Court of Common Pleas of Philadelphia
County Trial Division

Civil Cover Sheet

For Office of Judicial Records Use Only (Docket Number)

JANUARY 2018 002718

PLAINTIFF'S NAME	DEFENDANT'S NAME
City of Philadelphia	Allergan PLC
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
Law Department, 17th Floor, One Parkway Building, 1515 Arch Street, Philadelphia, PA 19102	Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054
PLAINTIFF'S NAME	DEFENDANT'S NAME
	Cephalon, Inc.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	1090 Horsham Road, North Wales, PA 19454
City Of Phila Vs Allergan Plc Etal-CMPLC	DEFENDANT'S NAME
	Teva Pharmaceuticals USA, Inc.
18010271800003	DEFENDANT'S ADDRESS
	1090 Horsham Road, North Wales, PA 19454

TOTAL NUMBER OF PLAINTIFFS	TOTAL NO. OF DEFENDANTS	COMMENCEMENT OF ACTION
1	10	☑ Complaint ☐ Petition Action ☐ Notice of Appeal ☐ Writ of Summons ☐ Transfer From Other Jurisdictions

AMOUNT IN CONTROVERSY	COURT PROGRAMS			
☐ $50,000.00 or less	☐ Arbitration	☐ Mass Tort	☐ Minor Court Appeal	☐ Settlement
☑ More than $50,000.00	☑ Jury	☐ Savings Action	☐ Statutory Appeals	☐ Minors
	☐ Non-Jury	☐ Petition	☑ Commerce (Completion of Addendum Required)	☐ W/D/Survival
	☐ Other:			

CASE TYPE AND CODE (SEE INSTRUCTIONS)

Tort other: nuisance

STATUTORY BASIS FOR CAUSE OF ACTION (SEE INSTRUCTIONS)

73 P.S. 201-1 -- 201-9.3; Phila. Code 19-3601 -- 19-3606

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)

IS CASE SUBJECT TO COORDINATION ORDER?

Yes ☐ No ☐

FILED
OFFICE OF JUDICIAL RECORDS
FIRST JUDICIAL DISTRICT OF PA
JAN 17 AM 9:24

TO THE OFFICE OF JUDICIAL RECORDS:

Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant:
Papers may be served at the address set forth below.

NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY	ADDRESS (SEE INSTRUCTIONS)
Marcel S. Pratt	City of Philadelphia Law Department 1515 Arch Street, 17th Floor Philadelphia, PA 19102
PHONE NUMBER: 215-683-5000	FAX NUMBER:
SUPREME COURT IDENTIFICATION NO.: 307483	E-MAIL ADDRESS: marcel.pratt@phila.gov
SIGNATURE: Marcel S Pratt	DATE: 1/17/18

01-101 (Rev. 8/2014)

Court of Common Pleas of Philadelphia County

Trial Division

Civil Cover Sheet

(Supplemental Parties)

For Office of Judicial Records Use Only (Docket Number)	

PLAINTIFF'S NAME	DEFENDANT'S NAME
	Endo Health Solutions Inc.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	1400 Atwater Drive, Malvern, PA 19355
PLAINTIFF'S NAME	DEFENDANT'S NAME
	Endo Pharmaceuticals, Inc.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	1400 Atwater Drive, Malvern, PA 19355

PLAINTIFF'S NAME	DEFENDANT'S NAME
	Janssen Pharmaceuticals, Inc.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	1125 Trenton Harbourton Road, Titusville, NJ 08560
PLAINTIFF'S NAME	DEFENDANT'S NAME
	Johnson & Johnson
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	1 Johnson & Johnson Plaza, New Brunswick, NJ 08933

PLAINTIFF'S NAME	DEFENDANT'S NAME
	Purdue Pharma L.P.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901
PLAINTIFF'S NAME	DEFENDANT'S NAME
	Purdue Pharma Inc.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901

PLAINTIFF'S NAME	DEFENDANT'S NAME
	The Purdue Frederick Company, Inc.
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS
	One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901
PLAINTIFF'S NAME	DEFENDANT'S NAME
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS

EXHIBIT A

COMMERCE PROGRAM ADDENDUM TO CIVIL COVER SHEET

This case ***is*** subject to the Commerce Program because it is not an arbitration matter and it falls within one or more of the following types (check all applicable):

1. Actions relating to the internal affairs or governance, dissolution or liquidation, rights or obligations between or among owners (shareholders, partners, members), or liability or indemnity of managers (officers, directors, managers, trustees, or members or partners functioning as managers) of business corporations, partnerships, limited partnerships, limited liability companies or partnerships, professional associations, business trusts, joint ventures or other business enterprises, including but not limited to any actions involving interpretation of the rights or obligations under the organic law (e.g., Pa. Business Corporation Law), articles of incorporation, by-laws or agreements governing such enterprises;

✔ 2. Disputes between or among two or more business enterprises relating to transactions, business relationships or contracts between or among the business enterprises. Examples of such transactions, relationships and contracts include:

   a. Uniform Commercial Code transactions;
   b. Purchases or sales of business or the assets of businesses;
   ✔ c. Sales of goods or services by or to business enterprises;
   d. Non-consumer bank or brokerage accounts, including loan, deposit cash management and investment accounts;
   e. Surety bonds;
   f. Purchases or sales or leases of, or security interests in, commercial, real or personal property; and
   g. Franchisor/franchisee relationships.

3. Actions relating to trade secret or non-compete agreements;
4. "Business torts," such as claims of unfair competition, or interference with contractual relations or prospective contractual relations;
5. Actions relating to intellectual property disputes;
6. Actions relating to securities, or relating to or arising under the Pennsylvania Securities Act;
7. Derivative actions and class actions based on claims otherwise falling within these ten types, such as shareholder class actions, but not including consumer class actions, personal injury class actions, and products liability class actions;
8. Actions relating to corporate trust affairs;
9. Declaratory judgment actions brought by insurers, and coverage dispute and bad faith claims brought by insureds, where the dispute arises from a business or commercial insurance policy, such as a Commercial General Liability policy;
10. Third-party indemnification claims against insurance companies where the subject insurance policy is a business or commercial policy and where the underlying dispute would otherwise be subject to the Commerce Program, not including claims where the underlying dispute is principally a personal injury claim.

Instructions for Completing Civil Cover Sheet

Rules of Court require that a Civil Cover Sheet be attached to any document commencing an action (whether the action is commenced by Complaint, Writ of Summons, Notice of Appeal, or by Petition). The information requested is necessary to allow the Court to properly monitor, control and dispose cases filed. A copy of the Civil Cover Sheet must be attached to service copies of the document commencing an action. The attorney or non-represented party filing a case shall complete the form as follows:

A. Parties

i. Plaintiffs/Defendants
Enter names (last, first, middle initial) of plaintiff, petitioner or appellant ("plaintiff") and defendant. If the plaintiff or defendant is a government agency or corporation, use the full name of the agency or corporation. In the event there are more than three plaintiffs and/or three defendants, list the additional parties on the Supplemental Parties Form. Husband and wife are to be listed as separate parties.

ii. Parties' Addresses
Enter the address of the parties at the time of filing of the action. If any party is a corporation, enter the address of the registered office of the corporation.

iii. Number of Plaintiffs/Defendants: Indicate the total number of plaintiffs and total number of defendants in the action.

B. Commencement Type: Indicate type of document filed to commence the action.

C. Amount in Controversy: Check the appropriate box.

D. Court Program: Check the appropriate box.

E. Case Types: Insert the code number and type of action by consulting the list set forth hereunder. To perfect a jury trial, the appropriate fees must be paid as provided by rules of court.

Proceedings Commenced by Appeal

Minor Court
- 5M Money Judgment
- 5L Landlord and Tenant
- 5D Denial Open Default Judgment
- 5E Code Enforcement
- Other:

Local Agency
- 5B Motor Vehicle Suspension - Breathalizer
- 5V Motor Vehicle Licenses, Inspections, Insurance
- 5C Civil Service
- 5K Philadelphia Parking Authority
- 5Q Liquor Control Board
- 5R Board of Revision of Taxes
- 5X Tax Assessment Boards
- 5Z Zoning Board
- 52 Board of View
- 51 Other:

Other:

Proceedings Commenced by Petition
- 8P Appointment of Arbitrators
- 8C Name Change - Adult
- 8L Compel Medical Examination
- 8D Eminent Domain
- 8E Election Matters
- 8F Forfeiture
- 8S Leave to Issue Subpoena
- 8M Mental Health Proceedings
- 8G Civil Tax Case - Petition
- Other:

Actions Commenced by Writ of Summons or Complaint

Contract
- 1C Contract
- 1T Construction
- 1O Other:

Tort
- 2B Assault and Battery
- 2L Libel and Slander
- 4F Fraud
- 1J Bad Faith
- 2E Wrongful Use of Civil Process
- Other:

Negligence
- 2V Motor Vehicle Accident
- 2H Other Traffic Accident
- 1F No Fault Benefits
- 4M Motor Vehicle Property Damage
- 2F Personal Injury - FELA
- 2O Other Personal Injury
- 2S Premises Liability - Slip & Fall
- 2P Product Liability
- 2T Toxic Tort
  - *T1 Asbestos*
  - *TZ DES*
  - *T2 Implant*
- 3E Toxic Waste
- Other:

Professional Malpractice
- 2D Dental
- 4L Legal
- 2M Medical
- 4Y Other:

1G Subrogation

Equity
- E1 No Real Estate
- E2 Real Estate
- 1D Declaratory Judgment
- M1 Mandamus

Real Property
- 3R Rent, Lease, Ejectment
- Q1 Quiet Title
- 3D Mortgage Foreclosure - Residential Owner Occupied
- 3F Mortgage Foreclosure - Not Residential Not Owner Occupied
- 1L Mechanics Lien
- P1 Partition
- Prevent Waste
- 1V Replevin

1H Civil Tax Case - Complaint
Other:

F. Commerce Program
Commencing January 3, 2000 the First Judicial District instituted a Commerce Program for cases involving corporations and corporate law issues, in general. If the action involves corporations as litigants or is deemed a Commerce Program case for other reasons, please check this block AND complete the information on the "Commerce Program Addendum". For further instructions, see Civil Trial Division Administrative Docket 01 of 2000.

G. Statutory Basis for Cause of Action
If the action is commenced pursuant to statutory authority ("Petition Action"), the specific statute must be identified.

H. Related Pending Cases
All previously filed related cases, regardless of whether consolidated by Order of Court or Stipulation, must be identified.

I. Plaintiff's Attorney
The name of plaintiff's attorney must be inserted herein together with other required information. In the event the filer is not represented by an attorney, the name of the filer, address, the phone number and signature is required.

The current version of the Civil Cover Sheet may be downloaded from the FJD's website http://courts.phila.gov

CITY OF PHILADELPHIA,
City of Philadelphia Law Department
1515 Arch Street, 17th Floor
Philadelphia, PA 19102

Plaintiff,

v.

ALLERGAN PLC
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

CEPHALON, INC.
1090 Horsham Road
North Wales, PA 19454

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, PA 19454

ENDO HEALTH SOLUTIONS, INC.
1400 Atwater Drive
Malvern, PA 19355

ENDO PHARMACEUTICALS, INC.
1400 Atwater Drive
Malvern, PA 19355

JANSSEN PHARMACEUTICALS, INC.
1125 Trenton Harbourton Road
Titusville, NJ 08560-0200

JOHNSON & JOHNSON
1 Johnson & Johnson Plaza
New Brunswick, NJ 08933

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

JANUARY 2018

JANUARY TERM, 2018

NO. 002718

JURY TRIAL DEMANDED

THIS IS NOT AN ARBITRATION CASE

COMPLAINT

ASSIGNED TO COMMERCE COURT PROGRAM

PURDUE PHARMA INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

THE PURDUE FREDERICK COMPANY, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

Defendants.

NOTICE TO DEFEND-CIVIL

You have been sued in court. If you wish to defend against the claim set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written appearance personally or by attorney and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed or any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT PERSONS AT A REDUCED OR NO FEE.

Philadelphia Bar Association
Lawyer Referral and Information Service
One Reading Center
Philadelphia, Pennsylvania 19107
Telephone (215) 238-1701

AVISO

Le han demandado a Usted en la corte. Si Usted quiere defenderse ante las demandas expuestas en las paginas siguientes, Usted tiene viente (20) dias de plazo a partir de la fecha de la demanda y la notificación. Hace falta asentar un comparencia escrita en persona o con un abogado y entregar a la corte en forma escrita sus defensas u objeciones a la demandas en contra de su persona. Sea avisado que si Usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Ademas la corte puede decidir a favor del demandante y requerir que Usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o propiedades u otros derechos personales importantes.

LLEVE ESTA DEMANDA A SU ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE PARA CONTRATAR UN ABOGADO, DEBE IR PERSONALMENTE O LLAMAR A LA OFICINA CUYA DIRECCIÓN SE ENCUENTRA ABAJO. ESTA OFICINA LE PUEDE DAR INFORMACIÓN SOBRE CONTRATAR UN ABOGADO Y/O INFORMACIÓN SOBRE AGENCIAS QUE PODRIAN OFRECER SERVICIOS LEGALES A PERSONAS CON NECESIDAD A UN PRECIO REDUCIDO O GRATUITO.

SERVICIO DE REFERENCIA LEGAL
One Reading Center
Filadelfia, PA 19107
(215) 238-1701

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

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Counsel for Plaintiff City of Philadelphia

COMPLAINT

CITY OF PHILADELPHIA,
City of Philadelphia Law Department
1515 Arch Street, 17th Floor
Philadelphia, PA 19102

Plaintiff,

v.

ALLERGAN PLC
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

CEPHALON, INC.
1090 Horsham Road
North Wales, PA 19454

TEVA PHARMACEUTICALS USA, INC.
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JANUARY 2018
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COMPLAINT

ASSIGNED TO COMMERCE COURT PROGRAM

PURDUE PHARMA INC. :
One Stamford Forum :
201 Tresser Boulevard :
Stamford, CT 06901 :
:
THE PURDUE FREDERICK COMPANY, INC. :
One Stamford Forum :
201 Tresser Boulevard :
Stamford, CT 06901 :
:
Defendants. :
:

COMPLAINT

TABLE OF CONTENTS

COMPLAINT

Plaintiff City of Philadelphia ("Philadelphia" or the "City"), upon personal knowledge as to its own acts, and upon information and belief as to all other matters based on the investigation of its counsel, alleges as follows:

INTRODUCTION

1. This action is brought by the City against manufacturers of prescription opioid drugs, Allergan, Cephalon, Teva, Endo, Janssen, Johnson & Johnson, and Purdue ("Defendants") as more fully described herein. The City – like many other municipalities, counties and states across the country – is struggling with a public health and safety crisis of unprecedented severity arising out of the deceptive marketing and sale of prescription opioids by Defendants in the City of Philadelphia, regionally and nationally.

2. As more fully set forth herein, the deceptive marketing and sale of prescription opioids for medical use in Philadelphia are responsible for an epidemic of opioid addiction, fatal and non-fatal overdoses and other adverse health effects. Current levels of opioid addiction, overdoses and other adverse health conditions, and their dramatic increases over the last 20 years, have materially and adversely impacted – and substantially interfered with – public health and safety in the City.

3. The opioid epidemic currently plaguing the City and its deleterious impact on public health and safety have created three overlapping crises for the City, its residents and the Philadelphia community as a whole: First, opioid addiction and the adverse health consequences of prescription opioid use have exacted a grim toll of human suffering on users and their families. Second, the opioid crisis – with its attendant increase in crime and family and social dysfunction which tear at the social fabric of the City – is responsible for a sharp deterioration of

public safety, order, economic productivity and the quality of life in sections and neighborhoods of the City and the City as a whole. Third, the City and its agencies, which are on the front lines of attempts to cope with and contain the epidemic and ensuing adverse impacts on public health and safety, have incurred large, burdensome, unnecessary and avoidable costs in the discharge of their duties.

4. Opioid addiction, intoxication and overdoses have imposed daunting burdens on City emergency response services involving police, fire, EMS and hospitals, at greatly increased cost to the City. The opioid epidemic has also imposed additional significant financial, personnel, and other burdens on City law enforcement authorities, the criminal justice system and on social services, health and other municipal agencies. The City has also been forced to incur substantially increased costs as a provider of health coverage to its employees and their families and of emergency health services to affected residents and its prison population. The imposition on the City of costs of increased municipal services attributable to the opioid epidemic – like the costs of the epidemic on the community as a whole – represents a shifting of the costs of the epidemic from those responsible to those harmed.

5. The current opioid epidemic in the City is part of a larger regional and national epidemic relating to prescription opioid use for medical purposes. This epidemic is directly attributable to the deceptive commercial activities of the Defendants and their improper marketing and promotion of prescription opioids in Philadelphia, regionally and nationally.

6. Prescription opioid drugs manufactured by the Defendants are, and at all times applicable to this action were, dangerous and have (and had) significant and severe adverse side effects on users. While they have a proper medical use if marketed and prescribed responsibly to treat *short-term* acute pain (such as associated with medical surgical procedures, accidents or

other medical conditions associated with short-term pain) or for end-of-life care, the defendants marketed and promoted prescription opioids for *long-term* daily use to treat chronic pain. The overwhelming weight of medical and scientific opinion is and has been that prescription opioids should rarely be used daily for long-term treatment of chronic pain.

7. Beginning in the mid-1990s, the Defendants, individually and collectively, engaged in massive, systematic marketing campaigns to promote aggressive use of prescription opioids for acute and chronic pain. The Defendants marketed both their own drugs and the entire therapeutic class of prescription opioids as safe and effective for common forms of chronic pain. The marketing campaigns of the Defendants individually and collectively succeeded in changing the prescribing practices of physicians around the country and in the Philadelphia area.

8. Prior to the Defendants' marketing of opioids to doctors in the Philadelphia area and nationally, the medical profession considered opioids to be dangerous and to have adverse side effects, including addiction and increased risk of fatal and non-fatal overdoses. Medical practitioners also recognized that the risk of opioid addiction was considerable for any type of user and that opioid addiction, once it took place, was difficult to reverse. Prior to Defendants' campaigns to influence doctors, third party payors and others, the medical profession held the view that the prescription and medical use of opioids should be cautious and limited.

9. After a comprehensive review of the increased use of prescription opioids for medical purposes during the last 20 years and its ill effects, public health authorities and medical researchers have now concluded that there never was satisfactory scientific evidence, during the period when Defendants engaged in the widespread promotion and sale of prescription opioids for long-term daily use, to establish that they were effective in treating chronic pain. They also have concluded that long-term daily use of prescription opioids was unsafe and exposed patients

to dangerous, unacceptable risks of addiction, fatal and non-fatal overdoses and other serious adverse health conditions and that such risks significantly and dangerously increased with the increased use of prescription opioids. In this light, Defendants' massive marketing, promotion and sale of prescription opioids as a treatment for chronic pain were medically and scientifically unfounded, deceptive, and legally and ethically inexcusable.

10. The City brings this action to obtain mandatory injunctive relief and compensatory and punitive damages. The injunctive relief seeks to require Defendants to cease all promotional activities of prescription opioids as a safe and effective treatment for chronic pain, to inform the medical community and the public of the true risks of daily, long-term prescription opioid use, and to pay for the cost of detoxification and treatment, including after-care, of every resident in the City currently suffering from opioid addiction attributable to prescription opioids.

11. Additionally, the City seeks its actual damages to recover the costs of procurement of and/or reimbursement for prescription opioids for long-term daily use and the costs of treatment of opioid addiction and other adverse medical conditions associated with long-term daily use incurred by City health plans or paid directly by the City. The City also seeks recovery of its costs of increased municipal services directly associated with opioid addiction, fatal and non-fatal overdoses, and other adverse health and public safety conditions, including increased emergency response costs and increased costs of City law enforcement authorities and of its criminal justice system and social and health agencies, which are attributable to long-term use of prescription opioids to treat chronic pain.

12. The City brings claims against the defendants for public nuisance, violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law (73 P.S. §§ 201-1 to 201-

9.3), and violation of the Philadelphia False Claims Act (Phila. Code §§ 19-3601 to 19-3606).

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 42 Pa. C. S. § 931(a). The amount in controversy exceeds $50,000, exclusive of interest and costs, which is the jurisdictional amount below which a compulsory arbitration referral pursuant to 42 Pa. C. S. § 7361(b) would be required.

14. Venue is proper in Philadelphia County pursuant to 42 Pa. C. S. § 931(c), Pa. R. Civ. P. 1006(b) and (c)(1), and Pa. R. Civ. P. 2179(a).

15. This action is not removable to federal court. Among other things, there is insufficient diversity for removal. The City is not considered a party for purposes of diversity of citizenship jurisdiction in any event. Further, the claims alleged in the Complaint do not permit federal question jurisdiction to be exercised, because the case does not arise directly or indirectly under the Constitution, laws, or treaties of the United States.

PARTIES

I. Plaintiff The City of Philadelphia.

16. The City of Philadelphia is a municipal corporation. It is the largest city in the Commonwealth of Pennsylvania and sixth-largest city in the United States. Philadelphia is home to approximately 1.6 million residents.

17. The City of Philadelphia includes Philadelphia County, which is merged with the City. They are collectively referred to here as the "City of Philadelphia," "City," or "Philadelphia."

18. The City provides a wide range of social services on behalf of Philadelphia residents, including health-related services. In addition, the City administers and provides

funding for the Philadelphia Police Department, Philadelphia Fire Department, Philadelphia Department of Prisons, the District Attorney's Office, the Defender Association of Philadelphia, the Philadelphia Department of Health, the Philadelphia Department of Behavioral Health and Intellectual disAbility Services, the Philadelphia Department of Human Services, and other public health and safety departments and agencies.

19. Philadelphia is one of the largest employers in Pennsylvania, employing thousands of individuals throughout its numerous departments and agencies.

20. The City self-funds its own medical benefits plan on behalf of its covered full-time employees, through which it pays medical costs, including the cost of treatment of, *inter alia*, opioid addiction and related diseases, and prescription drug costs (including for prescription opioids and medications to treat the effects of prescription opioids). The City's medical benefits plan provides benefits for approximately 4,000 non-union employees, as well as 2,300 union employees who have chosen not to participate in union medical plans.

21. The City also self-funds its own workers' compensation and disability plan, through which it pays disability costs and related benefits for covered employees.

22. The City's health, prescription, and workers' compensation and disability plans are administered by third-party service providers that are in the business of administering employee health plan accounts and workers compensation and disability benefits.

23. References to the City refer to the City as a municipality, including residents within its borders, the community as a whole, and City government by itself consisting of its departments and agencies.

II. Defendants.

A. The Allergan/Actavis Defendants.

24. Defendant Allergan plc is a publicly traded company, traded on the New York Stock Exchange. It is incorporated in Ireland with its principal place of business in Dublin, Ireland. Its U.S. headquarters are located in Parsippany, New Jersey. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in March 2015.

25. Defendant Allergan plc acquired, merged with, or otherwise combined with several Actavis entities (including Actavis plc and Actavis, Inc.), Watson entities (including Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc.), and Warner Chilcott entities (including Warner Chilcott Company, LLC and Warner Chilcott plc) that manufactured, marketed, and sold opioids. Upon information and belief, profits from the sale of opioid products by Actavis, Watson, and Warner Chilcott ultimately inured or inure to the benefit of Defendant Allergan plc.

26. At all times material hereto, Defendant Allergan plc and the Actavis, Watson, and Warner Chilcott entities (collectively referred to herein as "Allergan/Actavis") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Philadelphia, including but not limited to the following:

Table 1. Allergan/Actavis Opioids

Drug Name	Chemical Name	Schedule
Kadian	Morphine sulfate extended release	Schedule II
Norco	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic Duragesic	Fentanyl	Schedule II
Generic Kadian	Morphine sulfate extended release	Schedule II
Generic Opana	Oxymorphone hydrochloride	Schedule II

B. The Cephalon Defendants.

27. Defendant Cephalon, Inc. is a privately held Delaware corporation with its principal place of business in North Wales, Pennsylvania. In 2011, Cephalon, Inc. was acquired by Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Cephalon, Inc. is now a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

28. Defendant Teva Pharmaceuticals USA, Inc. is a privately held Delaware corporation, with its principal place of business in North Wales, Pennsylvania. Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Defendant Teva Pharmaceuticals USA, Inc. specializes in the manufacturing and marketing of generic drugs, including opioids.

29. At all times material hereto, Defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, "Cephalon") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Philadelphia, including but not limited to the following:

Table 2. Cephalon Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II
Generic oxycodone	Oxycodone hydrochloride	Schedule II

C. The Endo Defendants.

30. Defendant Endo Health Solutions Inc. ("Endo Health") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Health is a wholly owned subsidiary of Endo International plc, which is an Ireland-domiciled company.

31. Defendant Endo Pharmaceuticals, Inc. ("Endo Pharmaceuticals") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals

is a wholly owned subsidiary of Defendant Endo Health.

32. At all times material hereto, Defendants Endo Health and Endo Pharmaceuticals (collectively, "Endo") promoted, marketed, and sold both brand name and generic versions of opioids nationally and in Philadelphia, including but not limited to the following:

Table 3. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxycodone hydrochloride and aspirin	Schedule II
Percocet	Oxycodone hydrochloride and acetaminophen	Schedule II
Zydone	Hydrocodone bitartrate and acetaminophen	Schedule III
Generic Oxycodone	Oxycodone hydrochloride	Schedule II
Generic Oxymorphone	Oxymorphone hydrochloride	Schedule II
Generic Hydromorphone	Hydromorphone hydrochloride	Schedule II
Generic Hydrocodone	Hydrocodone	Schedule II

33. In 2017, Endo Pharmaceuticals removed Opana ER from the market due to serious risks of abuse.[1]

34. Endo manufactures and sells its generic opioids both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc.

D. The Janssen Defendants.

35. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation, with is principal place of business in Titusville, New Jersey. Jansen Pharmaceuticals is a wholly owned subsidiary of Defendant Johnson & Johnson. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

36. Defendant Johnson & Johnson ("J&J") is a publicly traded New Jersey

[1] *See* Opana Form 10-Q for the quarter ended June 30, 2017, at pg. 22, *available at* http://www.endo.com/investors/sec-filings.

corporation, with its principal place of business in New Brunswick, New Jersey. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, and Janssen Pharmaceuticals' profits inure to J&J's benefit.

37. At all times material hereto, Defendants Janssen Pharmaceuticals and J&J (collectively, "Janssen") promoted, marketed, and sold opioids nationally and in Philadelphia, including but not limited to the following:

Table 4. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta	Tapentadol	Schedule II
Nucynta ER	Tapentadol extended release	Schedule II
Ultram	Tramadol hydrochloride	Schedule IV

38. J&J is one of the world's largest legal poppy growers. J&J supplies precursor opium for much of the hydrocodone and oxycodone consumed in the United States.

E. The Purdue Defendants.

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

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

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

42. At all times material hereto, Defendants PPL, PPI, and PFC (collectively, "Purdue") promoted, marketed, and sold opioids nationally and in Philadelphia, including but not limited to the following:

Table 5. Purdue Opioids

Drug Name	Chemical Name	Schedule
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

43. More than half of Purdue's revenue emanates from the sale of opioids.[2]

44. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

45. Purdue and its top executives pleaded guilty in 2007 to criminal charges in connection with Purdue's deceptive OxyContin marketing practices, as discussed herein.

46. The defendants are collectively referred to herein as "Defendants."

FACTS RELEVANT TO ALL CAUSES OF ACTION

I. The Opioid Epidemic and Public Health and Safety Crisis Attributable to Prescription Opioids.

A. Prescription Opioids and Their Adverse Health Effects.

47. Most prescription opioids are natural and semi-synthetic drugs derived from opium. Prescription opioids include the drug formulations identified in the Tables above,

[2] Esme Deprez, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg Businessweek (Oct. 5, 2017), *available at* https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

including the most commonly prescribed formulations of hydrocodone, oxycodone, oxymorphone and hydromorphone.[3]

48. Opium and opium derivatives, including prescription opioids, have both pain relieving and euphoria-inducing characteristics. The pain-relieving properties of opium have been recognized for millennia. During and after the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

49. Unfortunately, prescription opioids pose the same dangers and hazardous side effects associated with opium and opium derivatives, such as morphine and heroin, and have a high degree of potential for abuse and addiction. Opium is the foundational component of heroin and prescription opioids, and both types of drugs function in an essentially identical fashion.

