UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL No. 2804
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	:	Case No. 17-md-2804
This document relates to:	:	: Judge Dan Aaron Polster
	:	
Case No. 1:19-op-45459-DAP	:	
	:	
JENNIFER ARTZ, LEGAL GUARDIAN OF CHILD I.A.A. and MELISSA BARNWELL, LEGAL GUARDIAN OF CHILD C.G., and ROMAN AND JACQUELINE RAMIREZ, LEGAL GUARDIANS OF CHILD R.R., and , on Behalf of Themselves and All Other Similarly Situated Legal Guardians,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.; JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC f/k/a ALLERGAN, INC.; ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; WATSON LABORATORIES, INC.;	:	

WARNER CHILCOTT COMPANY, LLC; :
ACTAVIS PHARMA, INC. f/k/a WATSON :
PHARMA INC.; ACTAVIS SOUTH ATLANTIC :
LLC; ACTAVIS ELIZABETH LLC; ACTAVIS :
MID ATLANTIC LLC; ACTAVIS TOTOWA LLC;:
ACTAVIS LLC; ACTAVIS KADIAN LLC; :
ACTAVIS LABORATORIES UT, INC. f/k/a :
WATSON LABORATORIES, INC.-SALT LAKE :
CITY; ACTAVIS LABORATORIES FL, INC. :
f/k/a WATSON LABORATORIES, INC. – :
FLORIDA; :
MALLINCKRODT PLC; MALLINCKRODT LLC;:
SPECGX LLC; DEPOMED, INC.; INDIVIOR, ;
INC.; RICHARD S. SACKLER; JONATHAN D. :
SACKLER; MORTIMER D.A. SACKLER; :
KATHE A. SACKLER; ILENE SACKLER :
LEFCOURT; BEVERLY SACKLER; THERESA :
SACKLER; DAVID A. SACKLER; RHODES :
TECHNOLOGIES; RHODES TECHNOLOGIES :
INC.; RHODES PHARMACEUTICALS L.P.; :
RHODES PHARMACEUTICALS INC.; TRUST :
FOR THE BENEFIT OF MEMBERS OF THE :
RAYMOND SACKLER FAMILY; THE P.F. :
LABORATORIES, INC.; CARDINAL HEALTH, :
INC.; MCKESSON CORPORATION; :
AMERISOURCEBERGEN DRUG CORP.; :
HEALTH MART SYSTEMS, INC.; H. D. SMITH, :
LLC d/b/a HD SMITH f/k/a H. D. SMITH :
WHOLESALE DRUG CO.; H. D. SMITH :
HOLDINGS, LLC; H. D. SMITH HOLDING :
COMPANY; CVS INDIANA, LLC; CVS HEALTH:
CORPORATION; CVS RX SERVICES, INC.; :
HBC SERVICE COMPANY; :
PRESCRIPTION SUPPLY, INC.; :
RITE AID CORPORATION; RITE AID OF :
MARYLAND, INC.; RITE AID OF MARYLAND, :
INC. d/b/a RITE-AID MID-ATLANTIC :
CUSTOMER SUPPORT CENTER, INC.; :
WALGREEN CO.; WALGREENS BOOTS :
ALLIANCE, INC.; WALGREEN EASTERN :
CO.; WAL-MART INC. f/k/a WAL-MART :
STORES, INC.; MIAMI-LUKEN, INC.; and :
COSTCO WHOLESALE CORPORATION; :
:
Defendants. :

SECOND AMENDED CLASS ACTION COMPLAINT

NOW COME Putative Class Representatives Roman and Jacqueline Ramirez, the Legal Guardians of Child R.R., and Melissa Barnwell, the Legal Guardian of Child C.G., and Jennifer Artz, the Legal Guardian of Child I.A.A., on behalf of themselves solely in their capacity as legal guardians and all other similarly situated legal guardians ("Plaintiffs" or the "Legal Guardians"), hereby filing their Second Amended Class Action Complaint against Defendants. In support thereof, Plaintiffs state as follows:

I. INTRODUCTION

1. This nationwide class action complaint presents the Court with a profound and unique opportunity to protect and improve the lives of America's infants and children, who, through no fault of their own, were diagnosed at birth with opioid-related Neonatal Abstinence Syndrome (NAS) (the "NAS Children").[1] Plaintiff Legal Guardians seek relief solely in their capacity as Legal Guardians and on behalf of all other Legal Guardians similarly situated (the "Putative Legal Guardian Class") for the following: ongoing medical testing and monitoring, medical and developmental referral, provision of training and information for the Legal Guardians, and the convening and oversight of a Court-supervised Science Panel for purposes of epidemiological studies of the NAS Children at issue in this Complaint, which shall also include the requirement that Defendants address medical issues as they develop during the administration of the Science Panel.[2] This relief is all medically necessary and arises because Plaintiffs have an absolute duty of care for symptomatic NAS Children (over whom Plaintiffs also have dominion) and Plaintiffs were thereby injured as a result of Defendants' negligence, negligence *per se*,

[1] NAS refers to the diagnosis of opioid dependence of an infant at birth.

[2] Alternatively, the Legal Guardians seek additional and further compensatory damages.

battery of the NAS Children, conspiracy, and violations of RICO.

2. **This generation of Americans is not yet lost, but absent the award of medically necessary relief, their Legal Guardians may discharge their duties to the NAS children, it will be. Time is of the essence, and the Court must come to the Legal Guardians' aid. Simply put, no other entity, including State or Federal governments and their subdivisions owe the duties of care to the NAS Children stet Legal Guardians do. And while these plaintiffs seek to benefit from the misfortune suffered by the children in the care of the Legal Guardians by claiming without basis in fact or law that they are "representing these interests" for purposes of extracting settlements from Defendants, it is beyond cavil that the governmental entities: (1) do not owe the duties of care of a Legal Guardian, nor (2) will they never assume such awesome duties of care.** This Court recognized such in its Mandamus Response Letter to the 6th Circuit, stating that "the city and county Plaintiffs do not seek recovery based on injuries to individual residents," and that even if successful, the relief sought would only "collaterally benefit their residents[,]" which include the Legal Guardians of the NAS Plaintiffs. (Case 19-3827, "In re: State of Ohio Originating Case No. 1:17-md-02804, et al.," Doc. 23 (10/01/2109).

3. Like tens of thousands of legal guardians of infants and children across the United States, Roman and Jacqueline Ramirez, Melissa Barnwell, and Jennifer Artz have the direct, non-collateral, and non delegable duties to care for NAS Children (Child R.R., Child C.G., and Child I.A.A, respectively) who were born addicted to opioids.[3] NAS is a clinical diagnosis, and

[3] By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 mgs of hydrocodone every 4 hours for 1 month. Keyes KM, et al. *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, Am J Public Health. 2014 Feb; 104(2):52-9. Similarly, the number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population. Califf RM, et al. *A Proactive Response to Prescription Opioid Abuse*, N Engl J Med.

"a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[4] Prenatal exposure to opioids necessarily results in adverse medical and developmental impacts to the NAS Children with which their Legal Guardians must contend and care. In addition to the illegal and criminally over-supplied secondary, diversionary market of pharmaceutical opioids that flooded the State of California and insured the nefarious and planned addiction of its citizens, the birth mothers of the NAS Children were also medically prescribed Defendants' opioids.

4. At all relevant times, Defendants manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of the prescription opioid drugs. The net result of this behavior was to flood the market with highly addictive, dangerous opioids, whether through the primary prescription market (including to the birth mothers of the NAS children) and the illegally oversupplied secondary (or diversionary) market. At all times, Defendants have manufactured, distributed, and sold prescription opioids in California without fulfilling their legal duty to prevent diversion and report suspicious orders. But for the dereliction of this legal duty, the robust secondary, diversionary market for opioids could not have existed.

II. PARTIES

A. Plaintiffs and the Putative Class

5. Plaintiffs Roman and Jacqueline Ramirez are residents of California. They are the

2016 Apr 14; 374(15):1480-5.

[4] Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome,* 134(2) Pediatrics 547, 547-48 (2014), *available at* http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.

birth parents and legal guardians of Child R.R., who was born with NAS.

6. Plaintiff Melissa Barnwell is a resident of California. She is the birth mother and legal guardian of Child C.G., who was born with NAS.

7. Plaintiff Jennifer Artz is a resident of California. She is the birth mother and legal guardian of Child I.A.A., who was born with NAS.

8. The Putative Class is defined as:

> Legal Guardians[5] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[6] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[7]
>
> Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are Legal Guardianships where a governmental agency, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child under.[8]

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[5] The term "Legal Guardian" is defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

"Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[6] The term "NAS" is defined to include additional, but medically-symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids. Additional specifics on these readily identifiable and ascertainable terms will be provided in Plaintiffs' Motion for Class Certification.

[7] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

[8] There are only two causes of NAS: (1) *in utero* exposure to opioids *via* the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for

Strictly in the alternative, and only if the Court finds that additional refinement of the class definition is necessary, Plaintiffs propose the following additional subclass definitions:[9]

a. Legal Guardians[10] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Cephalon Defendants";[11]

b. Legal Guardians[12] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Endo Defendants";[13]

c. Legal Guardians[14] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one

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dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

[9] The same definitions and exclusions found in the General Class Definition, *supra*, shall apply to these alternative subclasses.

[10] The term "Legal Guardian" is defined at fn. 5, *supra*.

[11] Defined in the "Manufacturer Defendants" section, *infra*.

[12] The term "Legal Guardian" is defined at fn. 5, *supra*.

[13] Defined in the "Manufacturer Defendants" section, *infra*.

[14] The term "Legal Guardian" is defined at fn. 5, *supra*.

or more of the "Mallinckrodt Defendants";[15]

d. Legal Guardians[16] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Actavis Defendants";[17]

e. Legal Guardians[18] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Janssen Defendants";[19]

f. Legal Guardians[20] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more Defendant or Purdue entity.[21]

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[15] Defined in the "Manufacturer Defendants" section, *infra*.

[16] The term "Legal Guardian" is defined at fn. 5, *supra*.

[17] Defined in the "Manufacturer Defendants" section, *infra*.

[18] The term "Legal Guardian" is defined at fn. 5, *supra*.

[19] Defined in the "Manufacturer Defendants" section, *infra*.

[20] The term "Legal Guardian" is defined at fn. 5, *supra*.

[21] Defined in the "Non-Defendant, Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

g. Legal Guardians[22] of United States residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the ten months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

h. Legal Guardians[23] of California residents born after March 16, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[24]

9. Legal Guardians have the absolute duty to protect and care for the welfare of the NAS Children in their care. An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian's unlimited, and non-delegable duty of care owed to the child, as well as the absolute dominion of the Legal Guardian over the child.

10. The Legal Guardians have been directly and foreseeably damaged and such damage will continue to occur in the future as they must continue to carry the substantial burdens and obligations of care to the NAS Children, as neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of the NAS Children's adolescent development. And, these needs absolutely exist regardless of the dosage any one child received

[22] The term "Legal Guardian" is defined at fn. 6, *supra.*

[23] *Id.*

[24] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

neonatally or if they were pharmacologically weaned from these horrific substances. These needs relate primarily to the well-known adverse effect of opioids on behavioral and regulatory development in exposed children. *Every single child diagnosed with opioid-related NAS must have robust medical testing, monitoring, intervention, provision of Legal Guardian training and information, and medical referral in order that the Legal Guardians may discharge their duties to maximize the NAS Childrens' welfare and outcomes as adults. Additionally, a court-ordered and supervised Science Panel must be convened to conduct epidemiological studies of the NAS Children, with Defendants required to address medical and developmental issues of the NAS Children as they develop during program administration.* To be clear, the Legal Guardians have direct and entirely foreseeable injuries-in-fact arising from their non-delegable duties of care owed to and dominion over NAS children who have both present symptoms and a substantially increased risk of additional injury, disease, and disorder. Plaintiff Legal Guardians and the Putative Class Members have injuries fairly traceable to each Defendant whose acts and/or omissions released a veritable torrent of highly-addictive and destructive opiates and opioids into the United States and into the birth mothers' bodies where they targeted the helpless infants; and these injuries are likely to be redressed by favorable decisions from a Court or jury granting the relief requested. Indeed, without entry of the relief requested, Plaintiff Legal Guardians and the Putative Class Members cannot discharge their duties owed to the NAS Children. The Plaintiff Legal Guardians and Putative Class Members have suffered and continue to suffer these injuries.

B. Defendants

11. Defendants are Manufacturers, Distributors, and Pharmacies who have dealt in highly addictive and highly profitable prescription opioids. These FDA Class II Controlled

Substances cannot find their way to a California female of child-bearing years without first being issued pursuant to a medical prescription.[25] Defendants' profits are theoretically limited by the amount of medically necessary opioids that can be sold through the controlled channels.

12. However, in an effort to end-run these stringent controls so that they could maximize profits, the Manufacturers exercised their unique and dangerous ability to create both a new supply AND a new demand (via addiction) for the product. They accomplished this by acting in concert and in abrogation of their shared legal duty both to investigate and notify authorities of all suspected diversions of these highly dangerous substances.

13. Instead, beginning in the mid-1990s,[26] the Manufacturer, Distributor, and Pharmacy Defendants acted in concert to create two new markets for prescription opiates which had not otherwise existed: (i) *an incredibly high-volume primary market* in which medical prescriptions of opioids for *widespread and chronic* pain[27,28] were written for Americans, including women of child-bearing age and (ii) *a secondary market* into which those opioids were easily diverted from the flooded primary market. Once exposed, users of the opioids could easily transition into the secondary market, which was necessarily supplied from the primary market. Soon the demand from the secondary market was further driving prescriptions written

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[25] Class II controlled substances enter the market from a "closed system" of manufacturing and distribution.

[26] As found by the trial court at bench trial in *State of Oklahoma, et al. v. Purdue Pharma L.P.,* (Cause No. CJ-2017-816, Dist. Ct. of Cleveland Co., Oklahoma, Balkman, J.), prior to the mid-1990's "there was no opioid epidemic." (Judgment of August 26, 2019).

[27] Of equal importance was the Manufacturer Defendants' promotion of opiate treatment *without dosage ceilings*. Thus, not only were they able to expand the demand to treatment of widespread and chronic conditions beyond cancer, but, once prescribed, the dosage of any one patient could be limitless.

Upon information and belief, not only was this done to flood the market (and increase profits), but it also served the purpose of disguising the true facts of the secondary market from the DEA and law enforcement.

[28] Prescriptions of Purdue's *OxyContin* for non-cancer related pain surged from approximately *670,000 in 1997 to 6.2 million in only 5 years.* Van Zee A. *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-7.

for the primary market. However, in order to maintain the highly profitable and ever-growing secondary market, the Distributor and Pharmacy Defendants also had to conceal from the public and all governmental authorities the true facts relating to the supply of opiates flooding the primary market. Without the silence and concealment of the Distributor and Pharmacy Defendants, the dual market scheme (and record profits) could not have existed.

