for OxyContin.

58. The cost of the OxyContin addiction started at $60.00 per day, and gradually increased to the $400-$500 range, to satisfy Daniel C. Luberda's withdrawal symptoms.

59. Ultimately, the addiction to OxyContin drove Daniel C. Luberda to the point where he robbed two (2) banks, leading to his arrest on December 21, 2010 and his five (5) year sentence of incarceration at a Federal prison commencing on August 19, 2011.

60. Daniel C. Luberda was never advised of or warned, in any way whatsoever about the addictive nature of OxyContin or the potential outcome of his use of the drug.

61. As a result of his addiction to OxyContin, which began when it was legally

prescribed by a medical doctor, in accordance with the recommendations of Defendant(s), Daniel C. Luberda has suffered financial losses, physical and mental harm, as well as, the deprivation of his freedom.

FIRST CAUSE OF ACTION

NEGLIGENCE

62. Plaintiff alleges, re-affirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 74 and further states that Defendants acted in a manner constituting negligence in that:

a. Defendants owed Plaintiff a duty to properly warn of the potential for and/or risk of addiction associate with their product.

b. Defendants breached this duty by failing to properly warn of the potential for and/or risk of addiction in the manner in which they labeled, marketed and misbranded their product.

c. Defendants' breach was the direct and proximate cause of the injuries and damages sustained by Plaintiff.

63. Further, that each Defendant named in this cause of action is jointly and severably liable for the above detailed negligence.

SECOND CAUSE OF ACTION

GROSS NEGLIGENCE

64. Plaintiff alleges, re-affirms, and incorporates by reference the alliterations and

facts contained in paragraphs 1 thru 64 and further states that Defendants acted in a manner constituting gross negligence in that:

a. Defendants owed Plaintiff a duty to properly warn of the potential for and/or risk of addiction associate with their product.

b. Defendants intentionally breached this duty by deceiving medical professionals and patients as to the potential for and/or risk of addiction through the manner in which they labeled, marketed and misbranded their product.

c. Defendants' breach was the direct and proximate cause of the injuries and damages sustained by Plaintiff.

65. Further, that each Defendant named in this cause of action is jointly and severably liable for the above detailed gross negligence.

THIRD CAUSE OF ACTION

COMMON LAW FRAUD

66. Plaintiff alleges, reaffirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 64 and further states that Defendants acted in a manner common law fraud in that:

a. Defendants deceived and/or misrepresented to Plaintiff as to the potential for and/or risk of addiction associate with their product.

b. Defendants intended on Plaintiff to rely on this deception and/or misrepresentation as promulgated in the labeling, marketing, and misbranding of

their product.

c. Plaintiff did in fact rely on said deceptions and/or misrepresentations.

d. Defendants' deceptions and/or misrepresentations were the direct and proximate cause of the injuries and damages sustained by Plaintiff.

67. Further, that each Defendant named in this cause of action is jointly and severably liable.

FOURTH CAUSE OF ACTION

VIOLATION OF SECTION 39-23-8- OF THE SOUTH CAROLINA CODE OF LAWS

68. Plaintiff alleges, re-affirms, and incorporates by reference the alliterations and facts contained in paragraphs 1 thru 64 and further states; the defendants marketing a misbranded drug, specifically OxyContin, into the commerce of South Carolina. The actions of allowing the misbranded OxyContin into the commerce of South Carolina was the direct and proximate cause of plaintiffs injuries.

PRAYER FOR RELIEF

Plaintiff hereby demands a jury trial.

69. Plaintiff is entitled to and also prays for the following relief:

70. Over $300,000.00 in damages for the money paid to obtain OxyContin.

71. Relief for emotional and physical pain and suffering attributed to the OxyContin addiction and the actions resulting there from.

72. For prejudgment interest on all damages to the extent allowed by law.

73. For an order declaring the conduct of defendants violates the statutes alleged.

74. Plaintiff requests unspecified punitive damages as allowed by law.

75. Plaintiff requests attorney's fees and costs to the extent allowed by law.

76. Plaintiff requests any further relief as the court may deem just and proper

Respectfully submitted,

/s/ Carla F. Grabert-Lowenstein
Carla F. Grabert-Lowenstein
Attorney for Plaintiff
314 Main Street
Conway, SC 29526
(843) 488-0912

April 9, 2013
Conway, South Carolina