50. Prescription opioids work by binding to receptors on the spinal cord and in the brain, altering the perception of pain. Long-term exposure to opioids results in structural and functional changes in regions of the brain that regulate impulse control. Opioid addiction is a medical disease that arises from repeated exposure to opioids. It can occur in individuals using prescription opioids to relieve pain under the supervision of a physician at prescribed doses, just as it can occur in individuals using opioids for non-medical purposes.

51. Prescription opioids are highly addictive based on a dual risk: (i) they induce euphoria (positive reinforcement), and (ii) cessation of chronic opioid use produces dysphoria

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[3] Fentanyl is also a prescription opioid and the subject of deceptive marketing and misuse. Fentanyl is a wholly synthetic prescription opioid that is similar to morphine but is 50 to 100 times more potent. *See* https://www.drugabuse.gov/drugs-abuse/fentanyl.

(negative reinforcement) or withdrawal.[4]

52. Discontinuing opioid use, even after just a few days of therapy, can cause patients to experience withdrawal symptoms. Withdrawal symptoms can include anxiety, nausea, vomiting, agitation, insomnia, muscle aches, abdominal cramping, and other serious conditions, which may persist for months or longer after a complete withdrawal from opioids, depending on how long the opioids were used.[5]

53. When opioids are used over time, patients grow tolerant to their analgesic and euphoric effects. As tolerance increases, a patient requires progressively higher doses in order to obtain the same levels of pain reduction to which he or she has become accustomed.[6] At higher doses, the effects of withdrawal are more substantial, leaving a patient at an even higher risk of addiction.

54. Opioids can slow breathing and cause severe respiratory depression, coma, or death. These hazards can occur even when used at prescribed doses, and can affect (sometimes fatally) even users who are not suffering from opioid addiction or opioid use disorder.

55. Prior to the marketing campaign launched by Defendants, physicians avoided using opioids for long-term treatment of chronic pain. Clinicians observed various negative outcomes from long-term opioid therapy: a mixed record in reducing long-term pain; failure to improve patient function; greater pain complaints over time as most patients developed tolerance to opioids; diminished ability to perform basic tasks; inability to make use of complementary

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[4] Roy Wise *et al.*, *The Development and Maintenance of Drug Addiction*, Neuropsychopharmacology (Nov. 6, 2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3870778/.

[5] *See, e.g.*, *Health Guide: Opiate Withdrawal*, The New York Times (2013), *available at* http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

[6] M. Katz, *Long-Term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Archives of Internal Med. 1422 (2010).

treatments like physical therapy due to opioid side effects; and opioid addiction.

56. Up to the mid-1990s, the medical profession viewed opioids as having legitimate uses, but believed that they should be prescribed cautiously and only on a limited basis because of concerns about addiction, tolerance leading to dose escalation, and physiological dependence resulting in difficulty discontinuing use. Physicians were reluctant to prescribe opioids on a long-term basis for common chronic pain conditions because of their addiction risks and side effects.[7]

57. In the late 1990s, the rate of prescription opioid use began accelerating rapidly. This acceleration was directly related to, and coincided with, efforts of the Defendants to deceptively promote the benefits of long-term prescription opioid use and minimize the risks of prescription opioids. The Defendants' efforts in this regard are discussed more fully below, at ¶¶ 197-399, *infra*.

B. The Lack of Scientific Evidence Supporting the Safety and Efficacy of Prescription Opioids for Long-Term Use.

58. Scientific evidence has not demonstrated the safety or efficacy of prescription opioids for long-term daily use to treat chronic pain.

59. As a result of the widespread, unsupported use of prescription opioids for long-term chronic pain, the U.S. Centers for Disease Control and Prevention ("CDC") developed the "CDC Guideline for Prescribing Opioids for Chronic Pain" in March 2016 (the "2016 CDC Guideline," "CDC guideline," or "guideline").[8] The 2016 CDC Guideline extensively discussed

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[7] Andrew Kolodny *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, at pg. 562 (Jan. 12, 2015) (hereinafter "Kolodny, Jan. 12, 2015"), *available at* http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

[8] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (March 18, 2016) (hereinafter "*CDC Guideline*, March 18, 2016"), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

the evidence (and lack thereof) supporting opioid use to treat long-term chronic pain.

60. Chronic pain generally refers to pain lasting three months or longer. In the 2016 CDC Guideline, the CDC stated: "Chronic pain has been variably defined but is defined within this [opioid treatment] guideline as pain that typically lasts >3 months or past the time of normal tissue healing. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause."[9]

61. As indicated by the CDC, there are no controlled studies of the use of opioids to treat chronic pain beyond 12 weeks, and no reliable evidence that opioids improve patients' pain and function long-term.[10]

62. Specifically, based on a detailed review of prior opioid studies, the CDC concluded that "evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with *insufficient evidence to determine long-term benefits versus no opioid therapy*."[11] The CDC Guideline further stated: "No 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 . . . ."[12] The 2016 CDC Guideline also stated: "Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)."[13]

63. As referred to in the 2016 CDC Guideline, the first randomized, placebo controlled studies appeared in the 1990s, and revealed evidence only for *short-term* efficacy of

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9 *Id.* at pg. 1.
10 *Id.* at pg. 2, 9.
11 *Id.* at pg. 9 (emphasis added).
12 *Id.* at pg. 15.
13 *Id.* at pg. 15.

opioids, and only in a minority of patients.[14]

64. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently noted the lack of available data to assess long-term outcomes.

65. For example, a 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and found that, while opioids had short-term efficacy, the data were insufficient to establish long-term effectiveness.[15]

66. A 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain, and that evidence did not allow judgments regarding long-term use.[16]

67. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy was "poor."[17]

68. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and only fair evidence for transdermal fentanyl (approved only for use for cancer pain).[18]

69. In 2015, a systematic review of the effectiveness and risks of long-term opioid

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[14] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin. J. Pain 303 (2007); Roger Chou *et al.*, *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

[15] Daniel Carr *et al.*, *Evidence Report on the Treatment of Pain in Cancer Patients*, Jnl. of the Nat'l. Cancer Institute Monographs No. 32 (2004), *available at* https://academic.oup.com/jncimono/article-lookup/doi/10.1093/jncimonographs/lgh012.

[16] BA Martell *et al.*, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, Annals of Internal Medicine (2007), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0024176/.

[17] L. Manchikanti *et al.*, *A Systematic Review of Randomized Trials of Long-Term Opioid Management for Chronic Non-Cancer Pain*, Pain Physician (2011), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0032394/.

[18] D. Koyyalagunta *et al.*, *A Systematic Review of Randomized Trials on the Effectiveness of Opioids for Cancer Pain*, Pain Physician (2012), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0052579/.

therapy found that the "[e]vidence is insufficient to determine the effectiveness of long-term opioid therapy for improving chronic pain and function."[19]

70. Relatedly, substantial evidence exists indicating that opioid drugs are *ineffective* to treat chronic pain, and actually *worsen* patients' health. While opioids may work sufficiently well in short term applications, long-term use very often leads to a decline in the patient's overall functionality, general health, mental health, and social function.

71. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in patients' functional outcomes over other non-addicting treatments.[20]

72. Studies have shown that increasing the duration of opioid use is strongly associated with an increasing prevalence of negative mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater utilization of health care services.

73. Over time, even high doses of opioids often fail to control pain due to tolerance levels rising, and many patients exposed to such doses are unable to function normally.[21]

74. The lack of evidence of the efficacy of opioids for long-term use is true for both general pain and specific pain conditions (*e.g.*, back pain or headaches). For example, studies of the use of opioids for chronic lower back pain have been unable to demonstrate an improvement

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[19] Roger Chou *et al.*, *The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic Review for a National Institutes of Health Pathways to Prevention Workshop*, Annals of Internal Medicine (Feb. 17, 2015), *available at* http://annals.org/aim/fullarticle/2089370/effectiveness-risks-long-term-opioid-therapy-chronic-pain-systematic-review.

[20] Andrea D. Furlan *et al.*, *Opioids for Chronic Noncancer Pain: a Meta-Analysis of Effectiveness and Side Effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

[21] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Medicine (Fall 2009), *available at* http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.

in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity sooner: "Opioids do not seem to expedite return to work in injured workers or improve functional outcomes of acute back pain in primary care. For chronic back pain, systematic reviews find scant evidence of efficacy. . . . Given the brevity of randomized controlled trials, the long term effectiveness and safety of opioids are unknown."[22]

75. Similarly, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly worse on the Migraine Disability Assessment, and had higher rates of depression compared to non-opioid users.[23]

76. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.[24]

77. As result of a growing body of evidence that opioids are neither safe nor effective for long-term use, in February 2017 the "Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain" strongly recommended "against

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[22] Richard Deyo *et al.*, *Opioids for Low Back Pain*, BMJ Publishing (Jan. 5, 2015), *available at* http://www.bmj.com/content/350/bmj.g6380.

[23] Dawn C. Buse *et al.*, *Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study*, Headache (Jan. 23, 2012), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4610.2011.02050.x/abstract;jsessionid=25D4FE8717B0D8C823D88F3DEA5983AC.f04t03.

[24] *Survey: Migraine Patients Taking Potentially Addictive Barbiturate or Opioid Medications Not Approved by FDA as Migraine Treatments* (May 15, 2017), *available at* https://www.thefreelibrary.com/Survey%3A+Migraine+Patients+Taking+Potentially+Addictive+Barbiturate+or+...-a0163389345.

initiation of long-term opioid therapy for chronic pain."[25]

C. The National Prescription Opioid Epidemic.

78. Starting in or about 1996 – and coinciding with a rapid increase in prescription opioid use for medical purposes as more fully set forth, *infra* – the United States has experienced an opioid epidemic which has been characterized as the worst drug epidemic in its history. In the public health community, an epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discreet period of time.[26] The principal disease associated with the opioid epidemic is opioid addiction, also known as opioid use disorder.

79. "Opioid addiction," "opioid use disorder," and "opioid abuse or dependence" are all terms that have been used to refer to, essentially, a "problematic pattern of opioid use leading to clinically significant impairment or distress . . . manifested by specific criteria such as unsuccessful efforts to cut down or control use, and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home."[27]

80. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable. Unfortunately, for a variety of reasons, including a shortage of and limitations on resources, the presence of shame and stigma, and the presence of barriers to treatment, only a

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[25] *Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (February 2017), available at https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf.

[26] *Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics* (2017), *available at* https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section11.html.

[27] *CDC Guideline,* March 18, 2016, at pg. 2, *supra* note 8. The current diagnostic manual used by most behavioral health professionals, DSM-V, uses the term "opioid use disorder" to refer to and define what has in the past essentially been referred to as opioid addiction. In this Complaint, Plaintiff will generally use the term "addiction" to refer to opioid use disorder, opioid addiction, and opioid abuse or dependence, unless context dictates otherwise. These diagnoses are "different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped)." *Id.*

small percentage of patients who need treatment actually receive the right types of treatment and levels of care, in the right settings, for the right lengths of time. In the absence of proper treatment the disease of addiction is progressive and, all too often, fatal.

81. In 2011, the CDC published an analysis of opioid use from 1999-2010 which indicated a sharp increase nationally in the prevalence of opioid addiction and opioid use disorder. The CDC's analysis was based on, *inter alia*, reported admissions into facilities that receive State alcohol and/or drug agency funds for the provision of substance abuse treatment. The study found a 900% increase in opioid users seeking treatment for opioid addiction in the period 1999-2010.[28] The results of the CDC research and analysis are reflected in the following graph (Figure 1):[29]

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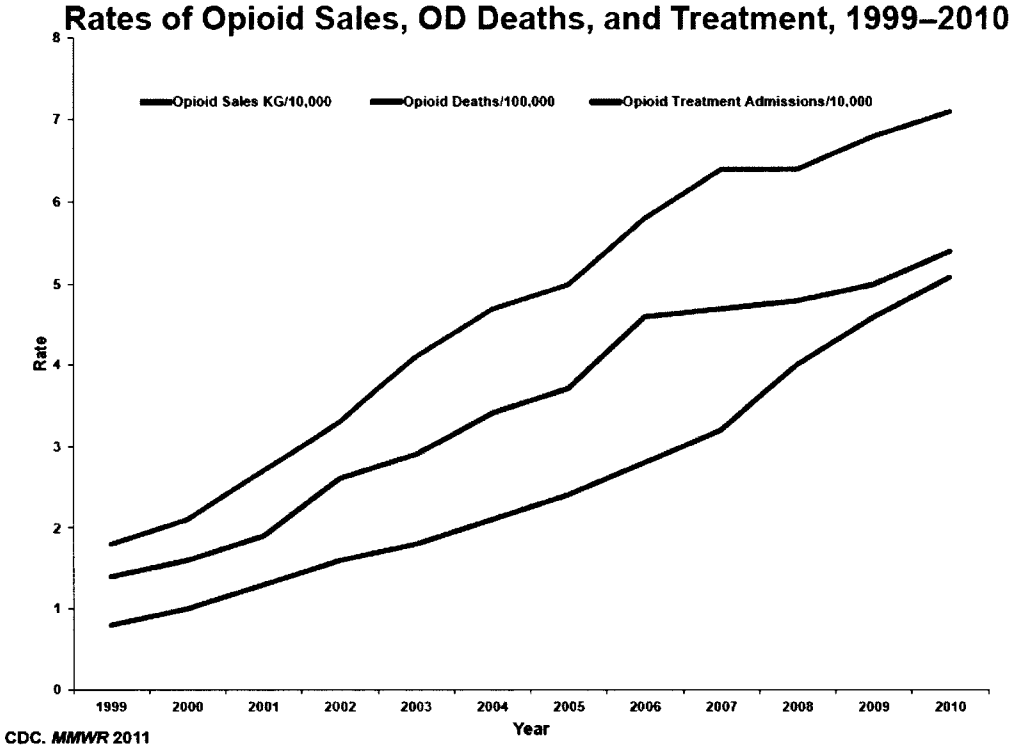
[28] *CDC Vital Signs* (Nov. 2011) (hereinafter "*CDC Vital Signs*, Nov. 2011"), *available at* https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html; *accord* Kolodny, Jan. 12, 2015, at pg. 560, *supra* note 7.

[29] Andrew Kolodny, M.D., *Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction*, at 23 (2016), *available at* http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf; *accord CDC Vital Signs*, Nov. 2011 (similar graph), *supra* note 28; *Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008*, CDC (Nov. 4, 2011) (similar graph), *available at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm.



82. As reflected in the above analysis at Figure 1, the sharp increase in opioid addiction during this period has also led to a sharp increase in opioid-related morbidity and mortality, including a disturbing increase in non-fatal and fatal opioid overdoses and other opioid-related adverse health effects. (Morbidity relates to the incidence or prevalence of diseases and mortality relates to death resulting from those diseases.)

83. According to the CDC, opioid addiction has led to an epidemic in opioid overdoses including overdose fatalities. In the period 1999-2014, the CDC estimated that there were 165,000 overdose deaths in the United States associated with prescription opioid use.[30] Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal

[30] *CDC Guideline*, March 18, 2016, at pg. 2, 18, *supra* note 8.

overdoses.[31] Thus, in the period 1999-2014, an estimated 5 million non-fatal opioid overdoses were also likely to have occurred.

84. In 2016, the CDC acknowledged the existence of two opioid epidemics involving addiction and overdoses.[32]

D. Increases in Opioid Addiction and Opioid Deaths Coincide with Increased Use of Prescription Opioids for Medical Purposes.

85. Coinciding with these dual epidemics, there has been a dramatic expansion of prescription opioid use for medical purposes in the last 20 years. From 1999-2010 (as reflected in Figure 1), the sale of prescription opioids in the U.S. nearly quadrupled.

86. In 2010 alone, 254 million prescriptions for opioids were filled in the United States – enough to medicate every adult in America around the clock for a month.[33] In 2010, 20% of all doctors' visits resulted in the prescription of an opioid.[34]

87. Americans constitute only 4.6% of the world's population yet consume 80% of the global opioid supply.[35]

88. Nearly 70% of adults nationwide have used opioid pain medication in their

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31 Andrea Hsu, *Hospitals Could Do More For Survivors Of Opioid Overdoses, Study Suggests*, NPR (Aug. 22, 2017), *available at* http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

32 *CDC Guideline*, March 18, 2016, at pg. 3, 34, *supra* note 8; *accord* CDC Press Release, *CDC Launches Campaign to Help States Fight Prescription Opioid Epidemic* (Sept. 25, 2017) (hereinafter "CDC Press Release, Sept. 25, 2017"), *available at* https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html (recognizing "opioid epidemic").

33 *CDC Vital Signs*, Nov. 2011, *supra* note 28; Katherin Eban, *OxyContin: Purdue Pharma's Painful Medicine,* Forbes (Nov. 9, 2011), *available at* http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.

34 M. Daubresse, *et al.*, Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).

35 *American Society of Interventional Pain Physicians (ASIPP) Fact Sheet*, at pg. 2, *available at* https://www.asipp.org/documents/ASIPPFactSheet101111.pdf.

lifetimes, and approximately 30% have used opioids in the previous year.[36]

89. In 2012, 7% of adults aged 20 and over reported using a prescription opioid in the past 30 days.[37]

90. A recently published federal survey estimates that 92 million Americans received an opioid prescription in 2015.[38]

91. Prescription opioids, once a niche drug class, are now the most prescribed therapeutic class of drugs in the U.S. – more than blood pressure, cholesterol, or anxiety drug medications.

E. Increases in Prescription Opioid Sales are the Principal Cause of Increased Addiction Rates and Overdose Deaths.

92. As reflected in Figure 1 above, over the past two decades, the rates of prescription opioid sales, opioid addiction, and opioid overdose deaths have risen together and closely track each other.

93. In 2017, the CDC noted that "[p]rescription opioid-related overdose deaths and admissions for treatment of opioid use disorder have increased in parallel with increases in opioids prescribed in the United States, which quadrupled from 1999 to 2010."[39] Similarly, the CDC noted in 2016 that "[s]ales of opioid pain medication have increased in parallel with opioid-related overdose deaths."[40]

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36 *The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations*, City of Philadelphia, at pg. 6 (May 19, 2017), *available at* http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

37 https://www.cdc.gov/nchs/data/databriefs/db189.htm.

38 Beth Han *et al.*, *Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health*, 167 (5) Annals of Internal Medicine 293-301 (2017), *available at* https://www.doh.wa.gov/Portals/1/Documents/2300/2017/AnnalsInternalMed.pdf.

39 *Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015*, at pg. 1 (July 7, 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6626a4.pdf.

40 *CDC Guideline*, March 18, 2016, at pg. 2, *supra* note 8.

94. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the principal cause of both opioid epidemics in the period 1999-2014 was the unprecedented increase in use of prescription opioids.[41] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated these data with data relating to admissions for treatment of opioid use disorders and overdose deaths.

95. As can be seen from Figure 1, which correlates prescription opioid usage and opioid addiction and overdoses starting in 1999, sharp, dramatic increases in the sale of prescription opioids for medical purposes closely track sharp, substantial increases in addiction as measured by treatment admissions (as previously described) and fatal overdoses.[42]

96. Using the above data and analysis, the CDC and other researchers have concluded that prescription opioid usage for daily use to treat chronic pain has been the principal causative factor driving both epidemics in opioid addiction and overdoses.[43]

97. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin. Apparently, as law enforcement and public health authorities and the medical profession have begun to limit the improper use of prescription opioids and for other reasons (including the high price of prescription opioids), which has reduced the supply of prescription opioids for legal use, many prescription opioid users suffering from opioid addiction have turned

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41 *Id.* at pg. 2.
42 Kolodny, Jan. 12, 2015, at pg. 560, *supra* note 7.
43 *CDC Guideline*, March 18, 2016, at pg. 2, *supra* note 8.

to heroin available on the black market.[44]

98. Based on the growing weight of scientific evidence, public health experts have concluded that the current opioid epidemics of addiction and overdoses have been caused primarily by opioid pain relievers marketed and sold by opioid manufacturers and their agents and prescribed by the medical community for long-term daily use to treat chronic pain. Studies show that the over-prescription of opioid pain relievers accounts for the use of opioids by the vast majority of persons addicted to opioids and experiencing opioid overdoses.[45]

99. The CDC has concluded that unless and until the prescription of opioids by the medical community is reduced to appropriate levels, the current epidemics of opioid addiction and overdoses will not be contained.[46] Even then, it may take decades before the populations currently addicted as a result of the opioid epidemic are appropriately treated.

100. Chronic pain patients and others – from users to their loved ones and communities at large – have been devastated by the prescription and use of opioids for medical uses. Some estimates of long-term prescription opioid users developing addiction are frighteningly high: one study found that between 30% and 40% of all long-term users of opioids experience problems with opioid use disorders.[47]

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[44] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. *See* Kolodny, Jan. 12, 2015, at pg. 560, *supra* note 7; *accord The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations*, City of Philadelphia, at pg. 7 (May 19, 2017), *available at* http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

[45] Kolodny, Jan. 12, 2015, at pg. 563, *supra* note 7; *CDC Guideline*, March 18, 2016, at pg. 2, *supra* note 8.

[46] Kolodny, Jan. 12, 2015, *supra* note 7, at pg. 565; *CDC Guideline*, March 18, 2016, at pg. 2-3, *supra* note 8.

[47] J. Boscarino *et al.*, *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) Journal of Addictive Diseases 185 (2011); J. Boscarino *et al.*, *Risk Factors for Drug Dependence Among Outpatients on Opioid Therapy in a Large US Healthcare System*, 105(10) Addiction 1776 (2010).

101. By 2014, nearly two million Americans either abused or were dependent on opioids.[48]

102. According to the CDC, "*91 Americans die every day from an opioid overdose.*"[49]

103. The opioid epidemic has led to many more overdose deaths than the heroin epidemic of the 1970s and crack cocaine epidemic of the 1980s and 1990s, prompting public health officials and commentators to conclude that the current opioid epidemic is the worst drug epidemic in U.S. history – worse than the previous heroin and crack cocaine epidemics combined.[50]

F. Recognition of an Opioid "Epidemic," "Crisis," and "Public Health Emergency."

104. The CDC has acknowledged the presence of an "opioid epidemic," also referred to as an "opioid overdose epidemic."[51]

105. A 2017 report by the U.S. Drug Enforcement Agency noted that the "opioid overdose crisis . . . is a public health and public safety emergency."[52]

106. The U.S. Department of Health and Human Services recognized the existence of an "opioid crisis" and stated that the "United States is in the midst of a prescription opioid

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48 Centers for Disease Control and Prevention, *Opioid Overdose, Prescription Opioids* (2017), *available at* http://www.cdc.gov/drugoverdose/opioids/prescribed.html.

49 Centers for Disease Control and Prevention, *Opioid Overdose, Understanding the Epidemic* (2017), *available at* http://www.cdc.gov/drugoverdose/epidemic/index.html (emphasis added).

50 Andrew Kolodny, M.D., *Responding to the Prescription Opioid and Heroin Crisis: An Epidemic of Addiction*, at 4 (2016), *available at* http://www.pdmpassist.org/pdf/TTAC_Opioid_Policy_Research_Collaborative_20170726.pdf.

51 *CDC Guideline*, March 18, 2016, at pg. 3, 34, *supra* note 8; *accord* CDC Press Release, Sept. 25, 2017 (recognizing "opioid epidemic"), *supra* note 32.

52 *Analysis of Overdose Deaths in Pennsylvania, 2016*, Drug Enforcement Agency Philadelphia Division and the University of Pittsburgh, at pg. 5 (July 2017) (hereinafter "*Analysis of Overdose Deaths in Pennsylvania*, July 2017"), *available at* https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf.

overdose epidemic."[53]

107. The U.S. Surgeon General noted in 2016 that opioid use has led to an "urgent health crisis" that specifically coincided with "*heavy marketing of opioids to doctors.*"[54]

108. Similarly, the National Institutes of Health identified the drug industry's "aggressive marketing" as a major cause of the opioid epidemic: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies.*"[55]

109. On October 26, 2017, the President of the United States declared a "public health emergency" caused by opioid addiction.[56] The action allows for shifting of resources within certain government programs to help people eligible for those programs receive treatment for opioid addiction and opioid use disorder.[57]

110. Most recently, on January 10, 2018, the Governor of Pennsylvania declared the

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53 *Opioids: The Prescription Drug & Heroin Overdose Epidemic*, U.S. Dept. of Health and Human Services (2017), *available at* https://www.hhs.gov/opioids.

54 https://turnthetiderx.org/ (emphasis added).

55 *America's Addiction to Opioids: Heroin and Prescription Drug Abuse* (2014) (emphasis added), *available at* https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

56 White House Office of the Press Secretary, *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis* (Oct. 26, 2017), *available at* https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis; *see also* The President's Commission on Combating Drug Addiction and the Opioid Crisis (Nov. 1, 2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

57 *Id.*

opioid epidemic a state-wide "disaster emergency."[58] The action allows for speeding up and expanding access to treatment; improving the availability of tools such as naloxone to first responders, opioid users, and their families; and enhancing coordination and data collection to bolster state and local responses.[59]

II. Philadelphia Faces an Opioid Epidemic and Resulting Public Health and Safety Crisis Equivalent to or Worse Than the National Public Health and Safety Crisis and Emergency.

111. The City – like the nation – is also now in the grips of an opioid-fueled public health and safety emergency of unprecedented dimensions that has endangered and continues to endanger the health, safety and peace of Philadelphia and its residents.

112. The City's public health and safety emergency includes historically high incidences of opioid addiction and opioid use disorder and of opioid-related deaths and non-fatal opioid overdoses. It also includes other adverse health effects of opioid addiction and opioid use disorder including historically high incidences of babies born with opioid withdrawal conditions, and an unprecedented increase in new hepatitis C virus ("HCV") infections caused by opioid injections. The epidemic has also been accompanied by an unprecedented level of opioid-related emergency room visits and hospitalizations; extensive provision of emergency response services by the Fire Department and other City agencies in reviving and transporting overdose victims; and the expenditure of enormous resources by the Police Department, District Attorney's Office, Public Defender's Office, City prison system, Health Department, Department of Behavioral Health and Intellectual disAbility Services, Department of Human Services, and other City departments and agencies providing health and related services to address increased crime and

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[58] Press Release, *Governor Wolf Declares Heroin and Opioid Epidemic a Statewide Disaster Emergency* (Jan. 10, 2018), *available at* https://www.governor.pa.gov/governor-wolf-declares-heroin-and-opioid-epidemic-a-statewide-disaster-emergency/.

[59] *Id.*

violence and family and social dysfunction linked to opioid use and addiction. The Medical Examiner's office is struggling to keep up with the rising tide of opioid deaths. In 2017, the homicide rate in Philadelphia reached its highest level since 2012, due in part to the opioid epidemic and competition from rival drug dealers who sell opioids.

113. The opioid epidemic and its deleterious impact on public health and safety in the City has created an overall substantial, repeated, and steadily increasing drain on the City's financial, personnel, medical, and other resources and capacities.

A. Public Health Impacts of the Opioid Epidemic in Philadelphia.

i. The Mayor's Task Force to Combat the Opioid Epidemic.

114. In 2016, the City established a task force of stakeholders working in public health called the *Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia* ("Task Force") to investigate the opioid epidemic in Philadelphia and make recommendations to address the ensuing public health and safety crisis. On May 19, 2017, the Task Force issued its final report and recommendations ("Final Report").[60] The Task Force also issued three Opioid Misuse and Overdose Reports since then,[61] and further Opioid Misuse and Overdose Reports are anticipated.