14. Defendants include the following entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships, and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

1. The Manufacturer Defendants

15. At all relevant times, the Manufacturer Defendants manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of the prescription opioid drugs. The net result of this behavior was to flood California with highly addictive, dangerous opioids, whether through the primary prescription market (including to California females of child-bearing age) and the secondary market. At all times, the Manufacturer Defendants have manufactured (including supplying processed active pharmaceutical ingredients "APIs" to the other Manufacturers) and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders. But for the dereliction of this legal duty, the robust secondary market for opioids could not have existed in California.

a. Actavis Entities

16. Defendant Allergan plc (f/k/a Actavis plc f/k/a Allergan, Inc.) is a public limited

company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. I n October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc in January 2013.

17. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly owned subsidiary of Defendant Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS

SCS, Inc. to distribute Kadian on its behalf.

18. Defendant Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application ("NDA") holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications ("ANDAs") for Norco.[29] Allergan Sales, LLC is the wholly owned subsidiary of Allergan plc.

19. Defendant Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc.

20. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic business to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/ka/ Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

21. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

[29] The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

22. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do business with the California Secretary of State as a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

23. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

24. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the NDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

25. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company

with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

26. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride.

27. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of Defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

28. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

29. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt

Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

30. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

31. Each of these Defendants and entities currently is or was previously owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, these Defendants and entities, and their U.S. Drug Enforcement Administration's ("DEA") registrant subsidiaries and affiliates which manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

32. Actavis manufactures or has manufactured Schedule II drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States.

b. Cephalon Entities

33. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation (collectively "Teva").

34. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

35. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, "Cephalon") work together to manufacture, promote, distribute, and sell both brand name and generic versions of Schedule II opioids including Fentanyl.

36. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in California, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

c. Janssen Entities

37. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

38. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products.

Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

39. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware, and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

40. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), n/k/a Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

41. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), n/k/a Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

42. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in California. Fentanyl is among the Schedule II drugs[30] that Janssen manufactures or manufactured.

43. Janssen made thousands of payments to physicians nationwide, including in California, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

[30] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

44. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

45. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is another J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

46. J&J also made payments to thousands of physicians nationwide, including in California, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

47. Information from the U.S. Department of Justice's Office of the Inspector General

shows that J&J made payments to prescribers, but does not indicate which drug was being promoted when J&J made these payments. At least one prescriber who previously served on Janssen's speakers' bureau received payment for speaking fees, meals, and travel from J&J. Upon information and belief, J&J would have similarly made payments to other participants in Janssen's speakers' bureau.

d. Endo Entities

48. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

49. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

50. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as "Par Pharmaceutical." Par Pharmaceutical was acquired by Endo International plc. in September 2015 and is an operating company of Endo International plc.

51. EHS, EPI, and Par Pharmaceutical and their DEA registrant subsidiaries and affiliates (collectively, "Endo") manufacture opioids sold nationally, and in California.

52. Endo made thousands of payments to physicians nationwide, including in California, ostensibly for activities including participating on speakers' bureaus, providing

consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

53. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of $1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

54. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.[31]

e. Mallinckrodt Entities

55. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri.

56. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and

[31] Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (accessed June 8, 2017).

affiliates (together "Mallinckrodt") manufacture, market, sell, and distribute pharmaceutical drugs throughout the United States, and in California. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

57. Defendant Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014 and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

58. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[32]

59. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its

[32] Mallinckrodt plc, Annual Report (Form 10-K.). 5 (N5 (Nov. 29, 2016), https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/0001567892-16-000098-index.htm.

facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

60. Among the drugs that Mallinckrodt manufactures or has manufactured are oxycodone hydrochloride and methadone hydrochloride.

61. Mallinckrodt made thousands of payments to physicians nationwide, including in California, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

f. Depomed

62. Defendant Depomed, Inc. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescription drugs in California and nationally. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement. This agreement closed on April 2, 2015.

g. Indivior

63. Defendant Indivior, Inc. ("Indivior") is a Delaware domestic corporation with its principal place of business in Richmond, Virginia. Indivior manufactures and distributes buprenorphine-based prescription drugs for treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivior, Inc. is a subsidiary of Indivior, PLC,

based in the United Kingdom. Indivior, Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Inc. Indivior, Inc. has manufactured and/or labeled Buprenorphine shipped to California.

2. Non-Defendant, Co-Conspirator Purdue Entities

64. Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

65. Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

66. The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

67. PPL, PPI, and PFC, and their DEA registrant subsidiaries and affiliates (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER throughout the U.S. and California. OxyContin is Purdue's best-selling opioid.

3. Defendant, Co-Conspirator Purdue Entities

68. Richard S. Sackler is a natural person residing in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990s, served as a member of the Board of Directors of Purdue and Purdue-related entities.

69. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut, and, upon information and belief, in New York State. He is a son of Raymond Sackler and has been a member of the Board of Directors of Purdue and Purdue-related entities since the 1990s.

70. Mortimer D.A. Sackler is a natural person residing in New York County, New

York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

71. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut, and, upon information and belief, in New York State. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

72. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

73. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

74. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

75. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and thus grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue related entities since 2012.

76. Rhodes Technologies ("Rhodes Tech") is a Delaware general partnership formed April 12, 2005, with its principal place of business in Coventry, Rhode Island. At all relevant times, Rhodes Tech or its predecessor has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical

preparations.

77. Rhodes Technologies Inc. ("Rhodes Tech Inc.") is a Delaware corporation formed January 28, 1999, with its principal place of business in Coventry, Rhode Island. Rhodes Tech Inc. is a general partner of Rhodes Tech. At all relevant times, Rhodes Tech Inc. has manufactured and supplied Purdue with oxycodone, the active pharmaceutical ingredient in OxyContin, for use in the manufacture of pharmaceutical preparations or has managed Rhodes Tech or its predecessor in doing so.

78. Rhodes Pharmaceuticals L.P. ("Rhodes Pharma") is a Delaware limited partnership formed November 9, 2007, with its principal place of business in Coventry, Rhode Island. At all relevant times, Rhodes Pharma has marketed a generic form of OxyContin, manufactured by Purdue Pharmaceuticals L.P. ("PPNC"), a Delaware limited partnership that is also a subsidiary of PPL; PPNC owns and operates a pharmaceutical manufacturing facility in Wilson, North Carolina.

79. Rhodes Pharmaceuticals Inc. ("Rhodes Pharma Inc.") is a New York corporation formed November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma. At all relevant times, Rhodes Pharma Inc. has marketed a generic form of OxyContin being manufactured by PPNC.

80. Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust") is a trust of which Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees.

81. The Raymond Sackler Trust is a direct or indirect beneficial owner of 50% of Purdue as well as the recipient of 50% of the profits of Rhodes Pharma Inc.

82. The P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business located in Totowa, New Jersey. It was, at all relevant times, engaged in the business of manufacturing OxyContin for Purdue. At all relevant times, PF Labs has been beneficially owned, managed, and controlled by the Sackler Family.

83. The foregoing Non-Defendant Co-Conspirators and Defendant Co-Conspirators are referred to collectively as the "Purdue Entities."

84. Collectively, Actavis, Cephalon, Janssen, Endo, Non-Defendant Co-conspirator Insys, Mallinckrodt, Depomed, Indivior, and the Defendant, Co-Conspirator Purdue Entities are referred to as the "Manufacturer Defendants."[33]

4. The Distributor Defendants

85. 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 Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is a substantial, contributing cause for the volume of prescription opioids plaguing all of the United States.

a. Cardinal Health, Inc.

86. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company" and is the fifteenth largest company by revenue in the U.S.,

[33] Together, Cephalon, Janssen and Endo are also sometimes referred to as "RICO Marketing Defendants."

with annual revenue of $121 billion in 2016. Through its various DEA registered subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal, including its subsidiaries and affiliated entities, has been licensed as a wholesale distributor of dangerous drugs in California and throughout the United States since 1990. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

b. AmerisourceBergen Drug Corporation

87. AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware. AmerisourceBergen has been licensed as a wholesale distributor of dangerous drugs in California and throughout the United States since 1988.

c. McKesson Corporation

88. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

89. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in California, Florida, Michigan, and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor." McKesson has been licensed as a wholesale distributor of dangerous drugs in California and throughout the United States at all times relevant to this Complaint.

d. Anda, Inc.

90. Defendant Anda, Inc. ("Anda"), through its various DEA registered subsidiaries and affiliated entities, including but not limited to Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is registered to do business with the California Secretary of State as a Florida corporation with its principal office located in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e., Defendant Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in California.

e. H. D. Smith

91. Defendant HD Smith Wholesale Drug Company ("H.D. Smith"), at all relevant times, operated as a licensed distributor wholesaler in California, licensed by the State of California Board of Pharmacy. H.D. Smith is a Delaware corporation with its principal place of business in Springfield, Illinois. H.D. Smith is a privately held independent pharmaceuticals distributor of wholesale brand, generic, and specialty pharmaceuticals. At all times relevant to

this Complaint, H.D. Smith distributed prescription opioids throughout the United States, including in California.

92. Cardinal, AmerisourceBergen, McKesson, Anda, H.D. Smith, and Prescription Supply are collectively referred to hereinafter as the "Distributor Defendants."

5. The Pharmacy Defendants

a. HBC Service Company

93. Defendant HBC Service Company, ("HBC") is an operating division of Giant Eagle, Inc. ("Giant Eagle"). HBC operated as a licensed distributor wholesaler in California, licensed by the State of California Board of Pharmacy. Giant Eagle is a Pennsylvania corporation with its principal place of business in Washington, Pennsylvania. At all times relevant to this Complaint, HBC distributed prescription opioids in California and throughout the United States.

b. The CVS Entities

94. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores in numerous States, including California, that sell prescription medicines, including opioids. At all times relevant to this Amended Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in California.

95. Defendant CVS Indiana L.L.C. is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Woonsocket, Rhode Island.

96. Defendants CVS Health Corporation, CVS Indiana L.L.C. and CVS Rx Services, Inc. are collectively referred to as "CVS." CVS, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in California.

c. The Rite Aid Entities

97. Defendant Rite Aid Corp. is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania.

98. Defendant Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a Maryland corporation with its principal office located in Lutherville Timonium, Maryland. Defendants Rite Aid Corporation and Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. are collectively referred to as "Rite Aid."

99. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite-Aid also operates retail stores, including in California, that sell prescription medicines, including opioids. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in California.

d. The Walgreens Entities

100. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois. Defendant Walgreen Eastern Co. is a New York corporation and a subsidiary of Walgreens Boots Alliance, Inc. that is engaged in the business of distributing pharmaceuticals, including prescription opioids. Defendant Walgreen Co. is an

Illinois corporation and a subsidiary of Walgreens Boots Alliance that operates retail drug stores. Defendants Walgreens Boots Alliance, Inc., Walgreen Eastern Co., and Walgreen Co. are collectively referred to as "Walgreens."

101. Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all relevant times, Walgreens has sold and continues to sell prescription opioids in close proximity to the hospitals, clinics, and other healthcare facilities in California and throughout the United States.

e. Wal-Mart

102. Defendant Wal-Mart Inc., f/k/a Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Wal-Mart, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in California.

f. Miami-Luken

103. Defendant Miami-Luken, Inc. ("Miami-Luken") is an Ohio corporation with its principal place of business located in Springboro, Ohio. During all relevant times, Miami-Luken has distributed substantial amounts of prescription opioids distributed prescription opioids throughout the United States, including in California.

g. Costco

104. Defendant Costco Wholesale Corporation ("Costco") is a Washington corporation with its principal place of business in Issaquah, Washington. During all relevant times, Costco has sold and continues to sell, in California and throughout the United States, prescription

opioids including the opioid drugs at issue in this lawsuit.

105. HBC, CVS, Rite Aid, Walgreens, Wal-Mart, Miami-Luken, and Costco are collectively referred to as the "Pharmacy Defendants."

III. JURISDICTION AND VENUE

113. This Court is vested with jurisdiction by virtue of the Class Action Fairness Act, 28 U.S.C. § 1332(d). Minimal diversity exists between named Plaintiffs of this putative class action, citizens of the State of California, and Defendants. The proposed class exceeds 100 persons. Further, the amount in controversy exceeds $5,000,000.00, as the value of the benefit to the Class will exceed $5,000,000.

114. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the State of California, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly within California by virtue of their manufacturing and marketing, distribution, dispensing, and sales of the prescription opioids made the subject of this Complaint, all of which constitute systematic and continuous contacts with the State of California. Furthermore, Defendants have all caused opioids to be directed into the nationwide diversionary market, such that it is entirely foreseeable that would arrive in California (and all other states) through the stream of commerce.

115. Venue is proper in this Court pursuant to this Court's Case Management Order One (Doc. 232) allowing direct filing into these MDL proceedings. Plaintiffs reserve the right to move for transfer at the conclusion of pretrial proceedings.

IV. FACTS

C. Opioids and NAS

116. Opioids are a class of drugs derived in whole or part from the poppy plant. These powerful euphoria-producing and pain-reducing medications include oxycodone, hydrocodone, and morphine. While the drugs have benefits, those must be balanced against the known risk of serious harm, including addiction, overdose, death, and injury to the fetus. Women who use opioids during their pregnancy are at exceptionally high risk for giving birth to a baby who suffers from NAS. Plaintiffs and the putative class members are Legal Guardians of NAS Children who were all *diagnosed at birth with opioid-related NAS.* By definition, there are no "exposure-only" or "asymptomatic" NAS Children for whom the Legal Guardians owe a duty of care.

117. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012.[34] Specifically, cases of NAS increased nationally from a rate of 1.2 per 1000 hospital births per year in 2000 to 5.8 per 1000, with a total of 21,732 infants diagnosed by 2012.[35] Best estimates are that a child with NAS is born every 25 minutes.[36] Per the California Office of Statewide Health Planning and Development, 1190 California infants were born suffering from NAS in 2014 alone, a 50% increase from 2004. That translates to approximately 1 in 400 births at present time.

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[34] Patrick SW, et al, *Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009-2012*, J Perinatol. 2015 Aug; 35(8):650-5.

[35] *Id.*; Patrick SW, et al, *Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009*, JAMA. 2012 May 9; 307(18):1934-40.

