Class Description

This white paper was developed by students enrolled in the course Law in Public Health Practice, offered by the University of Pittsburgh Graduate School of Public Health (GSPh) Department of Health Policy and Management. Students are enrolled from GSPh and the University of Pittsburgh School of Law. The purpose of this course is to engage students in "real life" public health issues, and work toward developing tangible solutions in the community. We partnered with Jennifer Fiddner and the Allegheny County Child Death Review Team to develop recommendations focused around addressing the opioid crisis in Allegheny County. It is our hope that these recommendations will provide a framework for reducing the rate of non-fatal and fatal overdoses in our county.

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EXECUTIVE SUMMARY

On October 26th, 2017, the Trump administration declared the opioid crisis in the United States a public health emergency. Despite recent media attention, issues of illicit and prescription opioid abuse and fatal overdoses have been steadily increasing over the past 2 decades. According to the Centers for Disease Control and Prevention (CDC), prescription opioid-related fatal overdoses were five times higher in 2016 compared to 1999. In just 5 years, fatal overdoses involving heroin increased fivefold between 2010 and 2016. The National Institute on Drug Abuse reported that the total number of fatal overdoses rose from 16,849 in 1999 to 52,404 in 2015.

The impact of the opioid crisis has had devastating effects statewide, as well as in Allegheny County. According to the CDC, Pennsylvania had the fourth highest state observed age-adjusted fatal drug overdose rate in 2016. In 2015 and 2016, 986 fatal accidental drug overdoses occurred in Allegheny County alone. These figures suggest that fatal overdoses will continue to rise indefinitely if no action is taken.

Numerous legal actions have been filed by municipalities, counties, and states across the U.S. against the pharmaceutical industry to address the growing opioid crisis. This report, a collaborative effort on behalf of students enrolled in the University of Pittsburgh Graduate School of Public Health, Law in Public Health Practice course, outlines the national, state, and local scope of the opioid crisis, and the various roles each contributing entity plays regarding this issue. Using county medical examiner data, we analyzed drug use trends between 2016 and 2017 to illustrate current behaviors involved in fatal overdoses among Allegheny County fatalities. Further, we identity five appropriate theories of liability under parens patriae authority that the Commonwealth of Pennsylvania could take in response to the number of rising overdoses.

Through the research conducted in this report, we recommend the following actionable items for the Child Death Review Team of the Allegheny County Health Department:

• Collaborate with the state and other counties to persuade the pharmaceutical industry to establish a fund of monetary resources
• Utilize the fund to address goals of the Child Death Review Team

We thank the Child Death Review Team and the Allegheny County Health Department for the opportunity to present and share the following findings.
BACKGROUND

2.1 Why Opioids?

Between January 2016 and January 2017, the Centers for Disease Control and Prevention (CDC) estimated 64,070 people died from drug-related overdoses in the United States. This is equivalent to a mortality rate of approximately 7.3 people every hour for 365 days. The number of fatal opioid-related overdoses increased fivefold between 1999 and 2016. In 2016, there were approximately 42,249 fatal opioid-related overdoses in the U.S. Fatal opioid-related overdoses have surpassed both motor vehicle traffic fatalities and firearm fatalities. Comparatively, only 36,161 individuals died from motor vehicle traffic accidents, and 36,252 individuals died from firearms in 2015. In Pennsylvania, fatal drug-related overdoses had a rate of 37.9 per 100,000 people in 2016. With fatal overdoses increasing exponentially each year, it is pertinent this issue be addressed. In the pages that follow we present the relevant information to define the scope of the opioid crisis in the United States and Allegheny County, Pennsylvania.