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[60] *The Mayor's Task Force to Combat the Opioid Epidemic in Philadelphia: Final Report and Recommendations*, City of Philadelphia (May 19, 2017) (hereinafter "*Mayor's Task Force Report*, May 19, 2017"), *available at* http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

[61] The three reports are: (i) *Opioid Misuse and Overdose Report*, Phila. Dept. of Public Health (Sept. 7, 2017) (hereinafter "*Opioids Misuse Report*, Sept. 7, 2017"), *available at* https://hip.phila.gov/Portals/_default/HIP/DataReports/Opioid/2017/Q2/OpioidMisuseOverdoseReport_Quarter2_2017_finalupdate_09122017_V2.pdf; (ii) *Opioid Misuse and Overdose Report*, Phila. Dept. of Public Health (Oct. 13, 2017), *available at* https://hip.phila.gov/Portals/_default/HIP/DataReports/Opioid/2017/Q2/OpioidMisuseOverdoseReport_Quarter2_2017_update_10132017.pdf; and (iii) *Opioid Misuse and Overdose Report*, Phila. Dept. of Public Health (Dec. 13, 2017), *available at* https://hip.phila.gov/Portals/_default/HIP/DataReports/Opioid/2017/Q3/Dec/OpioidMisuseOverdoseReport_Quarter3_2017_12132017.pdf.

The Final Report and three Opioid Misuse and Overdose Reports issued to date are collectively referred to herein as the "Reports."

115. The findings of the Final Report are sobering, disturbing and alarming. The Final Report concluded:

> The crisis caused by opioids encompasses opioid use, opioid use disorder, and related morbidity and mortality. Each of these is a problem of its own and each leads to many other individual and social problems. Opioid use and addiction are not new issues, but they have reached epidemic proportions in the city and demand a new and coordinated response.[62]

116. The Final Report noted that Philadelphia is facing an "opioid epidemic" and "public health crisis" caused by the enormous rise in the use of prescription opioids for medical purposes.[63]

117. The City Health Department conducted a survey of Philadelphia residents in 2017 and found that "32% of Philadelphia adults surveyed – nearly 1 in 3 – used a prescription opioid in the past year."[64] According to the Final Report, the City Health Department estimates that between 100,000 and 200,000 Philadelphia residents use prescription opioids on a regular basis. Approximately 50,000 of those individuals are estimated to misuse prescription opioids.[65]

118. Regarding opioid addiction and opioid use disorder, the Final Report stated:

> The physical and psychological impact of opioid use disorder on the residents and communities of Philadelphia is difficult to measure but cannot be overstated. *Approximately 14,000 people were treated for opioid use disorder in Philadelphia's publicly funded system in the 12-month period from October 2015 through September 2016.* The patients actively seeking and participating in care still represent only a fraction of those with opioid use disorder, including those

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62 *Mayor's Task Force Report*, May 19, 2017, at pg. 6, *supra* note 60.

63 *Id.* at pg. 2 and introductory page titled "Message from Mayor Kenney."

64 *Prescription Opioid and Benzodiazepine Use in Philadelphia, 2017*, Phila. Dept. of Public Health (Aug. 2017), *available at* https://www.phila.gov/health/pdfs/commissioner/chart/chart%20v2e9.pdf.

65 *Mayor's Task Force Report*, May 19, 2017, at pg. 8, *supra* note 60.

who use heroin and those in need of treatment.[66]

119. According to the Reports, in 2015, the most recent year for which such data are available, there were 599 hospitalizations attributable to opioid poisoning in Philadelphia. That is over twice the number of hospitalizations attributable to opioid poisoning in 2002.[67]

120. Again, according to the Reports, the number of opioid overdose deaths in Philadelphia more than tripled since 2003.[68] This is consistent with the national rate, where the number of drug overdose deaths involving opioids has quadrupled since 1999.[69]

121. According to the Reports, *in Philadelphia there were a staggering 907 drug overdose deaths in 2016 alone, of which 80% were opioid-related.*[70] And, "Philadelphia is on track to record 1,200 drug overdose deaths this year (2017), a 33 percent increase over last year."[71]

122. According to a joint analysis of Pennsylvania overdose deaths by the Drug Enforcement Agency ("DEA") and the University of Pittsburgh, the "presence of an opioid, illicit or prescribed by a doctor, was detected in 85 percent of drug related overdose deaths in Pennsylvania in 2016."[72]

123. According to the Final Report and other sources, Philadelphia suffers a higher incidence of drug overdose deaths on a per-capita basis relative to all other counties in

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66 *Id.* at pg. 8 (emphasis added).

67 *Opioids Misuse Report*, Sept. 7, 2017, at pg. 18, *supra* note 61.

68 *Id.* at pg. 25.

69 CDC, *Opioid Overdose: Understanding the Epidemic* (2017), *available at* http://www.cdc.gov/drugoverdose/epidemic/index.html.

70 *Mayor's Task Force Report*, May 19, 2017, at pg. 8, *supra* note 60; *Opioids Misuse Report*, Sept. 7, 2017, at pg. 2, 25, *supra* note 61; *Analysis of Overdose Deaths in Pennsylvania,* July 2017, at pg. 35, 90, *supra* note 52.

71 Harold Brubaker, *Drug Overdose Death Surge in Philly Continues This Year*, Philadelphia Inquirer (May 16, 2017), *available at* http://www.philly.com/philly/health/addiction/drug-overdose-death-surge-continuing-this-year-20170516.html.

72 *Analysis of Overdose Deaths in Pennsylvania,* July 2017, at pg. 5, *supra* note 52.

Pennsylvania and most large cities throughout the United States. Philadelphia was ranked first among all Pennsylvania counties in terms of the number of drug overdose deaths per 100,000 residents in 2015.[73] Philadelphia's rate of 47 drug overdose deaths per 100,000 residents was four times higher than New York City's (11 deaths per 100,000 residents) and three times higher than Chicago's (15 deaths per 100,000 residents) in 2015.[74] The vast majority of these overdose deaths were opioid related.

124. In Pennsylvania, the per-capita rate of overdose deaths "far exceed[ed] the national average" in 2016.[75]

125. The drug naloxone (usually sold under the brand name Narcan) is a potentially life-saving medication that reverses the effect of opioids and is used to treat opioid overdoses that would otherwise be fatal. In 2016, Philadelphia Fire Department personnel administered naloxone to over 4,000 individuals, in every zip code in the City, and the Philadelphia Police Department administered naloxone to 200 individuals.[76] In addition, approximately 5,500 doses of naloxone were distributed from a needle exchange program to individuals who use drugs and are at risk of a fatal overdose.[77] Thus, for the last year for which data are available, City emergency response services treated an estimated 5,000 to 10,000 opioid overdoses, a volume that was several multiples higher than the number of fatal overdoses. Employees in the City's libraries have had to administer naloxone to overdose victims at their facilities.

126. The Final Report also addressed the impact of opioid use disorder on not only addicted users, but on their families. The Final Report's conclusion was particularly distressing,

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73 *Id.* at pg. 9.
74 *Mayor's Task Force Report*, May 19, 2017, at pg. 8, *supra* note 60.
75 *Analysis of Overdose Deaths in Pennsylvania,* July 2017, at pg. 8, *supra* note 52.
76 *Mayor's Task Force Report*, May 19, 2017, at pg. 9, *supra* note 60.
77 *Id.* at pg. 9.

stating: "Philadelphia families are burdened with grief and loss to overdose, stigma associated with opioid addiction, and the multigenerational dynamic of the disease of addiction. The consequences of alcohol and drug misuse that impact families include compromised physical health and mental health, increased health care costs, loss of productivity at school and/or work, reduced quality of life, increased crime and violence, as well as child abuse and neglect."[78]

127. All of these circumstances – opioid deaths, opioid-related emergency department visits and hospital admissions, and drug overdoses requiring naloxone, as well as the family and social dysfunction as discussed above – are recognized, direct, and quantifiable measures of the adverse public health impact on Philadelphia due to the opioid epidemic.

ii. Opioid Use and Adverse Health Consequences in Philadelphia Repeat the National Pattern Linked to Prescription Opioids for Medical Uses.

128. The opioid epidemic and public health crisis in Philadelphia closely tracks the national pattern of dramatic expansion in prescription opioid sales and resulting opioid addiction and use disorders and overdoses beginning at least as early as 2001, as addressed above.

a. Opioid Addiction and Opioid Use Disorders.

129. The City Health Department tracks the prevalence and incidence of opioid addiction and opioid use disorder in a number of ways, including referring to data collected from state authorities and data the City Health Department collects regarding hospitalization for opioid use disorder.

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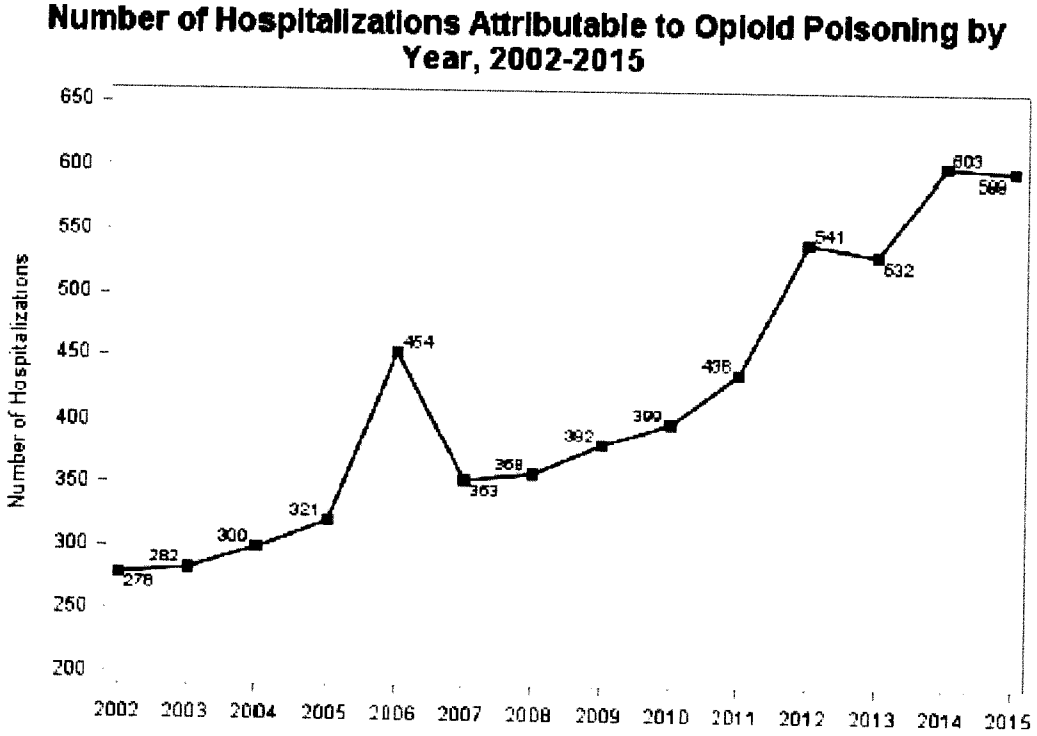
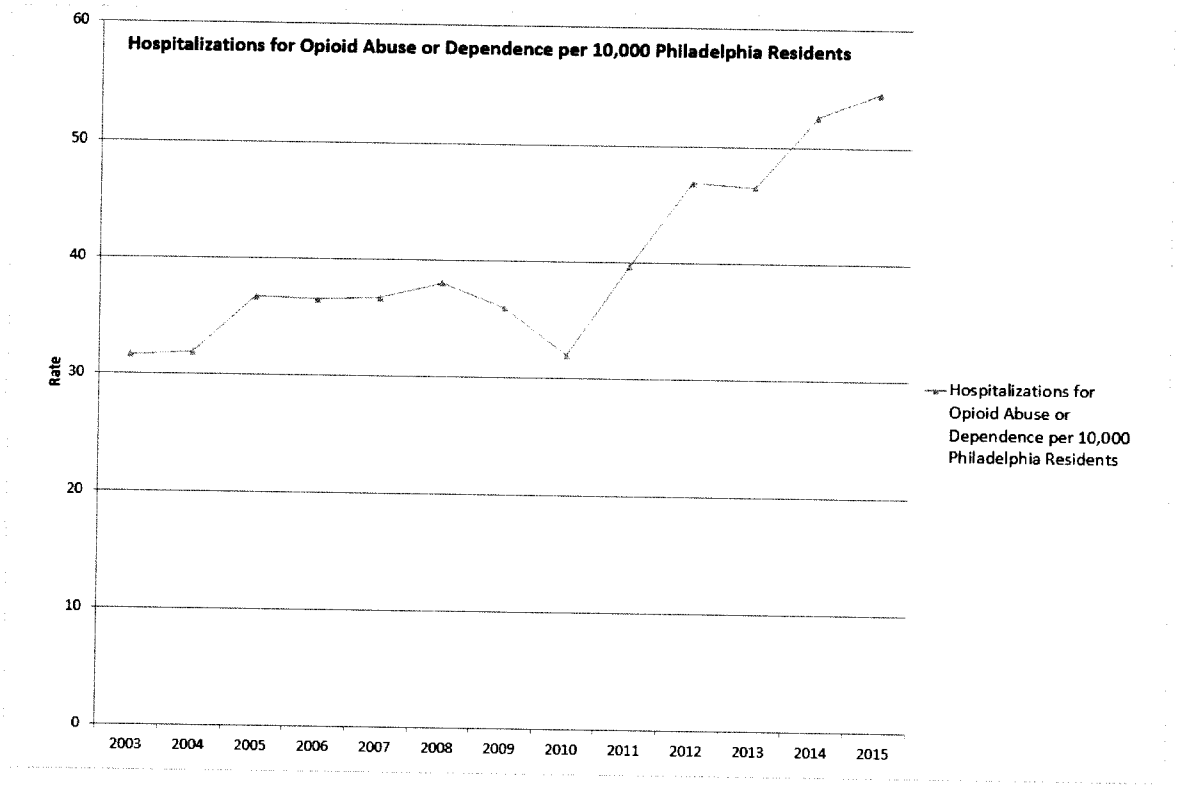
[78] *Mayor's Task Force Report*, May 19, 2017, at pg. 10, *supra* note 60.

130. Philadelphia data on hospitalizations attributable to opioid poisoning for the period 2002-2015 is as follows (Figure 2):[79]



[79] *Opioids Misuse Report*, Sept. 7, 2017, at pg. 18, *supra* note 61.

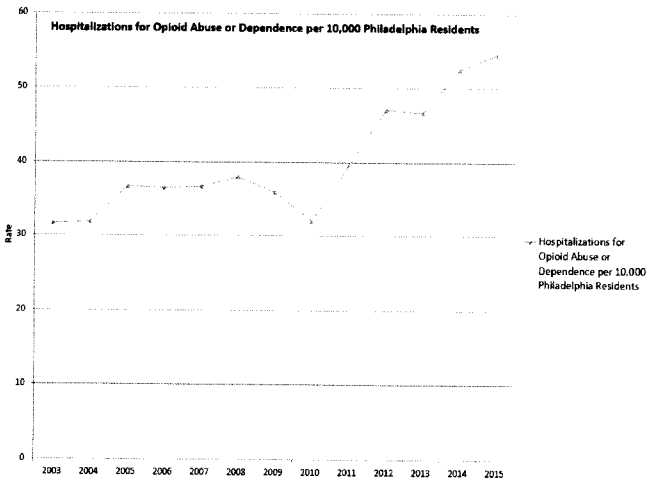
131. Similar Philadelphia data on hospitalizations for opioid abuse or dependence per 10,000 residents, for the period 2003-2015, is as follows (Figure 3):[80]



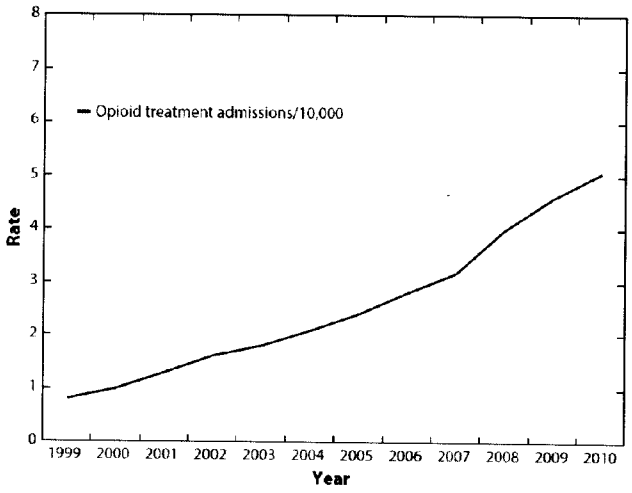
80 Hospitalization data was gathered by the City from the Pennsylvania Health Care Cost Containment Council.

132. Hospitalization data relating to the City as referred to above are similar to the national data utilized by the CDC, and the City and national trends track each other as indicated through a comparison of the following graphs:

Philadelphia (Figure 3):[81]



Nationwide (Figure 4):[82]



133. Accordingly, national trends on opioid addiction parallel trends at the local level in Philadelphia.

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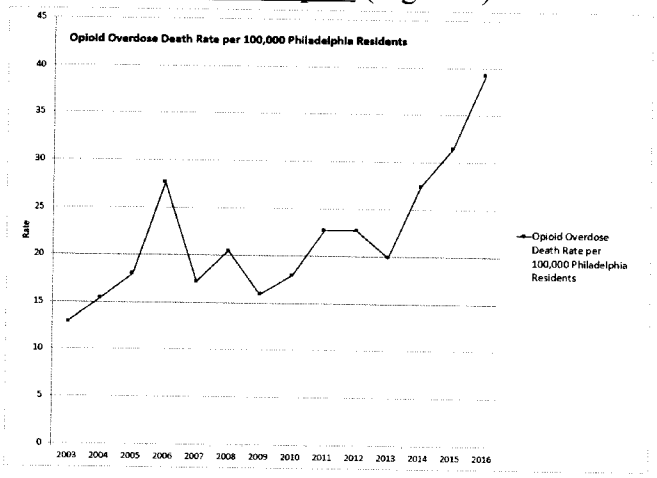
81 Hospitalization data was gathered by the City from the Pennsylvania Health Care Cost Containment Council.

82 This nationwide graph was extracted from Figure 1 above.

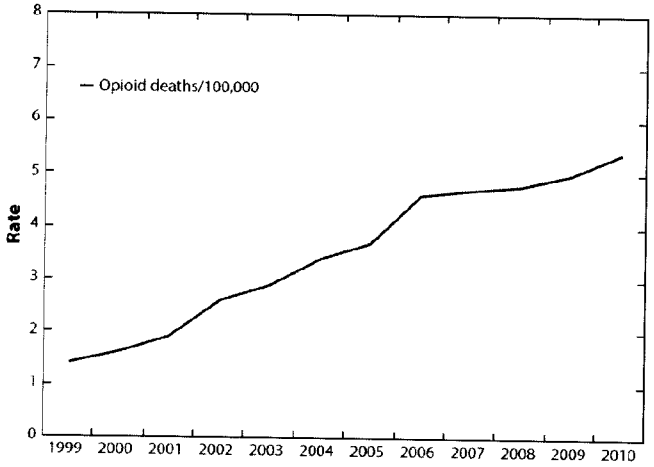
b. Opioid Overdoses.

134. Opioid overdose levels in Philadelphia are also similar to the national overdose levels and the City and national trends track each other as indicated in the following graphs:

Philadelphia (Figure 5):[83]



Nationwide (Figure 6):[84]

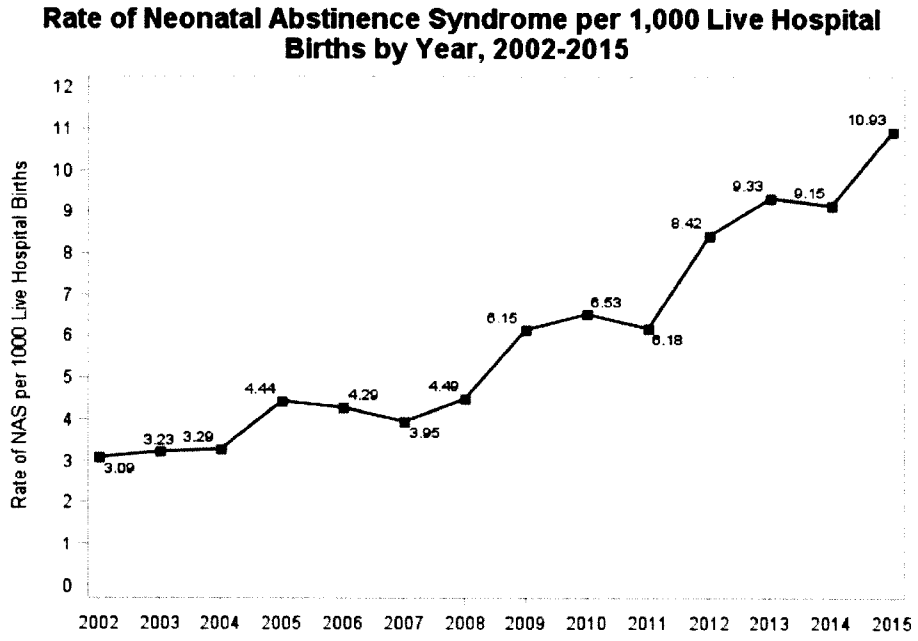


83 Overdose data was gathered by the City from the Philadelphia Medical Examiner's Office. A similar graph of opioid overdose data based on raw numbers (*i.e.*, not adjusted to a "per 100,000 Philadelphia Residents" figure) is located in the *Opioids Misuse Report*, Sept. 7, 2017, at pg. 25, *supra* note 61.

84 This nationwide graph was extracted from Figure 1 above.

c. Other Adverse Health Effects from Opioids.

135. Opioid use during pregnancy can lead to neonatal abstinence syndrome (NAS) and may interfere with a child's brain development and may result in subsequent consequences for mental functioning and behavior. In Philadelphia, the rate of NAS increased more than three-fold from 3 per 1,000 live births in 2002, to 11 per 1,000 live births in 2015.[85] The following graph illustrates the drastic increase in NAS in Philadelphia (Figure 7):[86]



136. Opioid use can also lead to infectious diseases such as hepatitis C virus (HCV) as a result of using needles to inject opioids.[87] If left untreated, HCV can result in liver cirrhosis, cancer, and end-stage liver disease. Incidences of HCV have increased in Philadelphia due to the

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85 *Mayor's Task Force Report*, May 19, 2017, at pg. 10, *supra* note 60.

86 *Opioids Misuse Report*, Sept. 7, 2017, at pg. 35, *supra* note 61.

87 *Mayor's Task Force Report*, May 19, 2017, at pg. 22, *supra* note 60; *see also* Sean Murphy *et al.*, *Association Between Hepatitis C Virus and Opioid Use While in Buprenorphine Treatment: Preliminary Findings* (2015) ("The prevalence of hepatitis-C-virus (HCV) infections is high among opioid-dependent individuals."), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638227/.

opioid epidemic. The Philadelphia Department of Public Health has noted that "concurrent with the increases in opioid overdose has been other adverse outcomes including increasing rates of . . . hepatitis C virus (HCV) transmission."[88] It also noted that the "number of newly-identified cases of HepC infection among 18-35 year olds nearly . . . doubled from 660 in 2010 to 1161 in 2016."[89]

137. Similarly, opioid abuse can lead to other health problems such as right-sided heart valve infections as a result of using needles to inject opioids. The incidence of right-sided heart valve infections has increased rapidly over the past decade as a consequence of the opioid epidemic.[90]

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88 https://hip.phila.gov/DataReports/Opioid.

89 *Hepatitis C Virus Infection in Philadelphia*, Phila. Dept. of Public Health (Nov. 2017), *available at* http://www.phila.gov/health/pdfs/commissioner/chart/chart%20v2e11.pdf.

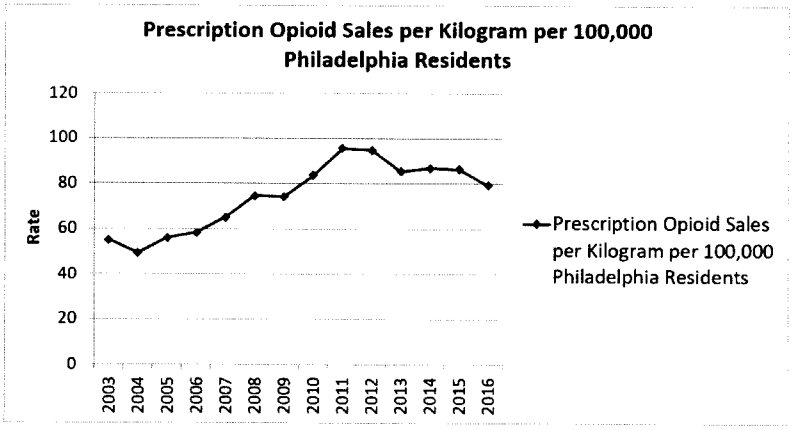
90 *Hospitalizations for Heart Infection Related to Drug Injection Rising Across the US*, Science Daily (Sept. 1, 2016), *available at* https://www.sciencedaily.com/releases/2016/09/160901092818.htm.

d. Use of Prescription Opioids for Medical Purposes.

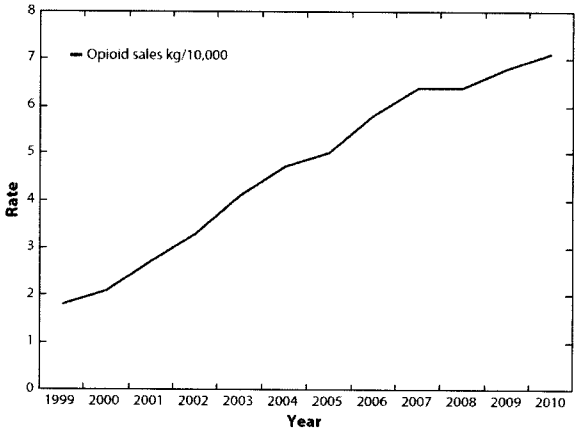
138. Use of prescription opioids for medical purposes in the City can also be correlated with the national pattern referred to above. The CDC's analysis of opioid prescriptions reflected in the graph in Figure 1, *supra*, is based on data on prescriptions for opioid pain relievers collected by the U.S. Drug Enforcement Agency. Similar data are available for Philadelphia County and can be directly compared with the CDC's data on prescription use and its adverse health effects.

139. The following graph reflects the use of prescription opioids in Philadelphia as measured by the number of prescriptions written for opioid pain relievers from 2003-2016 and compares to the national data:

Philadelphia (Figure 8):[91]



Nationwide (Figure 9):[92]

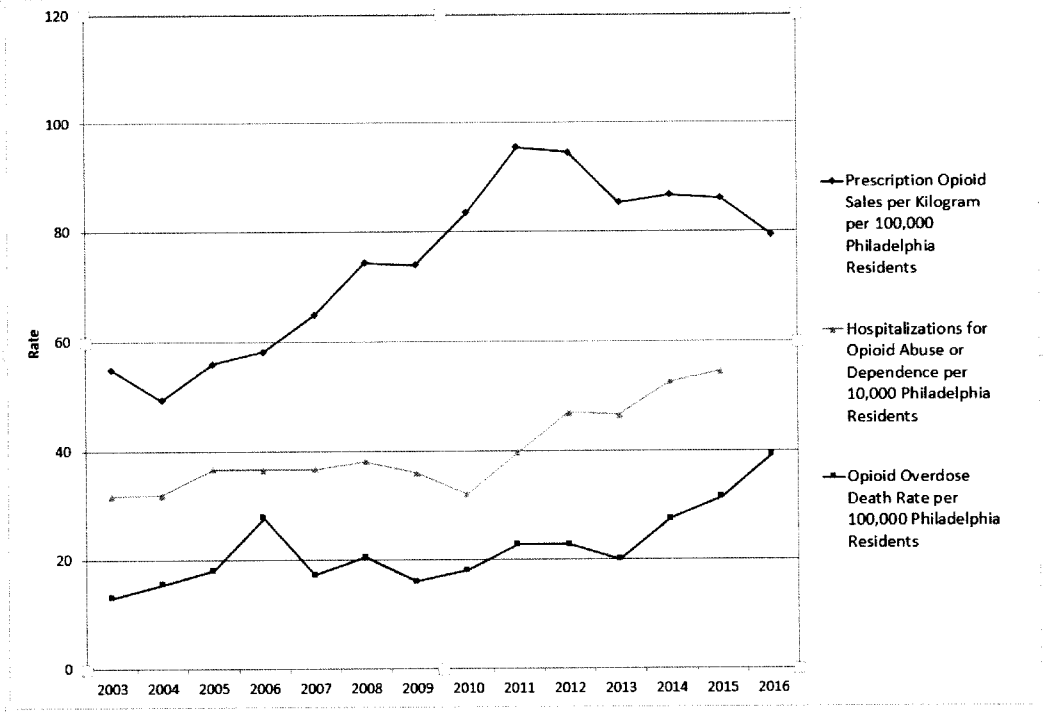


91 Prescription opioid sales data were gathered from DEA ARCOS Retail Drug Summary Reports. A similar graph of prescription opioid sales data based on raw numbers (*i.e.*, not adjusted to a "per 100,000 Philadelphia Residents" figure) is located in the *Opioids Misuse Report*, Sept. 7, 2017, at pg. 5, *supra* note 61.