[36] *Id.*

118. NAS-diagnosed children "are at increased risk for neuropsychological function."[37] The challenges presented to them and their caregivers at birth are summarized as: "Do they catch up, remain at a disadvantage, or do they proceed to function even more poorly than their peers over time?"[38] Unfortunately, the new research borne about as a result of the Opioid Epidemic reveals that all NAS-diagnosed infants and children "will have lower mental abilities and more signs of attention deficit."[39]

119. Specifically, children diagnosed with NAS exhibit:

i. by age 1: diminished performance on the Psychomotor Development Index,[40] growth retardation,[41] poor fine motor skills,[42] short attention span,[43] intellectual performance[44];

ii. between ages 2-3: significantly lower cognitive abilities, including lower motor development, lower IQ, and poor language development;

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[37] Nygaard E., *Longitudinal cognitive development of children born to mothers with opioid and polysubstance use*, Pediatr Res. 2015 Sep; 78(3):330-5.

[38] *Id.*

[39] *Id.* And, this is regardless of whether the child is removed from its birth mother or is in the care of a different Legal Guardian. *Id.*

[40] Strauss ME, et al, *Behavioral concomitants of prenatal addiction to narcotics*, J. Pediatr. 1976 Nov; 89(5):842-6; Wilson GS, et al, *Follow-up of methadone-treated women and their infants: Health, development, and social implications*, J. Pediatr. 1981 May; 98(5):716-22.

[41] Strauss ME, et al, *Behavioral concomitants of prenatal addiction to narcotics*, J. Pediatr. 1976 Nov; 89(5):842-6.

[42] Wilson GS, et al, *Follow-up of methadone-treated women and their infants: Health, development, and social implications*, J. Pediatr. 1981 May; 98(5):716-22, and Bunikowski R, et al, *Neurodevelopmental outcome after prenatal exposure to opiates*, Eur J Pediatr. 1998 Sep; 157(9):724-30.

[43] Wilson GS, et al, *Follow-up of methadone-treated women and their infants: Health, development, and social implications,* J. Pediatr. 1981 May; 98(5):716-22.

[44] Bunikowski R, et al, *Neurodevelopmental outcome after prenatal exposure to opiates*, Eur J Pediatr. 1998 Sep; 157(9):724-30.

iii. between ages 3-6: significant detrimental impact on self-regulation, including aggressiveness, hyperactivity, lack of concentration, lack of social inhibition,[45] lower IQs (8-15 point difference), poor language development, and behavioral and school problems; and

iv. 8.5 years and older: significantly greater difference in cognitive scores than at previous ages, especially in girls.[46]

120. The Legal Guardians must care for NAS Children who suffer from and face an increased risk of lifelong mental illness, mental impairment, loss of mental capacity, and addiction. The Legal Guardian's must discharge their duties to protect the NAS Children's welfare, including their entire health, their use of their bodies and minds, and their developmental outcomes, including their ability to avoid opiate addiction, learn, work normally, enjoy relationships with others, and function as a valuable citizen, child, parent, income-earner, and person enjoying life.

121. The NAS Children sustained an exposure to opioids greater than that expected by members of the general population. Indeed, they were all born addicted.

NAS is a generalized multi-system disorder that produces a constellation of symptoms in neonates and results from abrupt discontinuation of opioids consumed by the mother during pregnancy at the infant's birth.

122. Opioids represent a single class of exposures since they all cause their effects at

[45] Oloffson M, et al., *Investigation of 89 children born by drug-dependent mothers. II. Follow-up 1-10 years after birth,* Acta Paediatr Scand. 1983; 72:407-10; The researchers in this study came to the heartbreaking conclusion that "[T]here is an urgent need for health personnel to reexamine their roles in helping these children, who will otherwise develop into a new generation of social losers." *Id.*

[46] Nygaard E, *Longitudinal cognitive development of children born to mothers with opioid and polysubstance use*, Pediatric Res. 2015 Sep; 78(3):330-5.

the same receptors which are those that mediate the effects of endogenous opiates.

123. Opioids represent a single class of chemical substances since their molecular structures are very essentially the same.

124. Opioids have typical pharmacological effects which are common to the group: effects on the brain, nervous system and gastrointestinal system. The opioid compounds all act at the same biological receptors and mimic natural peptides which have powerful and wide-ranging activity in living systems. Thus, they can be considered a class of chemical drugs both in terms of their pharmacological dosage activity relationships and also their overall chemical structure. They produce common effects, bind to common receptors, and also have similar chemical structures. They all produce addiction and dependence and cause withdrawal symptoms on removal. Their activity as modulators of neurological signaling make them especially dangerous in adults due to rebound effects but are also known to have significant effects on fetal development since they alter the cellular signaling environment.

125. The effect of all opioids is produced through a single common pathway – the opioid receptor. The opioid receptor system is ancient and highly conserved, being present by the time that jawed vertebrates first appeared at least 450 million years ago. Clearly, differences between opioid products and potency exist but their mode of action via the opioid receptor system remains identical.

126. Fetal development relies on the balanced control of cell proliferation and cell death through apoptosis (otherwise termed "programmed cell death").

127. It is scientifically demonstrated that exposure to opiates will increase the rate of apoptotic cell death in developing biological systems. This represents a common mode of action

which leads to the large plethora of adverse conditions associated with fetal opioid exposure, including – sub-optimal brain maturation, a form of functional teratogenesis associated with reduced cognitive function.

128. The ongoing and robust medical monitoring and treatment of opioid-related NAS-diagnosed children is medically necessary. And, further, this is a rapidly transforming field, as multiple members of child care, psychological, and medical personnel are coming together to determine the best protocols for improving the outcomes after a diagnosis. *Hence, the absolute necessity that this Court convene a Science Panel*. For example, a recent (albeit extremely limited in size and geography), pilot program operated by the State of Kentucky's State Health Service Program offers a view of necessary treatment components after hospital discharge: (1) education of caregivers for techniques to relieve infant distress, including infant massage, calming techniques, and other coping skills; (2) education of caregivers about NAS and the associated symptoms; (3) frequent follow-up of the infant for growth and weight gain; (4) monthly development evaluations during infancy and toddler years to determine whether additional interventions and treatment are necessary.[47]

129. Researchers at Ohio's Case Western Reserve University School of Medicine recommend similar protocols, noting: "Intervention services for this population need to extend beyond infancy and the toddler years, since problems in cognitive, language, and behavioral functioning may persist throughout childhood."[48] In addition to the caregiver (i.e., Legal

[47] Kentucky Cabinet for Health and Family Services, Nutrition Branch, Newsletter (Fall/Winter 2016 supp.), http://chfs.ky.gov/NR/rdonlyres/FFF6F900-9982-412F-BEA5-E82542E6DF0F/0/NutritionBranch Newsletter24Supplement.pdf (page no longer hosted on site).

[48] Minnes S., et al, *Prenatal Tobacco, Marijuana, Stimulant, and Opiate Exposure: Outcomes and Practice Implications,* Addict Sci Clin Pract. 2011 Jul; 6(1):57-70.

Guardian) training, they recommend the following: specific individual therapy for speech and language, occupational, and behavioral; early intervention/enrichment; and ongoing cognitive and behavioral assessment.[49] Regarding the necessary time-span of necessary assessment and intervention, the researchers write: "Developmental and assessment and intervention should continue during the preschool and school years, when children may benefit from enriched educational programs and screening for special education services. Problems can compound when cognitive demands increase during the early school years. Other critical transition periods occur in the first, fourth, and sixth or seventh grades, when subtle learning of behavior problems may become more evident and lead to functional impairment."[50] Of equal concern is that these deficits may themselves lead to the creation of another generation of addicts. Dr. Barry Lester writes in the *Journal of Addiction Disorders*: "Prenatal drug exposure … may lead to lasting behavioral dysregulation that increases vulnerability to substance use, resulting in early onset substance use in adolescents."[51] ***Due to the substantially increased risk of disease and addiction, failure to provide the Legal Guardians with the requested medical monitoring and intervention will necessarily lead to "In re National Prescription Opiate Litigation 2.0" as the NAS Children become the next generation of American opioid addicts.***

D. Controlled Substances and the "Closed System" of Manufacturing and Distribution

130. Prescription opioids, which are the sole cause of *in utero* NAS, have an extremely high potential for addiction and injury and are categorized by the United States government as

[49] *Id.*

[50] *Id.*

[51] Lester B., et al, *Children of Addicted* Women, J Addict. Dis. 2010; 29(2): 259-276. Doi.10.1080/ 10550881003684921.

"Schedule II Controlled Substances."[52] The definition of such is described by the United States Department of Justice's Drug Enforcement Agency (DEA), Diversion Control Division on its public website:

ScheduleII/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse with may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.[53]

131. Because of their known high potential for injury and addiction, these prescription drugs may only be manufactured and distributed within a "closed" system in which gatekeeper Manufacturer and Distributor Defendants are charged with the duty to prevent diversion of drugs out of the legitimate channels and into the illicit market. The Manufacturer Defendants' and the Distributor Defendants' complete and abject failure to maintain the closed system was the direct and proximate cause of the harm described in this Complaint.

132. The Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of 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

[52] S*ee* Controlled Substances Act, 21 U.S.C. § 812, as supplemented by Title 21, C.F.R. § 1308.

[53] *See* https://www.deadiversion.usdoj.gov/schedules/ (last visited Oct. 17, 2018).

supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 USCA § 823(a)(1) (emphasis added). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

> 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).

133. Similarly, and of equal importance, each Distributor Defendant was also required to register with the DEA, pursuant to the Federal Controlled Substance Act. *See* 21 U.S.C. § 823(b) and (e); 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. 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). As with the Manufacturer Defendants, federal regulations 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).[54]

134. In addition to reporting all suspicious orders, Distributor Defendants must also *affirmatively stop shipment on any order which is flagged as suspicious* and only ship orders which 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.[55] Regardless, all flagged orders must be reported. *Id.*

135. Per the DEA in a letter to the Distributor Defendants in 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."[56] Additionally, "*even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.*"[57,58]

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[54] 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 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. 21 C.F.R. § 1301.74(b).

[55] *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).

[56] Letter from Joseph T. Rannazzisi, Dep. Asst. Adm'r, Office of Diversion Control, Drug Enforcement Admin, U.S. Dep. of Justice to Cardinal Health (Sept. 27, 2006). ("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.").

[57] *Id.*

[58] The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007, which implored them to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant

E. In Intentional and Wanton Disregard of Their Duties under the "Closed System," the Manufacturer Defendants Create Two New Markets for Prescription Opioids (and the Distributor and Pharmacy Defendants Support Them Every Step of the Way)

136. Defendants' profits were theoretically limited by the amount of medically necessary opioids that could be sold through controlled channels. *The stark reality Defendants faced was this: they could only sell so many prescription opioids to dying cancer patients.* "The logic was simple: While the number of cancer patients was not likely to increase drastically from one year to the next, if a company *could expand the indications for use of a particular drug*, then it could boost sales exponentially without any real change in the country's health demography."[59] And, without a new and robust primary market, there would be no supply for the secondary "spill-over" diversionary market that they intended.[60]

137. Once exposed, users of the opioids could easily transition into the secondary market, which was necessarily supplied from the primary market, and which Defendants were

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suspicious orders of controlled substances." The letter further explained:

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.*

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 (emphasis added).

[59] Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, Pacific Standard, March 4, 2015, found at: http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company (last visited Oct. 17, 2018).

[60] The axiomatic nature of this relationship is recognized in Dr. Art Van Zee's examination of the OxyContin market: "The high availability of OxyContin correlated with the increased abuse, diversion, and addiction, and by 2004 OxyContin had become a leading drug of abuse in the United States." *See The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am. J. Pub. Health. 2009 February; 99(2): 221-227.

legally charged with ensuring there was no supply for. Soon, the demand from the secondary market was further driving prescriptions written for the primary market.[61]

F. A New Primary Market of Prescriptions Opiates for Chronic, Widespread, Pain and Without Dose Limits

138. Thus began the Manufacturer Defendants' quest to open a new primary market for opioid prescriptions: treatment of (a) chronic, (b) widespread pain (c) without dose limits. And, their "ace in the hole" was this: not only could they convince physicians to write prescriptions into this new market, they could ensure through the insidious mechanism of addiction that patients, including California women of child-bearing age, would have to keep coming back for more.

139. With the insidious power to create both unlimited supply AND unlimited demand for these highly addictive substances, the Manufacturer Defendants set out to create the new primary market. Each of the elements of the new primary market were selected to maximize sales of the highly addictive drugs.

140. First, was the transition from a limited pool of disease and injury (cancer, disorders requiring surgery, etc.) to *widespread, common diseases*, such as arthritis, back pain, and joint pain. Thus, the universe of targeted patient conditions could be vastly expanded. Next was the successful promotion of highly addictive opioids for *chronic*, i.e., long-term conditions. Thus, step two was equally critical: ensuring that the newly targeted patient conditions would not result in one-time sales. And, finally, to ensure even further sales growth, the Manufacturer

[61] However, in order to maintain the highly profitable and ever-growing secondary market, the Distributor Defendants also had to conceal the true facts relating to the supply of opiates flooding the primary market. Without the silence and concealment of the Distributor and Pharmacy Defendants, the dual market scheme (and record profits) could not have existed.

Defendants promoted the notion that there were *no dose limits* and, indeed, that *patients who appeared to be addicted were actually patients who should be given even more and higher dosages for opioids.*[62]

141. In order to maximize profits, the Manufacturer Defendants collectively had to convince physicians to expand treatment of their patients to include chronic and "non-malignant", i.e., non-cancer, pain.[63] And, they had to do so despite the fact that the benefits of opioids are minimal, and the extreme risks are maximal. Prospective, randomized, controlled trials lasting at least 4 weeks that evaluated the use of opioids for chronic non-cancer-related pain showed only a small to modest improvement in pain relief and no consistent improvement in physical functioning.[64] The maximal adverse risks, however, are a witches' brew and include a "high incidence of opioid abuse behaviors" and "addiction."[65]

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[62] OxyContin was approved in 1996 for an 80mg dose. Four years later, Purdue sought and obtained FDA approval for a 160 mg dose. Mike Mariani writes: "These high-milligram pills were probably one of the biggest reasons that OxyContin became such a popular street drug… The euphoric effects and potential for abuse were comparable to heroin." Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, Pacific Standard, March 4, 2015, found at: http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company (last visited Oct. 17, 2018).

[63] The science and consensus for the use of opioids in the treatment of acute pain or pain associated with cancer is "robust," due to the obvious nature of the risk/benefit analysis. Acute usage does not result in addiction. And, in cancer patients, the benefits from pain abatement greatly outweigh the known risks.

[64] Van Zee A., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-27 (summarizing the results of thirteen medical studies cited at fns. 24-38).

[65] *Id.*

142. The market innovator that "inspired" all other Manufacturer Defendants to follow was Purdue,[66] the maker of OxyContin. And, it was not pharmacological innovation in which it led, but marketing innovation.