2.2 The History of Opioids

Derived from the *Papaver somniferum* poppy flower, opium is arguably the first drug to be used by man. The opium poppy was first cultivated “in the Tigris-Euphrates river systems of lower Mesopotamia” around 3400 BC. Recognition of opium was “widespread throughout Europe, the Middle East and North Africa” by 1000 BC. Although recognized for medicinal purposes, opium was often used recreationally and regarded by many for its pleasurable effects. Published in 1700, Dr. John Jones’s *Mysteries of Opium Reveal’d* refers to the “risk of addiction” amidst the extensive use of opium for various illnesses. Opium “addiction was common” but hardly addressed, due to the acknowledgment that dependence was a “price one paid for the relief of pain.” German pharmacist Friedrich Wilhelm Sert turner successfully isolated the compound morphine from raw opium gum resin around 1805. In 1823, poppy straw morphine was first derived from opium by French chemist Tilloy, and later mechanized by Janos Kabay in 1928 through a “commercially feasible extraction process.” The German military adopted Kabay’s process for the widespread use of morphine during the Second World War.

Following Serterner’s discovery, research continued to “isolate and identify” other compounds derived from opium. Mass produced morphine pills were first made available in Western Europe by Merck in the 1820s. French chemist Pierre-Jean Robiquetin identified methyl morphine, known as codeine, in 1832. Scottish physician Alexander Wood discovered “administering morphine by… hypodermic syringe injection” produced a more rapid and potent effect in 1843. By 1850, hypodermic syringes with follow pointed needles were marketed, allowing for “the widespread injection use of morphine.” Morphine addiction quickly became known as the “Soldier’s disease,” due to military dependence during the American Civil War, Franco-Austrian War, and Franco-Prussian War. By the turn of the century, there was “widespread recognition” that opium addiction had grown into a major social problem in the United States.

In 1874, British chemist C.R. Alder Wright “boiled… anhydrous morphine alkaloid in acetic anhydride” to create diacetylmorphine, later termed heroin. Heroin was trademarked in the U.S. in August 1899. In the early 1900’s, pharmaceutical companies Bayer and Squibb mass produced and sold inexpensive heroin hydrochloride tablets to New York City civilians. Subsequently, rampant heroin
addiction ensued. By the 1920s, heroin addicts were regularly prescribed morphine in outpatient treatment programs. In response to the increasing heroin abuse, the Narcotics Division of the U.S. Treasury Department “banned all legal sales of narcotics” in 1923. The criminalization of opiates and opioids caused the expansion of the black market, and its adoption of the illicit heroin trade. Originating from China, smuggled illicit heroin first debuted in the United States in 1925 in Chinatown, New York City. First synthesized in 1916, the semisynthetic opioid oxycodone was first used in clinical settings in 1917. It later entered the U.S. pharmaceutical market in 1939. Purdue Pharma further developed the compound to patent OxyContin in December 1995, a time-release analgesic “with an intended misuse-resistant polymer to inhibit its drug release mechanism.”

2.3 Opioid Use in the United States

As evidenced above, there is a long history of civilian opiate use. However, the more widely popular opioid pill has a shorter history. In 1970, the prescription drugs Percocet and Vicodin, which are synthetic derivations of opiate, entered the U.S. market. Variations of the opioids were consistently developed, and in 1996, OxyContin was released by Purdue Pharma. OxyContin entered the market amidst the “pain crusaders” revolution, in which pain was considered by the medical world as the fifth vital sign. Physicians in the U.S. were once hesitant to prescribe opioids to their patients because they were skeptical of the addictive tendencies. The 1990s proved to be a radical shift however, and physicians were no longer hesitant due in part to an uncovered letter in the New England Journal of Medicine (NEJM). The 1980 letter, written by Jane Porter and Hershel Jick, concerned a hospital study of 11,882 patients taking opioids, in which only 4 patients developed a new addiction to the opioid drugs. As such, pharmaceutical companies like Purdue cited this letter published in NEJM as evidence that opioids are safe and non-addictive, and consequently changed physicians’ attitudes toward opioids. Concurrently, Dr. Mitchell Max, the President of the American Pain Society, advocated for a system to quantify pain and make it “visible” much like the other vital signs utilized in medicine. In 2001, The Joint Commission on Accreditation of Healthcare Organizations, presently The Joint Commission, released standards with a system to put a numerical value to pain using a 10-point scale. This system became standard assessment for patients across many health care institutions.