92 This nationwide graph was extracted from Figure 1 above.

140. Just as reflected in the nationwide CDC analysis, reliable measures of prescription opioid use, opioid addiction/use disorders, and overdoses are available in Philadelphia, and the trend mirrors the national trend:[93]

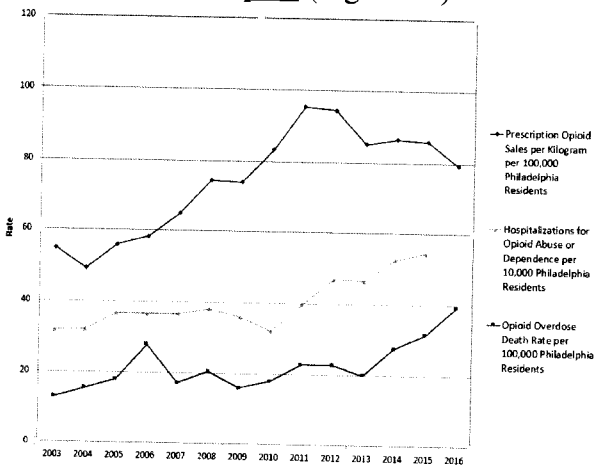
Prescription Opioid Sales, Hospitalizations, and Overdose Deaths in Philadelphia (Figure 10):



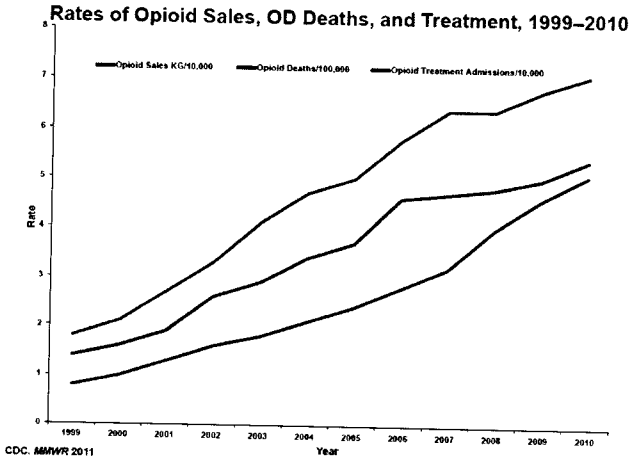
[93] Prescription opioid sales data were gathered from DEA ARCOS Retail Drug Summary Reports. Hospitalization data were gathered from the Pennsylvania Health Care Cost Containment Council. Overdose data were gathered from the Philadelphia Medical Examiner's Office.

141. The parallels in patterns of morbidity and mortality for prescription opioid use in Philadelphia and nationally are striking, as noted in the following graphs:

Philadelphia (Figure 10):[94]



Nationally (Figure 1):[95]



B. Public Safety Impacts of Opioids in Philadelphia.

142. As the Task Force and others have pointed out, the opioid crisis also imperils, and adversely affects, public safety in the City in a number of ways.

143. According to the Final Report, the disease of opioid addiction has prompted criminal acts by addicted individuals seeking to obtain opioids through illegal and sometimes violent means. This type of public safety issue both strains City resources and places all City residents at an increased risk of harm.

144. Opioid-related crimes include, among other things, theft of money or property to finance opioid addiction; theft of prescription opioids from friends, relatives or others; and crimes committed while under the influence of opioids.

145. Nationally, roughly 80% of individuals who are incarcerated are in jail for a crime

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94 Prescription opioid sales data were gathered from DEA ARCOS Retail Drug Summary Reports. Hospitalization data were gathered from the Pennsylvania Health Care Cost Containment Council. Overdose data were gathered from the Philadelphia Medical Examiner's Office.

95 This is a reproduction of Figure 1, *supra*.

committed while under the influence of alcohol or drugs, in order to obtain drugs (including opioids), or for a crime associated with the trade in illegal or diverted drugs.[96] Philadelphia's criminal justice system profile is no different – and indeed Philadelphia is one of the cities in the country most adversely impacted by the opioid epidemic.

146. In 2016, there were approximately 4,000 arrests in Philadelphia related to heroin.[97] Four out of five individuals who begin using heroin start the transition to heroin from prescription opioid pain medications.[98]

147. Opioid abuse has also adversely impacted neighborhood public safety and well-being throughout the City. The notorious railroad encampment of drug users in North Philadelphia that was known as "El Campamento" is a striking example of the many ways in which the opioid problem harmed public safety in the City. Until it was shut down in the summer of 2017 in no small part as a result of law enforcement efforts by the City, a sprawling encampment of drug users who injected themselves with opioids and heroin in broad daylight sprung up on the railroad tracks running under Gurney Street in the Kensington area of Philadelphia. Hundreds of drug users came from around the United States to what eventually became the largest open-air drug market on the East Coast, and some of them began living near the train tracks. Piles of trash and hundreds of thousands of used needles littered the encampment. In response to this enormous public health and safety crisis, the City entered into an agreement in June 2017 with Conrail, the railroad company which owns the tracks, to clean up the area. The effort, which included tearing down makeshift shacks and disposing of toxic waste, began at the end of July 2017. Ultimately, the City paid tens of thousands of dollars for

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[96] *Alcohol, Drugs and Crime*, Nat'l Council on Alcoholism and Drug Dependence (2017), *available at* https://www.ncadd.org/about-addiction/alcohol-drugs-and-crime.

[97] *Opioids Misuse Report*, Sept. 7, 2017, at pg. 22, *supra* note 61.

[98] *Mayor's Task Force Report*, May 19, 2017, at pg. 7, *supra* note 60.

security, waste removal and fencing at the Kensington encampment, plus substantial additional costs to police the area, among other things.

148. Further, opioid use is a significant cause of homelessness in Philadelphia, and a major reason why many in the homeless population remain without shelter. Opioids frequently are abused on the City's streets, including in public parks and in municipal buildings. A large number of individuals afflicted with opioid addiction who have lost stable housing have crowded into encampments on City property, with the byproducts of their abuse – piles of trash, needles, and other waste – littering City streets. The City's homeless population has increased as a result of the opioid epidemic, and the City has taken steps to expand City-funded programs and services available to the homeless population.

149. The Task Force also noted that "improper disposal of drug use equipment," such as used needles, poses a threat to neighborhood safety.[99] Accidental needle sticks are a safety hazard to City residents caused by the opioid epidemic.

150. According to the Final Report and other commentators, automobile accidents caused by impaired opioid users pose a safety risk. "[R]esearchers report a sevenfold increase in the number of drivers killed in car crashes while under the influence of prescription [opioid] painkillers. . . . Prescription [opioid] drugs can cause drowsiness, impaired thinking and slowed reaction times, which can interfere with driving skills."[100]

151. Children face safety risks when parents who abuse opioids are unable to care properly for their children.

152. Opioid-caused disturbances occur regularly on private and public property in the

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[99] *Mayor's Task Force Report*, May 19, 2017, at pg. 23, *supra* note 60.

[100] Steven Reinberg, *Significant Spike in Opioid-Related Car Crash Deaths*, CBS News (July 31, 2017), *available at* https://www.cbsnews.com/news/opioid-drugs-car-crash-fatalities-deaths/.

City and detract from their intended uses and value. Much opioid-related criminal activity – including prostitution and theft committed to support opioid addiction – takes place on City streets and in other public areas. These are just a few examples of how Philadelphia's real property interests have been adversely affected by the opioid epidemic.

C. The Opioid Epidemic Has Greatly Increased the City's Costs.

153. The City's efforts to address and abate these opioid related harms have come at considerable cost. Financial burdens to the City have expanded along with the increased sale, use, and misuse of prescription opioids in Philadelphia.

i. City-Funded Public Medical Costs.

154. As noted above, approximately 14,000 people were treated for opioid-use disorder in the City's publicly-funded health system during the 12-month period from October 2015 to September 2016.[101] The City incurred significant increased costs for these services during this period, as well as similar such costs for other periods.

155. The number of persons treated actually understates the extent of opioid addiction and treatment need, because patients participating in addiction treatment represent only a fraction of those with an opioid use disorder. National data establish that roughly one out of every ten people with a substance use disorder actually obtain treatment for the specific disorder.[102] Extrapolating on this basis, if there were 14,000 Philadelphia residents who received specialty treatment for an opioid use disorder, there were roughly 140,000 residents who likely needed

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[101] *Mayor's Task Force Report*, May 19, 2017, at pg. 8, *supra* note 60.

[102] Rachel Lipari *et al.*, *America's Need for and Receipt of Substance Use Treatment in 2015,* Substance Abuse and Mental Health Services Administration (Sept. 29, 2016), *available at* https://www.samhsa.gov/data/sites/default/files/report_2716/ShortReport-2716.html.

treatment and did not seek it.[103]

156. In Philadelphia, the nonprofit organization Community Behavioral Health ("CBH") is contracted and funded by the City of Philadelphia to manage the behavioral health services for Philadelphia Medicaid beneficiaries. Similarly, Philadelphia's Office of Behavioral Health manages care for uninsured Philadelphia residents.[104]

157. CBH maintains a network of treatment providers for various behavioral and medical needs, including opioid abuse. There are 13 opioid treatment providers within the CBH network ("CBH facilities"), as well as residential treatment facilities, halfway houses, hospitals, and other treatment facilities.[105] As noted, approximately 14,000 individuals who received care through the City's publicly-funded drug treatment network in 2016 received treatment for opioid-use disorders.[106] The City incurred significant costs for these City-funded and City-managed services.

158. In these CBH facilities, medication-assisted treatment with methadone is an important component of treatment for opioid-use disorder. *There are 13 methadone clinics in Philadelphia that receive City funding. In 2016, those clinics served nearly 6,000 Philadelphia residents who received methadone for their opioid use disorder.*[107] The City incurred significant costs to fund these methadone clinics. Methadone is administered daily in pill or liquid form,

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[103] Even that number is an undercount, because it includes only Philadelphia residents who receive treatment through the City's publicly-funded health system, and does not include others such as those residents who receive from the City private insurance or other forms of coverage and payment.

[104] *Mayor's Task Force Report*, May 19, 2017, at pg. 13, *supra* note 60.

[105] *Id.* at pg. 13.

[106] *Id.* at pg. 13.

[107] *Id.* at pg. 14.

which costs approximately $150 per month per person.[108]

159. The availability of other forms of medication-assisted opioid treatment in the CBH facilities, including Suboxone (buprenorphine plus naloxone), was increased in City-funded programs in 2015 and 2016 in response to the opioid epidemic.[109] Suboxone is often administered by a daily film placed under the tongue, which costs approximately $450 per month per person.[110]

160. Another form of medication-assisted treatment, Vivitrol (injectable extended-release naltrexone), has shown early promise and is provided in City-funded programs.[111] Vivitrol is administered by a monthly injection, which costs approximately $1,000 per month per person.[112]

161. Medication-assisted treatment includes not only the medications themselves, but also psychosocial treatments. City-funded programs provide these services.

162. The City, via the Department of Behavioral Health and Intellectual disAbility Services ("DBHIDS"), funded eight opioid-related substance use disorder early intervention programs in 2017. These programs target at-risk individuals in Philadelphia and provide individual, group and family therapy and service referrals.[113]

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[108] Cara Tabachnick, *Breaking Good: Vivitrol, a New Drug Given as a Monthly Shot, is Helping Addicts Stay Clean*, The Washington Post (March 13, 2015) (hereinafter "Washington Post, March 13, 2015"), *available at* https://www.washingtonpost.com/lifestyle/magazine/his-last-shot-will-a-monthly-jab-of-a-new-drug-keep-this-addict-out-of-jail/2015/03/05/7f054354-7a4c-11e4-84d4-7c896b90abdc_story.html?utm_term=.9058b0492059.

[109] *Mayor's Task Force Report*, May 19, 2017, at pg. 14, *supra* note 60.

[110] Washington Post, March 13, 2015, *supra* note 108.

[111] *Mayor's Task Force Report*, May 19, 2017, at pg. 14, 27, *supra* note 60.

[112] Washington Post, March 13, 2015, *supra* note 108.

[113] *The Opioid Epidemic in Philadelphia: Implementation of the Mayor's Task Force Recommendations*, at pg. 7 (Sept. 13, 2017) (hereinafter "*Implementation of Task Force Recommendations*, Sept. 13, 2017"), *available at* http://dbhids.org/wp-content/uploads/2017/04/OTF_StatusReport-1.pdf.

163. In direct response to the opioid epidemic, DBHIDS has taken several actions – many at considerable cost to the City – including the following:

a. Expanding the use of recovery houses and extending hours of some residential programs to accept individuals after 5 p.m. and during weekends;

b. Starting work on a web-based treatment capacity portal where all residential providers are required to enter their availability for new patients daily;

c. Authorizing higher levels of care in instances where patients face risks requiring immediate residential treatment;

d. Mandating all opioid treatment programs to offer all forms of medication-assisted treatment, including methadone, buprenorphine, and naltrexone in 2017. As a result of this mandate, naltrexone is now available in 14 outpatient treatment sites and 4 residential sites throughout Philadelphia;

e. Requiring all halfway houses to accept individuals on all forms of medication-assisted treatment and psychiatric medications, to increase patients' access to treatment; and

f. Initiating the development of a 24/7 walk-in center where individuals can receive immediate stabilization in an outpatient setting and get access to further treatment.[114]

164. The City has also incurred costs for opioid-related medical or surgical services provided to certain indigent or other qualifying residents. Such services may include treatment for infants born with NAS. Costs for treating NAS have been estimated at $60,000 per infant for

[114] *Mayor's Task Force Report*, May 19, 2017, at pg. 12, *supra* note 60.

hospital care alone.[115]

165. Opioid-related services also include treatment for hepatitis C virus (HCV). Recently approved treatments for HCV cost approximately $84,000 per patient.[116]

166. Approximately 80% of individuals with hospital stays in Philadelphia attributable to opioids received some form of public insurance paid by the City.[117]

167. Opioid-related deaths generally require an autopsy and toxicology screen, performed by the Philadelphia Medical Examiner's office.[118] The number of autopsies at the Medical Examiner's office has risen about 20 percent in three years, from 2,489 in 2013 to 3,018 in 2016. The increase, largely due to opioid deaths, required a doubling in the budget for supplies and materials (body bags, safety equipment, gowns, etc.) and the hiring of a new assistant medical examiner.[119] There were also increased costs for toxicology tests. These costs are funded by the City.

ii. The City's Increased Costs of Emergency Services Provided by Police, Fire and EMS and Attributable to the Opioid Epidemic.

168. The City provides a wide range of services to protect public health and safety, including police, fire, and EMS services.

169. These City services have been severely burdened by the opioid epidemic at

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[115] *What's Best for Babies Born to Drug-Addicted Mothers?,* USA Today (April 26, 2014), *available at* https://www.usatoday.com/story/news/health/2014/04/25/best-babies-born-drug-addicted-mothers/8170555/.

[116] *Jack Hoadley et al., The Cost of a Cure: Revisiting Medicare Part D and Hepatitis C Drugs* (November 3, 2016), *available at* http://healthaffairs.org/blog/2016/11/03/the-cost-of-a-cure-revisiting-medicare-part-d-and-hepatitis-c-drugs/.

[117] *Opioids Misuse Report*, Sept. 7, 2017, at pg. 20, *supra* note 61.

[118] http://www.phila.gov/health/medicalexaminer/Pathology.html; http://www.phila.gov/health/medicalexaminer/Toxicology.html.

[119] Sam Wood, *Victims of Opioid Overdoses Stack Up for Coroners, Costing Taxpayers Dearly*, Philadelphia Inquirer (Oct. 19, 2017), *available at* http://www.philly.com/philly/health/addiction/bodies-opioid-ods-coroners-oxycontin-marino-trump-cdc-cadavers-philadelphia-pathologists-autopsies-norristown-toxicology-20171018.html.

substantial increased costs to the City. For example, the City has faced increased expenditures for naloxone and related costs such as training EMS personnel to administer naloxone; increased volumes of 911 emergency calls and trips (so many, in fact, that the City often needs to send fire trucks because there are not enough ambulances available); increases in the number of personnel required; increases in the budget of the departments; increases in the amount of work applying for grants and other alternative sources of funding to offset increased opioid-related costs; increased turnover and recruitment costs; and increased occupational hazards arising from opioid use and abuse such as exposure to carfentanil (where only a few drops can be deadly) and accidental needle sticks, among others.

170. The City also spends hundreds of thousands of dollars per year to purchase naloxone to address opioid overdoses. The City administered nearly 10,000 doses of naloxone in 2015 via its fire department, police department, and as part of a needle exchange program. The City pays approximately $37 per dose for naloxone.

iii. The City's Increased Public Safety and Criminal Justice Costs Attributable to the Opioid Epidemic.

171. Opioid addiction has had major impacts on the City's policing and criminal justice system.[120] The opioid epidemic has caused an increase in crime, arrests and incarceration for opioid-related offenses.

172. As noted above, opioid-related crimes include theft of money or property to help finance opioid addiction; theft of prescription opioids from friends, relatives or others; unlawful possession or trafficking of opioids; and crimes committed while under the influence of opioids.

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[120] *Mayor's Task Force Report*, May 19, 2017, at pg. 11, *supra* note 60; *see also* Ltr. from Nat'l Assoc. of Attorneys General to America's Health Insurance Plans, at pg. 1-2 (Sept. 18, 2017) ("State and local governments alone spend nearly 8 billion dollars a year on criminal justice costs related to opioid abuse.") (citing sources), *available at* http://www.naag.org/assets/redesign/files/sign-on-letter/Final%20NAAG%20Opioid%20Letter%20to%20AHIP.pdf.

173. Public safety and criminal justice costs directly attributable to the opioid epidemic include increased costs for police resources, district attorney resources, public defender resources, judicial system resources, prison resources, and increased costs in the form of property losses due to crimes. Nationally, these costs have been calculated to be $7.6 billion per year for prescription opioid abuse and dependence.[121] Based on the disproportionate severity with which the opioid epidemic has impacted Philadelphia relative to the rest of the country, the City has suffered a disproportionate share of these financial burdens as a percentage of its population. Based on a measure of percentage of the national population alone, a rough estimate of these additional costs to the City would be approximately $30 to $40 million per year.

174. Further, the City established a "Drug Treatment Court" in 1997, which often directs criminal defendants to substance abuse disorder treatment instead of incarceration.[122] Approximately 37% of the individuals who participate in Drug Treatment Court have reported that they are opioid users. That percentage continues to increase and is currently estimated to be as much as 50%. Drug Treatment Court proceedings frequently result in individuals being enrolled in treatment services such as recovery housing, vocational training, employment placement programs, medication-assisted treatment, and trauma counseling. Over the past five years, 890 participants were accepted to Drug Treatment Court.[123] The City incurs significant costs for these programs as a direct result of the opioid epidemic.

175. The Philadelphia Department of Prisons ("PDP") has incurred increased costs for inmates incarcerated for opioid-related crimes. For example, many such inmates required additional hospitalization and medical care directly relating to their opioid addiction disorder.

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[121] Florence, *et al., The Economic Burden of Opioid Overdose, Abuse, and Dependence in the United States, 2013*, Medical Care, Vol. 54, No. 10, at pg. 903 (October 2016).

[122] *Mayor's Task Force Report*, May 19, 2017, at pg. 11-12, *supra* note 60.

[123] *Id.* at pg. 12.

176. The PDP also provides methadone and Suboxone (buprenorphine plus naloxone) to inmates who were receiving those opioid addiction treatments prior to incarceration.[124] Many inmates receive methadone in Philadelphia prisons, at a considerable cost to the City.

177. The PDP also incurs costs for medical assessments, detoxification programs, and enrollment in its cognitive behavioral therapy program related to opioid addiction. At considerable cost to the City, the PDP provides withdrawal management services to about 8,000 prisoners annually, approximately two-thirds to three-quarters of which are for opioids.[125]

178. Opioid addiction frequently affects released inmates. Based on the City's ongoing assessment of fallout from the opioid epidemic, there is a high correlation between prisoners released from Philadelphia prisons and subsequent overdose deaths involving opioids. In light of this risk, in 2017 the PDP began to distribute naloxone to released inmates who are at high risk of opioid abuse and overdose.[126]

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[124] *Id.* at pg. 11.
[125] *Id.* at pg. 11.
[126] *Implementation of Task Force Recommendations*, Sept. 13, 2017, at pg. 9, *supra* note 113.

iv. The City's Increased Homelessness and Foster Care Costs Attributable to the Opioid Epidemic.

179. The City, via its Department of Behavioral Health, increased the capacity of the City's "Housing First/Pathways to Housing" program in 2017 by adding 60 slots targeting individuals with opioid-use disorder.[127] The City incurs costs of $28,500 per year for each slot, including housing, medical treatment, psychiatric care, and social services,[128] at a total annual cost of approximately $1.7 million per year ($28,500 x 60) for this program which arises directly from the opioid epidemic.

180. The City has incurred increased costs for homelessness stemming from opioid addiction. The City secures both temporary and longer-term housing for the City's homeless, including for homeless individuals addicted to opioids. The City also provides certain health care and other services for the homeless. The City's Office of Homeless Services operated with a $45 million budget in 2016,[129] some of which was used to serve opioid-addicted homeless.

181. The City also incurs costs to fund its foster care system. Opioid abuse has led to an increase in foster care services and attendant costs due to the prevalence of parents struggling with opioid addiction. For example, in one nearby state (Ohio), "[h]alf of the state's foster-care population is made up of children with opioid-addicted parents."[130] In Philadelphia, the City pays a $21.25 per diem rate ($7,756 per year) to foster parents to cover expenses such as food,

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[127] *Id.* at pg. 7.

[128] Don Sapatkin, *In Philly, Finding a Place for the Homeless on Opioids*, Philadelphia Inquirer (Sept. 29, 2017), *available at* http://www.philly.com/philly/health/addiction/housing-first-treatment-second-philadelphia-pathways-for-homeless-opioid-users-20170929.html.

[129] *The Mayor's Operating Budget in Brief for Fiscal Year 2018*, at pg. 71 (March 2017), *available at* http://www.phila.gov/finance/pdfs/FY18-22%20Budget%20in%20Brief_ALL.pdf.

[130] Esme Deprez, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg Businessweek (Oct. 5, 2017), *available at* https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

clothing, school supplies, transportation, and other incidentals for the child.[131] The City's foster care costs have increased significantly as a direct result of the opioid epidemic.

v. The City's Increased Public Awareness Costs Attributable to the Opioid Epidemic.

182. The City granted a $1.9 million budget allocation to the Philadelphia Department of Public Health ("DPH") for fiscal 2018 (7/1/17 – 6/30/18) for the ongoing funding of a program targeting the opioid crisis.[132] The funds are being used to increase public awareness about the dangers of prescription opioids; attempt to reduce or narrow opioid prescribing through a campaign aimed at the highest-prescribing health care providers; improve the distribution and use of naloxone; and develop a real-time database to track openings in addiction treatment facilities.[133]

183. At considerable cost, the City, via DPH, launched a website (www.donttaketherisk.org) in May 2017 aimed at raising awareness of the dangers of opioids.[134]

184. At considerable cost, the City, via DPH and DBHIDS, mailed opioid prescribing guidelines to 16,000 health care providers in Southeastern Pennsylvania in 2017 to educate health care professionals about responsible opioid prescribing.[135]

185. At considerable cost, the City, via DPH, launched a detailing program in 2017 in which 1,400 health care providers across Philadelphia received one-on-one guidance on how to prescribe opioids judiciously. Leadership from DPH and DBHIDS visited all major health

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[131] City of Philadelphia Five Year Financial and Strategic Plan for Fiscal Years 2018-2022, at pg. 160 (March 2, 2017), *available at* http://www.phila.gov/finance//pdfs/FY18-22-Five-Year-Plan.pdf.

[132] *The Mayor's Operating Budget in Brief for Fiscal Year 2018*, at pg. ii (March 2017), *available at* http://www.phila.gov/finance/pdfs/FY18-22%20Budget%20in%20Brief_ALL.pdf.

[133] *Id.* at pg. ii.

[134] *Implementation of Task Force Recommendations*, Sept. 13, 2017, at pg. 6, *supra* note 113.

[135] *Id.* at pg. 6.

systems serving adult patients in Philadelphia and is working with them to reduce overprescribing of prescription opioids. The City's campaign was "Think NSAIDs," which emphasized the use of non-opioid pain treatments. DPH representatives also distributed guidelines on prescribing and tapering opioids. The campaign began in November 2017, ran for 8 weeks, and cost approximately $290,000 to administer.[136]

vi. The Task Force Recommendations to Combat the Opioid Epidemic Will Lead to Further Increased Costs to the City.

186. The Task Force made various recommendations to address Philadelphia's opioid epidemic and to change the behaviors of doctors and patients regarding opioid prescribing and use, including the following:

a. Conducting a consumer-directed media campaign about opioid risks;

b. Conducting a public education campaign about naloxone, including the availability of naloxone through various avenues;

c. Destigmatizing opioid use disorder and its treatment via public education programs;

d. Improving health care professional education about the dangers and abuse of opioids;

e. Establishing insurance practices that support safer opioid prescribing and related treatment;

f. Increasing the provision of medication-assisted opioid abuse treatment;

g. Expanding addiction treatment access and capacity at City-funded sites;

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[136] *The Opioid Epidemic in Philadelphia: Implementation of the Mayor's Task Force Recommendations*, at pg. 11 (Dec. 13, 2017) (hereinafter "*Implementation of Task Force Recommendations*, Dec. 13, 2017"), *available at* http://dbhids.org/wp-content/uploads/2017/12/OTF_StatusReport_December2017.pdf.

h. Embedding withdrawal management into all levels of patient care;

i. Implementing "warm handoffs" to treatment centers after overdose;

j. Providing safe housing, recovery, and vocational support systems;

k. Incentivizing medical providers to enhance the quality of substance-use disorder screening and treatment;

l. Expanding naloxone availability;

m. Further exploring comprehensive user engagement sites;

n. Establishing a coordinated rapid response to periodic surges in the number of overdoses;

o. Addressing homelessness among opioid users;

p. Expanding the Philadelphia court system's capacity for diversion of opioid abusers to treatment programs;

q. Expanding law enforcement's capacity in key areas relevant to opioid abuse; and

r. Providing substance use disorder assessment and treatment in the Philadelphia Department of Prisons.[137]

187. The Task Force recommendations represent a substantial effort to address the impact of the opioid epidemic in Philadelphia, and implementing even a few of the recommendations comes at a considerable cost to the City. Many of the Task Force recommendations – including urgent ones which should be implemented immediately – cannot be currently implemented because of the expense and current lack of funding. Certain additional steps are set forth in the injunctive relief requested herein, which can and must supplement the

[137] *Mayor's Task Force Report*, May 19, 2017, at pg. 15-25, *supra* note 60.

City's existing efforts in abating the many harms.

D. The City Incurs Increased Prescription Drug, Health Care, and Disability Costs for its Employees Attributable to the Opioid Epidemic.

188. In addition to the many social services costs set forth above, the City has spent significant amounts of money each year for purchases of prescription opioids (and related medical services) for its employees.

189. The City self-funds its own pharmacy benefits plan, through which it pays prescription drug costs for covered employees. Through this plan, the City pays for opioids prescribed by physicians to covered employees, their family members, and others.