> i. Arthur Sackler [the founder of Purdue, along with his two younger brothers Mortimer and Raymond] thriv[ed] … in the fledgling field of pharmaceutical advertising. It was here that he would leave his greatest mark. As a member of … a small New York-based advertising firm, Sackler expanded the possibilities of medical advertising by promoting products in medical journals and experimenting with televisions and radio marketing. Perhaps his greatest achievement, detailed in his biography in the Medical Advertising Hall of Fame, was finding enough different uses for Valium to turn it into the first drug to hit $100 million in revenue.
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> ii. (…)
>
> iii. Sackler was also among the first medical advertisers to foster relationships with doctors in the hopes of earning extra points for his company's drugs, according to a 2011 expose in *Fortune*. Such backscratching in the hopes of reciprocity is now the model for the whole drug marketing industry.
>
> iv. Starting in 1996, Purdue Pharma expanded its sales department to coincide with the debut of its new drug… Purdue increased its number of sales representatives from 318 in 1996 to 371 in 2000. By 2001, when OxyContin was hitting its stride, these sales reps received annual bonuses averaging over $70,000, with some bonuses nearing a quarter of a million dollars. In that year, Purdue Pharma spent $200 million marketing its golden goose.
>
> v. Boots on the ground was not the only stratagem employed by Purdue to increase sales for OxyContin. Long before the rise of big data, Purdue was compiling profiles of doctors and their prescribing habits into databases.
>
> vi. (…)
>
> vii. Between physician databases, incentive-happy sales reps, and an aggressive blitz package of promotional ephemera, Purdue's multifaceted

[66] Bankruptcy protection has been sought by former Defendants to this action Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick Company. While Plaintiffs are pursuing creditor relief in that proceeding against those parties, a discussion of the Purdue entities is helpful to understanding both the concert of action and unified scheme waged by the entire industry, especially given that Purdue was a "leader" and "early adopter" of so many nefarious activities that were replicated by Defendants.

> marketing campaign pushed OxyContin out of the niche offices of oncologists and pain specialists and into the primary care bazaar, where prescriptions for the drug could be handed out to millions upon millions of Americans. The most scathing irony is that what allowed OxyContin to reach so many households and communities was the claim that it wasn't dangerous.[67]

143. Concurrent with the innovative marketing techniques of Purdue, were the efforts of the entire industry to secure a highly potent and stable supply of the active pharmaceutical ingredient (API) in opioids. Upon information and belief, Janssen actively conspired with other Manufacturer and Distributor Defendants to significantly increase the supply of powerful opioid drugs in the market, thereby exacerbating the opioid epidemic.[68] *See* In a quest to dominate the growing opioid market, J&J grew poppies in Tasmania, Australia, and imported and sold APIs derived from these poppies necessary for the manufacture of opioid drugs to other Manufacturer Defendants.[69]

144. Beginning in 1990 and continuing until at least 2016, wholly owned two subsidiaries, Noramco and Tasmanian Alkaloids Limited ("Tasmanian Alkaloids"). supplied opioid manufacturers with raw ingredients necessary to meet the growing demand for powerful opioid drugs as the opioid epidemic increased in severity.[70]

145. As the opioid crisis worsened, Tasmanian Alkaloids engaged in the cultivation, breeding, and processing of opium poppy plants into compounds necessary for the production of opioid APIs in Tasmania. These raw ingredients were then imported to the United States by

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[67] Mike Mariani, "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

[68] Findings of Fact Nos. 6 through 15, *State of Oklahoma, et al. v. Purdue Pharma L.P.,* (Cause No. CJ-2017-816, Dist. Ct. of Cleveland Co., Oklahoma, Balkman, J.) (Judgment after Non-Jury Trial of August 26, 2019).

[69] *Id.* at Findings of Fact Nos. 9 through 11.

[70] *Id.* at Finding of Fact No. 11.

Noramco.[71]

146. Noramco imported the raw ingredients produced by Tasmanian Alkaloids to the United States, processed the raw ingredients into opioid APIs, and sold these APIs to opioid manufacturers.[72]

147. Johnson & Johnson's activities in the production of raw opioid APIs included the development of the Norman Poppy, a strain of the plant containing high levels of the compound *Thebaine*, which is a critical ingredient for the production of oxycodone, oxymorphone, nalbuphine, naloxone, naltrexone, and buprenorphine.[73] The high-Thebaine Norman Poppy was patented by Tasmanian Alkaloids in 1994 and was a transformational technology that enabled the growth of pharmaceutical opioids.[74]

148. Noramco sold opioid APIs to various other opioid manufacturers, including Teva and "all seven of the top US generic companies," through "long-term agreements. By 2016, when J&J transferred Noramco and Tasmanian Alkaloids to a private investment firm, Noramco was one of the nation's top suppliers of opioid APIs. In a 2015 presentation to potential buyers of the company, Noramco was described to potential buyers as the "#1 supplier of Narcotic APIs in the United States, the world's largest market." The same presentation lists Net Trade Sales for several of Noramco's APIs, including $94 million in Oxycodone and $52 million in hydrocodone in 2014 alone.

149. J&J's supply of raw opioid ingredients enabled the Manufacturer Defendants to

[71] *Id.* at Findings of Fact Nos. 9 through 11.

[72] *Id.* at Finding of Fact No. 12.

[73] Finding of Fact Nos. 14, *State of Oklahoma, et al. v. Purdue Pharma L.P.,* (Cause No. CJ-2017-816, Dist. Ct. of Cleveland Co., Oklahoma, Balkman, J.) (Judgment after Non-Jury Trial of August 26, 2019).

[74] *Id.* at Finding of Fact No. 11.

meet the growing demand for powerful and dangerous opioid drugs formed in the wake of the pharmaceutical industry's misleading mass marketing of opioid drugs to the medical community and directly to the public. By enabling the large-scale manufacture of these drugs, J conspired to create an opioid epidemic, addicting millions of Americans to opioid drugs and significantly increasing instances of NAS in the U.S.

G. The Secondary Market

150. As discussed at *supra*, "Controlled Substances and the 'Closed System' of Manufacturing and distribution," the Manufacturer, Distributor, and Pharmacy Defendants had an absolute and non-delegable duty to insure that a supply of controlled substances for a secondary market did not exist. To be clear, the diversion and misuse of controlled substances is a known high-risk factor with significant negative consequences for families, communities, and even entire states. When a manufacturer, distributor, or pharmacy that wants to deal in controlled substances registers with the DEA, they must take on a duty to prevent the known negative health effects of their addictive products.

151. In the case of prescription opiates, not only did Defendants wholly fail in that duty, but they intentionally endeavored to flood the primary market with such an excess of drugs that they either knew, or consciously and willfully disregarded the fact that this would result in misuse and diversion into a secondary market. **Indeed, Defendants flooded the United States with so many prescription opiates that our entire adult population could be dosed 6 times a day for a month.**[75]

[75] By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 mgs of hydrocodone every 4 hours for 1 month. Keyes KM, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, Am J Public Health. 2014 Feb; 104(2):52-9.

152. And, as will be shown, flooding an entire country with this many highly addictive opiates did not occur by accident. Instead, it occurred as the result of a highly coordinated, expensive, misleading, illegal, and callous manipulation of both the sales and distribution schemes for controlled substances within the United States.

H. The Multi-Faceted Marketing and Promotion Schemes

153. Each Manufacturer Defendant has conducted, and has continued to conduct, a scheme of marketing and promotion designed to persuade doctors that opioids can and should be used for chronic pain, thereby 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. That these efforts were widely successful is evidenced by sales increases. Nationwide, from 1996 to 2002, there was a 226%, 73%, and 402% increase in fentanyl, morphine, and oxycodone prescribing respectively.[76] And, during that same period, misuse burgeoned. Hospital emergency department mentions for fentanyl, morphine, and oxycodone increased 641%, 113%, and 346%, respectively.[77]

154. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely denied or trivialized the risks of opioids while overstating the benefits of using them for chronic pain. These false and misleading promotional claims: (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 the signs of addiction should be treated with more opioids;

[76] Gilson AM, et al., *A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002*. J Pain Symptom Manage. 2004 Aug; 28(2):176-88.

[77] *Id.*

(3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal could be easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

155. None of these marketing efforts disclosed, or even mentioned, the significant adverse health effects of opioids to unborn children. (This information was also available to the Distributor and Pharmacy Defendants). Indeed, Defendants purposely misrepresented that there were no teratogenic effects associated with the use of opioids to increase their profits. Defendants also purposely misrepresented the potential of opioids to result in the negative health impacts from *in utero exposure* as described in this complaint.

156. The Manufacturer Defendants 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.

157. The Manufacturer Defendants disseminated these common messages to reverse the previously held medical understanding of risks and benefits of opioid use.[78] 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, and through unbranded marketing and industry-funded front groups.

158. Purdue's efforts to promote OxyContin are illustrative of the multi-faceted

[78] The "positive" physical effects of opioids are two-fold: euphoria and pain-relief. (However, medical doctors may not prescribe, nor will insurance pay, solely so that a patient may feel euphoric as that is not a medical need.) Thus, the valid medical basis for prescribing opiates is to allay pain. While temporary relief of pain is a positive, this result must absolutely be weighed against the potential for negative outcomes. In the case of opioids the known potential negative outcome is iatrogenic addiction.

promotional scheme waged by the entire industry:

i. From 1996 to 2001, Purdue conducted more than **40 national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expense paid symposia, where they were recruited for Purdue's national speaker bureau.** It is well-documented that this type of pharmaceutical company symposium influences physicians' prescribing patterns, even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.

ii. One of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing. **Drug companies compile prescriber profiles on individual physicians—detailing the prescribing patterns of physicians nationwide—in an effort to influence doctors' prescribing habits. Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.** One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country.[79] The resulting database would help identify physicians with large numbers of chronic-pain patients. Unfortunately, the same database would also identify which physicians were simply the most frequent prescribers of opioids and, in some cases, the least discriminate prescribers.

iii. A lucrative bonus system encouraged sales representatives to increase sales of OxyContin in their territories, resulting in a large number of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them… Purdue paid $40 million in sales incentive bonuses to its sales representatives that year.

iv. From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671 **and [doubled] its total physician call list … to approximately 70,500 to 94,00 physicians. Through the sales representatives, Purdue used a patient starter coupon that provided**

[79] OxyContin's first full year on the market was 1996. However, Purdue had an earlier history of manufacturing opiates that were abused and diverted. Its product MS Contin (morphine based) had been profitable, but by the late 1980s, its patent was running out. OxyContin was developed, in the words of its VP for Clinical Research, to "cure the vulnerability of the … generic threat [to MS Contin] and that is why it is so crucial that we devote our fullest efforts to a successful launch of OxyContin." Harriet Ryan et al., *You Want a Description of Hell? OxyContin's 12-Hour Problem,* Los Angeles Times, May 5, 2016, found at: http://www.latimes.com/projects/ oxycontin-part1/ (last visited: Oct. 17, 2018).

> **patients with a free limited-time prescription for a 7-30 day supply.**[80] **By 2001, when the program was ended, approximately 34,000 had been redeemed nationally.**
>
> v. (…)
>
> vi. Purdue trained its sales representatives to carry the message that the risk of addiction was "less than one percent." The company cited … [two studies to support this premise]. Both of these studies, although shedding some light of the risk of addiction for acute pain, do not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. There are a number of studies [enough cites seven which looked at chronic usage], however, that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse.
>
> vii. From 1996 to July 2002, **Purdue funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants, providing a venue that had enormous influence on physicians prescribing throughout the county.** Particularly, with controlled drugs, the potential for blurring marketing and education carries a much higher public health risk than with uncontrolled drugs.[81]

I. Two Lies: Minimizing Risks and Maximizing Benefits

1. Minimizing Risks

159. 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 have been conclusively debunked by the FDA and CDC. These misrepresentations – which are 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 those at greatest risk for addiction could be identified and managed; (2) patients

[80] Yes, that's right. A free coupon for 30 days' worth of a highly addictive controlled substance.

[81] Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added).

who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned 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.

160. Opioid manufacturers, including Purdue and Defendant Endo, 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 and each continues to fail to correct its past misrepresentations.

161. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair written representations about the purportedly low risk of addiction include:

i. Purdue created literature and audiotapes for physicians and a "Partners Against Pain" Website in which it claimed over and over that the risk of addiction from OxyContin was extremely small.[82]

ii. 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.

[82] Van Zee A., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added), *citing* Irick, N., *Overcoming Barriers to Effective Pain Management* [audiotape]. Rochester, NY: Solutions Unlimited; March 2000; Carr, B., *The Impact of Chronic Pain—An Interdisciplinary Perspective*, Continuing Medical Education program. New York, NY: Power-Pak Communications; 2000; 925 Program 424-000-99-010-H01; Lipmann, A., *Use of Opioids in Chronic Noncancer Pain*. Continuing Medical Education program. New York, NY: Power-Pak Communications; April 2000:6; *Pain Management* [CD and slide instructional program for physicians]. Stamford, CT: Purdue Pharma; 2002; *Dispelling the Myths about Opioids* [brochure for physicians]. Stamford, CT: Purdue Pharma; 2002.

iii. Cephalon and Purdue sponsored the American Pain Foundation'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.[83]

iv. 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 misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

v. 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."

vi. 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."

vii. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

viii. 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."[84]

162. Consistent with the Manufacturer Defendants' published marketing materials,

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[83] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter "APF Treatment Options"], found at: https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Oct. 17, 2018).

[84] Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter "APF, Policymaker's Guide"], available at: http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last visited: Oct. 17, 2018).

upon information and belief, sales representatives for Purdue, Endo, Janssen, and Cephalon 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. Of these efforts, Dr. Art Van Zee writes: "Purdue trained its sales representatives to carry the message that the risk of addiction 'was less than one percent.'"

163. 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 alternative term for opioid addiction], [and] overdose . . .)."[85] 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."[86]

164. 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 announcement, 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." (Emphasis added.) According to the FDA, because of the "known serious risks" associated with long-term opioid use, including

[85] Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, Morbidity & Mortality WNly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (last visited Oct. 17, 2018).

[86] *Id.* at 2, 25.

"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.[87]

165. 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 meeting the clinical criteria for an opioid use disorder."[88] 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 California.

166. 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.,

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[87] 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), available at: http://paindr.com/wp-content/uploads/2013/09/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf (last visited Oct. 17, 2018); 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 (no longer available on website).

[88] Assurance of Discontinuance, In re Endo Health Solutions Inc. and Endo Pharm. Inc. (Assurance No. 15-228), at 13 (March 1, 2016), available at: https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last visited Oct. 17, 2018).

pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

167. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." A paid industry "Key Opinion Leader" (KOL)[89] Dr. Russell Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

i. 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.[90] The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.[91]

ii. 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 is under-treated… Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

iii. 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.

iv. 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

[89] As physicians must choose from a myriad of drug options to treat their patients, they often rely on fellow physicians perceived as having superior knowledge in the area. These "Key Opinion Leaders" are ferreted out through a data-driven profiling system, and then targeted by pharmaceutical companies to promote certain drugs. The KOLs can both help spread information about the drug and expand markets. Indeed, the cultivation and management of KOLs is seen by the pharmaceutical industry wholly as a "business function."

