Supreme Court of Pennsylvania

Court of Common Pleas
Civil Cover Sheet

LEHIGH COUNTY **County**

For Prothonotary Use Only:	TIME STAMP
Docket No:	

The information collected on this form is used solely for court administration purposes. This form does not supplement or replace the filing and service of pleadings or other papers as required by law or rules of court.

SECTION A

Commencement of Action:
☒ Complaint ☐ Writ of Summons ☐ Petition
☐ Transfer from Another Jurisdiction ☐ Declaration of Taking

Lead Plaintiff's Name:	Lead Defendant's Name:
The Commonwealth of Pennsylvania by James B. Martin	PURDUE PHARMA, L.P., et al.
Are money damages requested? ☒ **Yes** ☐ **No**	Dollar Amount Requested: (check one) ☐ within arbitration limits ☒ outside arbitration limits
Is this a *Class Action Suit*? ☐ **Yes** ☒ **No**	**Is this an *MDJ Appeal*?** ☐ **Yes** ☒ **No**

Name of Plaintiff/Appellant's Attorney: HAVILAND HUGHES - DONALD E. HAVILAND, JR. and WILLIAM H. PLATT II

☐ **Check here if you have no attorney (are a Self-Represented [Pro Se] Litigant)**

SECTION B

Nature of the Case: Place an "X" to the left of the **ONE** case category that most accurately describes your ***PRIMARY CASE.*** If you are making more than one type of claim, check the one that you consider most important.

TORT (*do not include Mass Tort*)
- ☒ Intentional
- ☐ Malicious Prosecution
- ☐ Motor Vehicle
- ☒ Nuisance
- ☐ Premises Liability
- ☒ Product Liability (*does not include mass tort*)
- ☐ Slander/Libel/ Defamation
- ☒ Other: UTPCPL

MASS TORT
- ☐ Asbestos
- ☐ Tobacco
- ☐ Toxic Tort - DES
- ☐ Toxic Tort - Implant
- ☐ Toxic Waste
- ☐ Other:

PROFESSIONAL LIABLITY
- ☐ Dental
- ☐ Legal
- ☐ Medical
- ☐ Other Professional:

CONTRACT (*do not include Judgments*)
- ☐ Buyer Plaintiff
- ☐ Debt Collection: Credit Card
- ☐ Debt Collection: Other
- ☐ Employment Dispute: Discrimination
- ☐ Employment Dispute: Other
- ☐ Other:

REAL PROPERTY
- ☐ Ejectment
- ☐ Eminent Domain/Condemnation
- ☐ Ground Rent
- ☐ Landlord/Tenant Dispute
- ☐ Mortgage Foreclosure: Residential
- ☐ Mortgage Foreclosure: Commercial
- ☐ Partition
- ☐ Quiet Title
- ☐ Other:

CIVIL APPEALS
Administrative Agencies
- ☐ Board of Assessment
- ☐ Board of Elections
- ☐ Dept. of Transportation
- ☐ Statutory Appeal: Other
- ☐ Zoning Board
- ☐ Other:

MISCELLANEOUS
- ☐ Common Law/Statutory Arbitration
- ☐ Declaratory Judgment
- ☐ Mandamus
- ☐ Non-Domestic Relations Restraining Order
- ☐ Quo Warranto
- ☐ Replevin
- ☐ Other:

NOTICE

Pennsylvania Rule of Civil Procedure 205.5. (Cover Sheet) provides, in part:

Rule 205.5. Cover Sheet

(a)(1) This rule shall apply to all actions governed by the rules of civil procedure except the following:

(i) actions pursuant to the Protection from Abuse Act, Rules 1901 et seq.

(ii) actions for support, Rules 1910.1 et seq.

(iii) actions for custody, partial custody and visitation of minor children, Rules 1915.1 et seq.

(iv) actions for divorce or annulment of marriage, Rules 1920.1 et seq.

(v) actions in domestic relations generally, including paternity actions, Rules 1930.1 et seq.

(vi) voluntary mediation in custody actions, Rules 1940.1 et seq.

(2) At the commencement of any action, the party initiating the action shall complete the cover sheet set forth in subdivision (e) and file it with the prothonotary.

(b) The prothonotary shall not accept a filing commencing an action without a completed cover sheet.

(c) The prothonotary shall assist a party appearing pro se in the completion of the form.

(d) A judicial district which has implemented an electronic filing system pursuant to Rule 205.4 and has promulgated those procedures pursuant to Rule 239.9 shall be exempt from the provisions of this rule.

(e) The Court Administrator of Pennsylvania, in conjunction with the Civil Procedural Rules Committee, shall design and publish the cover sheet. The latest version of the form shall be published on the website of the Administrative Office of Pennsylvania Courts at www.pacourts.us.

Donald E. Haviland, Jr., Esquire (PA I.D. No. 66615)
haviland@havilandhughes.com
William H. Platt II, Esquire (PA I.D. No. 83585)
platt@havilandhughes.com
HAVILAND HUGHES
201 S. Maple Way, Suite 110
Ambler, PA 19002
Ph: (215) 609-4661
Fax: (215) 392-4400

COURT OF COMMON PLEAS OF LEHIGH COUNTY, PENNSYLVANIA
CIVIL ACTION – LAW

THE COMMONWEALTH OF PENNSYLVANIA
By JAMES B. MARTIN
District Attorney of Lehigh County
455 W. Hamilton Street
Allentown, Pennsylvania 18101*;*

THE PEOPLE OF LEHIGH COUNTY
455 Hamilton Street
Allentown, Pennsylvania 18101; and

LEHIGH COUNTY, PENNSYLVANIA
17 South 7th Street
Allentown, Pennsylvania 18101

Plaintiffs,

v.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901; and

PURDUE PHARMA INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901; and

THE PURDUE FREDERICK COMPANY, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901; and

No. 2018-_____

JURY TRIAL DEMANDED

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, Pennsylvania 19454; and

CEPHALON, INC.
1090 Horsham Road
North Wales, Pennsylvania 19454; and

JOHNSON & JOHNSON
1 Johnson & Johnson Plaza
New Brunswick, New Jersey 08933; and

JANSSEN PHARMACEUTICALS, INC.
1125 Trenton Harbouton Road
Titusville, New Jersey 08560; and

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.
1125 Trenton Harbouton Road
Titusville, New Jersey 08560; and

JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.
1125 Trenton Harbouton Road
Titusville, New Jersey 08560; and

ENDO HEALTH SOLUTIONS, INC.
1400 Atwater Drive
Malvern, Pennsylvania 19355; and

ENDO PHARMACEUTICALS, INC.
1400 Atwater Drive
Malvern, Pennsylvania 19355; and

ALLERGAN FINANCE, LLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS
c/o The Corporation Trust Company of Nevada
701 South Carson Street, Suite 200
Carson City, NV 89701

ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, New Jersey 07054; and

WATSON LABORATORIES, INC.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, New Jersey 07054; and

ACTAVIS, LLC
Morris Corporate Center III
400 Interpace Parkway
Parsippany, New Jersey 07054; and

ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, New Jersey 07054; and

MALLINCKRODT, PLC
3 Lotus Park, the Causeway
Staines-upon-Thames,
Surrey, TW18 3 AG; and

MALLINCKRODT, LLC
675 James South McDonnell Boulevard
Hazelwood, Missouri 63042; and

McKESSON CORPORATION
One Post Street
San Francisco, California 94104; and

CARDINAL HEALTH, INC.
7000 Cardinal Place
Dublin, Ohio 43017; and

AMERISOURCEBERGEN DRUG CORPORATION
227 Washington Street
Conshohocken, Pennsylvania 19428

Defendants.

FILED 3/23/2018 3:50:51 PM,Clerk of Judicial Records, Civil Division, Lehigh County, PA
2018-C-0716 /s/D N

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims 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 in the complaint or for 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, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. 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 AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

LEHIGH COUNTY BAR ASSOCIATION
LAWYER REFERRAL SERVICE
PO BOX 1324
ALLENTOWN, PENNSYLVANIA 18105-1324
TELEPHONE: (610) 433-7094

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COMPLAINT

Plaintiffs, The Commonwealth of Pennsylvania by James B. Martin, District Attorney of Lehigh County, The People of Lehigh County, and Lehigh County, Pennsylvania, ("Plaintiffs" or "Lehigh County" or the "County") by and through their undersigned counsel, hereby file this Complaint against Defendants[1] Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Allergan PLC f/k/a Actavis PLC, Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis, LLC, Actavis Pharma, Inc., f/k/a Watson Pharma, Inc. (collectively, the "Brand Manufacturer Defendants"), McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Drug Corporation (collectively the "Distributor Defendants") and allege as follows:

I. INTRODUCTION

1. Plaintiffs bring this civil action to eliminate the hazard to the public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby, and to recoup monies that have been spent because of Defendants' unfair and deceptive acts and practices in distributing, marketing and selling brand name prescription opioids.[2] Such economic damages

[1] The Defendants comprise two categories of Defendants—the Brand Manufacturer Defendants and the Distributor Defendants as defined herein. To the extent appropriate, all Defendants shall be defined collectively and referred to as "Defendants".

[2] As used herein, the term, "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

were foreseeable to Defendants and were sustained because of Defendants unfair and deceptive, negligent, reckless and, at times, intentional actions and omissions.

2. Brand name opioid analgesics are widely prescribed and distributed, and the widespread abuse of brand opioids has resulted in a national epidemic of opioid overdose deaths and addictions.

3. To redress and punish the Defendants' violations of the consumer fraud laws and common law of Pennsylvania, Plaintiffs seek declaratory and injunctive relief, having their acts and practices declared unlawful and stopped. Specifically, Plaintiffs seek to have each Defendant comply fully with their obligations under the Comprehensive Drug Abuse and Prevention Control Act of 1970, 216 S.C. §§ 801, *et seq.* (the "CSA"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

4. Brand opioids are controlled substances under the CSA. As controlled substances under the CSA, the federal Drug Enforcement Agency ("DEA") regulates the manufacture, distribution, sale and possession of brand name opioids.

5. Because of their involvement in the distribution of brand name opioids, the CSA places a duty on all Defendants in this "closed distribution system", as registrants under the CSA, to maintain effective controls against diversion of controlled substances. All Defendants breached their duties under the CSA by failing to maintain such effective controls with regard to having effective processes and systems in place to detect "suspicious orders" for brand name opioids, and by failing to inform the DEA of "suspicious orders" of brand name opioids.

6. Plaintiffs also seek a judgment requiring all Defendants to pay (a) restitution, (b) damages, including multipliers of damages, (c) disgorgement, (d) civil penalties, (e) punitive

damages (f) attorneys' fees, costs and expenses, and (g) any other relief to which the Plaintiffs may be entitled.

7. Plaintiffs bring this suit against the manufacturers of brand name prescription opioids. The Brand Manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids and turned patients into drug addicts for their own corporate profit. Such actions were negligent, reckless, and at times, intentional.

8. Plaintiffs also bring this suit against the wholesale distributors of these highly addictive drugs. The Distributor Defendants breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction to hear this matter pursuant to 42 Pa. C.S.A. §931 which grants this Court "unlimited original jurisdiction of all actions and proceedings."

10. This Court has personal jurisdiction over all of the Defendants pursuant to 42 Pa. C.S.A. §5322 in that Defendants, (a) are registered to do business in this Commonwealth, (b) have their principal places of business or are otherwise located in this Commonwealth, (c) are transacting business in this Commonwealth, as defined by 42 Pa. C.S.A. §5322(a)(1), (d) are causing harm to Pennsylvania citizens by acts occurring outside the Commonwealth, 42 Pa. C.S.A. §5322(a)(4), and/or (e) have maintained the most minimum contacts with this Commonwealth allowed under the United States Constitution, 42 Pa. C.S.A. §5322(b).

11. Venue is appropriate in this Court because the Plaintiffs are situated in this County and this County has residents who have been harmed whom also reside here. Pa. R. Civ.

P. 1006(a). Moreover, various instrumentalities of the conduct described herein have been located in Lehigh County, making this a county in which "a transaction or occurrence took place out of which the cause of action arose."