190. The City pays significant sums for the costs of visits to doctors' offices when covered employees and their family members visit doctors to obtain opioid prescriptions. Many such individuals visit their doctors on a recurring basis due to the long-term nature of opioid treatments.

191. The City pays significant costs for opioid addiction treatment for covered employees and their family members. These costs include, *e.g.*, addiction counseling, rehabilitation costs (inpatient and outpatient), overdose costs (ambulance and emergency room visits), and costs to treat infants born with NAS.

192. The City also pays for medical care needed to treat opioid side effects such as opioid-induced constipation, and other health effects such as hepatitis C virus (HCV) and heart valve infections.

193. National data establish that medical costs incurred by insurers increase by an average of approximately $15,000 per annum for individuals who suffer from opioid abuse or

addiction.[138] The City incurs no less than this amount for medical costs per year for each affected employee or family member abusing or addicted to opioids that it insures.

194. Similarly, the City self-funds its own workers' compensation and disability plan, through which it pays disability costs and related benefits for covered employees. Coverage includes payments for wages while absent from work, and medical costs including doctor's visits and prescription opioid purchases, among other things.

195. Many City employees have been prescribed opioids in connection with injuries sustained at work. Those employees often remain out of work for extended periods of time due to prolonged opioid dependence. The National Council on Compensation Insurance has noted there is "ample evidence that long-term opioid use leads to longer [worker's compensation] claim duration, long-term disability, higher costs, and higher medical expenses."[139] In light of the addictive nature of opioids, the City has incurred costs for workers' compensation claims for longer periods than it otherwise would absent Defendants' conduct in creating the opioid epidemic.

196. The City has experienced lost productivity as a result of employees' work absences due to opioid abuse and addiction, and lost productivity in workers who do show up for work but are impaired by opioid use or withdrawal.

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[138] Noam Kirson *et al.*, *The Economic Burden of Opioid Abuse: Updated Findings*, Journal of Managed Care & Specialty Pharmacy, at 437 (April 2017) ("Opioid abusers generate an average of $14,810 in excess costs to payers in the 6 months before and after the initial abuse episode."), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

[139] NCCI *Issues Report: Worker's Compensation 2012*, at pg. 24, *available at* http://www.isg-se.com/wp-content/uploads/2012/05/IR_2012.pdf.

III. Defendants' Wrongful Conduct Created the Public Health and Safety Crisis and was False and Deceptive.

197. Pharmaceutical marketing can and does impact prescribing habits of physicians and practices of third party payors, health plan administrators and others. This fact has been confirmed and established in numerous studies.[140]

198. Defendants improperly marketed opioids for years using false, misleading and deceptive messages that overstated and/or misrepresented the safety and efficacy of opioids and understated the risks of those drugs.

199. Defendants' false and misleading marketing was effective in convincing prescribers, pharmacists, patients, third party payors, pharmacy benefit managers, health plan administrators, and others responsible for selecting and approving prescription opioids covered by health insurance plans that opioids could be safely used on a long-term basis to treat chronic pain; that opioids were an effective treatment for chronic pain; and that the benefits of using opioids to treat chronic pain far outweighed the risks.

200. Defendants' marketing campaigns specifically targeted prescribers, pharmacists, and patients, as well as individuals and groups responsible for selecting opioid drugs covered by health coverage plans and included on pharmacy formularies (*i.e.*, insurers, pharmacy benefit managers, and others).

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[140] *See, e.g.*, Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding that academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); Puneet Manchanda *et al.*, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

201. Defendants, however, knew that these marketing and product promotion claims were false, misleading, and likely to misinform or confuse the targets of the marketing and product promotion described above. Defendants knew that, as set forth in ¶¶ 58-77 *supra*, controlled studies of the safety and efficacy of prescription opioids were limited to short-term use in monitored settings (*e.g.*, hospitals) where the risks of addiction and other adverse outcomes were minimized, and long-term studies demonstrating the safety and efficacy of prescription opioids for long-term use did not exist.

202. Defendants also knew or disregarded that the effectiveness of prescription opioids wanes with prolonged use, requiring increases in dosage to achieve ongoing pain relief, which markedly increases the risk of significant side effects, addiction, and overdose when used for long-term treatment.

203. Despite these facts – well known to Defendants for many years – Defendants sought to create a false perception of the safety and efficacy of opioids for long-term daily use, including to treat such common conditions as lower back pain, arthritis, and headaches.

204. Defendants engaged in this deceptive conduct because they recognized that chronic pain patients could provide a much larger, and far more lucrative, market for prescription opioids than patients with cancer pain at the end of life. To take advantage of this massive market, Defendants engaged in marketing activities to promote prescription opioids for the management of chronic pain, thereby consciously and unconscionably elevating corporate profits above the interest of patients.

205. Defendants created a falsely favorable perception of prescription opioids through coordinated, sophisticated, and highly deceptive marketing that began in the mid-1990s and continues to the present.

206. In 1996, opioid sales and use began accelerating rapidly. This acceleration was triggered initially by the introduction in 1995 of Purdue's OxyContin, an extended release formulation of oxycodone, and Purdue's aggressive marketing of OxyContin. Other Defendants followed suit and began to aggressively market their own prescription opioids in a similar manner. The rapid acceleration of sales and use of prescription opioids continued for two decades, as alleged and illustrated in the graphs referred to in ¶¶ 81, 128-141, *supra*.

207. During this time, Defendants individually and collectively poured vast financial resources into marketing their own opioid products to distort medical and public perceptions of prescription opioids and create the false impression of a new "consensus" supporting the long-term daily use of opioids. Defendants' misleading tactics were wide-reaching and varied.

208. Specifically, as discussed more fully below, Defendants: (i) misrepresented that prescription opioids *improved patients' function*; (ii) concealed the link between long-term use of prescription opioids and *addiction*; (iii) misrepresented that *addiction risk could be effectively managed*; (iv) masked the signs of addiction by promoting the misleading concept of "*pseudoaddiction*"; (v) falsely claimed that *withdrawal symptoms could be easily addressed*; (vi) misrepresented that *increasing patient doses posed no significant additional health risks*; and (vii) *overstated the risks and understated the efficacy of non-opioid based alternative pain treatments*.

209. Defendants made these misleading statements concerning both their own branded products and prescription opioids generally. Defendants made these misrepresentations directly in their own marketing materials, as well as indirectly through the use of third party vehicles including: (i) so-called "key opinion leaders" ("KOLs"), *i.e.*, physicians who influence their peers' medical practices and prescribing behavior, who wrote favorable journal articles and

delivered supportive educational courses; (ii) "unbranded" education materials for patients, physicians and others disseminated through groups purporting to be independent patient-advocacy and professional organizations ("Front Groups"), which exercised influence through Defendant-controlled KOLs who served in leadership roles in these organizations and which were directly or indirectly controlled by Defendants; (iii) a body of biased and unsupported scientific literature which Defendants directly or indirectly created, funded, or exploited; (iv) so-called "treatment guidelines" which Defendants formulated or caused to be formulated; and (v) Continuing Medical Education courses ("CMEs") prepared and/or funded in whole or in part by Defendants. These third parties and third party vehicles are collectively referred to herein as Defendants' "Third Party Allies."

210. Defendants' direct and indirect approach, including use of purportedly independent third parties to lend credibility to the messaging ("third party validators"), was very effective. Defendants' efforts successfully altered the prescribing practices of the medical community, thereby dramatically increasing opioid prescription volumes and use. These efforts also successfully influenced third party payors, pharmacy benefit managers ("PBMs") and others responsible for maintaining and administering drug formularies on behalf of private and public health insurance plans.

211. Over-prescription of opioids resulting from the deceptive over-promotion by Defendants led to an artificial inflation of demand for prescription opioids. This created a population of users physically dependent on opioids, thereby leading to dramatically increased sales of prescription opioids, all to the improper and direct financial benefit of Defendants.

212. Defendants' broad marketing efforts have, indeed, been enormously profitable. In

2015, prescription opioids generated $9.6 billion in revenue for opioid manufacturers.[141] Defendant Purdue generated $35 billion alone in revenue from the sale of OxyContin from the product's inception to 2016.[142]

213. The vast demand for opioids today is sustained largely by Defendants' prior success in marketing and establishing prescription opioids as a treatment for chronic pain. The current demand for prescription opioids is comprised of individuals suffering from physiological dependence who require continued opioid prescriptions (and their agent-doctors who refill opioid prescriptions in the continued belief that opioids are safe in light of Defendants' prior product promotion) and new patients who, along with their physicians, wrongly believe that opioids are a viable and safe chronic pain treatment.

214. Defendants directed their misleading marketing efforts not only to physicians, pharmacists and patients, but also to third-party payors, PBMs and other health plan administrators including those responsible for approving Defendants' drugs for inclusion on drug formularies.

215. Physicians, along with formulary committees of third-party payors and PBMs, rely upon a variety of sources including independent studies for information relating to the safety and efficacy of prescription drugs which they prescribe or approve for use. However, often unbeknownst to the public and other persons and entities, many of these sources are directly controlled or heavily influenced by pharmaceutical manufacturers such as Defendants. Also, many of these sources of information are susceptible to exploitation by pharmaceutical

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[141] D. Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Financial Times (Aug. 10, 2016), *available at* https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[142] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), *available at* https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

manufacturers such as Defendants.

216. Defendants' culpability is not absolved or mitigated by the involvement of doctors in the prescription process or clinical evaluators at the third-party payors, PBMs or other health plan administrators. Defendants' deceptive marketing efforts were both widespread and highly persuasive. Their deceptive messages tainted many sources which doctors and health plan administrators relied on for information, and prevented them from making fully informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess Defendants' misleading statements, as well as clinical evaluators at or used by health plan administrators.

IV. Defendants Used "Branded" and "Unbranded" Opioid Marketing to Deceive Physicians, Patients and PBMs.

217. Drug companies' promotional activities can be characterized as "branded" or "unbranded." Branded marketing refers to marketing of a specific drug manufactured by a specific company. Unbranded marketing refers not to the marketing of a specific drug or brand, but rather a class of drugs or a particular disease, condition, or treatment.

A. Defendants' Deceptive Branded Marketing of Opioids.

218. Defendants' branded marketing generally must be consistent with its label, be supported by substantial scientific evidence, and not include false or misleading statements or material omissions about the safety and/or efficacy of the drug.

219. Drug companies, which are regarded as best suited to be knowledgeable about the properties and effects of their drugs, are responsible for providing prescribers, third-party payors, PBMs and other health plan administrators with information they need to accurately assess the risks and benefits of drugs for their patients and insureds.

220. Defendants' product marketing and promotion that fails to state accurately the safety, efficacy and risks of a prescription drug, or which fails to present the most important risks of the drug as prominently as its benefits, are deceptive on their face or lack fair balance and are, therefore, deceptive.

221. It is also improper for Defendants to distribute materials or make promotional statements that exclude contrary evidence or information about the drug's safety or efficacy, or present conclusions that cannot be supported by the results of clinical or other studies.

222. Further, it is improper for Defendants to make comparisons between their drugs and other drugs treating the same condition that represent or suggest that their drugs are safer or more effective, when they have not been demonstrated to be safer or more effective based on substantial evidence or substantial clinical experience.

223. Defendants made misleading statements in their branded marketing as set forth herein. In addition to direct statements concerning safety and efficacy in connection with their branded marketing, Defendants also brought to the attention of their target audience – physicians, patients, third-party payors, PBMs and others – the unbranded marketing set forth below.

B. Defendants' Deceptive Unbranded Marketing of Opioids.

224. Defendants often avoided using branded product promotion to spread their improper messages regarding the efficacy and safety of company-specific opioids.

225. Instead, Defendants disseminated much of their false, misleading, unbalanced, and unsupported statements through unbranded marketing materials – materials that promoted prescription opioid use but did not name a specific opioid while doing so. Through these unbranded materials and statements, Defendants presented information and guidelines

concerning prescription opioids generally that were false and misleading.

226. Further, by acting through third parties, Defendants were able to give the false appearance that their messages reflected the views of independent unbiased sources.

227. Defendants falsely cited to these sources as "independent" corroboration of their own statements.

228. Defendants' engineered third-party documents and marketing not only had greater credibility, but also broader diffusion among practitioners in the medical profession. Doctors generally did not resist receiving materials from purportedly independent entities on display in their offices, as they might with drug company pieces.

229. Defendants disseminated many of their false, misleading, unbalanced and unsupported promotional messages through the third party vehicles because the messages appeared to be independent. Through unbranded materials, Defendants presented information and guidance concerning opioids that were false, misleading, unsubstantiated, unbalanced, and incomplete.

230. Even where unbranded messages were disseminated through third-party vehicles, Defendants adopted those messages as their own when they cited to, edited, approved, and distributed such materials in their direct marketing activities knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete.

231. Defendants' sales representatives regularly distributed deceptive third-party marketing materials to Defendants' target audience, including physicians, patients, pharmacy benefit managers, formularies, insurers, third-party payors, health plan administrators and other participants in the prescribing or third-party approval chain.

232. Defendants took an active role in guiding, reviewing, and approving many of the

misleading statements issued by third parties, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted in concert with these third parties to promote the use of prescription opioids for the treatment of chronic pain.

233. The unbranded marketing materials that Defendants assisted in creating and disseminating failed to properly disclose the risks of opioid addiction, abuse, misuse, and overdose, or wrongfully denied or minimized those risks as alleged more fully herein. Those materials also misrepresented or concealed information concerning the efficacy of prescription opioids as a treatment for chronic pain.

i. Defendants' Use of Key Opinion Leaders to Further Their Deceptive Marketing.

234. Defendants cultivated a select group of doctors who were chosen and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with prescription opioids. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. Doctors hired by pharmaceutical companies to influence prescribing practices of their peers are known as key opinion leaders or KOLs.

235. These pro-opioid doctors have written, consulted on, edited, and lent their names to numerous books and articles, and given speeches and CMEs supportive of opioid therapy for treatment of chronic pain.

236. These same doctors served on committees that developed so-called "treatment guidelines" that strongly encouraged the use of prescription opioids to treat chronic pain, and on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

237. In return for their pro-opioid advocacy, Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. It is now clear that both written and oral statements by Defendants' KOLs either were false and misleading or lacked reasonable medical or scientific basis in fact.

238. Defendants cited and promoted their KOLs – and studies or articles by their KOLs – to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications or studies of doctors who were critical of the use of chronic opioid therapy.

239. Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of Defendants' agenda. Defendants also kept close tabs on the content of the materials published by these KOLs.

240. In their promotion of the use of opioids to treat chronic pain, Defendants' KOLs knew that their statements were false and misleading, or recklessly disregarded the truth in doing so, yet they continued to publish and voice their misleading messages to benefit themselves and Defendants. Two of the most prominent KOLs, Doctors Russell Portenoy and Lynn Webster, are described below. Doctors Portenoy and Webster are only examples of KOLs and their cooperation with Defendants. On information and belief, there were a number of other similarly compromised KOLs.

a. Dr. Russell Portenoy's Role in Defendants' Deceptive Marketing of Opioids.

241. 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 Defendants identified and promoted to further their marketing campaigns.

242. Dr. Portenoy received research support, consulting fees, and honoraria from

Defendants Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

243. Dr. Portenoy was instrumental in opening the door for the regular use of prescription opioids to treat chronic pain. He served on the American Pain Society ("APS") and American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of prescription opioids to treat chronic pain first in 1997 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 Defendants.

244. Dr. Portenoy also made frequent media appearances promoting prescription opioids and spreading misrepresentations on Defendants' behalf.

245. For example, he appeared on *Good Morning America* in 2010 to discuss the use of opioids to treat chronic pain. On this widely watched program, 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."[143]

246. Dr. Portenoy subsequently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[144] Among other things, 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 that promoted them overstated opioids' benefits and glossed over their risks.

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[143] *Good Morning America* television broadcast, ABC News (Aug. 30, 2010).

[144] Thomas Catan *et al., A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), *available at* https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

247. Dr. Portenoy also conceded to *The Wall Street Journal* that "[d]ata about the effectiveness of opioids does not exist."[145] He candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[146]

248. Bloomberg reported that Dr. Portenoy "recanted publicly in 2011, conceding that research he relied on to push his and Purdue's pro-opioid campaign didn't prove anything about the treatment of chronic pain."[147]

b. Dr. Lynn Webster's Role in Defendants' Deceptive Marketing of Opioids.

249. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and a former board member of AAPM, a front group that ardently supports chronic opioid therapy. He was a Senior Editor of Pain Medicine, the same journal that published Defendant Endo's special advertising supplements touting Opana ER.

250. Dr. Webster was the author of numerous CMEs sponsored by Defendants Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants, including nearly $2 million from Defendant Cephalon.

251. Dr. Webster had been under investigation by the DEA for overprescribing opioids. The DEA raided his clinic in 2010.[148] More than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

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145 *Id.*

146 *Id.*

147 Esme Deprez, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, Bloomberg Businessweek (Oct. 5, 2017), *available at* https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry.

148 Stephanie Smith, *Prominent Pain Doctor Investigated by DEA After Patient Deaths*, CNN (Dec. 20, 2013), *available at* http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

252. Dr. Webster created and promoted the Opioid Risk Tool,[149] a ten question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that 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 appeared on, or were linked to, websites run by Defendants Endo, Janssen, and Purdue.

253. In 2011, Dr. Webster presented, via webinar, a program sponsored by Defendant Purdue titled *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was – and still is – available to doctors nationwide.[150]

254. 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 between addiction and undertreated pain was to increase a patient's dose of opioids. As he and his co-author wrote in a book titled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."[151] Defendant Endo distributed this book to many doctors.

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[149] https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

[150] http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209.

[151] *See* book excerpt *available at* https://books.google.com/books?id=1C_DRcKq_KwC&pg=PT99&lpg=PT99&dq=%22Avoiding+Opioid+Abuse+While+Managing+Pain%22+%22clinician%E2%80%99s+first+response%22&source=bl&ots=DctEK1gFua&sig=IQiikIPhKQldfmLayEF-YlDTRfo&hl=en&sa=X&ved=0ahUKEwiZ7aep78DWAhVl0FQKHUF3CjUQ6AEIJjAA

255. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[152]

256. Misleading statements and materials created by KOLs were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

ii. Defendants' Misuse of Patient and Physician Education Materials and Front Groups to Further Their Marketing of Opioids.

257. Pharmaceutical industry marketing experts view patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[153]

258. Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true for opioids and conditions for which they are not approved.[154]

259. Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

260. Defendants entered into arrangements with numerous Front Groups to promote

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#v=onepage&q=%22Avoiding%20Opioid%20Abuse%20While%20Managing%20Pain%22%20%22clinician%E2%80%99s%20first%20response%22&f=false.

[152] John Fauber *et al.*, *Networking Fuels Painkiller Boom*, Milwaukee Wisconsin Journal Sentinel (Feb. 19, 2012), *available at* http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/.

[153] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

[154] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

opioids. These organizations depended upon Defendants for significant funding and, in some cases, for their survival.

261. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways – for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing.

262. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain.

263. Defendants funded these Front Groups in order to ensure supportive messages from seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

264. The following are examples of the Front Groups used by Defendants.

a. The American Pain Foundation's Role in Defendants' Deceptive Marketing of Opioids.

265. The most prominent of Defendants' Front Groups was the APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

266. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign through radio, television and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

267. All of APF's programs and materials were intended to, and did, reach a national

audience, including within Philadelphia.

268. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others for funding, which also thereby enabled APF to avoid using its line of credit. APF board member, KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

269. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying efforts against various legislative initiatives that might limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of Defendants, not patients.

270. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Defendants. APF also assisted in marketing projects for Defendants.

271. The close relationship between APF and Defendants demonstrates APF's clear lack of independence in its finances, management, and mission. APF's willingness to allow Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

272. In May 2012, the U.S. Senate Finance Committee began investigating APF to determine the links, financial and otherwise, between the organization and manufacturers of opioid painkillers.

273. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately."[155]

[155] https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

b. The American Academy of Pain Medicine's Role in Defendants' Marketing of Opioids.

274. The AAPM, with the assistance, prompting, involvement and funding of Defendants, issued treatment guidelines and sponsored and hosted CMEs essential to Defendants' marketing plans.

275. AAPM received over $2.2 million in funding since 2009 from Defendants and other drug manufacturers.

276. 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 programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California – or other resort locations.

277. AAPM describes the annual event as an "exclusive venue" for offering CMEs 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 marketing programs to doctors who attended this annual event.

278. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – for example 37 out of roughly 40 sessions at one conference alone addressed opioids.

279. AAPM's presidents have included top industry-supported KOLs including Dr. Portenoy, Dr. Perry Fine, and Dr. Lynn Webster. Dr. Webster was elected president of AAPM while he was under a DEA investigation.

280. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

iii. Defendants' Corruption of Scientific Literature to Further Their Deceptive Marketing of Opioids.

281. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants led physicians, patients, and health plan administrators to believe that such tests had already been performed.

282. Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the effectiveness of long-term opioid use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions and purchasing decisions of prescribers, patients, and health care payors. This literature was, in fact, marketing material intended to persuade doctors, patients, and third-party payors that the benefits of long-term prescription opioid use outweighed the risks.

283. To accomplish their goal, Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of misleadingly favorable articles in academic journals.

284. Defendants' plans for these materials did not originate in the departments within the Defendants' organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients. Rather, they originated in Defendants' marketing departments and with Defendants' marketing and public relations consultants.

285. One commentator noted the following regarding the pharmaceutical industry generally: "To give you an idea of how much the drug industry values sales and advertising, the

fact is that Big Pharma spends more on that than on actual drug research and development."[156]

286. In these marketing materials, Defendants or their surrogates often claimed to rely on "data on file" or presentation posters, neither of which was subject to peer review or other scientific safeguards or reliability. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data or the use of normal practices of scientific safeguards to assure reliability and were not subject to the scrutiny of others who are experts in the same field.

287. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Defendants knew that the articles distorted the significance or meaning of the underlying study.

288. Notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine – J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter") – in a manner that makes it appear that the item reported the results of a peer reviewed study. Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter to the editor, not a study, much less a peer-reviewed study. The letter merely states that the authors examined their files of hospitalized patients who had received opioids, and summarized what they found. The Porter & Jick Letter is reproduced here, in its entirety:

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[156] Jake Novak, *Big Pharma's Opioid Mess is About to Hit the Industry – Hard*, CNBC (Oct. 18, 2017), *available at* https://www.cnbc.com/2017/10/18/how-opioid-crisis-will-crush-big-pharma-commentary.html.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

289. The patients referred to in the Porter & Jick Letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids was limited to acute or end-of-life situations, not long-term use of opioids for chronic pain.

290. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor is there any indication whether the patients were monitored after they were discharged from the hospital.

291. None of these serious limitations were disclosed when Defendants and those acting on their behalf cited the letter, typically as the *sole scientific support* for the proposition that opioids are safe and rarely addictive. In fact, Dr. Jick later complained that his letter had been distorted and misused.

292. Defendants' campaign of misinformation has continued in subsequent years and even through the present. For example, a Purdue-funded study in 2017 in the Journal of Managed Care & Specialty Pharmacy stated: "[N]early 100 million Americans live with chronic pain . . . . For moderate to severe pain, opioids can provide significant symptom relief."[157] The study made no reference to the risks of using opioids or the difference in both efficacy and risk between short-term and long-term use.

293. Defendants wrongfully worked to not only create and promote favorable studies in the literature, but also to discredit or suppress negative information about prescription opioids. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy.

294. In order to do so, Defendants – often with the help of third-party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

295. Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – resulted in egregiously misleading marketing and promotion. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding risks and benefits of prescription opioids for long-term pain relief.

296. Defendants' misleading statements and scientific literature were directly or indirectly disseminated to patients, physicians, and others including third-party payors, PBMs and other health plan administrators.

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[157] Noam Kirson *et al.*, *The Economic Burden of Opioid Abuse: Updated Findings*, Journal of Managed Care & Specialty Pharmacy, at 427 (April 2017), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

297. Defendants' promotion of opioids via false, deceptive, misleading and incomplete statements in the medical and scientific literature did not stop at the physician level but also was aimed at, and directly and indirectly received by, other participants in the opioid marketing process including third-party payers and PBMs. For example, as part of the formulary listing process described below, manufacturer representatives submitted written materials, such as formulary dossiers and other written descriptions of the drugs, which in turn incorporated misleading data concerning the particular drug. Manufacturer representatives also disseminated other false, misleading and unsupported medical literature about opioids to third-party payors, PBMs and others, including so-called "studies" and other statements as alleged more fully herein that, in turn, relied on highly misleading statements concerning the alleged benefits and safety of opioids such as the Portenoy and Porter & Jick materials discussed above.

iv. Defendants' Misuse of Treatment Guidelines and Consensus Statements to Further Their Deceptive Marketing of Opioids.

298. "Treatment guidelines" and consensus statements have been particularly important in securing acceptance for long-term opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors targeted by Defendants, who generally are not experts and have no special training in the treatment of chronic pain.

299. Treatment guidelines and consensus statements not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and are relied on by third-party payors and PBMs in determining whether prescription opioids can be listed as approved pain relievers and whether they should pay for treatments for specific indications.

a. The Federation of State Medical Boards Was a Target of Defendants' Deceptive Marketing of Opioids.

300. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. State boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

301. Defendants Purdue, Endo, and Cephalon have provided grants to the FSMB to finance opioid-specific and pain-specific programs.[158]

302. Since 1998, the FSMB has been developing state medical board policies for the use of opioids to treat pain. The 1998 version, titled *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("1998 Guidelines"), was produced "in collaboration with pharmaceutical companies." With the influence of Defendants' marketing, the 1998 Guidelines provided not that opioids could be appropriate in limited cases after other pain treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

303. A 2004 version of the 1998 Guidelines, and a 2007 book titled *Responsible Opioid Prescribing: A Physician's Guide* ("Responsible Opioid Prescribing"), also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Philadelphia.

304. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers including some or all Defendants. In all, 163,131 copies were distributed by state medical boards (and through the boards, to practicing doctors), including the distribution of 601

[158] Ltr. from FSMB to U.S. Senate regarding Senate review of opioid abuse issues, June 8, 2012, at pg. 11-14, *available at* https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

copies in Pennsylvania, including in Philadelphia.[159]

305. Having influenced the 1998 Guidelines, the Defendants also used them to help convey the alarming message that "*under-treatment of pain" could result in official discipline*, and that no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

306. The Defendants' (and their agents') work with the FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be reprimanded if they failed to prescribe opioids to their patients with chronic pain.

b. The American Academy of Pain Medicine/American Pain Society Guidelines' Role in Defendants' Deceptive Marketing of Opioids.

307. The AAPM and APS are professional medical societies, each of which received substantial funding from Defendants.

308. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[160] The chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was KOL Dr. Portenoy. The consensus statement, which also formed the foundation of the Defendant-influenced 1998 Guidelines, was published on the AAPM's website and distributed to new AAPM members until 2012.

309. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and

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[159] *Id.* at pg. 19.

[160] *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf.

continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

310. The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel for Defendants and have influenced not only treating physicians, but also the body of scientific evidence addressing opioids. They were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were and are available online, and were made available nationwide and in Philadelphia.

311. Defendants widely cited and promoted the 2009 Guidelines as part of their deceptive marketing, without disclosing the lack of evidence to support their conclusions.

c. Guidelines that Did Not Receive Defendants' Support.

312. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug-company funding – reached very different conclusions.

313. For example, the 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that the "recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled

substance abuse and may, in fact, be facilitating it."[161]

314. ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain."[162]

315. ASIPP recommends long-acting opioids in high doses in only "specific circumstances with severe intractable pain," and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[163]

316. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[164]

317. Further, the *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued in 2010 by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD"), notes that their review revealed a lack of solid evidence-based research on the

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[161] Laxmaiah Manchikanti, *et al.*, American Society of Interventional Pain Physicians (ASIPP), *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, at pg. S5 (2012), *available at* http://painphysicianjournal.com/2012/july/2012;15;S1-S66.pdf.

[162] http://painphysicianjournal.com/2012/july/2012;15;S1-S66.pdf, at pg. S5.