As a result, physicians treated pain aggressively. OxyContin’s characteristic release mechanism emerged as the medical world’s answer to the search for a non-addictive painkiller. OxyContin was the first drug of its kind because it was an extended-release opioid that changed the dosage time from every 4 to 6 hours to every 12 hours. With the implementation and normalization of pain standards across the U.S., prescriptions for opioids consequently increased. From 1997 to 2002, OxyContin prescribed for chronic pain rose from 670,000 to 6.2 million in the U.S. Thus, the pharmaceutical industry profited while prescription opioid abuse escalated dramatically.

The exact number of prescriptions is unclear, but there is some evidence suggesting approximately 135 million prescriptions were written for opioids in 1996. The number of opioid prescriptions steadily increased in the U.S. and peaked at nearly 278 million in 2012. The researchers that published this prescription data were employees of Purdue Pharma, and therefore, may be partial. Eric Eyre, a Pulitzer Prize winner for his investigative journalism, published a series of articles in the Charleston Gazette-Mail on the number of oxycodone and hydrocodone pills sold in West Virginia. His findings were astounding: between 2007 and 2012, 780 million pills were sold in the state. Based on Eyre’s findings in West Virginia, it is unlikely the number of prescriptions written in the early years of elevated opioid prescribing as reported in the Journal of Pain Research is accurate. Therefore, it is difficult to ascertain the total number of prescriptions, and subsequent opioid pills sold in the U.S. Nevertheless, it is evident the number of opioid prescriptions increased during the late 1990s and well into the 2000s.

Prior to the climax of opioid prescribing, the Food and Drug Administration (FDA) took steps to mitigate potential opioid abuse. Purdue changed OxyContin labels in 2001, strengthening the language
warning consumers about the potential for misuse and abuse.\textsuperscript{30} Moreover, the FDA issued a warning letter to Purdue Pharma in 2003 about misleading advertisements of OxyContin.\textsuperscript{31} The FDA was further granted authority by the FDA Amendments Act of 2007 to require specified safety measures known as Risk Evaluation and Mitigation Strategies (REMS) for certain drugs.\textsuperscript{32} Additional steps to prevent opioid abuse included education for physicians on prescribing practices, collaborative stakeholder meetings to brainstorm preventative practices, and educational campaigns on safe opioid disposal methods.\textsuperscript{33} As a result, measures like the release of a crush resistant OxyContin to mitigate injection of the drug and subsequent abuse were implemented.\textsuperscript{34}

As opioid prescribing began to decline, still almost 215 million opioid prescriptions were filled by just under 62 million individuals in 2016. Accordingly, 20 percent of the U.S. population was written one or more opioid prescriptions.\textsuperscript{35} In 2016, 72.1 opioid prescriptions were written for every 100 residents in Allegheny County.\textsuperscript{36}

States and counties nationwide are seeing a noticeable transition from prescription to illicit drug abuse. The following statistics reflect the current state of prescription and illicit drug abuse in the U.S. and are attributed to the CDC and the Drug Enforcement Administration (DEA).

- Sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014, but there has not been an overall change in the amount of pain Americans report.\textsuperscript{37}
- From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids.
- Overdose deaths involving prescription opioids were five times higher in 2016 than 1999.\textsuperscript{38}
- An estimated 1 out of 5 patients with non-cancer pain or pain-related diagnoses are prescribed opioids in office-based settings.
- From 2007 – 2012, the rate of opioid prescribing has steadily increased among specialists more likely to manage acute and chronic pain. Prescribing rates are highest among pain medicine (49%), surgery (37%), and physical medicine/rehabilitation (36%). However, primary care providers account for about half of opioid pain relievers dispensed.\textsuperscript{39}
- Heroin-related overdose deaths increased fivefold from 2010 to 2016.
- From 2015 to 2016, heroin overdose death rates increased by 19.5%, with nearly 15,500 people dying in 2016.
- In 2016, males aged 25-44 had the highest heroin death rate at 15.5 per 100,000, which was an increase of 17.4% from 2015.\textsuperscript{40}
- The death rate of synthetic opioids other than methadone, which includes drugs such as tramadol and fentanyl, increased by 100.0% from 2015 to 2016.\textsuperscript{41}
- The number of fentanyl encounters more than doubled in the US from 5,343 in 2014 to 13,882 in 2015.\textsuperscript{42}
- According to the National Forensic Laboratory Information System, reports on fentanyl (both pharmaceuticals and clandestinely produced) increased from nearly 5,400 in 2014 to over 14,600 in 2015, as reported by federal, state, and local forensic laboratories in the United States.\textsuperscript{43}
The Link Between Prescription Drugs and Heroin Use