12. Plaintiffs bring this action exclusively under the common law and statutes of Pennsylvania, specifically the Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.S. § 201-1, *et. seq*. No federal claims are being asserted. No aspect of the claims asserted herein is brought pursuant to any federal law, including either Medicare or ERISA, nor is any aspect of the claims asserted herein brought for the purpose of interpreting a federal contract, or the terms of an ERISA plan. To the extent any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, or a claim for recovery of benefits under an ERISA plan, such claim is expressly and undeniably disavowed and disclaimed by the Plaintiffs.

III. PARTIES

A. Plaintiffs

13. Plaintiff, Lehigh County is organized and existing under the laws of the Commonwealth of Pennsylvania. Lehigh County contains 25 municipalities comprised of boroughs, townships, the City of Allentown and a portion of the City of Bethlehem. Plaintiff provides a wide range of services on behalf of its residents, those services including, services for families and children, public health, public assistance, law enforcement and emergency care. Plaintiff also owns and operates a public jail facility located at 38 North Fourth Street, Allentown, Pennsylvania.

14. The distribution and diversion of opioids into and throughout Pennsylvania ("the State"), and into and throughout Lehigh County and surrounding areas (collectively, "Plaintiffs'

Community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiffs here seek relief.

15. Plaintiffs directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiffs seek relief. Categories of past continuing sustained damages include, *inter alia*,: (1) costs for providing medical care, additional therapeutic care, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiffs.

16. Plaintiffs also seek the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct, by forcing Defendants to comply with their obligations under the law.

17. Plaintiffs also include the Commonwealth of Pennsylvania by James B. Martin, the District Attorney of Lehigh County and Lehigh County's Chief Law Enforcement Officer. Plaintiff James B. Martin has reason to believe that Defendants are engaged in or are using unlawful methods, acts and methods, and that this action is in the public interest. He hereby declares this action to be in the public interest pursuant to 73 P.S. § §§ 201-4, 201-4.1 and 201-8(b).

B. Defendants

1. <u>The Brand Manufacturer Defendants</u>

a. Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc.

18. Defendant, Purdue Pharma L.P., is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

19. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

20. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

21. Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company, Inc. (collectively, "Purdue") are in the business of manufacturing, promoting, marketing, and distributing brand opioids in the United States and Lehigh County. Purdue's opioid brands include, but are not necessarily limited to, the following:

a. OxyContin (oxycodone hydrochloride extended release), which is a Schedule II opioid agonist tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, OxyContin was indicated for the "management of moderate to severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release), which is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride), which is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an

opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride), which is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

e. Butrans (buprenorphine), which is a Schedule II opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitartrate), which is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride), which is a Schedule Il combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long term opioid treatment and for which alternative treatment options are inadequate.

22. In May 2007, Purdue entered into a “Consent Judgment” in an action with the People of the State of Illinois. Plaintiffs do not seek to enforce the provisions of the Consent Judgment and do not seek relief against Purdue under state consumer protection laws based on conduct related to Purdue's promotional and marketing practices regarding OxyContin for any time up to and including the effective date of the Consent Judgment, May 8, 2007. Plaintiffs highlight, however, that the Consent Judgment did not shield Purdue, its affiliates, or its co-promoters from liability for future violations of the law, including violations of the UTPCPL. Plaintiffs also highlight that the Consent Judgment did not shield Purdue, its affiliates, or its co-promoters from liability for promotional and marketing practices, during any span of time, regarding controlled-release drugs which do not contain oxycodone as an active pharmaceutical

ingredient. This would include, but would not be limited to, Purdue's MS Contin, Butrans and Hysingla drugs.

b. The Teva Defendants

23. Defendant, Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") acquired Cephalon, Inc. Defendant, Teva Pharmaceuticals USA, Inc. ("Teva USA"), is a wholly-owned subsidiary of Teva Ltd., an Israeli corporation. Teva USA is a Delaware corporation with its principal place of business in Pennsylvania (collectively, these defendants are referred to herein as "the Teva Defendants").

24. The Teva Defendants are in the business of manufacturing, promoting, selling, and distributing brand opioids in the United States, and Lehigh County. The Teva Defendants’ opioid brands include, but are not necessarily limited to, the following:

a. Actiq (fentanyl citrate), which is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer pain inpatients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

b. Fentora (fentanyl citrate), which is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

25. Teva USA and Cephalon work together closely to market and sell the Teva Defendants’ products in the United States. Teva USA conducts Teva Ltd.’s sales and marketing activities for the Teva Defendants in the United States and has done so since Teva Ltd.’s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines"

division. The United States Food and Drug Administration ("FDA") approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Lehigh County, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse effects.

26. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain. The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million in fines, damages, and penalties.

27. On September 29, 2008, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services. Among other things, the agreement required Cephalon to send doctors a letter advising them of the settlement terms and giving them a means to report questionable conduct of its sales representatives; required disclosure of payments to doctors on its web site; and required regular certification that the company has an effective compliance program.

c. **Allergan/Actavis/Watson**

28. Defendant, Allergan plc, is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc, acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in March 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012. The combined company changed its name to Actavis, Inc. as of January 2013 and then to Actavis plc in October 2013.

29. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit (collectively, these defendants are referred to herein as "Actavis").

30. Actavis is in the business of marketing and selling brand opioids in the United States and Lehigh County. Actavis' opioid brands include, but are not necessarily limited to, the following:

a. Kadian (morphine sulfate extended release), which is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Kadian was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

31. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

d. The Johnson & Johnson Defendants

32. Defendant, Janssen Pharmaceuticals, Inc., ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant, Johnson & Johnson ("J&J"), a New Jersey corporation with its principal

place of business in New Brunswick, New Jersey. Defendant, Ortho-McNeil- Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal, place of business in Titusville, New Jersey.

33. Defendant, Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Collectively, J&J and Janssen are referred to herein as the "Johnson & Johnson Defendants.").

34. The Johnson & Johnson Defendants' are in the business of manufacturing, promoting, selling, and distributing brand opioids in the United States and Lehigh County. The Johnson & Johnson Defendants' opioid brands include, or have included, the following:

a. Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

b. Nucynta ER (tapentadol extended release), which is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

c. Nucynta (tapentadol), which is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

35. Another corporation, Depomed, Inc., acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015 Asset Purchase Agreement, which closed on April 2, 2015.

36. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in sales.

e. The Endo Defendants

37. Defendant, Endo Health Solutions Inc., is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant, Endo Pharmaceuticals, Inc., is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (collectively, these defendants are referred to herein as "Endo.").

38. Endo is in the business of developing, promoting, and selling brand opioids in the United States and Lehigh County. Endo's opioid brands include, but are not necessarily limited to, the following:

a. Opana ER (oxymorphone hydrochloride extended release), which is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "management of pain severe enough to require daily, around-the clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

b. Opana (oxymorphone hydrochloride), which is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "relief of moderate to severe acute pain where the use of an opioid is appropriate."

c. Percodan (oxycodone hydrochloride and aspirin), which is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the "management of moderate to moderately severe pain."

d. Percocet (oxycodone hydrochloride and acetaminophen), which is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the "relief of moderate to moderately severe pain."

e. Zydone (hydrocodone bitartrate and acetaminophen), which is a Schedule II opioid agonist tablet indicated for the "relief of moderate to moderately severe pain" that Endo marketed from 1998 through 2013. However, the FDA's website indicates that this product is currently discontinued.

39. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012.

f. Mallinckrodt Defendants

40. Defendant Mallinckrodt PLC is an Irish public limited company with its headquarters in Staines-Upon-thames, Surrey, United Kingdom. Mallinckrodt Pharmaceuticals is a register business name of Mallinckrodt plc with its headquarters in Hazelwood, Missouri.

41. Mallinckrodt LLC, a subsidiary of Mallinckrodt, plc is a Delaware corporation with its headquarters in Hazelwood, Missouri.

42. Mallinckrodt LLC is registered with the Pennsylvania Department of State to do business in Pennsylvania.

43. Mallinckrodt plc and Mallinckrodt LLC are collectively referred to as "Mallinckrodt".

44. Mallinckrodt is in the business of marketing and selling brand opioids in the United States and Lehigh County.

45. Mallinckrodt manufactures brand opioids at its "Specialty Brands" division located in Bedminster, New Jersey. Mallinckrodt's opioid brands include the following:

a. Exalgo (hydromorphone hydrochloride extended release), which is a Schedule II opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.,* non-opioid analgesics) are inadequate. The FDA approved 8, 12, and 16 mg tablets of Exalgo in March 2010 and 32 mg tablets in August 2012.

b. Roxicodone (oxycodone hydrochloride), which is a Schedule II brand-name instant-release form of oxycodone hydrochloride indicated for the management of pain sever enough to require an opioid analgesic and for which alternative treatments are inadequate. Roxicodone was acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames of this drug include: Roxies, blues and stars.

c. Methadose (methadone hydrochloride) is a Schedule II brand name drug. Methadose was approved by the FDA on April 15, 1993for the 5 mg and 10 mg Methadose Tablets. It is marketed and sold as an "addiction treatment product" for "detoxification treatment of opioid addiction" and for "maintenance treatment of opioid addiction."

d. Xartemis XR (oxycodone hydrochloride and acetaminophen), which is a Schedule II drug. Xartemis XR was approved by the FDA in March 2014 for the management of acute pain sever enough to require opioid treatment in patients for who alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.

46. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.

47. Mallinckrodt debuted Xartemis (MNK-795) at the September 2013 PAINWeek in Las Vegas.

48. For purposes of this Complaint, any references to the methods, acts and practices of Purdue, the Teva Defendants, Actavis, Cephalon, the Johnson & Johnson Defendants, Endo, and Actavis shall include methods, acts and practices by and through those Defendants' officers, owners, members, directors, employees, salespersons, representatives, and/or other agents.

2. Wholesalers (The "Distributor Defendants")

49. Defendants McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal Health"), and AmerisourceBergen Drug Corporation ("AmerisourceBergen") (collectively hereafter, the "Distributor Defendants"), are wholesale pharmaceutical distributors of controlled and uncontrolled prescription medications, including opioids.

50. The Distributor Defendants are defined more fully below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with Pennsylvania and federal law in this regard. The Distributor Defendants are engaged in "wholesale distribution," as defined under Pennsylvania and federal law. Plaintiffs allege the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Lehigh County.

51. The Distributor Defendants' violations have already led to fines elsewhere. McKesson, the largest prescription drug wholesaler company in the United States, agreed on January 17, 2017, to pay a $150 million fine to the federal government for such misconduct. In December 2016, Cardinal Health reached a $44 million settlement with the federal government. One month later, Cardinal Health reached a $20 million settlement with the State of West Virginia, which has been among the states hardest hit by opioid abuse. AmerisourceBergen also recently agreed to pay West Virginia $16 million for similar violations.

52. Former FDA Commissioner David A. Kessler has called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern medicine." As alleged herein,

that "mistake" resulted in large part from the Distributor Defendants' willingness to turn a blind eye to suspicious orders.

53. Even where the Distributor Defendants have previously been forced to admit their failure to report suspicious orders, their conduct did not abate, nor did they comply with the directives of Pennsylvania and federal law, because the profits they realized by the distribution of opioids dwarfed the penalties imposed as a result of violations of the law. Thus, the incentive to push opioids by the Distributor Defendants remains.

a. McKesson

54. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters and principal place of business located in San Francisco, California. McKesson maintains operations in Pennsylvania at 470 Lapp Road, Malvern, PA 19355, and has been registered to do business in Pennsylvania since 1994.

55. McKesson is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest drug distributor, and the fifth largest company, in the United States. It distributes pharmaceuticals through a network of distribution centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

56. McKesson supplies various United States pharmacies increasing amounts of oxycodone and hydrocodone pills, products frequently misused that are part of the current opioid epidemic.

57. McKesson is a significant distributor of prescription opioids in the United States. McKesson distribution centers are required to operate in accordance with the statutory provisions of the CSA. The regulations promulgated under the CSA include a requirement to design and

operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. See 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). See 21 U.S.C. §842(a)(5) & (c)(l)(B).

58. In or about 2007, the United States Drug Enforcement Administration ("DEA") accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the United States Department of Justice ("DOJ") and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

59. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers - i.e., orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the CSMP.

60. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the Controlled Substances Act.

61. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of

controlled substances from distribution centers in four states to settle allegations that the company violated federal law. According to the DOJ, McKesson continued to fail to report suspicious orders between 2008 (the year of its settlement with DOJ) and 2012, and did not fully implement or follow the monitoring program. As part of the 2017 agreement, McKesson acknowledged that "at various times during the covered time period (2008-2012), it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA." See, Settlement Agreement and Release between the United States and McKesson Corporation, at 5 (January 17, 2017), at: https://www.justice.gov/opa/press-release/file/928471/download.

b. Cardinal Health

62. Defendant Cardinal Health, Inc. ("Cardinal Health") is a Delaware corporation with its headquarters and principal place of business located in Dublin, Ohio. Cardinal Health has business offices in Pennsylvania.

63. Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top United States companies with revenues of over $121 billion.

64. Cardinal Health has two operating segments, pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter, and consumer products in the United States. Of Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

65. Cardinal Health is a significant distributor of prescription opioids in the United States. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue.

66. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder. See 21 C.F.R. § 1300 et seq. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. See 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). See 21 U.S.C. §842(a)(5) & (c)(l)(B).

67. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.

68. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and
- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule

> II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

69. The settlement agreement was announced by the United States Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge - Washington Field Division, Karl C. Colder ("Colder"). See, Press Release, United States Attorney's Office for the District of Maryland, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), at: https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

70. In the press release announcing the settlement agreement, Rosenstein stated:

> Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA...Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes.

Id. In the press release, Colder clarified that the settlement specifically concerned oxycodone:

> DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy...Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety.

Id.

c. AmerisourceBergen

71. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its headquarters and principal place of business located in Chesterbrook, Pennsylvania.

72. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the United States through a network of 26 pharmaceutical distribution centers. It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

73. AmerisourceBergen is a significant distributor of prescription opioids in the United States. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder. See 21 C.F.R. § 1300 et seq. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. See 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). See 21 U.S.C. §842(a)(5) & (c)(l)(B).

74. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period. Moreover, public documents also demonstrate that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16

million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis. See, Eric Eyre, Drug firms poured 780M painkillers into WV amid rise of overdoses, Charleston Gazette-Mail (Dec. 17, 2016), at: https://www.wvgazettemail.com/news/health/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_78963590-b050-11e7-8186-f7e8c8a1b804.html

IV. FACTUAL BACKGROUND

A. The Opioid Epidemic

1. The National Opioid Epidemic

75. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.3

76. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.4

77. By 2011, the United States Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

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3 *See* Richard C. Dart *et al*., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

4 Katherine M. Keyers *et al*., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid use and Abuse in the United States,* 104 Am. J. Pub. Health e52 (2014).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

f. Almost 5,500 people start to misuse prescription painkillers every day.[5]

78. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.6

79. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.7

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[5] *See* Press Release, Centers For Disease Control and Prevention, United States Department of Health and Human Services, Prescription Painkillers Overdoses at Epidemic Levels (November 1, 2011), at: https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html

[6] *See* Robert M. Califf *et al*., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016), at: http://www.nejm.org/doi/full/10.1056/NEJMsr1601307

[7] *See* Centers for Disease Control and Prevention, United States Department of Health and Human Services, Provisional Counts of Drug Overdose Deaths, (August 8, 2016), at: https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf

80. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[8]

81. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[9]

82. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. ***Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,*** specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.[10]

83. The societal costs of prescription drug abuse are "huge."[11]

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[8] *See* Centers for Disease Control and Prevention, United States Department of Health and Human Services, *Today's Heroin Epidemic*, at: https://www.cdc.gov/vitalsigns/heroin/index.html

[9] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

[10] *See* Rose A. Rudd *et al.*, *Increases in Drug and Opioid Overdose Deaths – United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

[11] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept.*

84. Across the nation, local governments are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 115 Americans lose their lives after overdosing on opioids.[12]

85. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[13] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[14]

86. The United States opioid epidemic is continuing, and drug overdose nearly tripled during 1999-2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[15]

Justice, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter, "Brief of HDMA"].

[12] Opioid Crisis, NIH, National Institute on Drug Abuse, at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (citing at note 1, CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: United States Department of Health and Human Services, CDC; 2017, at: https://wonder.cdc.gov)

[13] *Id*.

[14] *Id.* (citing at note 2, Florence CS, Zhou C, Luo F, Xu L, *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States,* 2013. *Med Care*. 2016;54(10):901-906. doi:10.1097/MLR.0000000000000625).

[15] *See* Rose A. Rudd *et al*., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

87. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[16]

88. Every day brings a new revelation regarding the depth of the opioid plague. To name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because pervasive, deadly opioids are "everywhere" and mistaken as candy.[17]

89. In 2016, the President of the United States declared an opioid and heroin epidemic.[18]

90. In January 2018, the Governor of Pennsylvania declared the opioid and heroin epidemic a statewide disaster emergency.

91. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.[19] Meanwhile, the manufacturers and distributors of brand name prescription opioids extract billions of dollars of revenue from the addicted American public, including the residents of Lehigh County, while public entities experience tens

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16 *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies,* 374 N. Eng. J. Med. 1253 (2016).

17 Julie Turkewitz, 'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

18 *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

19 *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), at: https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf

of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

2. Background of the Opioid Industry

92. Since the Civil War, America has been exposed to opioids—first heroin and now heroin-like substitutes that are addicting and killing Pennsylvanians far too often, including residents of Lehigh County.

93. Heroin was first introduced as a legal pharmaceutical product by the Bayer Company in 1898. Heroin was manufactured to treat pain, but because it is highly addictive and deadly, by 1924, heroin was declared an illegal narcotic.

94. Opioids include brand-name drugs as well as generic drugs, and are all derived from or possess properties similar to heroin. This case concerns brand name drugs only.

95. In 1916, two German scientists created a drug called oxycodone—an opioid—which was introduced as a substitute for heroin. Oxycodone is manufactured by modifying an organic compound called thebaine. In 1939, oxycodone was introduced in the United States of America. By 1970, oxycodone was listed as a Schedule II drug in the Controlled Substances Act. Every opioid drug included in this Complaint is a Schedule II drug, meaning, *inter alia*, it is designated as potentially leading to severe psychological or physical dependence and thus is considered extremely dangerous.

96. In 1976, the FDA approved Percocet (ANDA 085106), which is a combination of oxycodone and paracetamol. Percocet is a Schedule II drug.

97. In 1984, the FDA approved Vicodin (ANDA 085667), which is a combination of acetaminophen and hydrocodone bitartrate. Vicodin is a Schedule II drug.

98. Oxycodone, Percocet and Vicodin are all opioids.

99. Today, as a result of the national crisis created by the over-prescription and abuse of opioids, and the publicity and attention it has generated, it is now known that these opioids are highly addictive to the degree that they should not be widely prescribed for chronic or casual pain, as they have been due to the Defendants' acts and practices described in this Complaint.

100. Initially, opioids were effective in treating short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. These categories of pain are different from long-term pain or "chronic pain". This case concerns the acts and practices of the Defendants to cause their opioids to be widely prescribed for the treatment of chronic and casual pain, despite their highly addictive properties and dangerous propensities.

3. Lehigh County Opioid Epidemic

101. Pennsylvania and Lehigh County were and continue to be victims of the well-documented opioid crisis. Seventy-eight percent of Pennsylvania counties had overdose death rates higher than the national average.

102. In 2016, 4,642 drug-related overdose deaths were reported by Pennsylvania coroners and medical examiners, an increase of 37 percent from 2015. In 2016, approximately 13 people died of a drug-related overdose each day.

103. In 2016 alone, in Lehigh County, 175 accidental overdoses involving opiates were reported.

104. The Pennsylvania drug-related overdose death rate in 2016 was 36.5 per 100,000 people, an increase from 26.7 per 100,000 people in 2015. The national drug overdose death rate in 2015 was 16.3 per 100,000 people.

105. The presence of an opioid, illicit or prescribed by a doctor, was identified in 85 percent of drug-related overdose deaths in Pennsylvania in 2016.

106. Fentanyl and fentanyl–related substances (FRS) were the most frequently identified in decedents (52 percent of deaths), a significant increase from 2015 when fentanyl/FRS were noted in 27 percent of deaths.

107. Two hundred, ninety-four people in the Lehigh Valley died of drug overdoses in 2017. By comparison, 175 people overdosed of either opioids or multiple drugs in 2014 and 2015 combined, according to the coroner reports.

108. In Lehigh County alone, in 2017, 197 people died of drug overdoses, with 150 of those deaths being opioid related. An additional 30 deaths determined to be drug overdoses await full toxicology results to determine opioid relatedness.

109. In 2016, 157 people died in Lehigh County from drug overdoses, with 113 of those deaths being opioid related.

110. In 2015, 115 people died in Lehigh County from drug overdoses, with 83 of those deaths being opioid related.

111. The deaths in Lehigh County due to drug overdoses greatly increased each year from 2014 through 2017.

112. The number of Pennsylvania adults who had friends or family experiencing problems with opioid abuse also rose sharply from 2014 to 2017.

B. The Brand Manufacturer Defendants' Unlawful Acts and Practices in Marketing and Selling Opioids for the Treatment of Chronic Pain

113. The Brand Manufacturer Defendants named in this lawsuit manufacture, distribute, market, and/or sell some form of opioids. As identified herein, these drugs are collectively referred to as the Brand Manufacturer Defendants' "Subject Drugs".

114. Throughout the 1980s, primary care professionals understood opioids to be dangerous as a result of their addictive qualities and were reluctant to prescribe them for long-

term or chronic pain. As a result, the Brand Manufacturer Defendants began a marketing campaign designed to "destigmatize" opioids as addictive, dangerous medicines. They created a false narrative designed to persuade primary care professionals that opioids were the best and most effective way of treating pain, while withholding information about the dangerous, addictive propensity of opioids.

115. In order to successfully "destigmatize" opioids, the Brand Manufacturer Defendants spent hundreds of millions of dollars: (a) developing educational and advertising materials that misrepresented the risks and benefits of opioids when used to treat chronic pain; (b) widely disseminating such materials; (c) deploying sales representatives who visited medical providers and delivered misleading messages about the use of opioids; (d) recruiting prescribing physicians as paid speakers, as a means of both securing these physicians' future "brand loyalty" and extending their reach to these physicians' peers; (e) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), to deliver scripted talks, to present continuing medical education programs ("CMEs"), and to serve on the boards and committees of professional societies and patient advocacy groups in order to deliver misleading messages and to develop guidelines supporting opioid use to treat chronic pain; and (f) funding, assisting, directing, and encouraging certain groups to develop educational materials and treatment guidelines to be distributed by the Brand Manufacturer Defendants in the above-described manner.

116. The Brand Manufacturer Defendants seized upon any opportunity they could to "destigmatize" opioids for the treatment of chronic pain, going as far as relying on an irrelevant, one-paragraph Letter to the Editor in the New England Journal of Medicine as scientific proof

that opioids were not addictive, and a group's warning that pain is the "Fifth Vital Sign" and that opioids were lifesaving drugs, among other things described herein.

117. The Brand Manufacturer Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized and/or obscured opioid serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated opioid superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. The Brand Manufacturer Defendants recruited certain doctors to assist them in their efforts.

118. There was and is today no reliable scientific evidence to support the Brand Manufacturer Defendants' marketing claims about opioids. To the contrary, there exists a body of evidence that the Brand Manufacturer Defendants' marketing claims misrepresented the truth about opioids.

119. Since the time of the launch of their Subject Drugs, as set forth herein, the Brand Manufacturer Defendants deliberately misrepresented the addictive potential of prescription opioids to encourage doctors in Lehigh County and throughout Pennsylvania to prescribe to consumers opioids for the treatment of chronic and casual pain, and to take more opioids than is either necessary or appropriate, by:

a. employing and/or encouraging their respective sales representatives to market and sell opioids as an appropriate medication for the treatment of pain, without informing their customers, healthcare providers, patients and the County of the highly addictive nature of these drugs;

b. promoting the use of opioids for chronic pain in general, despite knowing that these messages were inconsistent with the Brand Manufacturer Defendants' respective branded marketing materials;

c. advertising and promoting such messages through magazines, the media, and the internet, including on the Brand Manufacturer Defendants' own websites;

d. hiring and paying doctors and KOLs whom prescribed opioids to promote and "destigmatize" opioid speaking engagements, misleading studies and other means described herein; and

e. paying for, funding, aiding, abetting, assisting, incentivizing and directing trade groups, associations, patient advocacy groups (collectively referred to as, "Front Groups") to create and produce false and misleading educational materials and treatment guidelines to be distributed by the Brand Manufacturer Defendants.