[163] http://painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf, at pg. S68.

[164] American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids, at pg. 3, 10 (2011), *available at* https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

efficacy of long-term opioid therapy.[165]

318. Treatment guidelines and consensus statements were disseminated directly or indirectly to third party payors and PBMs as part of Defendants' marketing to formularies.

v. Defendants' Misuse of Continuing Medical Education Programs to Further Their Deceptive Marketing.

319. A CME is a professional education program provided to doctors. CMEs are analogous to continuing legal education programs provided to attorneys. Doctors are required to attend a certain number – and often type – of CME programs each year as a condition of licensure.

320. These programs are delivered in person (often in connection with professional organizations' conferences), online, or via written publications.

321. Doctors rely on CMEs not only to satisfy licensing requirements, but also to obtain information on new developments in medicine or to deepen their knowledge in specific areas of practice.

322. CMEs were often taught by KOLs who are highly respected in their fields, and were thought to reflect these physicians' medical expertise, thus CMEs could have been especially influential with doctors.

323. The countless doctors and other health care professionals who attend or view accredited CMEs constituted an enormously important audience for opioid education.

324. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs. As a result, general practitioners were especially susceptible

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[165] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full- er.pdf.

to Defendants' marketing.

325. Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the biased messages described throughout this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

326. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[166]

327. On information and belief, physicians and others involved in health plan administration, such as pharmacy benefit managers, formulary personnel and others in Philadelphia and nationwide, attended or reviewed Defendants' sponsored CMEs as the use and abuse of prescription opioids skyrocketed as alleged more fully above.

328. By sponsoring CME programs provided by Front Groups like APF, AAPM and others, Defendants expected instructors to deliver messages favorable to Defendants, as these organizations were dependent on Defendants for funding and other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct, immediate, and inherent effect on prescribers' views of opioids.

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[166] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n, at pg. 1 (Nov. 2011), *available at* http://www.msma.org/uploads/6/2/5/3/62530417/ama_ethical_opinion_9.0115_financial_relationships_with_industry_in_cme.doc.

329. Producers of CMEs and Defendants measure the effects of CMEs on prescribers' views on opioids, and prescribers' receptivity to and absorption of specific messages, confirming the strategic marketing purpose in supporting them and helping Defendants sharpen their CME marketing campaign going forward.

V. Defendants' Widely Disseminated Misrepresentations and Omissions Were Deceptive and Created a Likelihood of Confusion or Misunderstanding as to the Safety and Efficacy of Opioids for Long-Term Use.

330. Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and through third parties, included information that was false, misleading, contrary to credible scientific evidence, and lacked balance and substantiation.

331. These misrepresentations and omissions were part of an organized campaign intended to penetrate the market for pain medication and convince prescribers, third-party payors, PBMs, and the public that opioids can and should be used to treat chronic pain. To this end, Defendants' marketing materials omitted material information about the risks of opioids, and overstated their benefits. They also inaccurately suggested that long-term opioid therapy was supported by evidence, and consistently failed to disclose the lack of evidence in support of treating long-term pain with opioids.

332. These misrepresentations and omissions were specifically directed at a broad target audience that included both consumers and providers such as physicians and pharmacists, as well as pharmacy benefit managers and other insurers and reimbursement professionals.

333. There are seven primary categories of misleading, false, and unfounded representations that Defendants engaged in individually, collectively, and in conjunction with purportedly independent third parties. Specifically, Defendants:

a. misrepresented that opioids improve patients' function and quality of life;

b. downplayed the link between long-term use of opioids and addiction;

c. misrepresented that addiction risk can be effectively managed;

d. masked the signs of addiction by promoting the misleading concept of "pseudoaddiction";

e. falsely claimed that opioid withdrawal symptoms can be easily addressed;

f. misrepresented that increasing doses of opioids poses no significant additional risks of abuse or addiction; and

g. overstated the risks and understated the efficacy of non-opioid based alternative pain treatments.

334. Exacerbating each of these misrepresentations was the collective effort of Defendants and their third party agents and allies to hide from the medical community material facts, including, for example, that there actually was – and is – an absence of "adequate and well-controlled studies of opioid use longer than 12 weeks."[167]

335. All of these misrepresentations and omissions, summarized above and described in further detail below, were deceptive to both ordinary consumers and the other members of Defendants' target audience, including doctors, insurers, third-party payors, PBMs and other health plan administrators. The overall impression arising from the totality of what Defendants said – as well as what their statements and omissions reasonably implied – created a likelihood of misunderstanding, uncertainty, and confusion regarding the safe, recommended, and medically sound therapeutic uses of opioids to treat chronic pain.

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[167] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (hereinafter "Woodcock Ltr., Sept. 10, 2013"), *available at* http://docplayer.net/36264645-The-petition-requests-pertain-to-analgesia-products-therefore-this-response-is-limited-to-opioids-with-indications-for-analgesia.html.

336. Defendants' statements and omissions were not only likely to, but did in fact deceive and mislead consumers, insurers, PBMs and other health plan administrators and others into believing that opioids, when used to treat chronic pain, would be beneficial to patients' health, functioning, and quality of life, and would not lead to abuse or addiction, even at increasing doses. Defendants' target audience was further deceived and misled into believing that alternative, non-opioid pain treatments were inferior, ineffective, and unsafe.

337. Defendants disseminated their misrepresentations directly, and indirectly through Third Party Allies including KOLs and Front Groups. In disseminating these misrepresentations to Defendants' benefit, these Third Party Allies, while purporting to be independent patient-advocacy and professional organizations, in fact acted at Defendants' behest and direction as Defendants' agents or servants within the course and scope of their agency or service. Defendants accordingly are responsible for the conduct of their Third Party Allies as alleged herein.

338. Defendants have not only failed to correct their misrepresentations and omissions and failed to instruct their Third Party Allies to correct them, but continue to make these misrepresentations and omissions.

A. In Their Deceptive Marketing, Defendants and Their Third Party Allies Misrepresented that Prescription Opioids Improve Patients' Ability to Function and Improve their Quality of Life.

339. Each of the Defendants' documents and other materials outlined below was created to promote opioid sales and use so that doctors would prescribe them, patients would actively seek them, and insurers and health plan administrators would approve the drugs for inclusion in – and payment or reimbursement from – private and public health plans. These materials also encouraged doctors and others to continue or approve continuation of opioid

therapy in the belief that failure to improve pain, function, or quality of life with initial doses of opioids could be overcome by increasing doses or prescribing additional short-acting opioids on an as-needed basis for breakthrough pain.

340. In addition and as set forth above, Defendants ignored, however, not only that there was no evidence that opioids improved long-term functioning, but also a 2006 study of other studies that found that "[f]or functional outcomes . . . other [non-opioid] analgesics were significantly more effective than were opioids."[168]

341. As set forth previously at ¶¶ 58-77, *supra*, studies of the use of opioids for chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. For example, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not lead patients to return to work or physical activity.[169] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly worse on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users.[170]

342. As set forth previously, long-term use of opioids exposes users to a host of

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[168] Andrea D. Furlan et al., *Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[169] BA Martell *et al.*, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, Annals of Internal Medicine (2007), *available at* https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0024176/; Richard Deyo *et al.*, *Opioids for Low Back Pain*, BMJ Publishing (Jan. 5, 2015), *available at* http://www.bmj.com/content/350/bmj.g6380.

[170] *Survey: Migraine Patients Taking Potentially Addictive Barbiturate or Opioid Medications Not Approved by FDA as Migraine Treatments* (May 15, 2017), *available at* https://www.thefreelibrary.com/Survey%3A+Migraine+Patients+Taking+Potentially+Addictive+Barbiturate+or+...-a0163389345.

known, serious risks, including risks of misuse, abuse, addiction, overdose, and death. Chronic opioid therapy can also cause side effects including mental clouding and confusion, sleepiness, hyperalgesia, constipation, and immune-system and hormonal problems that degrade, rather than improve, patients' ability to function. Defendants omitted these adverse effects, as well as certain risks of drug interactions, from their publications and marketing efforts.

343. Each of the following specific statements by Defendants in their deceptive marketing of opioids falsely suggests that the long-term use of opioids actually improves patients' function and quality of life, and that scientific evidence supports such claims.

344. These statements, which were directly contrary to the true facts, created a likelihood of confusion or misunderstanding as to the purported benefits of chronic opioid therapy, and in particular the ability of opioids to improve both patients' ability to function and quality of life. These statements were also likely to, and did, make a difference in consumers' and others' purchasing, prescribing, and reimbursing decisions, since they were designed to convince these members of Defendants' target audience that opioids were safe and effective, and to choose opioids over alternative treatment therapies for chronic pain:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy."[171] b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of long-term Kadian therapy, including physical, social, vocational, and recreational function.[172]

[171] *City of Chicago v. Purdue Pharma et al.*, No. 14-cv-04361 (N.D. Ill.), Third Amended Complaint at ¶ 221, Oct. 25, 2016 (Dkt. 478) (hereinafter "*Chicago v. Purdue* Third Amend. Compl., Oct. 25, 2016"), *available at* http://www.feinberg.northwestern.edu/sites/ipham/conferences/globalhealthsymposium/docs/Third_Amended_Complaint_14_cv_04361.pdf.

[172] *Id.*

	c. Actavis distributed a product brochure and detailing document that claimed that use of Kadian to treat chronic pain would relieve "stress on your body and your mental health," allow patients to avoid "miss[ing] work," and cause patients to better enjoy their lives.[173] Government regulators warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . , results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[174] The regulators concluded that the representations were "false or misleading because they omit and minimize the serious risks associated with the drug, . . . and present unsubstantiated superiority and effectiveness claims. . . . These violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[175] d. On information and belief, Actavis sales representatives told prescribers that prescribing Actavis' opioids would improve their patients' ability to function and improve their quality of life.
Cephalon	e. Cephalon sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[176] Cephalon spent $150,000 to purchase copies of this book in bulk and distribute it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.[177] f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve."[178] The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with

[173] Warning Letter from Thomas Abrams, Dir., FDA Div. of Marketing, Advertising and Communications, to Doug Boothe, CEO, Actavis U.S. (Feb. 18. 2010), *available at* https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

[174] *Id.*

[175] *Id.*

[176] https://academic.oup.com/painmedicine/article/16/5/1027/2460527/Responsible-Opioid-Prescribing-A-Clinician-s-Guide; *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.

[177] *Id.*

[178] https://ce4less.com/Tests/Materials/E019Materials.pdf.

	prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report.[179] The publication is currently available online.[180] g. Cephalon sponsored a CME written by KOL Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 to December 15, 2008.[181] The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. h. Cephalon's 2006 marketing plan for marketing of Fentora, which was reviewed and approved at the highest levels of the company's management, was aimed at various types of pain management, including for "chronic pain patients," among other things. The marketing focus was to "generate awareness, understanding, and appropriate use of [Fentora] for breakthrough pain." A "target patient" was the patient "suffering from chronic pain."[182] i. On information and belief, Cephalon sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Endo	j. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed 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."[183] Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. k. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."[184] l. Endo distributed handouts to prescribers that claimed that use of Opana

[179] *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.
[180] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[181] http://www.medscape.org/viewarticle/563417_6.
[182] Cephalon 2006 Marketing Plan for Fentora, quoted in *U.S. v. Cephalon, Inc.*, No. 09-cv-02926 (E.D. Pa.) Fifth Amended Qui Tam Complaint at para. 66 (Sept. 13, 2013).
[183] *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.
[184] *Id.* at ¶ 221.

	ER to treat chronic pain would allow patients to perform work, for example as a chef.[185] The flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[186] m. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[187] n. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in original).[188] *Exit Wounds* omitted warnings of the risk of interactions between opioids and benzodiazepines, which increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. o. On information and belief, Endo sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Janssen	p. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it easier for people to live normally."[189] The myth/fact structure implies authoritative backing for the claims, which does not exist. The targeting of older adults also ignored heightened opioid risks in this population. q. Janssen sponsored, developed, and approved content of the website *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* was financed and

[185] *Id.* at ¶ 221.

[186] Warnings or limitations generally must be given equal prominence in product disclosures.

[187] https://academic.oup.com/painmedicine/article/16/5/1027/2460527/Responsible-Opioid-Prescribing-A-Clinician-s-Guide; *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.

[188] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

[189] *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.

	orchestrated by Janssen. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying that her experience would be representative of what other patients can expect to experience.[190] This video is still available today on youtube.com.[191] r. Janssen provided grants to APF to distribute to veterans the book *Exit Wounds*, which taught that opioid medications "*increase* your level of functioning" (emphasis in original).[192] *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. s. On information and belief, Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.
Purdue	t. Purdue's unbranded website *In the Face of Pain* (inthefaceofpain.com) contained testimonials from various "Advocates" who commented about opioids. One such advocate, Dr. Russell Portenoy, advocated the use of opioids because, in his words: "The negative impact of unrelieved pain on the lives of individuals . . . is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern."[193] This statement was available on inthefaceofpain.com through at least 2014 and 2015.[194] The New York Attorney General reached a settlement agreement with Purdue in 2015 regarding the misleading nature of these representations. See discussion *infra*. u. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain Vignettes." They were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, Paul, is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.[195]

[190] *Id.* at ¶ 221.

[191] https://www.youtube.com/user/LetsTalkPain.

[192] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

[193] Settlement Agreement between New York Attorney General and Purdue Pharma, at pg. 7 (Aug. 19, 2015) (hereinafter "NYAG-Purdue Settlement Agreement, Aug. 19, 2015"), *available at* https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf.

[194] *Id.* at pg. 7.

[195] *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.

	v. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in "improving daily function, psychological health, and health-related quality of life for chronic pain patients."[196] The guide is currently available online.[197] w. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve."[198] APF distributed 17,200 copies in one year alone, according to its 2007 annual report.[199] The guide is currently available online.[200] x. Purdue sponsored APF's book *Exit Wounds* (2009), which taught veterans that opioid medications "*increase* your level of functioning" (emphasis in original).[201] *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. y. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course."[202] Purdue also spent over $100,000 to support distribution of the book.[203] z. On information and belief, Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

[196] https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[197] *Id.*
[198] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[199] *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.
[200] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[201] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.
[202] https://academic.oup.com/painmedicine/article/16/5/1027/2460527/Responsible-Opioid-Prescribing-A-Clinician-s-Guide; *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.
[203] *Chicago v. Purdue* Third Amend. Compl. ¶ 221, Oct. 25, 2016, *supra* note 171.

B. In Their Deceptive Marketing, Defendants and Their Third Party Allies Omitted to Properly Disclose the Truth about the Risk of Addiction from Long-Term Opioid Use.

345. The dangerous and deceptive failure to disclose the risks that opioids are highly addictive is central to Defendants' marketing.

346. To reach chronic pain patients, Defendants and their Third Party Allies had to overcome doctors' legitimate fears that patients would become addicted. The risk of addiction is an extremely weighty risk, condemning patients to a disease that is chronic, progressive, and if not properly treated – often fatal. In addition, addiction recovery carries a lifetime risk of battling relapse.

347. Absent Defendants' campaigns to convince doctors otherwise, it would be highly unlikely for a reasonable physician to find that the benefits from long-term opioid use for many aspects of chronic pain sufficiently outweighed the risks of addiction to justify writing the prescription.

348. Through their well-funded, widespread, and comprehensive marketing efforts, Defendants and their KOLs and Front Groups were able to change the prescribing behavior of their peers despite the well-settled historical understanding and clear evidence that opioids taken long-term are very often addictive.

349. Defendants and their Third Party Allies: (a) maintained that the risk of addiction for patients who take opioids long-term was low; and (b) failed to properly disclose the addiction risk as an adverse effect, even though the frequency and magnitude of the risk compelled disclosure.

350. Defendants also used code words that conveyed to prescribers and patients that their product was less prone to abuse and addiction than competitor products. For example, sales

representatives for Defendants Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties, implying that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction.

351. Further, Defendant Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting that Endo had succeeded in making the drug harder to adulterate and abuse.[204] In fact, however, the clinical significance of Endo's crush resistant formulation or its impact on abuse and misuse has not been established for Opana ER, and Opana ER could still be ground and cut into small pieces by those looking to abuse the drug and could still be taken in unwarranted dosages or diverted to unauthorized users.

352. Similarly, Defendant Purdue falsely suggested that OxyContin was less likely to be abused.

353. Each of the statements alleged herein was created by Defendants with the expectation that, by instructing prescribers and patients that addiction rates are low, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue – APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011) – claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction."[205]

354. Acting directly or with and through third parties, each Defendant falsely claimed that the potential for addiction from opioids was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. For example, a 2015 literature survey found that rates of "misuse" averaged

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[204] https://www.prnewswire.com/news-releases/endo-announces-fda-approval-of-a-new-formulation-of-opana-er-designed-to-be-crush-resistant-135431073.html.

[205] http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

between 21% and 29%, and rates of "addiction" ranged between 8% and 12%.[206] These estimates are well in line with Purdue's own undisclosed studies, showing that between 8% and 13% of OxyContin patients became addicted,[207] but on which Purdue chose not to rely, instead citing the Porter-Jick letter as evidence of non-addiction.

355. Government regulators have noted that 26% of opioid patients obtain opioids from two or more prescribers, 16.5% seek early refills, and 20% use two or more pharmacies – all potential "red flags" for abuse or addiction.[208] Regulators in fact have ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that they found "high rates of addiction" in the medical literature.[209]

356. The significant and growing incidence of abuse, misuse, and addiction to opioids are also powerful evidence that Defendants' statements regarding the low risk of addiction were, and are, untrue. This was well-known to or ignored by Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse

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206 Kevin Vowles *et al.*, *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: a Systematic Review and Data Synthesis*, 156 PAIN 569-76 (April 2015), *available at* https://www.researchgate.net/publication/271445179_Rates_of_opioid_misuse_abuse_and_addiction_in_chronic_pain.

207 Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Quarterly 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Quarterly 305 (1999).

208 Len Paulozzi, M.D., *Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse*, *available at* https://wayback.archive-it.org/7993/20170405203727/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM233244.pdf.

209 September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/ UCM367697.pdf; Woodcock Ltr., Sept. 10, 2013, *supra* note 167.

and addiction.

357. Acting directly or through and with third parties, Defendants claimed in their deceptive marketing that the potential for addiction from long-term use of opioids was relatively small or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. Defendants' efforts to trivialize and conceal the potential for abuse and addiction posed by opioids created a likelihood of confusion or misunderstanding as to the safety of opioids, and falsely suggested that patients need not worry about addiction risks when using opioids for chronic pain management.

358. Examples of Defendants' misrepresentations are set forth below:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction.[210] b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is "less likely if you have never had an addiction problem."[211] The overall presentation suggests the risk is so low as not to be a concern. c. Kadian sales representatives told prescribers that Kadian was "steady state" and had extended-release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused.[212] d. Kadian sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused, and thereby less addictive, than other opioids.[213] e. Actavis sales representatives omitted any discussion with prescribers of addiction risks related to Kadian. In fact, a July 2010 "Dear Doctor"

[210] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.
[211] *Id.*
[212] *Id.*
[213] *Id.*

	letter mandated by government regulators required Actavis to acknowledge to the doctors to whom it marketed its opioid drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."[214] f. On information and belief, Allergan/Actavis sales representatives omitted any discussion of addiction risks when discussing Allergan/Actavis opioid products with prescribers.
Cephalon	g. Cephalon sponsored and facilitated the development of a guidebook titled *Opioid Medications and REMS: A Patient's Guide*, which claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."[215] h. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.[216] The guide is currently available online.[217] i. On information and belief, Cephalon sales representatives omitted any discussion of addiction risks when discussing Cephalon's opioid products with prescribers.
Endo	j. On Endo's website www.opana.com, Endo claimed until at least April 2012 that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[218] The New York Attorney General investigated this statement, found that Endo had no evidence for the

[214] *State of Ohio v. Purdue Pharma. et al.*, Common Pleas Court, Ross County, Ohio (May 31, 2017), Complaint ¶ 40, *available at* http://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Consumer-Protection/2017-05-31-Final-Complaint-with-Sig-Page.aspx.

[215] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.

[216] https://ce4less.com/Tests/Materials/E019Materials.pdf.

[217] *Id.*

[218] Settlement Agreement between New York Attorney General and Endo, at ¶ 20 (March 1, 2016) (hereinafter "NYAG-Endo Settlement Agreement, March 1, 2016"), *available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

	statement, and reached a settlement with Endo requiring corrective action.[219] See discussion *infra*. k. Similarly, Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[220] The New York Attorney General found that those statements were unwarranted. See discussion *infra*. l. Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, conveying that it was less likely to be abused. This claim was false. Government regulators warned in a May 10, 2013 letter that there was no evidence that Endo's design would "provide a reduction in oral, intranasal or intravenous abuse," and that Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse."[221] m. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[222] The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. n. Endo sponsored a website, PainAction.com, which stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[223] o. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult and Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients," which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients.[224] p. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized

[219] *Id.* at ¶ 20.
[220] *Id.* at ¶ 22.
[221] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.
[222] *Id.*
[223] *Id.*
[224] *Id.*

	the risk of addiction, stating: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."[225] q. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems."[226] This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. It is still available online today.[227] r. Endo contracted with the American Geriatrics Society ("AGS") to produce a CME promoting the 2009 Guidelines, titled *Pharmacological Management of Persistent Pain in Older Persons* (2009). The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[228] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. s. Endo sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[229] t. Endo provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[230] The overall presentation suggests that the risk is so low as not to be a concern. u. On information and belief, Endo sales representatives omitted discussion of addiction risks related to Endo's opioid drugs when

[225] *Id.*

[226] http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

[227] *Id.*

[228] https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.

[229] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.

[230] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

	discussing Endo's opioid products with prescribers.
Janssen	v. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" 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."[231] The overall presentation suggests that the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem. w. Janssen contracted with AGS to produce a CME promoting the 2009 Guidelines, titled *Pharmacological Management of Persistent Pain in Older Persons*. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[232] The study supporting this assertion does not analyze addiction rates by age. As previously noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug-company funding to promote them after their completion. x. Janssen provided grants to APF to distribute the book *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[233] The overall presentation suggests that the risk is so low as not to be a worry. y. Janssen ran a website, Prescriberesponsibly.com, which claimed that concerns about opioid addiction are "overstated."[234] z. A June 2009 Nucynta training module warned Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed."[235]

[231] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.
[232] https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.
[233] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.
[234] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.
[235] *Id.*

	aa. Janssen sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[236] bb. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to these drugs. In truth, however, as set out in Nucynta's product label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit."[237] cc. Janssen's sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug.[238] dd. On information and belief, Janssen sales representatives omitted discussion of addiction risks related to Janssen's opioid drugs when discussing Janssen's opioid products with prescribers.
Purdue	ee. A 2017 study funded by Purdue to analyze medical costs associated with opioid addiction noted: "[N]early 100 million Americans live with chronic pain . . . . For moderate to severe pain, opioids can provide significant symptom relief."[239] The study made no reference to the distinction in addiction risks between short-term and long-term use. ff. Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse* (2011), which under the heading "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa.[240] In fact, opioid users who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.[241] Thus, these representations deceptively reassured doctors that, as long as they do not observe those signs of misuse, they need not be concerned that patients are abusing or addicted to opioids.

[236] *Id.*

[237] *Id.*

[238] *Id.*

[239] Noam Kirson *et al.*, *The Economic Burden of Opioid Abuse: Updated Findings*, Journal of Managed Care & Specialty Pharmacy, at 427 (April 2017), *available at* http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16265.

[240] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.

[241] Purdue itself acknowledged in October 2010 that OxyContin was used non-medically by injection 4-17% of the time. *See Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.

	gg. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which inaccurately claimed that less than 1% of children prescribed opioids will become addicted.[242] The publication also asserted that pain is "undertreated" due to "misconceptions about opioid addiction." The guide is currently available online.[243] hh. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. The guide is currently available online.[244] ii. A Purdue-funded study with a Purdue co-author claimed that "evidence of the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[245] The study relied only on the Porter-Jick letter to the editor concerning a review of charts of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. The overall presentation suggests that the risk is so low as not to be a worry. jj. Purdue contracted with AGS to produce a CME promoting the 2009 Guidelines titled *Pharmacological Management of Persistent Pain in Older Persons*. The guidelines falsely claim that the "risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[246] None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide its funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. kk. Purdue sponsored APF's book *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who

[242] https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[243] *Id.*
[244] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[245] Peter Watson *et al.*, *Controlled-Release Oxycodone Relieves Neuropathic Pain: A Randomized Controlled Trial in Painful Diabetic Neuropathy*, 105 Pain 71 (2003), *available at* https://pdfs.semanticscholar.org/be4f/ff311b5869e11245dbc5ed433e59035d0f9c.pdf.
[246] https://geriatricpain.org/sites/geriatricpain.org/files/wysiwyg_uploads/ags_pharmacological_management_of_persistent_pain_in_olders_persons_2009_2.pdf.

	are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."[247] The overall presentation suggests that the risk is so low as not to be a concern. ll. Purdue sales representatives told prescribers that its drugs were "steady state," implying that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused.[248] mm. Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper-proof and, after a certain point, patients no longer experience a "buzz" from increased dosage.[249] nn. Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by drug addicts, and, therefore, less likely to be abused or diverted, or result in addiction.[250] oo. Purdue sales representatives emphasized that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide slow-onset, stable doses without "peaks and valleys" – encouraging prescribers to infer that these opioids are safer because they do no produce the euphoric high that fosters addiction. In a 2011 sales training document, Purdue acknowledged that the "fewer peaks and valley" message seen in a review of sales representative call notes was "problematic" – confirming both that the statements were made and that they were false.[251] pp. On information and belief, Purdue sales representatives omitted discussion of addiction risks related to Purdue's opioid drugs when discussing Janssen's opioid products with prescribers.

359. Rather than honestly disclose the risk of opioid abuse and addiction in their marketing materials, Defendants and their Third Party Allies improperly portrayed those who

[247] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

[248] *Chicago v. Purdue* Third Amend. Compl. ¶ 229, Oct. 25, 2016, *supra* note 171.

[249] *Id.*

[250] *Id.*

[251] *Attorney General of New Jersey v. Purdue Pharma, LP*, No. 245-17 (N.J. Super. Ct. Ch. Div. 2017), Complaint at ¶ 83, *available at* http://www.northjersey.com/story/news/new-jersey/2017/10/31/nj-sues-another-drug-company-opioid-crisis/816924001/.

were concerned about addiction as unfairly denying treatment to needy patients. For example, to increase pressure on doctors to prescribe long-term opioid therapy, Defendants deceptively suggested that doctors who did not treat their patients' chronic pain with opioids were failing their patients, and would potentially be subject to discipline.

360. Defendants and their Third Party Allies also claimed that overblown worries about addiction cause pain to be *under-treated* and cause opioids to be *under-prescribed* and over-regulated. This mantra reinforced Defendants' marketing messages that the risks of addiction and abuse were exaggerated and not significant.

361. For example, Janssen's website *Let's Talk Pain* warned in a video posted online that: "[S]trict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence."[252] The program continued on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."[253]

362. Similarly, a Purdue website called *In the Face of Pain*, under the heading "Protecting Access," complains that, through mid-2013, policy governing the prescribing of opioids was "at odds" with best medical practices by: (i) "unduly restricting the amounts that can be prescribed and dispensed;" (ii) "restricting access to patients with pain who also have a history of substance abuse;" and (iii) "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe."[254] This

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[252] *Chicago v. Purdue* Third Amend. Compl. ¶ 232, Oct. 25, 2016, *supra* note 171.
[253] *Id.*
[254] *Id.*

unsupported and untrue rhetoric aims to portray doctors who do not prescribe opioids as ignoring industry best practices, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

C. In Their Deceptive Marketing, Defendants and Their Third Party Allies Misrepresented that Opioid Addiction Risk Can Be Avoided or Managed.

363. Defendants continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants and their Third Party Allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, purport to identify those with allegedly higher addiction risks (stemming, for example, from personal or family histories of substance abuse or mental illness) so that doctors can more closely monitor patients at greater risk of addiction.