Despite the large number of individuals prescribed opioid drugs, there has been a decline in opioid prescriptions in recent years, but a concurrent increase in heroin use (see Figure 1). While it is estimated that approximately 3.6 percent of people who use non-medical pain relievers (NMPR) turn to heroin use within 5 years of initiating NMPR use, approximately 79.5 percent of heroin users initially used NMPR. Moreover, a recent study found heroin incidence rates were 19 times higher in individuals that previously used prescription opioids. Subsequent studies find similar results – between 75-80 percent of heroin users began with prescription opioids. The studies were conducted in geographically local regions, but the results are strikingly similar regardless of location. Further, these studies looked at both urban and non-urban populations.

The DEA and local, state, and federal partners also collect data on drug seizures in the U.S. All information is compiled in the National Forensic Laboratory Information System (NFLIS). When the DEA queried the system for Pennsylvania, data supported the shift from prescription opioids to heroin. Between 2002 and 2011, there was a “700 percent increase in cases involving opioid prescriptions.” Oxycodone and hydrocodone accounted for 87 percent of the prescription opioid seizures. Between 2012 and 2015, there was a noticeable shift in DEA seizures; prescription opioids decreased, while heroin increased. The DEA further found heroin seizures decreased in 2016 for the first time in 6 years simultaneously as fentanyl seizures increased. A visual representation of the transition from prescription opioids to heroin in Pennsylvania is evident in Figure 3. While DEA seizures are not a direct reflection of use, and seizures depend largely on DEA strategy, drug seizures by the administration are reflective of overall drug trends in the state in the long-term.
Reasoning behind the transition is overwhelmingly economical as heroin is cheaper than prescription drugs. Alternative explanations include measures to prevent drug abuse like the introduction of non-crushable OxyContin and the implementation of Prescription Drug Monitoring Programs (PDMPs). A non-crushable OxyContin formula was released in 2010 to deter users from crushing pills to snort, inject, or dissolve the drug. In a study conducted after the release of non-crushable OxyContin, many opioid users stated they stopped using OxyContin; instead, they used heroin because the high was the same, heroin was easier to use, and cheaper. Approximately 35.6 percent of study participants used OxyContin before the non-crushable formulation, but use dropped to 12.8 percent after the formulation changed. Simultaneously, fentanyl and hydromorphone use increased to 32.3 percent, and heroin use doubled among study participants.

PDMPs were implemented in 44 U.S. states by 2010. PDMPs are electronic databases that track controlled substances in the state, namely opioid prescriptions. The database is used by health care professionals and pharmacies to report and notify other health care professionals when a particular patient last received a prescription for a controlled substance. The system was implemented to decrease “doctor-shopping,” or when an individual sees multiple doctors close in time for the same injury in order to obtain multiple prescriptions for opioids. The peak of opioid prescriptions occurred in 2012, with an immediate 4.9 percent annual decrease between 2012 and 2016 (see Figure 4). Arguably, the implementation in most states by 2012 contributed to the decline in opioid prescriptions. This was due in part to physicians utilizing the databases and refusing a prescription, thus, creating a barrier to obtaining an opioid prescription. Moreover, rates of drug overdoses involving heroin increased from 0.7 per 100,000 in 1999 to 4.1 per 100,000 in 2015 (see Figure 5). An unforeseen consequence of implementing PDMPs across the U.S. may very well be an increase in heroin use and heroin-related fatal overdoses based on the data presented below.
Figure 4: Annual Prescribing Rate by Overall and High-Dosage Prescriptions 2006-2016

Source: QuintilesIMS® Transactional Data Warehouse.
High-dose prescriptions were defined as opioid prescriptions resulting in a daily dosage of ≥ 90 MME.