120. The Brand Manufacturer Defendants' ads deceptively portrayed the benefits of using opioids for chronic pain. For example, Endo's website opana.com included a pamphlet promoting Opana ER for treatment of common pain associated with physically demanding jobs, like construction workers, teachers and restaurant workers.

121. Examples of the Brand Manufacturer Defendants' misrepresentations about opioids include:

a. A patient education brochure concerning the use of Actavis' Kadian entitled *Managing Chronic Back Pain* falsely claimed addiction is "less likely if you have never had an addiction problem."

b. Endo-sponsored websites, "PainKnowledge," claimed that "[p]eople who take opioids as prescribed usually do not become addicted," and PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

c. An Endo-distributed pamphlet entitled *Living with Someone with Chronic Pain*, which misrepresented that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem."

d. A Janssen-approved patient education guide entitled, *Finding Relief: Pain Management for Older Adults* (2009), misrepresented a "myth" that opioids are addictive, and claimed that "[m]any studies show that opioids

are rarely addictive when used properly for the management of chronic pain."

e. A Mallinckrodt-sponsored program, entitled "Collaborating and Acting Responsibly to Ensure Safety" promoted the book *Defeat Chronic Pain Now!* telling consumers considering taking opioids "[o]nly rarely does opioid medication cause a true addiction", and "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance."

1. The New England Journal of Medicine Publishes One Paragraph That Empowered The Defendants to Hide The Truth About Opioids

122. On January 10, 1980, the New England Journal of Medicine (the "New England Journal") published the following one-paragraph Letter to the Editor:

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' 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 a history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, 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.

JANE PORTER
HERSHEL JICK, M.D. ("the Letter to the Editor")

123. After this Letter to the Editor was published, opioid prescriptions increased dramatically. The increase in prescriptions was caused, in large part, by the Brand Manufacturer Defendants who directly, through their sales representatives, and through other direct and indirect marketing efforts, began to cite the Letter to the Editor as evidence that opioids were non-addictive and an appropriate means to treat common or chronic pain—not just pain associated with late-stage, terminal cancer.

124. Years later, Dr. Jick complained that the Letter to the Editor was misapplied and misused.

125. For decades after, the Brand Manufacturer Defendants encouraged other consultants, medical professionals and doctors to publish and promote studies that favored and destigmatized opioids and their addictive qualities, based in part on the misleading Letter to the Editor.

126. For example, in 2001, the National Pharmaceutical Council ("NPC") sponsored the publication of the monograph entitled, "pain" Current Understanding of Assessment, Management, and Treatments." The monograph cited as one source the Letter to the Editor, among other questionable sources. The NPC counts as part of its executive leadership executives from Purdue, J&J, Endo and Mallinckrodt, among others. The NPC counts as its members other Defendants named in this Lawsuit.

2. The Brand Manufacturer Defendants Paid Dr. Russell Portenoy, Committeeman of the American Pain Society, to Endorse the Letter to the Editor.

127. The four main vital signs are measurements of the body's most basic functions: i.e., (a) body temperature, (b) pulse rate, (c) respiration rate, and (d) blood pressure.

128. However, in the mid-1990s, the American Pain Society ("APS) added "pain" as a "fifth vital sign".

129. This was done in an effort to increase the perceived value of opioids in pain treatment and to misinform healthcare providers and professionals that opioids were not addictive, but were medically beneficial, and even life-saving.

130. Dr. Russell Portenoy, a renowned pain management specialist and eventual President of APS, perpetuated the inaccuracies in the Letter to the Editor and the "fifth vital

sign" misrepresentation when he wrote that "opioid maintenance therapy can be a safe, salutary and more humane alternative" to surgery or to not treating a patient with chronic pain.

131. In 1994, Dr. Portenoy wrote:

> The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, but itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuated reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.

132. It was unknown at the time that Dr. Portenoy was a paid consultant for Brand Manufacturer Defendants Cephalon, Endo, Janssen and Purdue, among others.

133. Dr. Portenoy was also the Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York. On behalf of the Brand Manufacturer Defendants, Dr. Portenoy and APS repeatedly endorsed the use of opioids as a humane means of treating chronic pain (perpetuating the destigmatization of opioids) in 1997 and again in 2009.

134. In 2011, Dr. Portenoy's publications were repeatedly cited as source materials by the NPC in the monograph "Pain: Current Understanding of Assessment, Management, and Treatments."

135. Dr. Portenoy made frequent public appearances promoting the Brand Manufacturer Defendants' opioids. For instance, in 2010, he appeared on "Good Morning America" to discuss the use of opioids long-term to treat chronic pain. He stated, "[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

136. It was not until 2011 that Dr. Portenoy admitted that he was wrong. In a published interview, Dr. Portenoy conceded:

> Clearly if I had an inkling of what I know now then, I wouldn't have spoken in the way that I spoke. It was clearly the wrong thing to do.

137. After Dr. Portenoy admitted what he had done for the Brand Manufacturer Defendants was wrong, in just this past year, the New England Journal published the following statement criticizing the Letter to the Editor as follows:

> In conclusion, we found that a five-sentence letter published in the Journal in 1980 ***was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy***. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. ***Our findings highlight the potential consequences of inaccurate citation and underscore the need for diligence when citing previously published studie***s.

138. Dr. Portenoy was not the only doctor the Brand Manufacturer Defendants employed to try to "destigmatize" the use of opioids for the treatment of pain. Dr. Lynn Webster, the founder and Chief Medical Director of Lifetree Clinical Research and a member of

the American Academy of Pain Medicine ("AAPM"), authored numerous CMEs sponsored by Cephalon, Endo and Purdue. He also created a screening tool which purported to enable doctors to manage the risk that a patient will become addicted to or abuse opioids. Known as the "Opioid Risk Tool", several Brand Manufacturer Defendants promoted the screening tool on their websites. It is averred that several of the Brand Manufacturer Defendants paid Dr. Webster for his promotional and marketing services.

139. Both the APS and AAPM worked with the Brand Manufacturer Defendants, along with the American Pain Foundation ("APF"), to promote the Brand Manufacturer Defendants' misrepresentations about opioids. The APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed in May 2012. The APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks.

140. The United States Senate Finance Committee began investigating the APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The APF's board voted to dissolve the organization soon after. The AAPM issued treatment guidelines and sponsored and hosted medical education programs essential to the Brand Manufacturer Defendants' deceptive marketing of chronic opioid therapy. Additionally, the AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. The AAPM maintained a corporate relations council, whose members paid $25,000 per year to participate, in addition to other funding. Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended the AAPM's marquee annual meeting.

141. Other groups utilized by Cephalon, Endo, Janssen, and Purdue were the American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

142. Each Brand Manufacturer Defendant named herein knew that misrepresentations of the risks and benefits of opioid drugs were not supported by or were directly contrary to scientific evidence. Indeed, the falsity of the Brand Manufacturer Defendants' misrepresentations has been confirmed by the FDA and the Centers for Disease Control and Prevention ("CDC"), including in the CDC's Guideline for Prescribing Opioids for Chronic Pain, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). The 2016 CDC Guideline, which reinforces other previous findings by the FDA, includes the following excerpts in its review:

a. "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 (with most placebo-controlled randomized trials 6 weeks in duration)."

b. "Opioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder[.]"

c. There is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain[.]"

d. "Clinicians should use additional caution when initiating opioids for patients aged 65 years."

e. Clinicians discussing potential opioid therapy with patients should "[b]e explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely."

f. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

143. The CDC has declared that prescription painkiller overdoses are at epidemic levels. In support, it cited the following statistics:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

c. Overdoses involving prescription painkillers now kill more Americans than heroin and cocaine combined.

d. Approximately 5,500 people start to misuse prescription painkillers every day.

144. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin.

145. As a result, drug overdose deaths involving heroin have more than tripled in 4 years. This increase has been closely tied to opioid abuse and addiction.

146. Pennsylvania has been ranked in the top 10 states for opioid overdose deaths for years, with its rank rising from 9th place in 2013 to 6th place in 2015.

147. According to the Pocono Record, in 2015 more people in Pennsylvania died from drug overdoses than from automobile accidents.

C. The Defendants' Unlawful Distribution of Opioids

148. The Defendants owe a duty under both federal law and Pennsylvania law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids

originating from Plaintiffs' community as well as those orders which the Defendants knew, or should have known were likely to be diverted into Plaintiffs' community.

149. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

150. Manufacturers rely upon distributors to distribute their drugs. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics.

151. According to the United States Center for Disease Control ("CDC"), the increased distribution of opioids directly correlates to increased overdose death rates.

152. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. See Madel v. USDOJ, 784 F.3d 448 (8th Cir. 2015). Neither the DEA, nor the manufacturers or wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

153. Consequently, in addition to the Brand Manufacturers Defendants, Plaintiffs have named the three (3) wholesale distributors, Cardinal Health, McKesson, and AmerisourceBergen, also known as the "Big 3", which collectively dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. See Fed. Trade Comm'n v. Cardinal Health, Inc., 12F.Supp.2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders, as described in more detail herein.

Plaintiffs have reason to believe each of the "Big 3" engaged in unlawful conduct which resulted in the diversion of prescription opioids into Lehigh County, and that discovery will reveal their unlawful conduct. Plaintiffs naming of each of the "Big 3" herein as Distributor Defendants in this matter places the industry on notice that the Plaintiffs are acting to abate the public nuisance plaguing Lehigh County and its community.

154. Each Distributor Defendant repeatedly and purposefully breached its duties under Pennsylvania and federal law. Such breaches are the direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Lehigh County and its community.

155. The unlawful diversion of prescription opioids is a direct and proximate cause and/or substantial contributing factor to the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in Lehigh County and its community. This diversion and the epidemic are direct causes of harm for which Plaintiffs seek to recover here.

156. The opioid epidemic in Lehigh County remains an immediate hazard to public health and safety.

157. The opioid epidemic in Lehigh County is a temporary and continuous public nuisance and remains unabated.

158. The Distributor Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. The Defendants Have a Duty under Pennsylvania Law to Guard Against, and Report, Unlawful Diversion, and to Report and Prevent Suspicious Orders, Yet They Intentionally Failed to Take Any Action to Stop the Misuse of Opioids in Violation of Pennsylvania and Federal Law and Regulations.

159. The Distributor Defendants purchased opioids from manufacturers, including the named Brand Manufacturer Defendants herein, and sold them to pharmacies throughout Lehigh County.

160. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Lehigh County.

161. Pennsylvania law incorporates federal requirements set out under the Controlled Substance Act and related controlled substance laws and regulations.

162. The Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. § 780-112(c), incorporates 21 C.F.R. § 1301.74(b), which requires wholesalers and distributors of controlled substances, including the Distributor Defendants, to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." These requirements were intentionally and willfully ignored by the Distributor Defendants. Specifically, the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act requires:

> (c) Persons registered or licensed to manufacture or distribute or dispense a controlled substance, other drug or device under this act shall keep records and maintain inventories in conformity with the record-keeping, order form and inventory requirements of Federal law and with any additional regulations the secretary issues. Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form.

35 P.S. § 780-112.

163. The Pennsylvania Wholesale Prescription Drug Distributors License Act, 63 P.S. § 391.6(k), also incorporates by 21 C.F.R. § 1301.74(b), which requires wholesalers and distributors of controlled substances, including the Distributor Defendants, to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." These requirements were intentionally and willfully ignored by the Distributor Defendants. Specifically, the Wholesale Prescription Drug Distributors License Act requires:

> (k) COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAW— The licensee shall operate in compliance with applicable Federal, State and local laws and regulations. The licensee shall permit the department and authorized Federal, State and local law enforcement officials to enter and inspect its premises and delivery vehicles and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. The licensee that deals in controlled substances shall register with the Drug Enforcement Administration (DEA) and shall comply with all applicable DEA, State and local regulations.

63 P.S. § 391.6.

164. The Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, 35 P.S. § 780-112(c), and the Pennsylvania Wholesale Prescription Drug Distributors License Act, 63 P.S. § 391.6(k), both additionally incorporate 21 U.S.C. § 823, requiring the Distributor Defendants to establish effective controls against orders which the Distributor Defendants knew or should have known were likely to be diverted into Lehigh County.