[90] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007) at 62.

[91] *See* Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2d ed. 2012).

has not been effectively treated."

v. 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 role play, 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.

168. In the 2016 CDC Guideline, the CDC rejected the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

169. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practices 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 lacked 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. Examples include:

i. 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.

ii. 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."

iii. 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.

170. 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."[92]

171. 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 opioid dependence can easily be addressed 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. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example:

i. 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.

ii. 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.[93]

172. A fifth category of inaccurate statements the Manufacturer Defendants made to

[92] *Id.* at 11.

[93] APF, *Policymaker's Guide, supra* note 59, at 32.

sell more drugs is that opioid dosages could be increased 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 build up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

i. 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.

ii. 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.[94] This publication is still available online.

iii. Endo sponsored a website, "Pain Knowledge," 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."

iv. 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."[95]

v. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

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[94] *Id.* at 12.

[95] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

vi. 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.

vii. 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.[96]

viii. 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.

ix. 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.[97]

x. 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.[98]

173. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline 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."[99] More specifically, the CDC explains that "there is now an established body of scientific evidence

[96] APF, *Policymaker's Guide, supra* note 59, at 32.

[97] The College on Problems of Drug Dependence, About the College, http://cpdd.org (last visited Aug. 21, 2017).

[98] 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.

[99] 2016 CDC Guideline, *supra* note 60, at 22–23.

showing that overdose risk is increased at higher opioid dosages."[100] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression,[101] and death at higher dosages."[102] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[103]

174. Defendants' inaccurate marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions in the medical community that these opioids can cure addiction and abuse. 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 that it was designed 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."[104] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[105] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via

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[100] *Id.* at 23-24.

[101] Indeed, Purdue Pharma had withdrawn its hydromorphone-based opiate "Palladone" after only six months on the market in 2005, because patients kept dying when they stopped breathing or else went into comas.

[102] 2016 CDC Guideline, *supra* note 60, at 21.

[103] *Id.* at 16.

[104] 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, available at: https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2013/May/FDA_CDER_Final_RespEndo_Pharmaceuticals_Inc_Petition_Denial.pdf (last visited Oct. 17, 2018).

[105] *Id.* at 6.

injection."[106] 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 Opana ER be removed from the market.

2. Maximizing the Benefits, Especially as Compared to other Non-Addictive Alternatives

175. To convince doctors that opioids should be used 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.[107] 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.

176. Examples of the Manufacturer Defendants' false claims are:

i. 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.

ii. Endo distributed advertisements that claimed that 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.

iii. Janssen sponsored and edited a patient education guide entitled Finding

[106] *Id.* at 6, n.21

[107] *Id.* at 5.

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.

iv. 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."

v. 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.

vi. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

vii. 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."[108] This publication is still available online.

viii. 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.

ix. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."[109] 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."

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[108] APF, Treatment Options, supra note 58 at 15, NIPC, Persistent Pain and the Older Patient (2007), available at: https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Oct. 17, 2018).

[109] *Id*. at 1.

x. 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 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."

xi. 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."[110] The Policymaker's Guide was originally published in 2011.

xii. 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.

177. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature. 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."[111] 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

[110] APF, Policymaker's Guide*, supra* note 59, at 29.

[111] 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), [hereinafter Letter from Thomas Abrams to Doug Boothe], available at: https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (last visited Oct. 17, 2018).

substantial evidence or substantial clinical experience."

178. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by 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.[112]

179. 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 less medicine is released. 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

[112] 2016 CDC Guideline, *supra* note 60, at 12.

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.

180. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hourdosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

181. 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.[113]

182. 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 or has been shown to be safe or effective for chronic pain. Indeed, the

[113] 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).

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 for any other conditions, such as migraines, post-operative pain, or pain due to injury.[114] 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."[115]

183. 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, appropriate, and for which it is not 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:

i. 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.

ii. 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.

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[114] *See* U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), (page no longer available at the FDA website).

[115] *Id.*

iii. 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.

184. 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.

185. 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.[116]

186. 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 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.

J. The Manufacturer Defendants Targeted Susceptible Prescribers and their Vulnerable Patient Populations

187. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers with vulnerable patient populations in the United States. For example, the Manufacturer Defendants focused their 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.

188. The Manufacturer Defendants also targeted prescribers for vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patient prescribers 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

[116] 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, available at: http://www.latimes.com/projects/la-me-oxycontin-part2/ (last visited Oct. 17, 2018).

fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.[117] 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.

K. The Manufacturer Defendants made False Statements and Concealed Material Facts

189. As alleged herein, the Manufacturer Defendants made and/or disseminated false 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.

1. Purdue

190. Certain of the Purdue Entities are non-defendant co-conspirators of the named Defendants and are now pursuing bankruptcy relief. Regardless, it is still important to understand how their actions affected the other Defendants, who then adopted these techniques and strategy, as well as concurrently working in concert and conspiracy with the Purdue Entities through group efforts. Purdue made and/or disseminated false statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

i. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;

[117] 2016 CDC Guideline, *supra* note 60, at 13.

ii. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

iii. 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;

iv. 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;

v. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

vi. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

vii. 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;

viii. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

ix. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

x. 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;

xi. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

xii. 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;

xiii. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;

xiv. 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;

xv. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and

xvi. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

2. Endo

191. 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:

i. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

ii. 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;

iii. 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;

iv. 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;

v. 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;

vi. 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;

vii. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

viii. Funding and directing 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;

ix. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

x. 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;

xi. 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;

xii. 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

xiii. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

192. Par Pharmaceutical is an affiliate of Endo, which manufactures opioids sold throughout the United States. All allegations pertaining to Endo also apply to Par Pharmaceutical. Moreover, Par Pharmaceutical is a Manufacturer Defendant, and all allegations

against the Manufacturer Defendants herein apply equally to Par Pharmaceutical.

3. Janssen

193. 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:

i. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

ii. 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;

iii. 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;

iv. 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;

v. 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;

vi. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

vii. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

viii. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

ix. 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;

x. 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

xi. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

194. Regarding the conduct of these entities, an Oklahoma State District Court found:

> This court has found that sufficient evidence has been presented in this case to support a finding that Jansen engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs. Additionally, this court has found that the record presented so far in this case could allow a jury to reasonably conclude that Janssen's unbranded marketing efforts were a substantial factor in producing the harm alleged by Plaintiffs. Further, this court has found that evidence has been produced upon which a jury could reasonably conclude that Janssen failed to maintain effective controls against diversion, and that these failures were a substantial factor in producing the harm suffered by Plaintiffs.

See Opinion and Order Denying Janssen's Motion for Summary Judgment, Case 1:17-md-02804-DAP, Doc #2567, filed 09/09/2019.

195. Dr. Paul Janssen, the founder of Janssen Pharmaceutica, originally invented fentanyl in the 1950s. Fentanyl, an extremely powerful opioid, is a major factor in the opioid crisis, related to rising numbers of overdose deaths as well as the increasing prevalence of NAS. *See* Finding of Fact No. 5, Judgement After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

196. Additionally, misinformation from Janssen's direct marketing to doctors influenced the medical community's prescribing practices and perception of the dangers of opioids and encouraged doctors liberally and aggressively write a higher number of opioid

prescriptions. The rapid increase in the prescribing and sale of opioid drugs is directly and causally linked to negative consequences of the opioid epidemic including addiction and overdose deaths as well as rising rates of NAS and children entering the child welfare system. *See* Findings of Fact No. 53 and 55, Judgment After Non-Jury Trial in Oklahoma v. Johnson & Johnson, Case No. CJ-2017-816.

4. Cephalon

197. 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:

i. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

ii. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

iii. 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;

iv. 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;

v. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

vi. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

vii. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

viii. 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;

ix. 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

x. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

5. Actavis

198. 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:

i. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

ii. 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;

iii. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

iv. 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.

6. Depomed

199. Depomed sales representatives misrepresented the safety and efficacy of its opioid drugs to physicians. Depomed has, since at least October 2011, engaged in unsafe and/or unapproved marketing of Lazanda and (with the acquisition from Janssen in January 2015) of

Nucynta and Nucynta ER.

200. Depomed sales representatives promoted Lazanda for unsafe and unapproved uses.

201. Lazanda is only indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Despite the drug's explicit limitation, Depomed actively promoted Lazanda to physicians who do not treat cancer patients. Not only did Depomed instruct sales representatives to promote Lazanda to non-cancer treating physicians, the Company also discouraged sales representatives from marketing the drug to physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors' business.

202. When it launched Lazanda in 2011, the Company's management, from the start, disregarded the FDA's limitations concerning Lazanda's usage, instructing its sales representatives to target pain management physicians, particularly those who historically wrote large numbers of ROOs and Lazanda-like drugs.

203. Sales representatives were pressured to target pain management physicians. Area managers at Depomed regularly supplied sales representatives with lists of target physicians containing few, if any, physicians treating cancer patients. Of the typical call list containing approximately 100 physicians, under five generally treated cancer patients.

204. Depomed also strongly discouraged sales representatives from targeting physicians treating cancer patients. Sales representatives had to "make a case" for using any portion of their allotted marketing money to call on cancer treating physicians. And employees

who did call on cancer treating physicians were disciplined.

205. One Depomed sales representative, who worked in the Los Angeles area, was chastised by management for targeting, almost exclusively, physicians treating cancer patients despite the fact that he had been very successful in generating business from these physicians. This representative was reprimanded for targeting physicians who could prescribe Lazanda for its indicated use, and was told to stop targeting these physicians, and to think about how well he could be doing if he was targeting potentially higher writers. Depomed explicitly told sales representatives to market only to non-cancer treating physicians by their managers, most notably Todd Wittenbach, the company's then head of sales for the United States.

206. Depomed sales representatives were also trained to deal with (rightful) pushback from physicians. For example, when confronted with the common statement from a physician that "it's extremely rare that we see cancer patients," Depomed trained sales representatives to divert the conversation to the physician's use of other, similar medications. For example, sales representatives were trained to respond by saying "well tell me about your patients taking Actiq," and then extol the relative benefits of switching those patients to Lazanda.

207. Due to the worsening headwinds within the opioid market, Depomed ultimately sold Lazanda to Slán Medicinal Holdings on November 7, 2017.

208. Depomed sales representatives promoted Nucynta and Nucynta ER for unsafe and unapproved uses.

209. On April 2, 2015, Depomed acquired from Janssen and its affiliates the U.S. rights to the Nucynta franchise of pharmaceutical products for $1.05 billion in cash. The Nucynta franchise is an opioid that includes Nucynta ER (tapentadol) extended release tablets

indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy (DPN), severe enough to require daily, around-the-clock, long-term opioid treatment, Nucynta IR (tapentadol), an immediate release version of tapentadol, for the management of moderate to severe acute pain in adults, and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

210. Nucynta's annual sales increased in the U.S. from $189.9 million in 2015 to approximately $281.3 million in 2016, quickly becoming Depomed's best-selling product. This marked a 48% year-over-year growth in sales of Nucynta in just one year.

211. The marketing strategy causing the astronomical growth in sales, however, was fueled by Depomed's illegal practices in connection with its marketing of Nucynta for unsafe and unapproved uses. In particular, Depomed promoted the use of opioids for all manner of pain management while downplaying the drug's addictive nature, often promoting the drug as a safer alternative to opioids, despite this not being on the FDA label.

212. Further, Depomed promoted an increase in dosage while focusing on family physicians and internal medicine doctors who were less knowledgeable about the dangers of opioids. In February 2017, Depomed's former CEO increased its sales force for the specific purpose of targeting primary care physicians.

213. Depomed's marketing push was "Think Differently." Sales representatives were told that Nucynta is a "safer opioid." They were told to tell physicians about Nucynta and its value to patients in terms of, among other things, improved safety relative to other opioids on the market.

214. Depomed actively targeted primary care physicians with marketing presentations

that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market Nucynta in this manner, and also did not have any independent scientific evidence to support these claims.

215. The FDA-approved labels for both Nucynta IR and Nucynta ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." Nowhere on the FDA-approved label does it say or mention that Nucynta is safer, more tolerable, less abusive, or less addictive than other opioids. Despite this, Nucynta has a long history of its manufacturer (formerly Janssen) claiming these benefits in its sales pitches and marketing.

216. Nonetheless, Depomed directed its sales representatives to market Nucynta for unsafe and unapproved uses as a safer, less abusive, less addictive opioid that did not create the same euphoric feeling as other opioids, even though this was not on the FDA-approved label.

217. Depomed management knew that the FDA-approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way.

218. On June 23, 2015 investor call, August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

219. Additionally, in a March 14, 2015 presentation at the ROTH Conference, then Depomed CEO Schoeneck stated: "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." In February 2017,

Schoeneck also told investors that Depomed was "initiating label enhancement studies, aimed at further differentiating Nucynta by highlighting its respiratory depression and abuse potential profile. These labeling studies will focus on the properties of the tapentadol molecule, and its uniqueness in the pain marketplace." The purpose of this was to "be able to get it hopefully into the label."

220. Depomed represented that Nucynta was uniquely positioned to combat the negative public sentiment against opioids. Former President and CEO James Schoeneck described to investors that Nucynta had "different properties than the other opioids, particularly when it comes to the kind of activity that the CDC and others are most concerned about" and that "there'll be relatively little impact on [Depomed] compared to where some other companies may fall in at."

221. Depomed knew that it could not promote Nucynta as a safer, less addictive, less abusive opioid that did not have the same euphoric feeling on patients because these properties were not on its FDA-approved label. Despite this knowledge, Depomed trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

222. Due to the worsening headwinds within the Opioid market, Depomed ultimately entered into a commercialization agreement with Collegium Pharmaceutical, Inc., for the NUCYNTA brand on December 4, 2017.

7. Indivior

223. Indivior manufactures and distributes buprenorphine-based prescription drugs for

treatment of opioid dependence. Buprenorphine is a Schedule III drug. The company offers medication under the brand name Suboxone and sublingual tablets under the brand name Subutex. Indivior has manufactured and/or labeled Buprenorphine shipped to California. Indivior is a Pharmaceutical Defendant, and all allegations against the Pharmaceutical Defendants herein apply equally to Indivior.

L. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False Statements about Opioids

224. The Manufacturer Defendants spread their misinformation detailed above by multiple channels, including by deployed seemingly unbiased and independent third parties that they controlled, including recruited speakers. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered 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.

225. The Manufacturer Defendants also directly targeted marketing efforts of their branded opioids directly to doctors and patients in California. In fact, they specifically targeted susceptible prescribers and vulnerable patient populations, including those in California. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false, reckless, and/or negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of California.