Figure 5: Age Adjusted Rates of Drug Overdose Deaths by Drug or Drug Class and Year in the U.S. 1999-2015

Source: National Vital Statistics System, Mortality File, CDC WONDER.

1 Drug overdose deaths, as defined, that involve natural and semi-synthetic opioids (T40.2).
2 Drug overdose deaths, as defined, that involve heroin (T40.1).
3 Drug overdose deaths, as defined, that involve synthetic opioids other than methadone (T40.4).
4 Drug overdose deaths, as defined, that involve cocaine (T40.5).
5 Drug overdose deaths, as defined, that involve psychostimulants with abuse potential (T43.6).
6 Drug overdose deaths, as defined, that involve methadone (T40.3).
2.5 Stakeholders

2.5.1 Pharmaceutical Manufacturers and Distributors

During our research, we identified relevant pharmaceutical manufacturers and distributors including: Allergan, Endo International, Johnson & Johnson, Purdue Pharma, Teva Pharmaceutical Industries, Pfizer, Janssen Pharmaceuticals, Endo Pharmaceuticals, Cephalon, Watson Pharmaceuticals, Mallinckrodt Pharmaceuticals, Actavis Generics, McKesson, Cardinal Health and AmeriSourceBergen. The pharmaceutical industry as a whole is discussed further in Section 3 - Pharmaceutical Industry.

Pharmaceutical manufacturers are considered stakeholders of the opioid crisis because they manufacture pharmaceutical opioids. Thus, pharmaceutical manufacturers profit from prescription drug abuse. Beginning in the 1990s, manufacturers such as Purdue Pharma engaged in directed marketing campaigns advertising prescription opioids to prescribing physicians. These campaigns generated high concentrations of prescription opioids prescribed to U.S. chronic pain patients, and in turn initiated devastating increases of addiction and overdose rates.

Pharmaceutical distributors are considered stakeholders of the opioid crisis because they actively participated in the national distribution of pharmaceutical opioids, and potentially failed to uphold their duty under the Controlled Substances Act. Furthermore, pharmaceutical distributors also profit from prescription drug abuse.

2.5.2 Licit and Illicit Opioid Users and the Deceased

All users of licit and illicit prescription opioids are considered stakeholders of the opioid crisis based on their consumption of opioids and opiates. Illicit opioid users are considered stakeholders due to the link between illicit drug use and prescription drug use mentioned above. As such, between 75-80 percent of heroin users began with prescription opioids. Deceased individuals illustrate the burden of the opioid crisis on users, families, and friends, and thus are considered stakeholders.
2.5.3 Healthcare Industry and Care Providers

The healthcare industry and care providers are considered stakeholders primarily due to prescribing practices and use of PDMPs. Provider prescribing practices may dictate the risk of addiction for chronic pain patients if dosages and prescription refills are unmonitored. Further, providers and pharmacists are responsible for the education of safe practices regarding prescription opioid consumption. PDMPs are in place to prevent prescription opioid addicts from “doctor shopping,” and obtaining multiple filled prescriptions. However, physician utilization of PDMP’s may not be universal across practices due to individual choice or a lack of digitalized practice environment.°

2.5.4 Federal, State, and County Entities

Federal, state, and county government entities are considered stakeholders in the opioid crisis because each entity is responsible for the health and livelihood of its residents. As such, they should ensure reasonable access to affordable care and addiction services such as: medication assisted treatment, clean needle exchange, naloxone distribution, and mental health and social services.