165. Opioids are a controlled substance and are categorized as "dangerous drugs" under Pennsylvania law. See 35 P.S. § 780-104(2). These "Schedule II" drugs are controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

166. Each Brand Manufacturer and Distributor Defendant was required under Pennsylvania law to register as distributors of controlled substances with the Secretary of Health of the Commonwealth of Pennsylvania. 35 P.S. § 780-106.

167. Each Brand Manufacturer and Distributor Defendant was required under Pennsylvania law to obtain a license from the Pennsylvania Department of Health as a manufacturer and/or wholesale distributor of prescription drugs. 63 P.S. § 391.4.

168. Each Defendant herein is licensed by the Pennsylvania Department of Health and is a "registrant" with the Secretary of Health of the Commonwealth of Pennsylvania either as a manufacturer or a wholesale distributor in the chain of distribution of Schedule II controlled substances and assumed a duty to comply with all security requirements imposed under the regulations adopted by Pennsylvania Legislature and Department of Health.

169. As wholesale drug distributors, each Distributor Defendant was required under Pennsylvania law to register with the Drug Enforcement Agency (DEA), pursuant to the federal Controlled Substance Act. See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed by that statutory scheme. Those requirements are adopted and incorporated into Pennsylvania law, as indicated above.

170. Each Defendant has an affirmative duty under Pennsylvania and federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs.

Federal law requires that manufacturers and distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). Those requirements are adopted and incorporated into Pennsylvania law, as indicated above. Specifically, Pennsylvania incorporates these requirements through its Controlled Substance, Drug, Device and Cosmetic Act, which mandates that "Persons registered . . . to . . . distribute . . . a controlled substance, other drug or device under this act shall keep records and maintain inventories in conformity with the recordkeeping, order form and inventory requirements of Federal law and with any additional regulations the secretary issues." 35 P.S. § 780-112. Pennsylvania additionally incorporates these requirements through its Wholesale Prescription Drug Distributors License Act, which mandates that licensees 1.) establish, maintain and adhere to written policies and procedures that conform to "any action initiated at the request of the department, the Unites States Food and Drug Administration or other Federal, State or local law enforcement or other government agency" and 2.) "operate in compliance with applicable Federal, State and local laws and regulations." 63 P.S. § 391.6(h)(2)(i); 63 P.S. § 391.6(k).

171. Federal regulations, incorporated by Pennsylvania law, similarly impose a non-delegable duty upon manufacturers and wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

172. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. See 21 C.F.R. 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the manufacturer's and wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

173. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. See, Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. Id.

174. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. See, 1970 U.S.C.C.A.N. 4566, 4571-72.

175. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.

176. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly…distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as…the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) (hereinafter, "Rannazzisi Letter") ("This letter is being sent to every commercial entity in the United States registered with the DEA to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

177. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders. See Brief for Healthcare Distribution Management Association ("HDMA") and NACDS, supra note 85, 2016 WL 1321983, at *4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

178. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." See, Rannazzisi Letter, supra note 83, at 2.

179. The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." Id. at 1.

180. The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm." Id. at 2.

181. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007. See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8. This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Id. The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (*e.g.*, "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of

> responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the norm al pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

Id. Finally, the DEA letter references the Revocation of Registration issued in *Southwood*

Pharmaceuticals, Inc., 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious." *Id*.

182. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society." See Brief of HDMA, supra note 19, 2012 WL 1637016, at *2.

183. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the HDMA, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines created by the HDMA, "Industry Compliance Guidelines," set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest. See, Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

184. Each of the Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Lehigh County and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Lehigh County's communities.

185. Each Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

186. Each Defendant owes a duty under federal and Pennsylvania law to investigate and refuse suspicious orders of prescription opioids.

187. Each Defendant owes a duty under federal and Pennsylvania law to report suspicious orders of prescription opioids.

188. Each Defendant owes a duty under federal and Pennsylvania law to prevent the diversion of prescription opioids into illicit markets in Pennsylvania and Lehigh County and its communities.

189. The Defendants were each on notice that the controlled substances they distributed or prescribed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy and problematic purposes.

190. The Defendants were each on notice that there was an alarming and suspicious rise in distributing opioids within Lehigh County during the relevant time period of this claim.

191. The Defendants knew or should have known that they were supplying vast amounts of dangerous drugs in Lehigh County that was already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

192. The Defendants intentionally failed in their duty to take any action to prevent or reduce the distribution of these drugs for the purpose of their own massive profits.

193. The Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the flow of opioid drugs into Lehigh County.

194. The Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

195. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

196. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Lehigh County and its communities, and the damages caused thereby.

2. The Defendants Breached their Duties.

197. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses. See Rannazzisi Decl. ¶ 10, filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

198. The sheer volume of prescription opioids distributed to pharmacies in Lehigh County, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Lehigh County, is excessive for the medical need of the community and patently suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. See, Masters

Pharmaceuticals, Inc., 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

199. Additionally, the Distributor Defendants' grossly negligent distribution to pharmacies outside Pennsylvania also caused an influx of illicit diversion of opioids within Lehigh County.

200. The Distributor Defendants failed to report "suspicious orders" originating from Lehigh County, or which the Distributor Defendants knew or should have known were likely to be diverted to Lehigh County and its community, to the federal and state authorities, including the DEA and/or Pennsylvania's Board of Pharmacy and related authorities.

201. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency in Lehigh County and its community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Lehigh County and its community.

202. All Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Lehigh County and its community, and/or in areas from which the Defendants knew opioids were likely to be diverted to Lehigh County and its community.

203. The Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

204. The Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities

including the DEA of suspicious orders when discovered, in violation of their duties under federal and Pennsylvania law.

205. The Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels. See Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

206. The federal and Pennsylvania laws at issue here are public safety laws.

207. The Defendants' violations of public safety statutes constitute prima facie evidence of negligence and negligence per se under Pennsylvania law.

208. The Defendants supplied prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

209. The unlawful conduct by the Defendants is purposeful and intentional. The Defendants refuse to abide by the duties imposed by federal and Pennsylvania law which are required to legally acquire and maintain a license to distribute prescription opiates.

210. The Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

211. The Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

3. The Defendants Failed to Comply with Pennsylvania and Federal Law and Misrepresented their Compliance with their Legal Duties.

212. The Defendants have repeatedly misrepresented their compliance with their legal duties under Pennsylvania and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Defendants' compliance with their legal duties.

213. Further, the Defendants have refused to recognize any duty beyond reporting suspicious orders. For instance, in Masters Pharmaceuticals, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to investigate orders (*e.g.*, by interrogating pharmacies and physicians) and take action to halt suspicious orders before they are filled." *See*, Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4–5.

b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only report suspicious orders, but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications." *Id.* at *8

c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious." *Id.* at *14.

d. The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the

importance of ensuring that DEA has complied with the APA before attempting to impose such duties." *Id.* at *22.

e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." *Id.* at *24–25.

f. Also inaccurately, the Associations argued that, "[i]mposing a duty on expertise – to investigate and halt orders m ay force distributors to take a shot-in-the-dark approach to com plying with DEA 's demands." *Id.* at 26.

214. The positions taken by the trade groups are representative of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs. See Brief of HDMA, supra note 19, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

215. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and— if it is able to determine that the order is not likely to be diverted into illegal channels— ship the order." Id. at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. Id. at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. Id. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. Id. at 220.

216. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." See Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Administration, and McKesson Corporation, January 17, 2017, available at: https://www.justice.gov/opa/press-release/file/928476/download

217. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice , as required by 21 C.F.R § 1306.04(a)." Id. at 4.

218. McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers" including the McKesson Distribution Centers located in 12 different locations, and of which could have foreseeably caused the diversion of opioids into Lehigh County. Id.

219. Due to these violations, McKesson agreed that its authority to distribute controlled substances from the 12 facilities would be partially suspended. Id. at 6.

220. As punishment for its wrongdoing, McKesson agreed to pay a $150 million fine and suspended the sale of controlled substances from distribution centers in several states. Id. at 8.

221. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted its failure to report suspicious orders of controlled substances to the DEA. Id. at 4.

222. In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed in its obligations to do so. Id.

223. The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations." Id; see also, Settlement Agreement and Release between the United States and McKesson Corporation, at 5 (January 17, 2017) (hereinafter, "2017 Settlement Agreement and Release") ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA"), at: https://www.justice.gov/opa/press-release/file/928471/download

224. As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000. Id. at 6.

225. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in several states.

226. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

227. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. See, Evaluation and Inspections Division, Office of the Inspector General, United States Department of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), at: https://oig.justice.gov/reports/2014/e1403.pdf

228. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. Id. These actions include the following:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen

entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health

Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado, Aurora, Illinois, Delran, New Jersey, LaCrosse, Wisconsin, Lakeland, Florida, Landover, Maryland, La Vista, Nebraska, Livonia, Michigan, Methuen, Massachusetts, Sante Fe Springs, California, Washington Courthouse, Ohio, West Sacramento, California.

229. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the United States Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued. See Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, October 22, 2016, at: https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.c0e6a44e920b; see also, Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid

Crisis, Wash. Post, March 6, 2017, at: https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.cd4ba03fb447; Eric Eyre, DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, February 18, 2017, at: https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html

230. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants fraudulently convinced the public that they were complying with their legal obligations, including those imposed by licensing regulations, though they were not in compliance. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

231. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity." See, Lenny Bernstein et al., How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Wash. Post, October 22, 2016, at: https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.42947b406a35

232. Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results in favor of profits.

233. Similarly, Defendant McKesson publicly stated that it had a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country." See, Scott Higham et al., Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Wash. Post, December 22, 2016, at: https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.9aac30165395

234. Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program in favor of profits.

235. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. The Plaintiffs did not know of the existence or scope of the Distributor Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

236. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and in Lehigh County and its community.

237. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

238. Despite the charges, fines, and penalties brought against and imposed upon the Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Lehigh County and elsewhere, harming Plaintiffs.

239. The wrongful actions and omissions of the Defendants which have caused the diversion of opioids has been a substantial contributing factor to and/or proximate cause of the opioid crisis.

240. During the relevant time period, the Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Lehigh County and elsewhere, causing diversion of opioid pain killers within Lehigh County.

241. Many of these orders should have been stopped, or at the very least, investigated by the Defendants as potential suspicious orders.

242. The sheer volume of the increase in opioid pain medications, including but not limited to OxyCodone, being distributed to retailers, should have put the Defendants on notice to investigate and report such orders.

243. The Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Lehigh County and elsewhere.

244. The Distributors knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Lehigh County.

245. The Defendants made substantial profits from the opioids sold in Lehigh County and elsewhere.

246. By the actions and inactions described above, the Defendants showed a reckless disregard for the safety of the residents of Lehigh County.

247. By the actions and inactions described above, the Defendants caused great harm to Lehigh County.

248. The Defendants abandoned their duties imposed under federal and Pennsylvania law, took advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in Pennsylvania and Lehigh County.

249. The Defendants have continued to unlawfully ship massive quantities of opioids into communities like Lehigh County, fueling the epidemic.

250. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." See Richard C. Dart et al., Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 New Eng. J. Med. 241 (2015), at: http://www.nejm.org/doi/full/10.1056/NEJMsa1406143

251. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions. See Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016), at: http://www.nejm.org/doi/full/10.1056/NEJMra1507771

252. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications." See Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016), at: http://www.nejm.org/doi/full/10.1056/NEJMsr1601307

253. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths. See Press Release, Centers for Disease

Control and Prevention, United States Department of Health and Human Serices, Prescription Painkiller Overdoses at Epidemic Levels (November 1, 2011), at: https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

254. The Defendants repeatedly and purposefully breached their duties under Pennsylvania and federal law, and such breaches are the direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into Lehigh County.

255. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in Pennsylvania and Lehigh County. This diversion and the epidemic are direct causes of foreseeable harms incurred by Lehigh County.

256. The Defendants intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief, as alleged herein. Plaintiffs also seek the means to abate the epidemic created by the Distributor Defendants' wrongful and/or unlawful conduct.

257. Plaintiffs seek economic damages from the Defendants as reimbursement for the costs associated with efforts to eliminate the hazards to public health and safety to Lehigh County.

258. Plaintiffs seek economic damages from the Defendants to pay for the cost to Lehigh County to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

259. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."

See Rose A. Rudd et al., Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014, Morbidity & Mortality Wkly. Rep. 1378 (November 2015), at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.html.

260. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain. See Johns Hopkins Bloomberg School of Public Health, The Prescription Opioid Epidemic: An Evidence-Based Approach (G. Caleb Alexander, et al., 2015), at: https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

261. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels." See Office of National Drug Control Policy, Executive Office of the President of the United States, Epidemic: Responding to America's Prescription Drug Abuse Crisis (2011), at: https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

262. It is believed that the Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Lehigh County during the relevant time period.

263. The Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Lehigh County.

264. The Defendants made substantial profits from the opioids sold in Lehigh County.

265. The Defendants violated the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act and related Federal Regulations for distributors, including the aforementioned sections, by failing to properly report suspicious orders.

266. By the actions and inactions described above, the Defendants showed a reckless disregard for the safety of the residents of Lehigh County.

267. By the actions and inactions described above, the Defendants caused great harm to Lehigh County.

268. Having profited enormously through the aggressive and irresponsible distribution of opiates, the Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon Lehigh County and its community.

D. The Brand Manufacturer Defendants' Unlawful Failure to Prevent Diversion and to Monitor, Report, and Prevent Suspicious Orders.

269. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Brand Manufacturer Defendants under federal law.

270. Like the Distributor Defendants, the Brand Manufacturer Defendants were required to register with the DEA to manufacture Schedule II controlled substances, like prescription opioids. See 21 U.S.C. § 823(a). A requirement of such registration is the:

> maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes . .

21 U.S.C.A. § 823(a)(1) (emphasis added).

271. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall

> inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Brand Manufacturer Defendants breached these duties.

272. The Brand Manufacturer Defendants had access to, and possession of, the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Brand Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Brand Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Brand Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

273. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 U.S.C.A. § 823(a)(1).

274. Through, inter alia, the charge back data, the Brand Manufacturer Defendants could monitor suspicious orders of opioids.

275. The Brand Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

276. The Brand Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

277. The Brand Manufacturer Defendants have misrepresented their compliance with federal law.

278. The wrongful actions and omissions of the Brand Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail herein.

279. The Brand Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Lehigh County.

E. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.

280. As the Brand Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of Pennsylvania, including Lehigh County and its community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like Lehigh County, fueling the epidemic.

281. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."20

282. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.21

283. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."22

284. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.23

285. As indicated above, the opioid epidemic has escalated in Lehigh County with devastating effects. Substantial opiate-related substance abuse, hospitalization and death mirrors the Defendants' increased distribution of opiates.

286. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Lehigh County and areas from which such opioids are being diverted into Lehigh County and its

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[20] *See* Richard C. Dart *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 New Eng. J. Med. 241 (2015), at: http://www.nejm.org/doi/full/10.1056/NEJMsa1406143

[21] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies,* 374 N. Eng. J. Med. 1253 (2016).

[22] *See* Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016), at: http://www.nejm.org/doi/full/10.1056/NEJMsr1601307

[23] *See* Press Release, Ctrs. For Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkillers Overdoses at Epidemic Levels (Nov. 1, 2011), at: https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

community, has resulted in the Defendants-caused opioid epidemic to include heroin addiction, abuse, and death.

287. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Pennsylvania, including Lehigh County and its community.

288. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Lehigh County.

289. Defendants repeatedly and purposefully breached their duties under Pennsylvania and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into Lehigh County.

290. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in Pennsylvania and Lehigh County. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiffs.

291. The Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiffs seek relief, as alleged herein. Plaintiffs also seek the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

292. Plaintiffs seek economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

293. Plaintiffs also seek economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

294. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."24

295. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.25

296. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."26

297. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon Lehigh County.

V. FRAUDULENT CONCEALMENT AND TOLLING OF LIMITATIONS PERIOD

298. All Defendants have concealed from the public the details of their unfair and deceptive conduct during the time that they engaged in that conduct so as to avoid detection and cessation of their ill-gotten profits and benefits.

299. The Brand Manufacturer Defendants concealed their unlawful acts and practices from Lehigh County by suppressing information about the addictive propensities of their Subject

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[24] *See* Rose A. Rudd *et al*., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016), at 1145.

[25] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander *et al*., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

[26] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

Drugs, and misrepresenting the truth about opioid addiction in their marketing and promotion of opioids.

300. The Brand Manufacturer Defendants prevented the County from learning the truth about opioid addiction and abuse by insisting on contract confidentiality and secrecy from their customers, including medical providers, PBMs, pharmacists and others who purchased their Subject Drugs.

301. The Brand Manufacturer Defendants also worked behind-the-scenes with their government affairs employees, attorneys and lobbyists to ensure that confusion about opioids was maintained.

302. The Brand Manufacturer Defendants' wrongful conduct also was of such a nature as to be self-concealing, because Defendants had direct knowledge about their products that could not be known unless shared publicly.

303. The Brand Manufacturer Defendants have been aware of their wrongful acts and practices since at least the time their Subject Drugs were launched, and probably before that time due to their knowledge of the industry.

304. The Brand Manufacturer Defendants' failure to properly disclose their wrongful conduct, especially the marketing and sales promotion acts and practices alleged herein, was and is willful, intentional, wanton, malicious, and outrageous. It was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of Plaintiffs.

305. Similarly, by misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. The Plaintiffs did not know of the existence or scope of the Distributor Defendants' industry-wide fraud and could not

have acquired such knowledge earlier through the exercise of reasonable diligence due to the Distributor Defendants' self-concealing wrongful conduct as alleged above.

306. Given the Defendants' concealment of their unfair and deceptive conduct, Lehigh County had no way of knowing of their unlawful schemes, illegal promotional activities, illegal sales and marketing programs and conduct, illegal noncompliance with federal and state laws requiring the monitoring, reporting, and refusal to distribute suspicious drug orders, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence.

307. Lehigh County could not have discovered the unlawful conduct alleged herein at an earlier date by the exercise of due diligence because of the unfair and deceptive practices and techniques of secrecy employed by the Defendants and their co-conspirators to avoid detection of, and to conceal, their unlawful conduct and conspiracies. These techniques of secrecy included, but were not limited to, secret meetings and communications between the Defendants and their co-conspirators, the making of misrepresentations and misstatements about their conduct to governmental authorities, the medical community and the public, secret kickbacks to select medical providers, and other conduct alleged herein, all intentionally designed to avoid detection of their unlawful schemes and activities. To this day, all Defendants continue to conceal the complete details of their conduct from the public, including Lehigh County. Defendants have yet to acknowledge publicly the truth about the Subject Drugs and their conduct.

308. By reason of the foregoing, the claims of the Plaintiffs are timely under any applicable statute of limitations (as tolled by the filing of this Complaint) pursuant to the discovery rules and the doctrine of fraudulent concealment.

309. Defendants' failure to properly disclose their unlawful conduct and conspiracies and other acts and omissions as alleged herein, was and is willful, wanton, malicious, outrageous, and unconscionable, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the law and the rights and interests of Lehigh County.

COUNT I
PLAINTIFFS v. THE BRAND MANUFACTURER DEFENDANTS
UNFAIR AND DECEPTIVE ACTS AND PRACTICES IN VIOLATION OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW,
73 P.S. § 201-1 – 201-9.3, *et seq.*

310. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

311. The Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 – 201-9.3, et seq., (or "UTPCPL") makes it unlawful for a person or business to, among other things, employ "[u]nfair methods of competition" and "unfair or deceptive acts or practices" by representing that goods or services "have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have," or by "causing likelihood of confusion or misunderstanding as to the 'approval or certification of goods or services.'" 73 P.S. § 201-2(4)(ii), (v).

312. The Brand Manufacturer Defendants have engaged in unfair or deceptive acts or practices as set forth herein which violated the UTPCPL.

313. In numerous instances, in the course of marketing, offering for sale, and selling opioids, the Brand Manufacturer Defendants represent or represented, expressly or by implication, through a variety of means, including telephone calls, seminars, written communications, sales calls and internet communications, as set forth above that opioids were, among other things, safe, life-saving, and non-addictive.

314. In truth and in fact, in numerous instances in which the Brand Manufacturer Defendants have made the representations set forth above opioids were highly addictive, dangerous, and non-life-saving.

315. Therefore, the Brand Manufacturer Defendants' representations are and were confusing, misleading, or are and were not substantiated at the time they were made and thus constitute unfair or deceptive acts and practices in violation of 73 P.S. § 201-2(4)(xv) and (xxi).

316. The Brand Manufacturer Defendants engaged in trade or commerce within Lehigh County that constitutes unfair methods of competition or unfair or deceptive acts or practices, as prohibited by Section 201-3 of the UTPCPL and, therefore, are liable for civil penalties up to $1,000 per violation, or, if the victim is sixty years of age or older, the civil penalty shall not exceed $3,000 per violation, pursuant to 73 P.S. § 201-8(b), in addition to other relief which may be granted.

317. The District Attorney is empowered to bring this action on behalf of himself and his residents as "persons" who have purchased and paid for Defendants' Subject Drugs, have purchased and paid for services related to the treatment of those who have taken opioids, and have suffered direct and proximate harm as a result of the Defendants' actions.

318. In distributing, marketing and selling opioids to residents of Lehigh County, and in engaging in the unlawful conduct more fully described herein, the Brand Manufacturer Defendants are engaging in trade or commerce that directly or indirectly harmed consumers in Lehigh County within the meaning of 73 P.S. § 201-2(3).

319. At all times relevant to this Complaint, the Brand Manufacturer Defendants, directly and indirectly through third parties, violated the UTPCPL, and/or conspired and agreed, or aided and abetted others to violate the UTPCPL, by making and disseminating untrue, false,

and misleading statements to medical providers and consumers in Pennsylvania to promote the sale and use of opioids to treat chronic pain, and by causing untrue, false, and misleading statements about opioids to be made or disseminated to medical providers and consumers in Pennsylvania in order to promote the sale and use of opioids to treat chronic pain. These untrue, false, and misleading statements included, but were not limited to:

a. Misrepresenting the truth about how opioids lead to addiction;

b. Misrepresenting that opioids improve function;

c. Misrepresenting that addiction risk can be managed;

d. Misleading doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"

e. Falsely claiming that withdrawal is simply managed;

f. Misrepresenting that increased doses pose no significant additional risks;

g. Falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment; and,

h. Misrepresenting compliance with federal and Pennsylvania law with regard to the required monitoring, reporting, and related obligations with suspicious orders of controlled substances.

320. The Brand Manufacturer Defendants' conduct as more fully described herein constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of 73 P.S. § 201-2(4), including, but not limited to, the following:

a. causing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services, within the meaning of 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, within the meaning of 73 P.S. §201-2(4)(v);

c. advertising goods or services with the intent not to sell them as advertised, within the meaning of 73 P.S. § 201-3(4)(ix);

d. making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions, within the meaning of 73 P.S. § 201-2(4)(xi); and

e. engaging in any other deceptive conduct which creates a likelihood of confusion or of misunderstanding, within the meaning of 73 P.S. § 201-2(4)(xxi).

321. The Brand Manufacturer Defendants' conduct more fully described herein is proscribed and unlawful pursuant to 73 P.S. §201-3.

322. At all times relevant to this Complaint, the Brand Manufacturer Defendants, directly and/or indirectly through third parties by conspiring and agreeing with or aiding and abetting such third parties, also violated the UTPCPL by making statements that omitted or concealed material facts to promote the sale and use of opioids to treat chronic pain. The Brand Manufacturer Defendants and their third-party co-conspirators repeatedly failed to disclose and/or suppressed material facts about the risks of opioids, including the risk of addiction, and their risks compared to alternative treatments for pain. Such material omissions were deceptive and misleading in their own right, and further rendered even otherwise truthful statements about opioids untrue, false, and misleading, creating a misleading impression of the risks, benefits, and superiority of opioids for treatment of chronic pain.

323. At all times relevant to this Complaint, the Brand Manufacturer Defendants, directly and/or indirectly, through third parties, and by conspiring and agreeing with or aiding and abetting third parties, made and disseminated the foregoing untrue, false and misleading statements, and material omissions, through an array of marketing channels, including but not limited to: in-person and other forms of direct detailing; speaker events, including paid for meals, conferences, and teleconferences, and continuing medical education; studies and journal articles, and supplements thereto; advertisements and brochures; and patient education materials.

324. The Brand Manufacturer Defendants knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions statements to be made or disseminated, that they were untrue, false or misleading and therefore likely to deceive the public. In addition, the Brand Manufacturer Defendants knew or should have known that their marketing and promotional efforts created an untrue, false, and misleading impression of the risks, benefits, and superiority of opioids.