364. Defendants' marketing assertions that doctors can readily identify and manage addiction risk are not true. There is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction, and there is no scientific evidence that screening or any other precautions can remove the risk of addiction.

365. Despite the use of screening tools, patients with past substance use disorders – which every tool rates as a risk factor – receive, on average, higher doses of opioids from their physicians.

366. In addition to making deceptive representations about screening, Defendant Purdue has deceptively marketed its so-called "abuse-deterrent" opioids – a reformulated version of OxyContin and Hysingla ER – in a manner that falsely implied these drugs can curb abuse and

even addiction. In this marketing, which began in 2010, Purdue focused not on oral abuse, which is the most common form of prescription opioid abuse, but instead claimed that abuse and addiction result from product diversion, with abusers snorting or injecting the drug. Purdue misleadingly assured prescribers and other members of its target audience that its new formulation, which made its opioids more difficult to crush or inject, would prevent or reduce misuse, abuse, or diversion.

367. Specifically, Purdue and its sales representatives have falsely claimed or implied that Purdue's abuse-deterrent formulations: (i) prevent tampering and cannot be crushed or snorted; (ii) prevent or reduce opioid abuse, diversion, and addiction overall; and (iii) are safer than other opioids. At the same time, Purdue either failed to disclose that the abuse-deterrent formulations do not impact the most common forms of abuse – oral ingestion – or affirmatively misrepresented that most abuse is by non-oral means.[255]

368. In fact, there is no substantial scientific evidence that Purdue's abuse-deterrent opioids actually reduce opioid abuse. As the 2016 CDC Guideline states, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," and the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[256]

369. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations

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[255] *Attorney General of New Jersey v. Purdue Pharma, LP*, No. 245-17 (N.J. Super. Ct. Ch. Div. 2017), Complaint at ¶ 124, *available at* http://www.northjersey.com/story/news/new-jersey/2017/10/31/nj-sues-another-drug-company-opioid-crisis/816924001/.

[256] *CDC Guideline*, March 18, 2016, at pg. 22, *supra* note 8; *see also* Theodore J. Cicero & Matthew J. Ellis, *Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from OxyContin*, 72(5) JAMA Psychiatry 424-430 (May 2015).

is particularly dangerous because it persuades doctors, who might otherwise curtail their opioid prescribing, to continue prescribing Purdue's opioids in the mistaken belief that they are safer. It also allows prescribers, patients, and other members of Purdue's target audience to discount evidence of opioid addiction and attribute it to other, less safe opioids – *i.e.,* to believe that while patients might abuse or overdose on non-abuse deterrent opioids, Purdue's opioids did not carry that risk.

370. A 2014 *Evidence Report* by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain," identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[257]

371. Defendants' representations that the risk of addiction could be readily avoided or managed, and Purdue's representations that its abuse-deterrent formulations could help thwart addiction and abuse, are deceptive and without scientific support, as described below. These misrepresentations by Defendants, which were intended to persuade prescribers, patients, and health care payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead Defendants' target audience into believing that addiction, misuse, and abuse could easily be avoided or managed. Defendants' misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of

[257] *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Agency for Healthcare Research and Quality (Sept. 19, 2014), *available at* https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-pain-opioid-treatment_research.pdf.

patients, doctors, and other third-party payors, as they minimized the risks associated with opioids for chronic pain, and influenced the public to choose opioids over other pain relief therapies.

372. The misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.[258]
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."[259] The guide is currently available online.
Endo	c. Endo paid for a 2007 supplement available for CME credit in the Journal of Family Practice. This publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.[260]
Purdue	d. Purdue's unbranded website *In the Face of Pain* (inthefaceofpain.com) stated that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds" with best medical practices.[261] The New York Attorney General reached a settlement agreement with Purdue in 2015 regarding the misleading nature of this website. The New York Attorney General found that the website created a false impression of impartiality and concealed that Purdue made significant financial contributions to many paid speakers whose testimonials appeared on the website.[262] See discussion *infra*. e. Purdue sponsored a CME program taught by a KOL titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks,*

[258] *Chicago v. Purdue* Third Amend. Compl. ¶ 238, Oct. 25, 2016, *supra* note 171.
[259] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[260] *Chicago v. Purdue* Third Amend. Compl. ¶ 238, Oct. 25, 2016, *supra* note 171.
[261] *Id.*
[262] NYAG-Purdue Settlement Agreement, Aug. 19, 2015, at pg. 7-8, *supra* note 193.

	and Improving Outcomes (2012). This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior.[263] f. Purdue sponsored a 2011 webinar taught by KOL Dr. Webster, titled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."[264] g. On information and belief, Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. h. On information and belief, Purdue sales representatives told prescribers that Purdue's abuse-deterrent formulations of its oral opioids OxyContin and Hysingla are more difficult to abuse and less likely to be diverted.

D. In Their Deceptive Marketing, Defendants and Their Third Party Allies Created Confusion as to Opioid Addiction Risks by Promoting the Misleading Term "Pseudoaddiction."

373. Defendants and their Third Party Allies developed and disseminated each of the following misrepresentations about "pseudoaddiction" so that, by instructing patients and prescribers that signs of addiction are actually the result of under-treated pain, doctors would prescribe more opioids to more patients and continue prescribing them, and patients would continue to use opioids despite signs of addiction.

374. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatments of this issue, blurring the line between undertreated pain and true addiction, as if

[263] https://docmh.com/chronic-pain-management-and-opioid-use-easing-fears-managing-risks-and-improving-outcomes-pdf.

[264] *Chicago v. Purdue* Third Amend. Compl. ¶ 238, Oct. 25, 2016, *supra* note 171.

patients could not experience both.

375. KOL Dr. Webster subsequently conceded that: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. . . . It led us down a path that caused harm. It is already something we are debunking as a concept."[265] Despite this partial confession, the Defendant manufacturers actually continued and even increased their marketing campaign to downplay the risks of addiction.

376. Each of the Defendants' statements identified below falsely states or suggests that the concept of pseudoaddiction is substantiated by scientific evidence and accurately describes the condition of undertreated patients who need, and should be treated with, more opioids. These misrepresentations, which were intended to persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead Defendants' target audience about the true safety of opioids and risks of addiction. These misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as Defendants' misleading marketing promoted the concept of "pseudoaddiction" and thereby downplayed the true risks of addiction and convinced the public to choose opioids over other pain relief therapies.

377. The misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."[266]
Cephalon	b. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007),

[265] John Fauber *et al.*, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012), *available at* http://bangordailynews.com/2012/02/19/health/networking-fuels-painkiller-boom/.

[266] *Chicago v. Purdue* Third Amend. Compl. ¶ 240, Oct. 25, 2016, *supra* note 171.

	which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding opioids are all signs of "pseudoaddiction."[267] Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.[268]
Endo	c. Endo distributed copies of a book by KOL Dr. Webster titled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents described the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and that "increasing the dose in most cases . . . should be the clinician's first response."[269] d. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted 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."[270] e. Endo trained its sales representatives to distinguish addiction from "pseudoaddiction." The New York Attorney General reached a settlement with Endo in 2016 regarding this representation and others, finding that "the 'pseudoaddiction' concept has never been empirically validated and in fact has been abandoned by some of its proponents."[271] See discussion *infra*.
Janssen	f. From 2009 to 2011, Janssen's website *Let's Talk Pain* stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."[272]
Purdue	g. Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse* (2011), which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [addictive drug-seeking

[267] *Id.*
[268] *Id.*
[269] *Id.*
[270] *Id.*
[271] NYAG-Endo Settlement Agreement, March 1, 2016, at ¶ 23, *supra* note 218.
[272] *Chicago v. Purdue* Third Amend. Compl. ¶ 240, Oct. 25, 2016, *supra* note 171.

	behaviors] in patients who have pain that has not been effectively treated."[273] h. Purdue distributed to physicians, and posted on its unbranded website *Partners Against Pain,* a pamphlet titled *Clinical Issues in Opioid Prescribing* (2006). This pamphlet included a list of conduct, including "illicit drug use and deception," that it defined as indicative of "pseudoaddiction" or undertreated pain. It also stated: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."[274] i. Purdue sponsored FSMB's *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 opioids, are all signs of "pseudoaddiction."[275] Purdue also spent over $100,000 to support distribution of the book. j. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which stated: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."[276] The guide is currently available online.

E. In Their Deceptive Marketing, Defendants and Their Third Party Allies Claimed that Opioid Withdrawal Symptoms Can Be Readily Managed.

378. In an effort to further downplay the risks and devastating impact of addiction, Defendants and their Third Party Allies frequently claimed that, while patients become "physically" dependent on opioids, physical dependence can be adequately addressed by

[273] *Id.*
[274] *Id.*
[275] https://academic.oup.com/painmedicine/article/16/5/1027/2460527/Responsible-Opioid-Prescribing-A-Clinician-s-Guide; *Chicago v. Purdue* Third Amend. Compl. ¶ 240, Oct. 25, 2016, *supra* note 171.
[276] https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

gradually tapering patients' doses to avoid the adverse effects of withdrawal. Defendants and their Third Party Allies promoted this false and misleading message so that prescribers and patients would be more likely to initiate long-term opioid therapy and would fail to recognize the actual risk of addiction.

379. Defendants failed to properly disclose that discontinuing long-term use of opioids can be very difficult. These effects make it less likely that patients will be able to stop using opioids.

380. In truth, physiological dependence on opioids starts to develop after a few days of regular use. Common withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain, among other things.[277]

381. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to return to opioids.

382. Each of the Defendants' representations below falsely states or suggests that opioid withdrawal is manageable, so that physicians and users would increase opioid use.

383. These misrepresentations, which were intended to persuade prescribers, patients, and third-party payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead Defendants' target audience about the difficulty of treating and managing withdrawal in opioid users. These misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors. Defendants' misleading marketing was

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[277] *See, e.g., Health Guide: Opiate Withdrawal*, The New York Times (2013), *available at* http://www.nytimes.com/health/guides/disease/opiate-withdrawal/overview.html?mcubz=3.

intended to minimize the reality of managing withdrawal symptoms, and thereby encourage the public to choose opioids over other pain relief therapies and to continue taking, prescribing, or paying for opioids when used to treat long-term pain.

384. The misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to convey that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis' sales representative training also claimed that opioid withdrawal would take only a week, even in addicted patients.[278]
Endo	b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.[279]
Janssen	c. A Janssen PowerPoint presentation used for training its sales representatives titled *Selling Nucynta ER* indicated that the "low incidence of withdraw symptoms" is a "core message" for its sales force. This message was repeated in numerous Janssen training materials between at least 2009 and 2011. The studies purportedly supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses, and would therefore not be representative of withdrawal symptoms in the patient population taking long-term opioids. Patients on long-term treatment will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied on a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use. Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window of severe withdrawal symptoms painted a misleading picture of the likelihood and severity of withdrawal associated with long-term opioid therapy. Janssen also knew or should have known that patients involved in the study were not taking the drug long enough to develop rates of withdrawal symptoms comparable to withdrawal symptoms suffered by patients who use opioids for chronic pain – a use for which Janssen promoted Nucynta ER.[280] d. Janssen sales representatives told prescribers that patients on Janssen's

[278] *Chicago v. Purdue* Third Amend. Compl. ¶ 244, Oct. 25, 2016, *supra* note 171.
[279] *Id.*
[280] *Id.*

	opioid drugs were less susceptible to withdrawal than those on other opioids.[281]
Purdue	e. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* (2011), which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.[282] The guide is currently available online. f. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans' low potency and its extended release mechanism.[283] g. In 2007, Purdue pled guilty to criminal charges stemming from its misleading marketing and promotion of OxyContin as having manageable withdrawal symptoms. Purdue admitted that it misrepresented to doctors that "patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug."[284] See discussion *infra*. h. On information and belief, Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be reasonably managed.

[281] *Id.*

[282] https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[283] *Chicago v. Purdue* Third Amend. Compl. ¶ 244, Oct. 25, 2016, *supra* note 171.

[284] https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt.

F. In Their Deceptive Marketing, Defendants and Their Third Party Allies Improperly Minimized the Risks of Increased Doses of Opioids.

385. As part of their marketing campaign, Defendants and their Third Party Allies also claimed that prescribers and patients could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high." Defendants suggested that patients would eventually reach a stable, effective dose as the dosage strength increased.

386. Each of Defendants' representations also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

387. Defendants made these misleading representations and omissions about the known risks of higher doses of opioids so that prescribers and patients would be more likely to continue to prescribe and use opioids. The misrepresentations also helped persuade physicians and patients not to discontinue opioids when patients' increased tolerance required them to seek higher doses.

388. In fact, patients receiving increasingly higher doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose than those on low doses. As compared to non-opioid pain remedies, an opioid patient's tolerance to pain-reducing properties of opioids develops faster than tolerance to the adverse respiratory effects of opioids. Thus, the practice of continuously escalating opioid doses to match pain tolerance can, in fact, lead to overdose due to respiratory complications even where opioids are taken as recommended in line with a patient's pain needs.

389. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects. This contributes to a cycle of continued use, even when the drugs

provide diminishing pain relief and are causing harm.

390. Each of the representations from Defendants and their Third Party Allies misleadingly minimized the risks that increased doses of opioids pose to patients. These misrepresentations were likely to, and did, confuse, deceive, and mislead Defendants' target audience about the risks associated with higher doses of opioids to treat chronic pain. These misrepresentations and omissions were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as Defendants' misleading marketing promoted the message that patients would not be at risk if they continued to increase their doses of opioids. This misleading message influenced Defendants' target audience to choose opioids over other, non-opioid treatments and medications.

391. The misrepresentations included the following:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis' opioid, Kadian.[285]
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.[286] The guide is currently available online. c. Cephalon sponsored a CME written by KOL Dr. Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC in 2007 and 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin

[285] *Chicago v. Purdue* Third Amend. Compl. ¶ 248, Oct. 25, 2016, *supra* note 171.
[286] https://ce4less.com/Tests/Materials/E019Materials.pdf.

	and acetaminophen are less effective to treat breakthrough pain because of dose limitations, implying that opioids benefitted from less restrictive dose limitations.[287] d. On information and belief, Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.
Endo	e. Endo sponsored a website, painknowledge.com, through APF and NIPC, which in 2009 claimed that opioids may be increased until "you are on the right dose of medication for your pain." Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.[288] f. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004). It is still available online today.[289] In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."
Janssen	g. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids.[290]
Purdue	h. Through at least June 2015, Purdue's website *In the Face of Pain*, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe what – in their view – is a sufficient dose of opioids, they should find another doctor who will increase the dosage.[291] In so doing, Purdue exerted influence over prescribers who face pressure to accede to the patients' demands for increased dosages. i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones.[292] This falsely suggested that high dose opioids are safe and appropriate. It did not disclose the risks from high dose opioids. The guide is currently

[287] http://www.medscape.org/viewarticle/563417_6.
[288] *Chicago v. Purdue* Third Amend. Compl. ¶ 248, Oct. 25, 2016, *supra* note 171.
[289] http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.
[290] *Chicago v. Purdue* Third Amend. Compl. ¶ 248, Oct. 25, 2016, *supra* note 171.
[291] *Id.*
[292] https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

	available online. j. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[293] The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language failed to disclose the heightened risks at elevated doses. The guide is currently available online. k. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled *Overview of Pain Management Options*, was edited by KOL Dr. Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses.[294] l. Purdue sales representatives told prescribers that high-dose opioids were effective for treating patients long-term, and omitted any discussion that increased tolerance would require increased – and increasingly dangerous – doses.[295]

G. In Their Deceptive Marketing of Opioids, Defendants and Their Third Party Allies Materially Overstated the Risks of Alternative Forms of Pain Treatment.

392. Defendants and their Third Party Allies also misleadingly emphasized or exaggerated the risks of alternative therapies, such as non-opioid analgesics. These misrepresentations, which were intended to persuade prescribers, patients, and health care payors to choose opioids over competing medications and therapies, were likely to, and did, confuse, deceive, and mislead Defendants' target audience about the purported inferiority and dangers of non-opioid pain medications.

393. Further, these misrepresentations were not only likely to, but did in fact, make a difference in the purchasing and prescribing decisions of patients, doctors, and other third-party payors, as Defendants' misleading marketing was *specifically designed* to encourage the

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[293] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[294] *Chicago v. Purdue* Third Amend. Compl. ¶ 248, Oct. 25, 2016, *supra* note 171.
[295] *Id.*

purchasing, prescribing, and reimbursing public to choose opioids over other pain relief therapies.

394. In connection with their inaccurate and unsupported emphasis on the purported risks of non-opioid products, Defendants and their Third Party Allies routinely minimized or ignored the risks of long-term opioid therapy. These opioid risks – which are in addition to the life-threatening risks associated with misuse, abuse, and addiction – include: hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[296] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; NAS (when an infant exposed to opioids withdraws from the drugs after birth); and potentially fatal interactions with alcohol and benzodiazepines which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions), and other drugs.

395. Despite these serious risks, Defendants asserted or implied that opioids were appropriate first-line treatments and safer than alternative non-opioid treatments, including non-steroidal anti-inflammatory drugs ("NSAIDs") such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were improper, and made their omissions minimizing opioid risks all the more misleading.

396. As part of this marketing ploy, Defendants and their Third Party Allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000 to 20,000 deaths annually (more than opioids), when in truth the number is closer to

[296] Woodcock Ltr., Sept. 10, 2013, *supra* note 167.

3,200.[297]

397. Defendants' description of NSAID risks starkly contrasted with Defendants' representation of opioid risks, which, according to Defendants, included mostly mild conditions such as nausea, constipation, and sleepiness (but not addiction, overdose, or death). In fact, compared with NSAIDs, prescription opioids are responsible for approximately five times as many fatalities annually.

398. As with Defendants' other misrepresentations as alleged more fully herein, Defendants' misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While the volume of opioid prescriptions has exploded over the past two decades, the use of NSAIDs has declined during that same time.[298]

399. Each of the following representations reflects deceptive claims and omissions by Defendants and their Third Party Allies about the risks of opioids relative to NSAIDs:

Allergan/ Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs.[299] b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons.[300] c. On information and belief, Actavis sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

[297] https://ce4less.com/Tests/Materials/E019Materials.pdf at pg. 10; *see also* https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

[298] https://fitness.mercola.com/sites/fitness/archive/2013/08/16/back-pain-overtreatment.aspx.

[299] *Chicago v. Purdue* Third Amend. Compl. ¶ 252, Oct. 25, 2016, *supra* note 171.

[300] *Id.*

Cephalon	d. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[301] The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The guide is currently available online. e. On information and belief, Cephalon sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Endo	f. Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.* The study cited an example, meant to be representative, of a patient with a "massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years).[302] The study recommended treating the patient with opioids instead. g. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer titled *Pain: Opioid Therapy.* This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it.[303] h. Endo provided grants to APF to distribute the book *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[304] i. On information and belief, Endo sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

[301] https://ce4less.com/Tests/Materials/E019Materials.pdf.

[302] *Chicago v. Purdue* Third Amend. Compl. ¶ 252, Oct. 25, 2016, *supra* note 171.

[303] *Id.*

[304] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

Janssen	j. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase [in] the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness" (which the brochure claims will dissipate), and constipation.[305] k. Janssen sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines.[306] *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[307] l. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.[308] m. On information and belief, Janssen sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.
Purdue	n. Purdue sponsored APF's book *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.[309] o. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ

[305] *Chicago v. Purdue* Third Amend. Compl. ¶ 252, Oct. 25, 2016, *supra* note 171.

[306] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

[307] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

[308] *Chicago v. Purdue* Third Amend. Compl. ¶ 252, Oct. 25, 2016, *supra* note 171.

[309] https://www.amazon.com/Survival-Management-Returning-Veterans-Families/dp/B002NRP2YC.

	from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[310] The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The guide is currently available online. p. Purdue sponsored a CME issued by the American Medical Association in 2007, 2010, and 2013. The CME, titled *Overview of Management Options*, was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs, but not opioids, are unsafe at high doses.[311] q. On information and belief, Purdue sales representatives told prescribers that NSAIDs were less beneficial or more risky than opioids.

VI. Defendants' Misleading Marketing Was Directed at a Broad Target Audience, Including Third-Party Payors Like the City and its Pharmacy Benefit Managers.

400. Defendants' misleading marketing was directly and indirectly disseminated to third-party payors, PBMs and other health plan administrators, with the intention that third-party payors, PBMs and other health plan administrators rely upon it.

401. A PBM is an administrator of prescription drug programs for private and public health plans, including self-insured companies and government entities.

402. PBMs have acted as middlemen in these prescription drug benefits transactions in the United States since the mid-1990s. Initially, they merely handled claims transactions. Over time, however, they began handling more aspects of the U.S. pharmaceutical reimbursement process including "pharmacy network administration, formulary design and management, manufacturer rebate negotiation, drug utilization review (to determine whether a patient's prescriptions may interact), physician communication and education (including

[310] https://ce4less.com/Tests/Materials/E019Materials.pdf.
[311] *Chicago v. Purdue* Third Amend. Compl. ¶ 252, Oct. 25, 2016, *supra* note 171.

formulary compliance incentives), mail-order pharmacy services, generic substitution plans, and assumption of risk."[312]

403. PBMs (as well as third party payors and health plan administrators, in some instances) prepare and administer a "formulary," which is a list of drugs that are approved for coverage by the health plan. In general, in order for a drug to be listed on the formulary, it must be assessed by the PBM (or third party payor or health plan administrator, in some instances) for clinical safety, efficacy, and where applicable, cost effectiveness. In designing formularies, a PBM generally uses a Pharmacy and Therapeutics Committee comprised of clinical pharmacists and physicians who review the drugs in each therapeutic class and the evidence of each drug's effectiveness, safety, contra-indications and costs.[313]

404. The committee generally evaluates the clinical utility of the drug for a health plan based on information in the medical literature and clinical content about the product supplied by the manufacturer. This content is approved for distribution to the plan by senior executives representing legal, regulatory, and medical functions.

405. According to the American Pharmacists Association, PBMs are primarily responsible for developing and maintaining the formulary.[314]

406. In 2007, the function of PBMs changed from "simply processing prescription transactions to managing the pharmacy benefit for health plans."[315] PBMs also created a

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[312] *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 71 (D. Mass 2005).

[313] Patricia M. Danzon, PhD, *PBM Compensation and Fee Disclosure*, 2014 ERISA Advisory Council, at pg. 1 (2014), *available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/ACDanzon061914.pdf.

[314] *Pharmacy Benefit Management*, American Pharmacists Association (2009), *available at* https://www.pharmacist.com/sites/default/files/files/Profile_24_PBM_SDS_FINAL_090707.pdf.

[315] Allison Dabbs Garrett *et al.*, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Valparaiso University Law Review 1, at pg. 34 (Fall 2007), *available at* http://scholar.valpo.edu/cgi/viewcontent.cgi?article=1131&context=vulr.

formulary that encouraged or even required "health plan participants to use preferred formulary products to treat their conditions."[316]

407. "PBMs are the 800-pound gorillas of pharmaceutical reimbursement."[317] According to published estimates, over 95% of Americans with health benefits receive drug coverage through a PBM.[318] As of 2016, PBMs managed pharmacy benefits for 266 million Americans.[319] Because such a large percentage of Americans are covered by these PBMs, formulary status can greatly influence a manufacturer's sales of a drug.[320] Indeed, *the commercial success of a drug in the U.S. depends in significant part on the manufacturer's success in placing its drug on as many formularies as possible*. With respect to the largest PBMs (such as Caremark), inclusion on their formularies is of maximum impact.

408. Drug manufacturers are acutely aware of the powerful role of PBMs in the marketplace and the need to obtain approval of PBMs before successfully placing a drug on any given formulary. Defendants were, at all times relevant hereto, aware that PBM approval was important to the commercial success of their pharmaceutical products.

409. Drug manufacturers including Defendants maintain a team of sales personnel, sometimes called National Account Managers ("NAMs"), who are specialized sales representatives. Among other things, through various marketing and selling tactics, it is the NAMs' responsibility to influence and negotiate placement of the particular drug on the

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316 *Id.*

317 *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 71 (D. Mass 2005).

318 Federal Trade Commission, Ltr. to Senator Richard L. Brown, North Dakota Senate, at pg. 4 (March 8, 2005), *available at* http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf.

319 *That's What PBMs Do,* Pharmaceutical Care Management Association (March 14, 2016), *available at* https://www.youtube.com/watch?v=gfrJPsPsFYI.

320 J. Shepherd, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*, Emory University School of Law, Legal Studies Research Paper Series, Research Paper No. 13-245, at pg. 8 (March 2013), *available at* http://ssrn.com/abstract=2234212.

formulary, and to oversee and assist in making submissions regarding the various attributes of the particular drug, including the drug's alleged benefits and risks.

410. Obtaining placement of a drug on a formulary generally involves a combination of verbal and written communications between sales personnel (including NAMs) of the manufacturer and the third-party payor or PBM. The manufacturer's team typically meets with the formulary director or his or her designee to discuss the nature, safety and efficacy of the drug, and financial information including the costs, discounts, and other relevant contractual issues. The manufacturer's representatives may also make a written presentation, such as a "slide" presentation, as well as a clinical presentation where a clinical expert, such as a medical science liaison, presents information to the clinical evaluators at the third-party payor or PBM relating to the safety and efficacy of the drugs proposed to be listed.

411. The drug manufacturer may also prepare and disseminate a formulary "dossier," which describes the drug, the clinical evidence relating to safety and effectiveness, the price, the cost-effectiveness and other aspects of the drug.

412. Further, if a third-party payor or PBM finds that a drug has a clinical, financial, or other advantage over competing drugs, that drug may be given a "preferred status" on its formulary, which is a higher preference compared to other drugs. Third-party payors or PBMs place approved drugs on their formularies in tiers, ranging from I to V. Tier I drugs are most preferred by third-party payors and PBMs because they are usually the least expensive for the third-party payor or PBM. As the tier level increases, so does the co-payment that the consumer is typically required to pay.

413. Drug manufacturers often offset those increased costs by offering co-pay coupons, with the sole objective to increase the sales of their respective drugs. Among other

things, manufacturers' use of coupons also helps enable the manufacturer to both market and sell more of its product by offsetting the costs incurred directly by the consumer.

414. By directly and indirectly promoting opioids as safe and effective for long-term use using false and misleading statements, Defendants influenced third-party payors and PBMs in the placement of opioids on their formularies and in paying or reimbursing for opioid prescriptions purely for financial gain.

415. Defendants' deceptive and misleading marketing practices were widespread and succeeded in increasing the number of opioid prescriptions written and filled, both in Philadelphia and nationwide. Because Defendants misstated and withheld material information about the true safety and efficacy of opioids, third-party payors and PBMs, among others, did not have sufficiently complete information to make informed decisions regarding the safety and efficacy of prescription opioids and the listing of those drugs on their prescription drug formularies or those of their customers.

416. During the relevant period covered by the Complaint, neither the City nor its PBMs were aware of the deceptive nature of Defendants' marketing activities, and the City and its PBMs paid for or reimbursed prescriptions filled on behalf of their plan participants.

417. Third-party payors and PBMs were subject to and influenced by Defendants' misrepresentations and omissions regarding the purported safety and efficacy of prescription opioids, which in turn influenced the number of prescription opioids which they paid for or reimbursed. Third-party payors and PBMs and their pharmacy and therapeutic committees were influenced by Defendants' misrepresentations of opioids' safety and efficacy when approving and/or placing opioids on formularies. Third-party payors and PBMs were influenced by Defendants' misrepresentations of opioids' safety and efficacy in reimbursing and/or paying for

prescriptions of opioids on behalf of their members.

418. The City's health plan, insofar as the purchase or reimbursement of prescription drugs were concerned, has been administered by Caremark, a PBM, from 2010 to the present. Prior to engaging Caremark, prescription drug decisions concerning the City's health plan were administered by a Caremark affiliate, Advance PCS, another PBM, which Caremark acquired in 2003.

419. The contract between the City and Caremark requires Caremark to, *inter alia*, manage the City's formulary.

420. As part of Caremark's management of the City's formulary, and as is standard in such an arrangement, Caremark provided the following services to the City, among others: filling or dispensing prescriptions, claims administration, pharmacy network administration, formulary design and management, manufacturer rebate negotiation, drug utilization review (to determine whether a patient's prescriptions may interact), and physician communication and education (including formulary compliance incentives).