226. 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' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

1. Direct Marketing

227. 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.

228. 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.

229. 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.

229. 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 track, precisely, the rates of initial prescribing and renewal by individual doctor, 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.

230. 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."[118]

[118] Letter from Thomas Abrams to Doug Boothe, *supra* note 83 at 2.

2. Indirect Marketing

231. The Manufacturer Defendants' indirectly and collusively 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").

232. The Manufacturer Defendants deceptively marketed opioids throughout the United States through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and 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.

233. 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 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.

234. 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. 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 and 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.

235. 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 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 include contributing to the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promoting prescribing practices which have worsened the opioid crisis.

236. 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 doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

237. Defendants utilized many KOLs, including many of the same ones. 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.

238. 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."[119]

239. 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."[120] Portenoy candidly stated: "Did I teach about pain management,

[119] Good Morning America (ABC television broadcast Aug. 30, 2010).

[120] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, available at: https://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (last visited Oct. 17, 2018).

specifically about opioid therapy, in a way that reflects misinformation? Well, ...I guess I did".[121]

240. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unremarkable pain clinic in Salt Lake City, Utah. Dr. Webster was President of 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).

241. 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 investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

242. 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 Tool" into their own guidelines, indicating also their reliance on the

[121] *Id.*

Manufacturer Defendants and those under their influence and control.

243. 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 throughout the United States.[122]

244. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen 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."[123] 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."[124]

245. 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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[122] *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).

[123] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, MedGenMed. 2007; 9(4): 2 (2007).

[124] 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, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

246. 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.

247. 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 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").[125]

248. The most prominent of the Manufacturer Defendants' Front Groups was APF which, upon information and belief, received more than $10 million in funding from opioid

[125] *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, 2017), https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf (last visited May 31, 2018).

manufacturers from 2007 until it closed its doors in May 2012, 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 all 50 states.

249. 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 total income of about $3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Purdue and Defendants Cephalon, Endo, and others to avoid using its line of credit.

250. 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, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' 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 non profit organizations that share [its] business interests."

251. Plaintiffs are informed, and believe, 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.

252. 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."[126]

253. Another front group for the Manufacturer Defendants was AAPM. With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

254. 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

[126] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Tied to Pain Groups*, Wash. Post, May 8, 2012, available at: https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?utm_term=.b9627ff19557 (last visited Oct. 17, 2018).

programs at offsite 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.

255. Upon information and belief, AAPM is viewed internally by Endo 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. Dr. Webster was even elected president of AAPM while under a DEA investigation.

256. 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.

257. 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, was taken down from AAPM's website only after a doctor complained.[127]

[127] *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*. Clin J Pain. 1997 Mar; 13(1):6-8.

258. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[128] Treatment guidelines have been relied upon by doctors, especially general practitioners and family doctors targeted by the Manufacturer Defendants. 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.

259. 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.[129]

260. 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,

[128] Chou R, et al., *Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain. 2009 Feb; 10(2):113-30.*

[129] *Id.*

were disseminated in the State and/or Plaintiff's Communities during the relevant time period, are still 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.

261. 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 is comprised of 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.

M. The Manufacturer Defendants Misrepresented Their Misconduct

262. 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.

263. At all times relevant to this Complaint, the Manufacturer Defendants took steps to conceal and misrepresent 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 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

264. 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.

N. Defendants' Abject Failure to Maintain the Closed System of Manufacturing and Distribution

265. Concurrent with their promotional and marketing campaign, the Manufacturers exercised their unique and dangerous ability to create both a new supply AND a new demand (via addiction) for the product. They accomplished this by acting in concert and in abrogation of their shared legal duty with Distributor and Pharmacy Defendants both to investigate and notify authorities of all suspected diversions of these highly dangerous substances.

266. 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.

267. Federal statutes and regulations are clear: just like opioid distributors (and pharmacies), opioid manufacturers are required 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).

268. 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.[130]

269. 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[.][131]

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[130] *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), available at: https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders (last visited Oct. 17, 2018).

[131] *Id.*

270. Among the allegations resolved by the settlement, 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."[132]

271. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[133]

272. 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:
>
> 1. conduct adequate due diligence of its customers;
>
> 2. detect and report to the DEA orders of unusual size and frequency;
>
> 3. 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:
>
> 4. orders that resulted in a disproportionate amount of a substance which is

[132] *Id.*

[133] *Id.*

most often abused going to a particular geographic region where there was known diversion,

5. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and

6. 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.[134]

273. 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."[135]

274. 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

[134] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 2-3 (July 10, 2017) [hereinafter 2017 Mallinckrodt MOA], available at: https://www.justice.gov/usao-edmi/press-release/file/986026/download (last visited Oct. 17, 2018).

[135] *Id.* at 3-4.

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."[136]

275. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor and Pharmacy Defendants.

276. The same business practices utilized by Mallinckrodt regarding "chargebacks" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Distributor and Pharmacy Defendants. Through, inter alia, the chargeback data, the Manufacturer Defendants could monitor suspicious orders of opioids. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful. The Manufacturer Defendants have misrepresented their compliance with federal law.

277. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's claims below.

278. 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 throughout the United States.

279. This Court has found that similarly situated parties have presented sufficient

[136] *Id.* at 5.

evidence to support a finding that each Manufacturer Defendant engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs. This Court has also found that Plaintiffs in this case have produced evidence upon which a jury could reasonably conclude that each Manufacturer Defendant failed to maintain effective controls against diversion, and that these failures were a substantial factor in producing the harm suffered by Plaintiffs. *See* Opinion and Order denying Janssen's Motion for Summary Judgment, Case 1:17-md-02804-DAP, Doc #2567, filed 09/04/2019. *See also* Opinion and Order Regarding Defendants' Summary Judgment Motions on Causation, Case 1:17-md-02804-DAP, Doc #2578, Filed 09/09/2019.

O. The Distributor and Pharmacy Defendants Were on Notice of and Failed to Stop the Illegal Diversion of Opiates

281. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90% of all revenues from drug distribution in the United States – an estimated $378.4 billion in 2015. The distributors then supply opioids to Pharmacy Defendants, doctors, and other healthcare providers, who then dispense the drugs to patients.

282. Manufacturer, Distributor, and Pharmacy Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

283. For example, at the wholesale level of distribution, diversion occurs whenever

distributors and/or pharmacies allow opioids to be lost or stolen in transit, or when distributors and or pharmacies fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

284. Plaintiffs and the Class have been significantly damaged by the effects of the Distributor and Pharmacy Defendants' opioid diversion.

285. Distributor and Pharmacy Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

286. In addition to having common law duties, the Distributor and Pharmacy Defendants are governed by the statutory requirements of the CSA, 21 U.S.C. § 801 et seq. and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor and Pharmacy Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard. By violating the CSA, the Distributor Defendants are also liable under the law of California as herein alleged.

287. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread

diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

288. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

289. All opioid distributors (including pharmacies) are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors and pharmacies must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

290. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors and pharmacies' controlled substances, acquisition transactions,

and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

291. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

292. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

293. To maintain registration, distributors and pharmacies must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

294. For years, the Distributor and Pharmacy Defendants have known of the problems and consequences of opioid diversion in the supply chain and have committed repeated violations of the laws and regulations of the United States as cited above, consequently making them liable under California law.

295. To combat the problem of opioid diversion, the DEA has provided guidance to distributors (including pharmacies) on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the "red flags" distributors should look for to identify potential diversion.

296. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Distributor Defendants attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association, now the HDA. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance

documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

297. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors, including the Distributor Defendants, providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

298. The September 27, 2006, letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

299. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants, including the Distributor Defendants, providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded

registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

300. The HDMA, the Distributor Defendants' own industry group, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

301. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

302. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

303. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity" (emphasis added).

304. McKesson has 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."

305. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have miserably and negligently failed.

306. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

307. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its

facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

308. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

309. H.D. Smith has also routinely been found to have violated its duties to report suspicious orders and halt suspicious shipments of prescription opioids. According to a recent letter from the U.S. House of Representatives Committee on Energy and Commerce, data provided to the Committee showed that between 2007 and 2008, H.D. Smith provided two pharmacies in Williamson, West Virginia, a town with a population of 3,191, combined total of nearly 5 million hydrocodone and oxycodone pills – approximately 1,565 hydrocodone and oxycodone pills for every man, woman, and child in Williamson, West Virginia. According to press reports, H.D. Smith distributed approximately 13.7 million hydrocodone and 4.4 million

oxycodone pills to West Virginia between 2007 and 2012. Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state for at least a decade. Upon information and belief, H.D. Smith engaged in similar wrongful activities in California.

310. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva acquired Anda for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in California.

311. In its capacity as a wholesale distributor, Anda is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Anda.

312. Relying on state laws and regulations, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations. Although distributors, including some Distributor Defendants, have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

313. The Distributor Defendants have supplied massive quantities of prescription opioids in California with the actual or constructive knowledge that the opioids were ultimately being consumed by citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

314. Each Distributor Defendant knew or should have known that the amount of opioids that it allowed to flow into California was far in excess of what could be consumed for

medically necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

315. The Distributor Defendants did not adequately control their supply lines to prevent diversion. Distributors of Schedule II controlled substances are required to prevent opioid diversion and protect against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in California; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

316. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing patients and citizens of California to perform due diligence inspections to ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

317. On information and belief, the compensation that the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the patients and citizens of California, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

318. It was reasonably foreseeable to the Distributor Defendants that their conduct in

flooding the consumer market of California with highly addictive opioids would allow opioids to fall into the hands of women of child-bearing years, as well as women who were already pregnant. Thus, it is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including neonatal addiction and NAS and a new and substantially different burden of care for the Legal Guardians of the NAS Children.

319. The Distributor and Pharmacy Defendants knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

320. The Distributor and Pharmacy Defendants knew or should have known that a substantial amount of the opioids dispensed to patients and citizens of California were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third parties, Plaintiffs and the Class.

321. The Distributor and Pharmacy Defendants were aware of widespread prescription opioid abuse of persons who would become patients in California, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas – and in such quantities, and with such frequency – that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

322. The Distributor and Pharmacy Defendants could and should have taken action

that: (a) limited to 7 days supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate- release formulations of opioids before extended-release opioids are dispensed. If any Distributor or Pharmacy Defendant had adhered to effective controls to guard against diversion, the Class would have avoided harm.

323. The Distributor and Pharmacy Defendants made substantial profits over the years based on the diversion of opioids affecting California. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiffs and the Class. The Distributor Defendants knew full well that Plaintiff Legal Guardians and the Class would be unjustly forced to bear these injuries and damages.

324. The Distributor and Pharmacy Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiff legal Guardians and the Class. Their conduct poses a continuing economic threat to the Legal Guardians who must care for the welfare of the NAS Children.

P. The Pharmacy Defendants Were Also on Notice of and Contributed to the Illegal Diversion of Opioids

325. In addition to the facts and allegations set out above in connection with the Distributor Defendants, additional facts and allegations apply to the Pharmacy Defendants. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into

communities, they continued to participate in the oversupply and profit from it.

326. Each of the Pharmacy Defendants does substantial business throughout the United States and in California. This business includes the distribution and dispensing of prescription opioids to individuals.

1. The Pharmacy Defendants Have a Duty to Prevent Diversion

327. Each participant in the supply chain of opioid distribution, including the Pharmacy Defendants, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity. The Pharmacy Defendants developed and maintained extensive data on opioids they distributed and dispensed. Through this data, they had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in California in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the Pharmacy Defendants also provided Defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of consideration. The Pharmacy Defendants' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

328. The Pharmacy Defendants, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills

the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

329. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

330. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

331. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

332. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

333. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Pharmacy Defendants themselves. That data allows them to observe patterns or

instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

334. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

335. Despite their legal obligations as registrants under the CSA, the Pharmacy Defendants allowed widespread diversion to occur—and they did so knowingly.

336. Performance metrics and prescription quotas adopted by the Pharmacy Defendants for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of the Pharmacy Defendants and into communities throughout the country. The policies remained in place even as the epidemic raged.

337. This problem was compounded by the Pharmacy Defendants' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

338. The Pharmacy Defendants also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

339. Upon information and belief, the Pharmacy Defendants failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

340. Upon information and belief, the Pharmacy Defendants also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

341. Upon information and belief, the Pharmacy Defendants also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

342. The Pharmacy Defendants were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Multiple Enforcement Actions Against the Pharmacy Defendants Confirms Their Compliance Failures

343. The Pharmacy Defendants have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of them have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Pharmacy Defendants.

344. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from the Pharmacy Defendants. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

345. The litany of state and federal actions against the Pharmacy Defendants demonstrates that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

346. Throughout the country and in California in particular, the Pharmacy Defendants were or should have been aware of numerous red flags of potential suspicious activity and diversion.

347. On information and belief, from the catbird seat of their retail pharmacy operations, the Pharmacy Defendants knew or reasonably should have known about the disproportionate flow of opioids into California and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of

illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

348. On information and belief, the Pharmacy Defendants knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in Plaintiff's community.

349. On information and belief, because of (among other sources of information) regulatory and other actions taken against the Pharmacy Defendants directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sales data that they developed and monitored, the Pharmacy Defendants were well aware that their distribution and dispensing activities fell far short of legal requirements.

350. The Pharmacy Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent the diversion of opioids.

a. CVS

351. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

352. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue

dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

353. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[137]

354. This fine was preceded by numerous others throughout the country.

355. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.[138]

356. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.[139]

357. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.[140]

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[137] Press Release, U.S. Dep't of Just., U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act,* (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

[138] Press Release, U.S. Dep't of Just., U.S. Attorney's Office Dist. of Md., *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances,.* (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled.

[139] Press Release, U.S. Dep't of Just., U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations,* (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-act-allegations.

[140] Dialynn Dwyer, *CVS Will Pay $795,000, Strengthen Policies Around Dispensing Opioids in Agreement with State,* Boston.com (Sept. 1, 2016),

358. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.[141]

359. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.[142]

360. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[143]

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https://www.boston.com/news/local-news/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-in-agreement-with-state.

[141] Press Release, U.S. Dep't of Just., U.S. Attorney's Office Dist. of Mass., *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions,.* (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

[142] Press Release, U.S. Dep't of Just., U.S. Attorney's Office Dist. of R.I., *Drug Diversion Claims Against CVS Health Corp. Resolved With $450,000 Civil Settlement,* (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

[143] Press Release, U.S. Dep't of Just., U.S. Attorney's Office M. Dist. of Fla., *United States Reaches $22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances,* (May 13, 2015),

361. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.[144]

362. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.[145]

363. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[146]

b. Walgreens

364. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

365. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing

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https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[144] Patrick Danner, *H-E-B, CVS Fined Over Prescriptions,* San Antonio Express-News http://www.expressnews.com/business/local/article/H-E-BCVS-fined-over-prescriptions-5736554.php. (Last Updated Sept. 5, 2014, 8:00 PM).