325. The Brand Manufacturer Defendants also held themselves out as law-abiding distributors and manufacturers of drugs but instead withheld from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of opioids, while simultaneously marketing opioids, or aware of marketing opioids, to these doctors, and by disseminating, or being aware of the dissemination of, patient and prescriber education materials, advertisements, and CMEs the Brand Manufacturer Defendants knew would reach these same prescribers, violating Pennsylvania and Federal law by not reporting these doctors.

326. Further, the Brand Manufacturer Defendants also held themselves out as law-abiding distributors and manufacturers of drugs but instead withheld from law enforcement "suspicious orders" of controlled substances, as describe more fully above, in violation of Pennsylvania and Federal law, by not reporting these "suspicious orders". The Brand Manufacturer Defendants also failed to set up a monitoring system and/or report the results of a monitoring system with regard to "suspicious orders" in violation of Pennsylvania and federal law. This deceptive conduct created a likelihood of confusion and of misunderstanding to Plaintiffs.

327. Given the infinitely better-resourced and highly sophisticated nature of the Brand Manufacturer Defendants' practices, and their intimate knowledge of Pennsylvania and federal

legal requirements, Plaintiffs and its residents of Lehigh County reasonably relied on the Brand Manufacturer Defendants to uphold their legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.

328. In sum, the Brand Manufacturer Defendants: (a) directly engaged in untrue, false, and misleading marketing; (b) disseminated the untrue, false, and misleading marketing through third parties; (c) conspired and agreed to cause, or aided and abetted the untrue, false and misleading marketing through third parties; and (d) created a likelihood of confusion and misunderstanding in choosing to benefit from those untrue, false, and misleading marketing to profit rather than report those activities and suspicious orders.

329. All of this conduct, separately and collectively, was intended to deceive Pennsylvania consumers who used or paid for opioids for chronic pain; Pennsylvania physicians who prescribed opioids to consumers to treat chronic pain; and Pennsylvania payors, including the Plaintiffs, who purchased or reimbursed the purchase of opioids for chronic pain and otherwise paid for the services related to opioid addiction. As a direct and proximate result of the foregoing acts and practices, the Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of the UTPCPL as described in this Complaint.

330. By reason of the foregoing, the County was injured in that the Brand Manufacturer Defendants' marketing and sales of opioids for chronic pain caused Lehigh County to pay for opioids and the treatment of opioid addiction such that the Brand Manufacturer Defendants caused and are responsible for those costs.

331. The Brand Manufacturer Defendants are liable for their actions, and are jointly and severally liable for the actions of their co-conspirators, for each of these violations as

independent, unfair and deceptive acts in violation of the UTPCPL, and for their course of conduct comprising an unfair and deceptive act or practice in violation of the UTPCPL.

332. As a result of the Brand Manufacturer Defendants' unfair and deceptive acts and practices, the County suffered and will continue to suffer ascertainable losses and damages in an amount to be determined at trial, which amounts should be awarded pursuant to 73 P.S. §201-9.2. These amounts should be trebled, in this Court's discretion, as appropriate.

333. In addition, 73 P.S. §§ 201-4, 201-4.1 and 201-8(b) specifically allows the District Attorney of Lehigh County to bring claims for restoration, an injunction and a civil penalty for each violation by the Brand Manufacturer Defendants. The District Attorney hereby seeks restoration of the costs incurred in dealing with the aforesaid opioid epidemic as caused by the Brand Manufacturer Defendants. He seeks declaratory and injunctive relief to have their conduct declared unlawful and an injunction issued. He seeks a civil penalty in the amount of at least $1,000, and up to $3,000, for each unfair and deceptive act or practice, including but not limited to, each time the Brand Manufacturer Defendants failed in their duties under federal and state law.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order (a)awarding declaratory and injunctive relief, (b) awarding judgment in their favor and against the Brand Manufacturer Defendants under the UTPCPL (c) awarding Plaintiffs their actual or compensatory damages; (d) compelling the Brand Manufacturer Defendants to pay restoration of any money acquired as a result of the Brand Manufacturer Defendants' consumer fraud and deceptive practices; (e) compelling the Brand Manufacturer Defendants to pay civil penalties for each violation, which civil penalty shall be in addition to the other relief which may be granted under sections 4 and 4.1 of the UTPCPL [§§ 201-4 and 201-4.1]; (f) compelling the Brand

Manufacturer Defendants to pay the costs of the suit, including attorneys' fees; and (g) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT II
PLAINTIFFS v. THE DISTRIBUTOR DEFENDANTS'
UNFAIR AND DECEPTIVE ACTS AND PRACTICES IN VIOLATION OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW,
73 P.S. § 201-1 – 201-9.3, *et seq.*

334. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

335. The UTPCPL makes it unlawful for a person or business to, among other things, employ "[u]nfair methods of competition" and "unfair or deceptive acts or practices" by representing that goods or services "have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have," or by "causing likelihood of confusion or misunderstanding as to the 'approval or certification of goods or services.'" 73 P.S. § 201-2(4)(ii), (v).

336. The Distributor Defendants engaged in unfair or deceptive acts or practices as set forth herein which violated the UTPCPL.

337. Lehigh County is empowered to bring this action on behalf of itself and its residents as "persons" who have purchased and paid for Subject Drugs, have purchased and paid for services related to the treatment of those who have taken opioids, and have suffered direct and proximate harm as a result of the Distributor Defendants' actions.

338. "Persons" include, but are not limited to, natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entities within the meaning of 73 P.S. § 201-2(2).

339. In distributing, marketing and selling opioids to residents of Lehigh County, and in engaging in the unlawful conduct more fully described herein, the Distributor Defendants are engaging in trade or commerce that directly or indirectly harmed consumers in Lehigh County and the County within the meaning of 73 P.S. § 201-2(3).

340. The Subject Drugs were used for personal, family or household use.

341. At all times relevant to this Complaint, the Distributor Defendants, directly and indirectly through third parties (such as wholesalers, retailers, PBMs and medical providers), violated the UTPCPL, and/or aided and abetted others to violate the UTPCPL, by engaging in unfair and deceptive acts and practices by failing to comply with their obligations under federal and state law.

342. The Distributor Defendants' conduct, as more fully described herein, constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of 73 P.S. § 201-2(4), including, engaging in any other deceptive conduct which creates a likelihood of confusion or of misunderstanding, within the meaning of 73 P.S. § 201-2(4)(xxi).

343. The Distributor Defendants' conduct more fully described herein is proscribed and unlawful pursuant to 73 P.S. §201-3.

344. Defendants also held themselves out as law-abiding distributors of drugs but instead withheld from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of opioids, while simultaneously distributing opioids to these same prescribers, violating Pennsylvania and Federal law by not reporting these doctors.

345. Further, Defendants also held themselves out as law-abiding distributors of drugs but instead withheld from law enforcement "suspicious orders" of controlled substances, as describe more fully above, in violation of Pennsylvania and Federal law, by not reporting these

"suspicious orders". the Distributor Defendants also failed to set up a monitoring system and/or report the results of a monitoring system with regard to "suspicious orders" in violation of Pennsylvania and federal law. This deceptive conduct created a likelihood of confusion and of misunderstanding to Plaintiffs.

346. As a direct and proximate result of the foregoing acts and practices, the Distributor Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of the UTPCPL as described in this Complaint.

347. By reason of the foregoing, the County was injured in that Defendants' unfair and deceptive acts and practices caused Lehigh County to pay for opioids and the treatment of opioid addiction such that Defendants caused and are responsible for those costs.

348. The Defendants are liable for their actions, and are jointly and severally liable for the actions of their co-conspirators, for each of these violations as independent, unfair and deceptive acts in violation of the UTPCPL, and for their course of conduct comprising an unfair and deceptive act or practice in violation of the UTPCPL.

349. As a result of the Defendants' unfair and deceptive acts and practices, the County suffered and will continue to suffer ascertainable losses and damages in an amount to be determined at trial, which amounts should be awarded pursuant to 73 P.S. §201-9.2. These amounts should be trebled, in this Court's discretion, as appropriate.

350. In addition, 73 P.S. §§ 201-4, 201-4.1 and 201-8(b) specifically allows the District Attorney of Lehigh County to bring claims for restoration, an injunction and a civil penalty for each violation by the Distributor Defendants. The District Attorney hereby seeks restoration of the costs incurred in dealing with the aforesaid opioid epidemic as caused by the

Distributors Defendants. He seeks declaratory and injunctive relief to have their conduct declared unlawful and an injunction issued. He seeks a civil penalty in the amount of at least $1,000, and up to $3,000, for each unfair and deceptive act or practice, including but not limited to, each time the Distributor Defendants failed in their duties under federal and state law.

WHEREFORE, Plaintiffs respectfully request that this Court enter an order (a)awarding declaratory and injunctive relief, (b) awarding judgment in their favor and against the Distributor Defendants under the UTPCPL (c) awarding Plaintiffs their actual or compensatory damages; (d) compelling the Distributor Defendants to pay restoration of any money acquired as a result of the Distributor Defendants' consumer fraud and deceptive practices; (e) compelling the Distributor Defendants to pay civil penalties for each violation, which civil penalty shall be in addition to the other relief which may be granted under sections 4 and 4.1 of the UTPCPL [§§ 201-4 and 201-4.1]; (f) compelling the Distributor Defendants to pay the costs of the suit, including attorneys' fees; and (g) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT III
PLAINTIFFS v. ALL DEFENDANTS
NEGLIGENCE AND NEGLIGENT MISREPRESENTATION

351. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

352. Defendants' acts violate Pennsylvania common law against negligence and negligent misrepresentation.

353. Plaintiffs seek economic damages which were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

354. In Pennsylvania, to maintain an action in negligence, a plaintiff must establish that the defendant(s): (1) owed a duty of care to the plaintiff, (2) that the defendant failed to perform the duty of care, (3) the failure was the proximate cause of the plaintiff's damages, and (4) the plaintiff sustained an actual loss or injury. All such essential elements exist here.

355. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling, and especially distributing such, controlled substances like opioid drugs in Lehigh County and the community.

356. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in Lehigh County and the community.

357. The existence of a duty depends on the foreseeability of the injury. Each Defendant owed a duty to the Plaintiffs and to the community because the injuries alleged herein were foreseeable, and in fact foreseen, by the Defendants.

358. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, like Lehigh County, and the significant costs which would be imposed upon the governmental entities associated with those communities, like Plaintiffs. The "closed system" of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances like opioids and preventing their diversion and abuse.

359. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of

addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Defendants.

360. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

361. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

362. As described elsewhere in the Complaint in language expressly incorporated herein, the Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for nonmedical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

363. As described elsewhere in the Complaint in language expressly incorporated herein, the Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiffs' community and destinations from which they knew opioids were likely to be diverted into Plaintiffs' community, in addition to other misrepresentations alleged and incorporated herein.

364. As described elsewhere in the Complaint in language expressly incorporated herein, the Brand Manufacturer Defendants breached their duties to exercise due care in the

business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable.

365. The Brand Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

366. In misrepresenting the characteristics, uses and benefits of their Subject Drugs as set forth herein, the Brand Manufacturer Defendants were making representations about their drugs that were not truthful.

367. These representations were material to the transactions at hand in that Lehigh County residents used opioids in reliance on these representations, and Plaintiffs paid for both the cost of the drugs and the services related to the addiction caused by the drugs.

368. The Brand Manufacturer Defendants made these misrepresentations about opioids for the purpose of generating revenue, thus constituting false representations which they knew or, in the absence of recklessness, should have known, to be false.

369. The Brand Manufacturer Defendants made these misrepresentations with the intent of misleading Lehigh County and its residents.

370. Lehigh County and its residents justifiably relied upon these misrepresentations in purchasing and/or reimbursing for the Brand Manufacturer Defendants' Subject Drugs and in treating opioid addiction, in an amount to be determined at trial.

371. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

372. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

373. The causal connection between the Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

374. As described above in language expressly incorporated herein, Defendants' breaches of duty and misrepresentations caused, bear a causal connection with, and/or proximately resulted in the damages sought herein.

375. Defendants were selling and distributing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants' knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

376. Defendants' unlawful and/or intentional actions create a rebuttable presumption of negligence under Pennsylvania law.