421. Further, Caremark and its predecessors utilized pharmacy and therapeutics committees comprised of clinical pharmacists and physicians, who reviewed the drugs in each therapeutic class as well as evidence of each drug's effectiveness, safety, contra-indications and costs.

422. Caremark and its predecessors were subject to and influenced by Defendants' misrepresentations and omissions regarding the purported safety and efficacy of prescription opioids, which in turn influenced the number and amount of prescription opioids which they paid for or reimbursed. Caremark and its predecessors and their pharmacy and therapeutic committees were influenced by Defendants' misrepresentations of safety and efficacy when

approving and/or placing opioids on the formularies. They were also influenced by the Defendants' misrepresentations of opioids' safety and efficacy in reimbursing and/or paying for prescriptions of opioids on behalf of the City's health plan participants.

423. Defendants' failure to adequately inform Caremark and its predecessors that the use of prescription opioids for chronic pain was dangerous and likely to lead to abuse, misuse, and addiction (among other side-effects), and their false and misleading promotion of the efficacy of opioids over competing, safer non-opioid pain relievers, caused Caremark and its predecessors to pay for or approve payment for prescription opioids, which they would otherwise not have.

424. The City's PBMs were subjected to Defendants' deceptive and misleading marketing activities, including misrepresentations and omissions about the purported safety and efficacy of opioids. Due to these activities, the City's PBMs approved Defendants' prescription opioids for inclusion on the City's drug formulary and for which the City paid or reimbursed substantial sums. Inclusion of prescription opioids on these formularies led to the use of Defendants' prescription opioids by City employees.

425. Defendants' actions were a substantial factor in causing the City's PBMs and/or the City to pay for opioids for chronic pain in the quantities and amounts that the City did.

426. In response to the opioid epidemic, Caremark and the City have taken steps to curb the City's purchases of opioids. For example, on September 21, 2017, Caremark announced changes to its PBM practices for all clients nationwide (including the City) aimed at limiting prescription opioid use and abuse. Specifically, Caremark's PBM changes included "limiting to seven days the supply of opioids dispensed for certain . . . patients who are new to therapy; limiting the daily dosage of opioids dispensed based on the strength of the opioid; and requiring

the use of immediate-release formulations of opioids before extended-release opioids are dispensed."[321] In 2017, the City mailed opioid prescribing guidelines to 16,000 health care providers in Southeastern Pennsylvania to educate them about responsible opioid prescribing.[322] The aim was to achieve a reduction in opioid prescribing, including with respect to prescriptions for the City's employees.

427. Further, the City, via the Department of Public Health, is continuing to work with public and private health insurers to establish policies that support safer opioid prescribing and improve access to medication assisted treatment for opioid addiction. As a result of the City's efforts, and several managed care organizations in Philadelphia are implementing policies to reduce overprescribing of opioids to their members.[323]

VII. Guilty Pleas and Prior Attorney General Settlements with Certain Defendants in Connection with Improper Opioid Marketing.

A. Purdue's 2007 Guilty Plea for OxyContin Marketing Misrepresentations.

428. In 2007, Purdue and three top executives were indicted in Virginia and pled guilty to fraud in promoting OxyContin as non-addictive and appropriate for chronic pain.

429. As part of its guilty plea, Purdue admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:
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> * * *
>
> b. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than

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[321] https://cvshealth.com/newsroom/press-releases/cvs-health-fighting-national-opioid-abuse-epidemic-with-enterprise-initiatives.

[322] *Implementation of Task Force Recommendations*, Sept. 13, 2017, at pg. 6, *supra* note 113.

[323] *Implementation of Task Force Recommendations*, Dec. 13, 2017, at pg. 11, *supra* note 136.

immediate-release opioids;

c. [Purdue] sponsored training that taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

d. [Purdue] told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. [Purdue] told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[324]

430. Under the plea agreement, Purdue agreed to pay $600 million in criminal and civil penalties – one of the largest settlements in history for a drug company's marketing misconduct.[325] Also, Purdue's Chief Executive Officer, General Counsel, and Chief Medical Officer pled guilty and agreed to pay a total of $34.5 million in penalties.[326]

431. Purdue's wrongdoing continued basically unabated even with this prior plea and was and continues to be a key cog in the current opioid epidemic. Purdue's improper marketing campaign set the stage for a lengthy course of conduct in which Purdue and the other Defendants herein conditioned physicians to believe that opioids were safe and effective treatments for the long-term treatment of chronic pain.

432. Purdue made many subsequent misleading statements regarding its own opioid products and opioids generally, continuing long after its 2007 guilty plea as alleged herein.

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[324] https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt.
[325] *Id.*
[326] *Id.*

B. Purdue's 2015 Settlement with the New York Attorney General.

433. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding Purdue's marketing of opioids.

434. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, the Purdue website www.inthefaceofpain.com failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's failure to disclose these financial connections misled consumers regarding the objectivity of the testimonials.

435. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. . . . .
>
> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
>
> Although Purdue created the content on www.inthefaceofpain.com . . . the site creates the impression that it is neutral and unbiased. However, prior to this investigation, the website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost $231,000, for speaker programs, advisory meetings and travel costs, to 11 of the Advocates whose testimonials appeared on the site. The videos on YouTube also fail to disclose Purdue's payments to the Advocates.
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> *Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the*

potential bias of these individuals.[327]

436. As part of the settlement, Purdue agreed to make certain disclosures on www.inthefaceofpain.com and its similar websites, and to pay a monetary penalty.[328]

437. Again, however, Purdue's improper marketing of opioids has continued following its prior regulatory settlements, all as alleged more fully herein. As summarized in an October 30, 2017 article in *The New Yorker*:

> Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's people who are dangerous."[329]

438. Further, according to that article, Purdue has continued to search for new users through the present, both domestically and now increasingly overseas, and in August 2015 even sought to market OxyContin to children as young as 11.[330]

C. Endo's 2016 Settlement with the New York Attorney General.

439. On March 1, 2016, the NYAG entered into a settlement agreement with Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. regarding Endo's marketing and sales of Opana ER.

440. On Endo's website www.opana.com, Endo claimed until at least April 2012 that

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[327] NYAG-Purdue Settlement Agreement, Aug. 19, 2015, at pg. 7-8 (emphasis added), *supra* note 193.

[328] *Id.* at pg. 15-17.

[329] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), *available at* https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

[330] *Id.*

"[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[331] The NYAG found that Endo had no evidence for that statement.[332]

441. Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[333] The NYAG found that those statements were unwarranted.[334]

442. Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction." *The NYAG found that the "pseudoaddiction" concept has never been empirically validated* and has been abandoned by some of its proponents, all as alleged above.[335]

443. The NYAG also noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted . . . adverse events from marketing pamphlets."[336]

444. As part of the NYAG settlement, Endo agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive," (ii) "make statements that most patients who take opioids do not become addicted," and (iii) "use the term 'pseudoaddiction' in any training or marketing."[337]

445. Endo also paid a $200,000 penalty in connection with the settlement.[338]

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[331] NYAG-Endo Settlement Agreement, March 1, 2016, at ¶ 20, *supra* note 218.
[332] *Id.* at ¶ 20.
[333] *Id.* at ¶ 22.
[334] *Id.* at ¶ 22.
[335] *Id.* at ¶ 23.
[336] *Id.* at ¶ 30.
[337] *Id.* at ¶ 41.
[338] *Id.* at ¶ 54.

VIII. The City Seeks Injunctive Relief to Abate the Public Nuisance and/or Cease Defendants' Misleading Marketing of Opioids.

446. The City seeks injunctive relief to enjoin Defendants' improper conduct and abate the nuisance to the fullest extent practicable and appropriate. Specifically, the City seeks an order requiring the Defendants to:

a. Stop disseminating and/or causing the dissemination of misleading information about the safety and efficacy of opioids;

b. Provide, participate in, and support the effective dissemination of accurate information to medical providers, pharmacists, consumers, and others about the risks and benefits of opioids and alternatives to opioids, including information about efficacy and information about the dangers and risks of opioid misuse, addiction, and overdose;

c. Provide, participate in, and support the effective dissemination of accurate information to medical providers, pharmacists, consumers, and others about addiction treatment options (including medication assisted treatment), and about the availability and proper use of narcan;

d. Perform and support a public outreach campaign to inform Philadelphia residents about the dangers of opioids, to be disseminated via television, radio, print, online, and other means;

e. Provide, participate in, and support accurate detailing efforts regarding opioids and alternatives;

f. Cease funding of nonprofit groups that advocate for opioids;

g. Participate in and support appropriate changes to Electronic Medical Record systems, to ensure default settings and alerts for opioids are appropriate;

h. Provide, participate in, and support drug disposal programs and syringe

disposal programs;

i. Participate in, and support, harm reduction efforts, including syringe exchanges, testing and treatment for hepatitis C virus (HCV) and other consequences of opioid addiction, housing services, and syringe disposal;

j. Provide, participate in, and support programs to identify and treat addiction;

k. Fund the cost of detoxification and treatment, including the costs of medications used as part of medication assisted treatment, for every resident in the City currently suffering from opioid addiction attributable to prescription opioids;

l. Participate in and support a "warm hand-off" system from emergency departments (and as appropriate, first responders) to addiction treatment;

m. Provide and support the provision of naloxone for community distribution, and distribution to patients, families, first responders, prison personnel, and others;

n. Provide, participate in, and support monitoring relating to the opioid crisis, including outcome data and the staff and equipment that will be needed within the Medical Examiners Office to obtain and organize this data;

o. Participate in, and support, a real-time, City-wide dashboard of opioid-related data, including locations of deaths and non-fatal overdoses and available treatment slots;

p. Provide regular, detailed reports to the City regarding the sale and distribution of Defendants' opioids within the City;

q. Participate in and support programs to monitor pharmaceutical marketing efforts in Philadelphia, including the registration of pharmaceutical representatives and

review of their materials and activities relating to prescription opioids; and

r. Such other relief as the Court deems appropriate.

COUNT I
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

447. The City incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

448. The opioid epidemic in the City and the resulting public health and safety crisis constitute a public nuisance. The use of prescription opioids for medical purposes beginning at least in the mid-1990s and continuing to the present has led to a sharp increase in the incidence and prevalence of opioid addiction and related diseases. The result has been an epidemic of opioid addiction, overdoses and deaths that has significantly interfered with public health, safety and peace. The increased incidence and prevalence of these conditions have harmed individual prescription opioid users, damaged the community as a whole, and caused a serious deterioration in public order, public safety, economic productivity, and the quality of life in the City and in the community as a whole. The opioid epidemic has also required City government to increase significantly the provision of services at dramatically increased costs, thereby shifting the imposition of the social costs of the opioid epidemic to the City, its residents and the community as a whole from those responsible.

449. The Defendants herein have engaged in systematic deceptive marketing and promotion of prescription opioids for medical uses for several decades. This misconduct, directly and through their Third Party Allies as set forth above, has created, caused and/or substantially contributed to the public nuisance.

450. Defendants' misconduct as set forth above has created or contributed to a

substantial and unreasonable interference with rights common to the general public, including the right to be free of an unreasonable interference with public health, safety and peace.

451. Defendants' interference with the public health, safety and peace of the City through their misconduct has been unreasonable, as established by the following circumstances as more fully alleged previously herein:

a. Defendants' misconduct is responsible for the opioid epidemic in the City and significantly interfered with public health, safety and peace in the City;

b. Defendants' misconduct has produced a permanent or long-lasting effect and will continue unless the prescription and use of opioids as a treatment for chronic pain and as marketed and sold by Defendants are reduced to appropriate levels and unless City residents suffering from opioid addiction and opioid use disorder receive adequate substance abuse treatment; Defendants knew or had reason to know that their misconduct has had and continues to have a significant adverse impact on public health, safety and peace;

c. Defendants' conduct is and was unlawful, including, without limitation, pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law (73 P.S. § 201-1 to 201-9.3) and the Philadelphia False Claims Act (Philadelphia Code §§ 19-3601 to 19-3606) as more fully set forth herein; and

d. Defendants' interference with rights common to the public is and was unreasonable based on the totality of the circumstances.

452. The unreasonableness of Defendants' conduct and the resulting substantial harm imposed on Philadelphia residents and the infringement of their rights is evident from the gravity of the harm, *e.g.*, opioid addiction and opioid poisoning, and from the accompanying serious

effects that interfered with and degraded, and continues to interfere with and degrade, the public health and safety of the City.

453. The opioid epidemic and resulting public health and safety crisis touch and harm many neighborhoods, workplaces and communities in the City. The harm is not confined to any City zip code or census tract, or to people of any race, ethnicity, religion, gender, sexual preference, or other demographic, but affects the public health, safety, order and well-being of the City as a whole.

454. The deterioration of public health and safety caused by the opioid epidemic tears at the social and economic fabric of the City; its impact is not limited to opioid users adversely affected by the side-effects of prescription opioids, but have been socialized and ultimately borne by the community and the City as a whole.

455. The negative effects of the opioid crisis on the City's public health, safety and peace are substantial and community-wide, and include, but are not limited to, the effects of opioid addiction and opioid poisoning, including fatal and non-fatal overdoses, hospitalizations, increased incidents of other diseases and death, as well as increased costs for medical care, social services, law enforcement and criminal justice and the adverse economic impact associated with opioid addiction and opioid use disorder and other adverse health conditions resulting from the use of prescription opioids.

456. The following additional circumstances also further support the City's public nuisance claim:

a. Defendants had sufficient control over, and responsibility for, the public nuisance they created, as alleged more fully herein. Defendants were in control of the "instrumentality" of the nuisance, namely prescription opioids, including the process of

marketing and promotion and creation and maintenance of the demand for prescription opioids at all relevant times, which included control of the misleading representations they conveyed through branded and unbranded marketing and product promotion. Defendants could have ameliorated, at least in part, the public nuisance by ceasing their improper marketing of opioids and their dissemination of misleading messages about the safety and efficacy of opioids, and by disseminating corrective statements that informed physicians, consumers, third-party payors and health plan administrators and others about the true risks of prescription opioids.

b. Defendants are not immune from public nuisance claims because they produced and marketed otherwise and/or allegedly legal products. Lawful conduct of businesses, like lawful conduct of individuals, has long been held to constitute a public nuisance if it unreasonably interferes with public health, safety, or peace. In any event, Defendants' conduct – and the deceptive marketing and product promotion and misrepresentations and omissions embodied therein – was unlawful. *See* ¶ 451(c).

c. Defendants have interfered with common public rights, which were understood for centuries to be and have become common rights to public health, safety, order, peace, comfort, or convenience, rather than specific, individual rights.

457. Defendants' misconduct has not been insubstantial or fleeting as it has involved sophisticated and highly deceptive conduct involving expenditures of tens of millions of dollars per year by the Defendants to market and promote prescription opioids and which they engaged in for decades. The misconduct is ongoing and has produced permanent or long-lasting harm including the worst drug epidemic in the history of the country and in the City, along with all of the deleterious consequences thereof as more fully alleged herein. Defendants' misconduct has

caused deaths, serious injuries, and a significant disruption of public health, safety and peace in the City, as further alleged herein.

458. The injury, damage and costs to the City from Defendants' misconduct were both significant and either known or wholly foreseeable to Defendants. While reaping billions of dollars in revenues and profits through their misconduct, the Defendants improperly shifted the burden, harm and costs of their public nuisance to the City and the community as a whole, and its residents, which the City has had to address to its detriment, as alleged herein.

459. The public nuisance for which Defendants are responsible has caused, and continues to cause, substantial, extraordinary and repeated injury to the City and its residents that will continue unless enjoined and remedied by the Court.

460. The City has been injured and continues to be injured in that, among other things, it has been forced to pay for a variety of social, public health, emergency, medical, and other services, the need for which arose from the opioid epidemic as alleged above. The City has also been directly injured in that it has paid for long-term opioid prescriptions, related medical treatment, and disability benefits for City employees using City funds related to prescription opioids marketed by Defendants as alleged more fully herein.

461. The City sues in its public capacity for all appropriate injunctive and mandatory relief to abate the ongoing public nuisance, restore the City's public health, safety and peace, and recover all appropriate damages, expenses, costs and fees.

462. The City also sues in its proprietary capacity to recover the additional costs it has incurred in addressing the nuisance and other appropriate damages, expenses, costs and fees.

463. The City has suffered and continues to suffer special harm that is different in kind and degree from that suffered by individual residents of the City as alleged herein. The harm to

City residents includes opioid addiction, opioid use disorder, opioid poisoning including overdoses and death, among other things, and, through the epidemic for which the Defendants are responsible, created a public and safety crisis which extends to the City's neighborhoods and communities. The harm to the City itself includes social services costs, emergency costs, equipment costs, and medical and prescription costs, among other things.

464. Defendants also are liable for punitive damages to reflect the aggravating circumstances of their intentional, willful, wanton, malicious and oppressive conduct as set forth herein. Defendants acted or failed to act knowingly, willfully and deceptively, with gross negligence, maliciously, and/or wantonly with conscious disregard of the public's health, safety, and welfare.

465. WHEREFORE, the City demands judgment against Defendants, jointly and severally, for the following:

a. injunctive relief as noted above;

b. abatement of the public nuisance, to the fullest extent allowed by law, including an abatement fund;

c. damages expenses, costs and fees to the fullest extent allowed by law, in excess of $50,000, exclusive of interest and costs;

d. punitive damages;

e. litigation costs (including expert fees) and attorneys' fees;

f. prejudgment interest; and

g. such other and further relief as the Court deems just and proper.

COUNT II
VIOLATION OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 P.S. §§ 201-1 to 201-9.3 (AGAINST ALL DEFENDANTS)

466. The City incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

467. This Count does not sound in fraud.

468. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") prohibits companies from employing "[u]nfair methods of competition" and "unfair or deceptive acts or practices," which are defined to include, *inter alia*, the following conduct:

a. "Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services." 73 P.S. § 201-2(4)(ii);

b. "Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have . . . ." 73 P.S. § 201-2 (4)(v); or

c. "Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding." 73 P.S. § 201-2 (4)(xxi).

469. Under Pennsylvania law, an act or practice is unfair or deceptive if it had the capacity to deceive, or was likely to deceive, a substantial portion of the public, and was likely to make a difference in the purchasing decision.

470. Defendants' conduct as alleged herein constitutes unfair or deceptive acts or practices in violation of the above provisions of the UTPCPL in that:

a. At all relevant times, Defendants directly, or indirectly through their Third Party Allies, made and disseminated, or caused to be made and disseminated, materially

false and misleading statements directed at the Defendants' target audiences, which included the PBM responsible for selecting the drugs covered by the City's health coverage plans and included on the City's pharmacy formularies;

b. These false and misleading statements by Defendants directly, or indirectly through their Third Party Allies, were specifically intended to promote the sale and use of opioids to treat chronic pain to members of their target audiences;

c. At all relevant times, Defendants directly, or indirectly through their Third Party Allies, made statements that omitted material facts to promote the sale and use of opioids to treat chronic pain;

d. Defendants directly, or indirectly through their Third Party Allies, repeatedly failed to disclose or minimized material facts about the risks of opioids, including the life-threatening risks of abuse, misuse, and addiction, and their risks compared to alternative treatments. These omissions were directed at and affected all of the members of the target audiences described above;

e. Such material omissions by Defendants directly, or indirectly through their Third Party Allies, were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids misleading, creating a false impression of the risks, benefits, and superiority of opioids for treatment of chronic pain;

f. At all relevant times, Defendants, directly or indirectly through their Third Party Allies, made and disseminated the foregoing misleading and deceptive statements and omissions through an array of marketing channels including, but not limited to: in-person and other forms of detailing; speaker events, including meals, conferences, and teleconferences; CMEs; journal articles and studies; advertisements; and brochures and

other patient education materials;

g. These materially false and misleading statements and omissions by Defendants directly, or indirectly through their Third Party Allies, were widely disseminated to the purchasing public, including the target audiences alleged above;

h. Defendants knew or should have known that their marketing and promotional efforts created a misleading impression of the risks, benefits and purported superiority of opioids;

i. Defendants' conduct, including their deceptive representations and concealments of material fact, created a significant likelihood of confusion and/or misunderstanding as to the safety, efficacy, and risks of opioids, including the risks associated with the use of opioids for chronic pain;

j. Defendants' conduct had a tendency to deceive a substantial segment of the target audiences, and their misrepresentations and concealments of material facts were likely to be misinterpreted in a misleading way; and

k. Defendants' acts and practices – taken individually and collectively – were likely to make a difference in the prescribing decisions of doctors; usage and purchasing decisions of patients; the formulary decisions of PBMs; and the payment decisions of end-payors like the City, because their misrepresentations and other wrongful acts were specifically designed to mislead and convince these individuals and groups that opioids were safe and superior to alternative treatments for chronic pain.

471. As a direct result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in violations of the UTPCPL as alleged herein.

472. The City was injured in that Defendants' branded and unbranded marketing of opioids for chronic pain led to doctors prescribing, patients using, the City's PBMs approving, and the City paying or reimbursing for unnecessary long-term opioid treatment with Defendants' opioids.

473. The City operates as a consumer when it purchases goods or services, which it does when it pays for the procurement of and/or reimbursement for prescription opioids.

474. The City, via its PBMs acting as the City's agents, was subjected to Defendants' improper marketing as alleged above, including Defendants' materially false representations and omissions about the purported safety and efficacy of opioids. The City, via its PBMs, justifiably relied upon these misrepresentations and omissions in determining that Defendants' opioids should be listed on the City's approved drug formulary, resulting in the City paying or reimbursing for prescriptions of Defendants' opioids.

475. But for Defendants' deceptive conduct in violation of the CPL, the City would not have expended millions of dollars in connection with the purchase or reimbursement of prescription opioids or the treatment for opioid addiction, opioid use disorder, or any other opioid-related adverse health effect involving the opioid epidemic. As a direct and proximate result of Defendants' deceptive conduct, the City has been injured.

476. Philadelphia has suffered economic injuries that are direct, ascertainable, and quantifiable. The City's damages constitute both an "ascertainable loss of money or property" and "actual damages" for purposes of 73 P.S. § 201-9.2(a).

477. The Court "may, in its discretion, award up to three times the actual damages sustained." 73 P.S. § 201-9.2(a).

478. The City is entitled to treble damages in light of the severe, willful, and long-

running nature of Defendants' conduct, the opioid epidemic it caused, and the resulting harm to public health and safety.

479. The City is also entitled to an award of its litigation costs and attorneys' fees pursuant to 73 P.S. § 201-9.2(a).

480. WHEREFORE, the City demands judgment against Defendants, jointly and severally, for the following:

a. injunctive relief to enjoin Defendants' continued violations of the CPL as requested in detail above;

b. damages to the fullest extent available by law in excess of $50,000, exclusive of interest and costs;

c. treble damages;

d. litigation costs (including expert fees) and attorneys' fees;

e. prejudgment interest; and

f. such other and further relief as the Court deems just and proper.

COUNT III
VIOLATION OF PHILADELPHIA FALSE CLAIMS ACT
PHILA. CODE §§ 19-3601 to 19-3606
(AGAINST ALL DEFENDANTS)

481. The City incorporates by reference all paragraphs set forth above as if fully set forth herein at length.

482. This Count does not sound in fraud.

483. The Philadelphia False Claims Act ("PFCA") is violated when any person:

> (1) Knowingly presents or causes to be presented to an officer or employee of the City a false claim for payment or approval by the City; (2) Knowingly makes, uses or causes to be made or used a false record or statement to get a false claim paid or approved by the City; [or] (3) Conspires to defraud the City by getting a false claim allowed or paid by the City.

Phila. Code § 19-3602.

484. The PFCA defines a "false claim" as a "claim, or information relating to a claim, which is false or fraudulent." Phila. Code § 19-3601(3).

485. The PFCA defines a "claim" as "[a]ny request or demand, whether under a contract or otherwise, for money or property . . . which is made to any employee, officer or agent of the City or to any contractor, grantee or other recipient of money or property . . . ." Phila. Code § 19-3601(1).

486. The PFCA defines "knowingly" as follows: "Acting with actual knowledge of the information, in deliberate ignorance of the truth or falsity of the information, or in reckless disregard of the truth or falsity of the information. *No proof of specific intent to defraud is required.*" Phila. Code § 19-3601(5) (emphasis added).

487. Defendants' practices, as alleged above, violated § 19-3602(1) – (3) of the Philadelphia Code in that:

a. Opioid prescriptions written for patients covered by the City's health plans are filled by pharmacies, which submit claims for payment to the City's PBMs;

b. The City, via its PBMs acting as the City's agent, was subjected to Defendants' deceptive promotion and marketing as alleged herein, including misrepresentations and omissions about the purported safety and efficacy of opioids and specifically as to the risks of use for long term chronic pain;

c. The City, via its PBMs, relied, directly or indirectly, upon those misrepresentations and omissions and was thereby induced to list Defendants' opioid products on the City's approved drug formulary and to thereafter pay false claims for their prescriptions;

d. Defendants, through their misleading marketing of opioids for chronic pain, knowingly caused to be presented to the City false claims for payment or approval by the City;

e. Defendants knew or should have known that their marketing and promotional efforts created a misleading impression about the risks, benefits, and/or superiority of opioids for chronic pain;

f. Defendants knew or should have known that, as a natural consequence of their misconduct, governmental entities such as the City would pay false claims for opioid prescriptions to treat chronic pain; and

g. Defendants' misrepresentations were material because they had a natural tendency to influence or be capable of influencing whether doctors prescribed opioids, patients used opioids, PBMs approved opioids for payment by listing them on their formularies, and third-party payors like the City paid for opioids.

488. By reason of Defendants' unlawful acts, the City has been damaged. The City has spent significant funds per year to pay false claims for improper prescriptions of Defendants' opioids, as well as related office visits.

489. The PFCA provides that any company that violates the Act "shall be liable to the City for three (3) times the amount of damages which the City sustains." Phila. Code § 19-3602. Treble damages are mandatory, not discretionary. Defendants are liable to the City for treble damages under the Act.

490. The PFCA also provides that any company that violates the Act "shall have committed a Class III offense and be subject to the fines set forth in Section 1-109(3) of this Code." Phila. Code § 19-3602.

491. Section 1-109(3) of the Act states: "For violations that are designated in this Code as Class III offenses, the maximum fine shall be as follows: . . . for any violation committed on January 1, 2009 or thereafter, two thousand (2,000) dollars for each violation." Lower fines are available for violations occurring before 2009.

492. The Defendants are liable to the City for fines under the Act.

493. The PFCA also provides that any company that violates the Act "shall be liable for attorneys' fees and costs for any civil action brought to recover such damages." Phila. Code § 19-3602. An award of attorneys' fees and costs is mandatory, not discretionary.

494. Defendants are liable to the City under the Act for its attorneys' fees and litigation costs under.

495. WHEREFORE, the City demands judgment against Defendants, jointly and severally, under the PFCA for the following:

a. damages to the fullest extent available by law in excess of $50,000, exclusive of interest and costs;

b. treble damages;

c. appropriate fines;

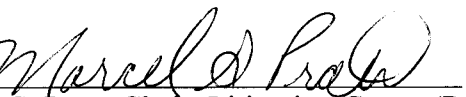
d. litigation costs (including expert fees) and attorneys' fees;

e. prejudgment interest; and

f. such other and further relief as the Court deems just and proper.

Dated: January 17, 2018

Respectfully submitted,

By: 

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VERIFICATION

I, Thomas Farley, M.D., M.P.H., hereby state that I am the Health Commissioner for the City of Philadelphia, and that I have authority to make this verification on behalf of the City of Philadelphia. The averments in the foregoing complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements made herein are subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsification to authorities.

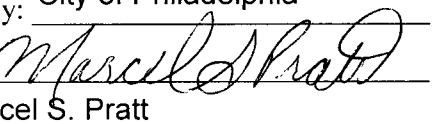
Dated: 1/16/18

Thomas Farley, M.D., M.P.H.

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

Submitted by: City of Philadelphia

Signature: 

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