[145] Andrew Knittle, *Oklahoma Pharmacy Board Stays Busy, Hands Out Massive Fines at Times,* NewsOK http://newsok.com/article/5415840. (Last Updated May 4, 2015, 5:00 PM).

[146] Press Release, U.S. Dep't. of Just., U.S. Attorney's Office W. Dist. of Okla., *CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act,* (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.

violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription opioids to be diverted for abuse and illegal black market sales.[147] The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

366. Walgreens' operations in Florida, which, upon information and belief were similar to those in all other states, including California, highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[148] They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet, Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.[149]

367. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for

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[147] Press Release, U.S. Dep't of Just., U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act,* (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[148] Appendix B of Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012), https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf.

[149] *Id.*

significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[150]

368. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[151] The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high risk. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[152]

c. Rite Aid

369. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the third-largest drugstore chain in the United States, with annual revenue of more than

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[150] *Id.*

[151] Felice J. Freyer, *Walgreens to Pay $200,000 Settlement for Lapses with Opioids,* APhA (Jan. 25, 2017), https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids.

[152] *Id.*

$21 billion.

370. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.[153] The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

d. Wal-Mart

371. Wal-Mart, through its various DEA registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States.

372. In its capacity as a wholesale distributor, Wal-Mart is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Wal-Mart.

373. In its capacity as a wholesale distributor, Wal-Mart is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Wal-Mart.

e. Miami-Luken

374. During all relevant times, upon information and belief, Miami-Luken has distributed substantial amounts of prescription opioids to providers and retailers in California and

[153] Press Release, Dep't of Just., *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act,* U.S. Dep't of Just. (Jan. 12, 2009), https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations.

other states.

375. On November 23, 2015, the DEA issued an Order to Show Cause to begin the process of revoking Miami-Luken's Certificate of DEA Registration.

376. In its revocation proceeding, the DEA has alleged that Miami-Luken failed to maintain effective controls against diversion of controlled substances and that the company failed to operate a system to disclose suspicious orders of controlled substances when it shipped controlled substances, particularly oxycodone and hydrocodone, to customers in southern Ohio, eastern Kentucky, and southern West Virginia.

377. In early 2016, Miami-Luken agreed to pay the state of West Virginia $2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.

378. In its capacity as a wholesale distributor, Miami-Luken is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Miami-Luken.

379. In its capacity as a wholesale distributor, Miami-Luken is a "Distributor Defendant" as used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Miami-Luken.

f. CostCo

380. Costco failed to track and report suspicious sales of its opioid drugs.

381. Costco is a "registrant" under the federal CSA, 21 C.F.R. § 1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

382. Contrary to its duties as a registrant, in 2017, Costco Wholesale was fined $11.75 million as a result of a multijurisdictional investigation by the DOJ relating to CSA violations.

383. According to the investigation, Costco pharmacies filled prescriptions that were incomplete, lacked valid DEA registration numbers or were for substances beyond various doctors' scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies.

384. Between January 1, 2012, and December 31, 2015, certain Costco pharmacies dispensed controlled substances inconsistent with their compliance obligations under the CSA and its implementing regulations. The violations include: filling prescriptions from practitioners who did not have a valid DEA number, incorrectly recording the practitioner's DEA number, filling prescriptions outside the scope of a practitioner's DEA registration, filling Prescriptions that did not contain all the required information, failing to maintain accurate dispensing records, and failing to maintain records for their central fill locations in Sacramento, California, and Everett, Washington.

385. According to U.S. Attorney Eileen M. Decker: "These are not just administrative or paperwork violations – Costco's failure to have proper controls in place in its pharmacies played a role in prescription drugs reaching the black market…."

386. Furthermore, Costco could and should have taken action that: (a) limited to 7 days supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate- release formulations of opioids before extended-release

opioids are dispensed.

387. Having knowledge and/or notice of the damages that Costco's conduct had caused to Plaintiffs and the Class, Costco failed to take other steps to help curb the damages already incurred by Plaintiffs due to Defendants, including Costco, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Costco ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

388. Costco could have and should have implemented these measures at any point in the last 15 years.

389. And the failure to take such steps that Costco should have taken was negligent and did result in significant damages to Plaintiffs and the Class.

390. In its capacity as a wholesale distributor, Costco is a Distributor Defendant, and all allegations against the Distributor Defendants herein apply equally to Costco.

391. In its capacity as a wholesale distributor, Costco is a "Distributor Defendant" as

used in the existing complaint. Plaintiffs adopt all allegations and causes of action alleged against the Distributor Defendants in the existing complaint against Costco.

V. INCORPORATION BY REFERENCE OF *SUMMIT COUNTY* PLEADINGS

392. Plaintiffs submit this supplemental pleading and Amended Complaint incorporating as if fully set forth herein its own prior pleadings and, if indicated below, the common factual allegations identified and the RICO causes of action included in the Corrected Second Amended Complaint and Jury Demand in the case of *The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al.,* Case No. 1:18-op-45090 ("*Summit County* Pleadings"), *In Re National Prescription Opiate Litigation,* in the United States District Court for the Northern District of Ohio, Doc. ##: 513, 514,[154] and as may be amended in the future, and any additional claims asserted herein. Plaintiffs also hereby amend their complaint to alter the defendants against which claims are asserted complaint and they are no longer identified as defendants herein, they have been dismissed without prejudice except as limited by CMO-1, Section 6(e). Doc. #: 232.

393. Plaintiffs hereby incorporate by reference to this document the common factual allegations set forth in the *Summit County* Pleadings as identified in the Court's Order implementing the Short Form procedure:

– Common Factual Allegations (Paragraphs 130 through 670 and 746 through 813)

– RICO Marketing Enterprise Common Factual Allegations (Paragraphs 814-848)

[154] Docket #: 513 is the redacted Summit Second Amended Complaint and Docket #: 514 is the unredacted Summit Corrected Second Amended Complaint filed under seal in Case No. 1:17-md-02804-DAP. The redacted Summit Corrected Second Amended Complaint is also filed in its individual docket, Case No. 1:18-op-45090-DAP, Docket #: 24.

– RICO Supply Chain Enterprise Common Factual Allegations (Paragraphs 849-877)

By my signature below, I, Marc E. Dann, Counsel for Plaintiffs, certify that in identifying all Defendants, co-counsel has followed the procedure approved by the Court and reviewed the ARCOS data that we understand to be relevant to Plaintiffs.

I further certify that, except as set forth below, each Defendant newly added herein appears in the ARCOS data co-counsel reviewed.

I understand that for each newly added Defendant not appearing in the ARCOS data, I must set forth below factual allegations sufficient to state a claim against any such newly named Defendant that does not appear in the ARCOS data.

/s/ Marc E. Dann
Marc E. Dann (0039425)
DannLaw

VI. DISCOVERY RULE AND TOLLING

394. Defendants' conduct was well-concealed, and only recently uncovered through exhaustive investigation and research. Defendants deliberately conducted much of their deception through in-person sales visits, in order to avoid generating a potentially discoverable paper trail of their misconduct. Defendants also concealed from the general public their internal communications about their deceptive course of conduct, including their plans to hook more patients on higher doses for longer periods and, separately, their knowledge of inappropriate prescribing by high-prescribing doctors that they had targeted to prescribe their opioids.

395. Discovering the nature and extent of Defendants' conduct has been a time-consuming and complex process, further strained by Defendants' lack of cooperation and baseless denials. Any statutes of limitation otherwise applicable to any claims asserted herein against all Defendants have been tolled by the discovery rule, rules regarding fraudulent concealment, and/or the fact that the torts are ongoing.

VII. CLASS ACTION ALLEGATIONS

A. Certification under FED. R. CIV. P. 23(b)(2)

396. This action is brought under Federal Rule of Civil Procedure 23(b)(2) in that Defendants both acted and refused to act on grounds that apply generally to the class, so that final injunctive relief is appropriate respecting the class as a whole. The Guardian Plaintiffs bring this action on behalf of themselves and all other similarly situated legal guardians as representatives of the following class:

397. The Putative Class is defined as:

Legal Guardians[155] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")[156] at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[157]

Excluded from the class are any infants and children who were treated with opioids after birth, other than for pharmacological weaning. Also excluded from the class are Legal Guardianships where a governmental agency, such as a public children services agency,

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[155] The term "Legal Guardian" is defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities.

"Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

[156] The term "NAS" is defined to include additional, but medically-symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids. Additional specifics on these readily identifiable and ascertainable terms will be provided in Plaintiffs' Motion for Class Certification.

[157] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

has affirmatively assumed the duties of "custodian" of the child under.[158]

Strictly in the alternative, and only if the Court finds that additional refinement of the class definition is necessary, Plaintiffs propose the following additional subclass definitions:[159]

a. Legal Guardians[160] of California residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Cephalon Defendants";[161]

b. Legal Guardians[162] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Endo Defendants";[163]

c. Legal Guardians[164] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome"

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[158] There are only two causes of NAS: (1) *in utero* exposure to opioids *via* the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

[159] The same definitions and exclusions found in the General Class Definition, *supra*, shall apply to these alternative subclasses.

[160] The term "Legal Guardian" is defined at fn. 5, *supra*.

[161] Defined in the "Manufacturer Defendants" section, *infra*.

[162] The term "Legal Guardian" is defined at fn. 5, *supra*.

[163] Defined in the "Manufacturer Defendants" section, *infra*.

[164] The term "Legal Guardian" is defined at fn. 5, *supra*.

("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Mallinckrodt Defendants";[165]

d. Legal Guardians[166] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Actavis Defendants";[167]

e. Legal Guardians[168] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured or distributed by one or more of the "Janssen Defendants";[169]

f. Legal Guardians[170] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were

[165] Defined in the "Manufacturer Defendants" section, *infra*.

[166] The term "Legal Guardian" is defined at fn. 5, *supra*.

[167] Defined in the "Manufacturer Defendants" section, *infra*.

[168] The term "Legal Guardian" is defined at fn. 5, *supra*.

[169] Defined in the "Manufacturer Defendants" section, *infra*.

[170] The term "Legal Guardian" is defined at fn. 5, *supra*.

manufactured or distributed by one or more Defendant or Purdue entity.[171]

g. Legal Guardians[172] of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received and/or filled a prescription for opioids or opiates in the ten months prior to the birth of said infant or child and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.

h. Legal Guardians[173] of California residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS") at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured, distributed, or filled by a Defendant or Purdue entity.[174]

398. The members of the class are readily identifiable from medical records and pharmacy records. The use of uniform billing codes for NAS- diagnosed children will render this determination a simple mechanical one.

399. Upon information and belief, the class consists of thousands of members and is so numerous that individual joinder of all members is impracticable. The members of the class are geographically dispersed throughout the State of California.

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[171] Defined in the "Non-Defendant, Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

[172] The term "Legal Guardian" is defined at fn. 6, *supra.*

[173] *Id.*

[174] Defined in the "Non-Defendant Co-Conspirator Purdue Entities" and "Defendant Co-Conspirator Purdue Entities" sections, *infra*.

400. There are questions of law and fact common to the class, which predominate over any questions affecting only individual members of the class. The wrongs suffered and remedies sought by Plaintiffs and the other members of the class are premised upon a uniform unlawful scheme perpetuated by Defendants. Plaintiffs have pled a claim for compensatory relief only in the alternative. Should Plaintiffs move for class certification with a request for compensatory relief, the sole question that might affect individual members of the class is the exact monetary recovery of past medical expenses for the NAS Children for which the Legal Guardians were responsible. This recovery is both incidental and nearly insignificant as compared to the injunctive relief sought.

401. Questions common to the class include, but are not limited to, the following:

- Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and/or report suspicious orders of prescription opioids?

- Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and/or report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids for treatment of chronic pain?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids for treatment of non-cancer, including but not limited to widespread conditions such as arthritis and joint pain?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids as drugs without dose limits?

- Did the Manufacturer Defendants use false statements and omissions to promote and market opioids by misrepresenting both their risks and benefits?

- Did the Manufacturer Defendants negligently manufacture, market, promote, and sell opioids?

- Did the Distributor and Pharmacy Defendants negligently sell and distribute opioids?

- Did the Manufacturer Defendants wantonly, recklessly, or with gross negligence manufacture, market, promote, and sell opioids?

- Did the Distributor and Pharmacy Defendants wantonly, recklessly, or with gross negligence sell and distribute opioids?

- Were Plaintiffs and the class members damaged as a direct and proximate result of Defendants' acts and omissions?

402. Plaintiffs' claims are typical of those of the class and are based on the same legal theories as those of the class members. Plaintiffs' claims and those of the class members all arise from the same pattern or practice by Defendants, set out above.

403. Plaintiffs will fairly and adequately protect the interests of the members of the class. Plaintiffs have retained counsel who are highly experienced and competent in class-action litigation, and Plaintiffs and their counsel intend to prosecute this action vigorously. Neither Plaintiffs nor their counsel have any interests that might cause them not to vigorously pursue this action. Plaintiffs' interests are coextensive with those of the class, and Plaintiffs have no interests adverse to those of the class members.

404. Plaintiffs have made arrangements with counsel for the discharge of their financial responsibilities to the class. Plaintiffs' counsel has the necessary financial resources to adequately and vigorously litigate this class action.

B. Alternative Certification under FED. R. CIV. P. 23(b)(3)

405. Alternatively, and only if the Court finds that this is not an appropriate action for FED. R. CIV. P. 23(b)(2) certification, Plaintiffs request alternative certification under 23(b)(3).

406. Common questions of law predominate. Furthermore, a class action is superior to

all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum, because the damages suffered by the individual class members are relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. Moreover, the individual class members are may be unaware of their rights. Thus, it is unlikely that the class members, on an individual basis, can obtain effective redress for the wrongs done to them. Additionally, the court system would be adversely affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single proceeding, with economies of scale and comprehensive supervision by a single court.

C. Alternative Certification under FED. R. CIV. P. 23(b)(1)

407. Prosecuting separate actions by individual class members would create a risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for Defendants.

D. Interim Appointment of Class Counsel under FED. R. CIV. P. 23(g)(2)

408. Interim appointment of class counsel to represent the putative class in prosecuting this action is warranted and is necessary to defend against expected motions to dismiss and to manage precertification matters on behalf of the putative class.

VIII. CAUSES OF ACTION

A. RICO – First Cause of Action (On Behalf of the National Class and the California Subclass)

409. The following first federal RICO cause of action asserted in the *Summit County* Pleadings as identified in the Court's implementing order and any subsequent amendments, Doc. #: 514, is incorporated herein by reference, in addition to the causes of action already asserted in Plaintiffs' complaint, as follows:

First Claim for Relief – Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Marketing Enterprise (Against only Defendants Cephalon, Janssen, Endo, and Mallinckrodt (the "RICO Marketing Defendants")) (*Summit County* Pleadings, Paragraphs 878-905).