377. Plaintiffs seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the Defendants' actions and omissions. Plaintiffs do not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the Defendants' actions.

378. As a direct result of the Defendants' actions and omissions as set forth herein, Lehigh County was harmed in that it was unaware of the Defendants' misconduct and would not have had to pay for opioids, and the treatment of opioid addiction, at the levels and of the amount it did, had it known the truth about opioids.

379. Plaintiffs seek all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

WHEREFORE, The People of Lehigh County and Lehigh County, respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants (b) awarding Plaintiffs their actual or compensatory damages; (c) compelling Defendants to pay the costs of the suit, including attorneys' fees; and (d) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT IV
PLAINTIFFS v. ALL DEFENDANTS
NEGLIGENCE PER SE

380. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

381. As described elsewhere in this Complaint in language expressly incorporated herein, each Defendant had a duty under Pennsylvania law to maintain effective controls against the diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids.

382. Pennsylvania recognizes that a violation of a statute or ordinance may serve as the basis for negligence per se.

383. Defendants' actions and omissions in violation of the law constitute negligence per se.

384. Defendants' actions and omissions were intentional and/or unlawful.

385. It was foreseeable that the breach of duty described herein would result in the economic damages for which Plaintiffs seek recovery.

386. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes requiring that, as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

387. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, and proximately resulted in, harm and damages sought by the Plaintiffs.

388. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence per se. Plaintiffs do not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

389. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

WHEREFORE, The People of Lehigh County and Lehigh County, respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants (b) awarding Plaintiffs their actual or compensatory damages; (c) compelling Defendants to pay the costs of the suit, including attorneys' fees; and (d) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT V
PLAINTIFFS v. ALL DEFENDANTS
AIDING AND ABETTING

390. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

391. Defendants knowingly and voluntarily agreed to engage in unfair and deceptive practices to promote the use of opioids for the treatment of chronic pain by making and disseminating false, unsubstantiated, and misleading statements and misrepresentations to prescribers and consumers. Defendants enlisted various KOLs and groups to make and disseminate these statements in furtherance of their common strategy to increase opioids sales, and Defendants—along with the groups with whom each of them conspired—knew that the statements they made and disseminated served this purpose.

392. By engaging in the conduct described in this Complaint, Defendants agreed with the above-described groups that they would deceptively promote the risks, benefits, and superiority of opioid therapy. As part of its agreements with those groups, Defendants provided financial support for groups' deceptive statements promoting opioids, and the groups used that support to more broadly disseminate deceptive messaging promoting opioids, which resulted in increased drug sales.

393. Each of the participants to the coordinated conduct outlined herein was aware of the misleading nature of the statements issued, and of the role they played in the scheme to deceptively promote opioids as appropriate for the treatment of chronic pain. Defendants and such third parties nevertheless agreed to misrepresent the risks, benefits, and superiority of using opioids to Lehigh County patients and prescribers in return for increased pharmaceutical sales, financial contributions, reputational enhancements, and other benefits.

394. Defendants played an active role in determining the substance of the misleading messages issued by the groups, including by providing content themselves, editing and approving content developed by their co-conspirators, and providing slide decks for speaking engagements. Defendants further ensured that these misstatements were widely disseminated, by both distributing the misstatements themselves and providing their co-conspirators with funding and other assistance with distribution. The result was an unrelenting stream of misleading information about the risks, benefits, and superiority of using opioids to treat chronic pain from sources Defendants knew were trusted by prescribers.

395. Defendants participated in unlawful acts or lawful acts in an unlawful manner and took substantial steps in furtherance therefore, by:

a. Violating, aiding and abetting in the violation, or causing the violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law;

b. Creating and disseminating misrepresentations about opioids;

c. Perpetrating a public nuisance; and

d. Committing common law unjust enrichment.

396. By reason of the foregoing, Lehigh County has been injured and continues to be injured in that Defendants' ongoing concerted actions in marketing opioids caused doctors and other health care providers to prescribe and the County to pay for long-term opioid treatment using opioids manufactured by Defendants or by other drug makers, Defendant caused and are responsible for those costs and claims. In addition, the County has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

WHEREFORE, The People of Lehigh County and Lehigh County, respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants (b) awarding Plaintiffs their actual or compensatory damages; (c) compelling Defendants to pay the

costs of the suit, including attorneys' fees; and (d) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT VI
PLAINTIFFS v. ALL DEFENDANTS
PUBLIC NUISANCE

397. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

398. Defendants' wrongful and illegal actions and conduct have created, and constitute, a public nuisance.

399. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

400. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

401. The residents of Lehigh County have a common right to be free from conduct that creates an unreasonable jeopardy to public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

402. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, unlawfully, recklessly, and negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Lehigh County by their untrue, false, and misleading promotion, and marketing of opioids for use by residents of the County.

403. Defendants' marketing conduct and subsequent sale of its opioid products is not only unlawful, but has also resulted in substantial and unreasonable interference with the public health, and the public's enjoyment of its right not to be defrauded or negligently injured.

404. Defendants intentionally, unlawfully, recklessly, and negligently manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiffs' community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the residents of Lehigh County, a higher level of fear, discomfort and inconvenience to the residents of Lehigh County, and direct costs to Lehigh County.

405. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure Lehigh County and its residents.

406. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

407. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

408. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally in Lehigh County is of a continuing nature.

409. Defendants' conduct is not insubstantial or fleeting. Indeed, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a

"crisis" or an "epidemic." Defendants' conduct has caused deaths, serious injuries, and a severe disruption of public peace, order and safety. Defendants' conduct is ongoing, and it is producing permanent and long-lasting damage.

410. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

411. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiffs' community and the Commonwealth of Pennsylvania is a public nuisance.

412. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

413. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiffs' community will be diverted, leading to abuse, addiction, crime, and public health costs.

414. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

415. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

416. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

417. Defendants are aware, or reasonably should have been aware, of the unreasonable interference that their conduct has caused in Lehigh County. Defendants are in the business of

manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law. See, e.g., 21 U.S.C. § 812 (b)(2).

418. Defendants' conduct in marketing, distributing, and selling prescription opioids which the Defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Lehigh County and elsewhere, and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

419. Defendants know, or reasonably should know, that their conduct has caused, and will continue to cause, deaths and injuries to residents in Lehigh County, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

420. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Lehigh County not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiffs' community where opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

421. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

422. Defendants' actions were a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

423. The presence of diverted prescription opioids in Plaintiffs' community, and the consequence of prescription opioids having been diverted in Plaintiffs' community, proximately resulted, and continues to result, in significant costs to the Plaintiffs and to Plaintiffs' community in order to enforce the law, equip its police force, and treat the victims of opioid abuse and addiction.

424. Stopping the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this epidemic, save lives, prevent injuries, and make Plaintiffs' community a safer place to live.

425. Defendants' conduct is a direct and proximate cause of deaths and injuries to the residents of Plaintiffs' community, costs borne by Plaintiffs' community and the Plaintiffs, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

426. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiffs' community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiffs have a clearly ascertainable right to abate conduct that perpetuates this nuisance.

427. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiffs' community; however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

428. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Plaintiffs' community.

429. Defendants' actions also created a qualified nuisance. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

430. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

431. The damages available to the Plaintiffs include, inter alia, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiffs seek all damages flowing from Defendants' conduct. Plaintiffs further seek to abate the nuisance and harm created by Defendants' conduct.

432. As a direct result of Defendants' conduct, the Plaintiffs and Plaintiffs' community have suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The Plaintiffs here seek recovery for their own harm.

433. The Plaintiffs and Plaintiffs' community have sustained specific and special injuries because their damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

434. The Plaintiffs further seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

435. Plaintiffs seek all legal and equitable relief as allowed by law, including, inter alia, abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

436. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

437. Defendants are aware, or reasonably should have been aware, of the unreasonable interference that their conduct has caused in the Plaintiffs' community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are

specifically known to Defendants to be dangerous because, inter alia, these drugs are defined under federal and state law as substances posing a high potential for abuse and severe addiction.

438. The public nuisance created by the Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to Lehigh County, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Distributor Defendants' abandonment of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those residents of Plaintiffs' community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gatekeeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to

opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.

i. The significant and unreasonable interference with the public rights caused by the Defendants' conduct taxed the human, medical, and public health, law enforcement, and financial resources of the Plaintiffs' community.

j. Defendants' interference with the comfortable enjoyment of life in the Plaintiffs' community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

439. The Plaintiffs and Plaintiffs' community have sustained specific and special injuries because its damages include health services and law enforcement expenditures, as described in this Complaint.

440. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations.

441. Plaintiffs do not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

442. Plaintiffs seek all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, inter alia, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

WHEREFORE, The People of Lehigh County and Lehigh County, respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants (b) awarding Plaintiffs their actual or compensatory damages; (c) compelling Defendants to pay the

costs of the suit, including attorneys' fees; and (d) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT VII
PLAINTIFFS v. ALL DEFENDANTS
UNJUST ENRICHMENT
VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT

443. Plaintiffs incorporate the allegations within all preceding and following paragraphs within this Complaint as if they were fully set forth herein.

444. Defendants have unjustly retained a benefit to Lehigh County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

445. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Defendants have unjustly enriched themselves at Lehigh County's expense. Lehigh County has made payments for opioid prescriptions, and Defendants benefited from those payments. Because of their deceptive promotion of opioids, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the County lacks a remedy provided by law.

446. In addition, and by reason of the foregoing, the County was injured and continues to be injured in that Defendants' ongoing concerted actions in illegally and deceptively marketing opioids caused doctors and other healthcare providers to prescribe and the County to pay for long-term opioid treatment using opioids manufactured by Defendants or by other drug makers, Defendants caused and are responsible for those costs and claims. The Count has suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain.

WHEREFORE, The People of Lehigh County and Lehigh County, respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants (b) awarding Plaintiffs their actual or compensatory damages; (c) compelling Defendants to pay the costs of the suit, including attorneys' fees; and (d) awarding the Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment on each Cause of Action against Defendants in excess of $75,000, jointly and severally, awarding Plaintiffs:

1. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;
2. treble damages, penalties, and costs pursuant to Consumer Fraud – Deceptive Practices, violation of 73 P.S. § 201-1 – 201-9.3, *et seq*.
3. restoration and civil penalties for each violation, which civil penalty shall be in addition to the other relief which may be granted under sections 4 and 4.1 of the UTPCPL [§§ 201-4 and 201-4.1];
4. a declaratory judgment and an injunction requiring Defendants to abate the public health nuisance and to comply with the law;
5. punitive damages;
6. interests, costs, and attorney's fees; and
7. such other and further relief as this Court deems just and proper.

Respectfully submitted,

Dated: March 23, 2018

s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr., Esquire
William H. Platt II, Esquire
HAVILAND HUGHES
201 S. Maple Way, Suite 110
Ambler, PA 19002
Ph: (215) 609-4661
Fax: (215) 392-4400
haviland@havilandhughes.com
platt@havilandhughes.com

VERIFICATION

I, James B. Martin, hereby verify that I am the District Attorney of Lehigh County, that I am authorized to make this Verification and that the facts set forth in the foregoing complaint are true and correct to the best of my knowledge, information and belief. If the foregoing contains averments which are inconsistent in fact, signer has been unable after reasonable investigation to ascertain which of the inconsistent averments are true, but signer has knowledge or information sufficient to form a belief that one of them is true and understands that this Verification is made subject to the penalties of 18 Pa. C.S.A. §4904 relating to unsworn falsification to authorities.

Dated: March 23, 2018

JAMES B. MARTIN

FILED 3/23/2018 3:50:51 PM,Clerk of Judicial Records, Civil Division, Lehigh County, PA
2018-C-0716 /s/D N

VERIFICATION

I, Phillips Armstrong, hereby verify that I am the County Executive for the County of Lehigh, that I am authorized to make this Verification and that the facts set forth in the foregoing pleading are true and correct to the best of my knowledge, information and belief. If the foregoing contains averments which are inconsistent in fact, signer has been unable after reasonable investigation, to ascertain which of the inconsistent averments are true, but signer has knowledge or information sufficient to form a belief that one of them is true and understands that this Verification is made subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities

Phillips M. Armstrong

March 23, 2018
Date

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: Haviland Hughes

Signature: *s/Donald E. Haviland, Jr.*

Name: Donald E. Haviland, Jr.

Attorney No. (if applicable): PA Id 66615