410. Plaintiffs seek injunctive relief and damages for Defendants' violation of RICO only as set forth below.

B. RICO – Second Cause of Action (on Behalf of the National Class and the California Subclass)

411. The following second federal RICO cause of action asserted in the *Summit County* Pleadings as identified in the Court's implementing order and any subsequent amendments, Doc. #: 514, is incorporated herein by reference, in addition to the causes of action already asserted in Plaintiffs' complaint, as follows:

Second Claim for Relief – Violation of RICO, 18 U.S.C. § 1961 et seq. – Opioid Supply Chain Enterprise (Against only Defendants Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (the "RICO Supply Chain Defendants")) (*Summit County* Pleadings, Paragraphs 906-938).

412. Plaintiffs seek injunctive relief and damages for Defendants' violation of RICO only as set forth below.

C. Third Cause of Action – Negligence (Only on Behalf of the California Subclass)

413. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as though fully set forth herein, as well as the RICO short-form joinder.

414. As Legal Guardians, Plaintiffs and the Putative Class Members owe immense, nearly unlimited, and non-delegable duties of care to protect the health and welfare of the NAS Children. An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian's duty of care owed to the NAS Children, as well as the Legal Guardian's dominion over the NAS Children. Injury to the Legal Guardians by Defendants was both direct and entirely foreseeable because of the known health risks to birth mothers, the known risks of NAS to the infants they carried, and the known adverse impact and increased burden on the ability of the Legal Guardians to care for the NAS Children after birth.

415. Defendants owe a non-delegable duty to the Legal Guardian Plaintiffs and the Putative Class Members to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

416. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

417. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of the NAS Children in the care of the Legal Guardian Plaintiffs and the Putative Class Members.

418. Defendants' behavior caused a substantial injury and damage to the Legal Guardian Plaintiffs and the Putative Class Members who care for the NAS Children.

419. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

a. Consciously supplying the U.S. market with highly addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;

b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential patient;

c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;

d. Failing to properly train or investigate their employees;

e. Failing to properly review and analyze prescription orders and data for red flags;

f. Failing to report suspicious orders or refuse to fill them;

g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;

h. Failing to police the integrity of their supply chains; and

i. Creating misleading information with the intention of having prescribing physicians rely upon it.

420. Each Defendant had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

421. Each Defendant sold prescription opioids in the supply chain knowing (a) there was a substantial likelihood many of the sales were for non-medical purposes and, (b) opioids are

an inherently dangerous product when used for non-medical purposes, and (c) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

422. Defendants were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

423. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business.

424. Defendants were also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

425. Defendants are in a limited class of registrants authorized to legally distribute controlled substances. This places Defendants in a position of great trust and responsibility vis-a-vis Legal Guardian Plaintiffs and the Putative Class Members Plaintiffs and the Class. Defendants owe a special duty to the Legal Guardian Plaintiffs and the Putative Class Members who care for the NAS Children. That duty cannot be delegated to another party.

426. The NAS Children are without fault.

427. The injuries to the NAS Children would not have happened in the ordinary course of events if Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

428. Defendants owed a duty to prevent the exposure of the NAS Children to opioids, whether through a prescription to their birth mother or through the existence of the illegal secondary, diversionary market to which California birth mothers had access. As to the diversionary, market, the Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of 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). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

> 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).

429. Similarly, and of equal importance, each Distributor and Pharmacy Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21

U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor and Pharmacy 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. Federal law requires that Distributors, including Pharmacy 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). As with the Manufacturer Defendants, federal regulations 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).[175]

1. In addition to reporting all suspicious orders, Distributor Defendants must also *affirmatively stop shipment on any order which is flagged as suspicious* and only ship orders which 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.[176] Regardless, all flagged orders must be reported. *Id.*

[175] 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 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. 21 C.F.R. § 1301.74(b).

[176] *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).

2. Defendants' breach of each of the aforementioned duties resulted in a foreseeable harm to Plaintiff.

430. The aforementioned conduct of Defendants proximately caused damage to the Legal Guardian Plaintiffs and the Putative Class Members who care for the NAS Children.

D. Fourth Cause of Action – Negligence *Per Se* (Only on Behalf of the California Subclass)

431. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as though fully set forth herein, as well as the RICO short-form joinder which follows.

432. Defendants owed non-delegable statutory duties to Plaintiffs and the class. These duties were established to prevent the specific type of harm of which Plaintiffs suffered. Defendants had a duty to prevent the diversion of the drugs which harmed Plaintiffs and the class members. The Manufacturer Defendants were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of 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). Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

> 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).

433. Similarly, and of equal importance, each Distributor and Pharmacy Defendant was also required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each Distributor and Pharmacy Defendant is a "registrant" as a 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. 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). As with the Manufacturer Defendants, federal regulations impose a *non-delegable duty* upon 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).[177]

[177] 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 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. 21 C.F.R. § 1301.74(b).

434. In addition to reporting all suspicious orders, Distributor Defendants must also *affirmatively stop shipment on any order which is flagged as suspicious* and only ship orders which 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.[178] Regardless, all flagged orders must be reported.[179]

435. The harm caused to Plaintiffs and the class members were a direct and foreseeable result of Defendants' breach of their statutory duties.

E. Fifth Cause of Action – Violations of the Unfair Competition Law (Only on Behalf of the California Subclass)

436. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as though fully set forth herein.

437. Under Bus. & Prof. Code Sec. 17200 et al. ("Unfair Competition Law"), this claim is brought by Plaintiffs against Defendants on behalf of themselves and on behalf of the putative class members. This action may be maintained as a class action under Sec. 1781 of the Consumer Legal Remedies Act (the CLRA) for the reasons set forth above.

438. Plaintiffs and all class members are consumers within the meaning of Civil Code Sections 1761(d) and 1770(a).

439. By virtue of Defendants' affirmative acts, concealment and/or failure to disclose the true nature of the opiates they manufactured, marketed, and distributed, products with known significant and adverse health consequences, while also downplaying or hiding these adverse consequences at the same time as incorrectly overstating the known benefits. Defendants have

[178] *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).

[179] *Id.*

violated the CLRA. In addition, Defendants have violated the following provisions of the CLRA:

> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have;
>
> (7) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

Cal. Civ. Code Sec. 1770.

440. Plaintiffs and each of the class members seek damages and injunctive relief as set forth below.

441. Plaintiffs seek restitution of all costs incurred as a result of caring for an NAS Child, and this request is ancillary to their request injunctive relief.

442. Plaintiffs further seek disgorgement of all profits realized by Defendants in California.

443. Plaintiffs further seek all civil penalties at the highest amount allowed by law.

IX. EQUITABLE RELIEF AND ALTERNATIVE COMPENSATORY DAMAGES SOUGHT

444. Plaintiffs reassert the allegations in the foregoing paragraphs as if fully set out herein. Plaintiff Legal Guardians and the Putative Class Members have a duty of care for the welfare of NAS Children who were exposed to opioids, a known toxic substance, at a concentration higher than expected for the general population and who suffer the physical injury of NAS.

445. The NAS Children in the care of Plaintiff Legal Guardians and the Putative Class Members face a lifetime of latent, dreaded medical and emotional conditions proven to be linked

to *in utero* exposure to opioids, including but not limited to: brain damage, muscular-skeletal developmental disorders, speech and language disorders, cognitive developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders and increased risk of addiction. These injuries and increased risks of disease are necessarily an injury to the Plaintiff Legal Guardians and the Putative Class Members as a result of their unlimited duty of care owed to the NAS Children.

446. In order to discharge their duty of care, Plaintiff Legal Guardians and the Putative Class Members must demand from Defendants ongoing medical testing and monitoring of the NAS Children, medical and developmental referral, provision of training and information. Such relief will bring to light the onset of these medical and emotional conditions so that treatment and intervention may begin at the earliest point possible. Notably, *Plaintiff Legal Guardians do not seek the recovery of injunctive or declaratory relief arising from the normal and regular costs of caring for a child; instead, they only seek recovery necessitated by the NAS diagnosis and underlying in utero opioids expose of the NAS Children.*

447. In order to discharge their duty of care, Plaintiff Legal Guardians and the Putative Class Members must also demand that this Court convene and supervise a Science Panel[180] for purposes of epidemiological studies of the NAS Children in their care, which shall collect and analyze medical monitoring results so that other heretofore unrecognized latent, dread diseases that may be associated with *in utero* exposure may be identified and that the Legal Guardians and treating professionals may better care for NAS Children, as well as so that medical professionals engaged in the research and development of new treatment will have access to a

[180] The Science Panel shall be composed of academic and medical institutions acceptable to the Court, as well as the Putative Class Representatives and their Counsel.

broader universe of data. A fund for expenses for maintenance and administration of this Science Panel shall be created by and costs borne by Defendants. The costs, nature, and extent of epidemiology and actions of the Science Panel shall be subject to approval of the Court pursuant to Putative Class Representatives and Counsel's recommendations and input. The Court shall retain oversight and require that Defendants shall address medical issues as they develop during the administration of the Science Panel.

448. Further, the NAS Children and the Class will require on-going care for the aforementioned conditions which are known to result from in utero exposure to opioids including but not limited to medical care, psychiatric care, psychological care, physical therapy, cognitive therapy and speech therapy.

449. The harm visited upon the NAS Children and the Class is irreparable.

450. Money damages will not suffice because it is impossible to predict with any certainty the costs of such monitoring and surveillance for each individual class member nor is it possible to predict new treatment and intervention protocol that may be developed as data from medical monitoring of the Class is provided to the medical research community.

451. Further, money damages will not suffice because an award of money damages for future monitoring and surveillance would not result in comprehensive programs whereby important information is shared among the medical community so that new treatments, protocols, intervention and test may be developed.

452. Plaintiffs, on behalf of all similarly situated legal guardians, seek a Court-administered fund replenished from time-to-time by Defendants to achieve such injunctive and equitable relief as necessary for the continuing benefit of the class.

453. Plaintiffs and the Class also seek injunctive relief, including enjoining Defendants and all other persons acting in concert or participation with them from engaging in unfair or deceptive practices in violation of law as described herein, and by temporary, preliminary or permanent injunction force Defendants and all other persons acting in concert or participation with them to abide by the Controlled Substances Act, provide the required control measures, and prevent unauthorized users from obtaining opioids.

454. In addition to Medical Monitoring, Plaintiffs and the Class seek injunctive relief aimed at changing the standard of care for those born exposed to opioids in utero from becoming addicted to opioids and spreading confidential information upon the record so that medical science has a better understanding of the potential negative health impacts of exposure to opioids in utero:

a. Order Defendants to seek FDA approval of labeling, warnings and package inserts changing the standard of care to discourage the prescription of opioids for dental surgery performed on minors.

b. Order Defendants to seek FDA approval of labeling, warnings and package inserts changing the standard of care to discourage the prescription of opioids to patients who were exposed to opioids in utero.

c. Order Defendants to immediately spread upon the public record all scientific and medical studies, data, experiments, white papers, research or other materials relating to synthetic opioids regardless of whether such material had ever been provided to the FDA or whether Defendants assert trade secret protection.

455. Alternatively, the Legal Guardian Plaintiffs and the Putative Class Members seek recovery of compensatory damages for their care of the NAS Children which arise from their exposure to opioids and diagnosis with NAS. Legal Guardian Plaintiffs and the Putative Class Members do not seek recovery for the normal and regular costs of caring for a child. Plaintiffs assert that these damages are only being sought in the alternative and would not adequately compensate Plaintiffs, and thus, equitable relief is the proper remedy.

X. CLAIM FOR PUNITIVE DAMAGES

456. Plaintiffs reassert each and every allegation set forth in all preceding paragraphs as if fully restated herein.

457. The conduct of Defendants as set forth herein was malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs. Plaintiffs and the Class are thus entitled to recover punitive damages against Defendants.

458. Defendants were malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs, in their activities and in failing to warn Plaintiffs of dangers well known to Defendants, which acts exhibited a deliberate disregard for the rights and safety of Plaintiffs.

459. Defendants realized the imminence of danger to Plaintiffs and other members of the public, but continued with deliberate disregard and complete indifference and lack of concern for the probable consequences of their acts.

460. As a direct result of Defendants' deliberate disregard for the rights and safety of others, gross negligence, malicious, oppressive, willful, wanton, reckless, and/or criminal

indifference to civil obligations affecting the rights of others, including Plaintiffs, Plaintiffs suffered the injuries and dangers stated above.

461. Defendants' acts as described herein exhibited deliberate disregard for the rights and safety of others and were malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs. An award of punitive and exemplary damages is therefore necessary to punish Defendants, and each of them, and to deter any recurrence of this intolerable conduct. Consequently, Plaintiffs are entitled to an award of punitive damages.

462. The conduct of Defendants as set forth herein was malicious, oppressive, willful, wanton, reckless, and/or criminally indifferent to civil obligations affecting the rights of others, including Plaintiffs. Plaintiffs and the Class are thus entitled to recover punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter Defendants and others from similar wrongful conduct in the future.

WHEREFORE, Plaintiffs and the Putative Class respectfully request any and all injunctive relief to which Plaintiffs and the Class show themselves to be justly entitled, including but limited to:

A. Ordering Defendants to provide for the benefit of the Plaintiff Legal Guardians and the Putative Class Members ongoing medical monitoring, testing, intervention, provision of caregiver training and information, and medical referral, all of which are medically necessary for the NAS Children in their care, and all future medical care reasonably necessary to treat these children.

B. Ordering the creation of a Science Panel as set forth above.

C. Alternatively, all incidental compensatory damages and medical expenses incurred by Plaintiff Legal Guardians and the Putative Class Members in connection with their care of the NAS Children. It is expressly alleged that all compensatory damages sought in the alternative are incidental to the injunctive relief requested by Plaintiffs and the Class, and are for those caused by the *in utero* exposure to opioids and NAS diagnosis suffered by the NAS Children

D. Awarding punitive damages.

E. Awarding attorneys' fees and costs incurred by Plaintiff Legal Guardians and the Putative Class Members.

F. Awarding all other relief, at law or in equity, to Plaintiff Legal Guardians and the Putative Class Members which may be just and proper.

XI. JURY DEMAND

Plaintiffs seek a trial by jury for all counts so triable.

DATED: October 8, 2019.

Respectfully submitted,

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Counsel for Legal Guardians of NAS Children

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of October, 2019, a copy of the above and foregoing has been electronically filed with the Clerk of Court using the CM/ECF system, which provides an electronic service notification to all counsel of record registered as CM/ECF users.

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