2.5.5 Other

We acknowledge the fact that this is not a comprehensive list of all stakeholders involved. However, we have identified these as the primary stakeholders with respect to the opioid crisis as it is now.

3 PHARMACEUTICAL INDUSTRY

In 2015 the pharmaceutical industry accounted for 10.7 percent of total U.S. healthcare expenditures and 1.9 percent of the overall GDP.° Equivalent to $333 billion in sales, the U.S. has the world’s largest pharmaceutical market. The second largest global market is China, which is one-third the size of the U.S. market.°

There are currently hundreds of lawsuits filed against multiple opioid manufacturers and distributors concerning the increase in opioid related overdoses. Manufacturers include: Allergan, Endo International, Johnson & Johnson, Purdue Pharma, and Teva Pharmaceutical Industries, Pfizer, Janssen Pharmaceutica, Endo Pharmaceuticals, Cephalon, Watson Pharmaceuticals, Mallinckrodt Pharmaceuticals, Actavis Generics.° Distributors include: McKesson, Cardinal, and AmeriSourceBergen. Due to the sheer size of the pharmaceutical industry, we analyzed the leading companies’ financials, which are summarized in Figures 7 and 8, to gain a better understanding of each company’s resources and ability to address the opioid crisis.
Figure 7: Opioid Pharmaceutical Manufacturer Revenue and Market Value

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Revenue</th>
<th>Market Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purdue Pharma</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>$71.89 billion FY 2016**</td>
<td>$337.642 billion FY 2016**</td>
</tr>
<tr>
<td>Pfizer</td>
<td>$52.824 billion FY 2016**</td>
<td>$203.725 billion FY 2016**</td>
</tr>
<tr>
<td>Allergan</td>
<td>$15.9407 billion FY 2017**</td>
<td>$57.09 billion FY 2017**</td>
</tr>
<tr>
<td>Endo Pharmaceutical</td>
<td>$3.469 million FY 2017**</td>
<td>$1.28 billion FY 2017**</td>
</tr>
</tbody>
</table>

**Purdue is a privately held company and therefore not obligated to disclose their financial statements. However, Forbes estimates Purdue Pharma’s net worth at $13 billion in 2016. 83**

Pharmaceutical distributors are regarded as the intermediaries between pharmaceutical manufacturers and distribution sites, such as pharmacies. Primary pharmaceutical distribution companies purchase products from manufacturers and store products in warehouses and distribution centers across the U.S. 84 Currently, Cardinal Health, McKesson, and AmerisourceBergen control 85 percent of the prescription drug distribution market in the U.S. 85

McKesson, rated fifth among Fortune 500 companies, accrued $198.5 billion in revenue for fiscal year 2017. According to investigative journalist Eric Eyre, McKesson’s former CEO John Hammergren was “the nation’s highest-paid executive in 2012.” Hammergren individually “collected compensation worth $89 million” in 2015. Cardinal Health, ranked fifteenth among Fortune 500 companies, compensated CEO George Barrett $127 million over the past 3 years. 86 Collectively, Cardinal Health, McKesson, and AmerisourceBergen CEOs “received salaries and other compensation of more than $450 million.” 87

Figure 8 outlines fiscal year 2017 revenue and fiscal year 2016 market value for Cardinal Health, McKesson and AmerisourceBergen. 88

Figure 8: Pharmaceutical Distributer Revenue and Market Value FY 2017

<table>
<thead>
<tr>
<th>Distributor</th>
<th>Revenue Fiscal Year 2017</th>
<th>Market Value-as of 3/31/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>McKesson Corporation</td>
<td>$198.5 billion 89</td>
<td>$31.439 billion 90</td>
</tr>
<tr>
<td>AmeriSourceBergen</td>
<td>$153.1 billion 91</td>
<td>$19.229 billion 92</td>
</tr>
<tr>
<td>Corporation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>$130 billion 93</td>
<td>$25.725 billion 94</td>
</tr>
</tbody>
</table>
Below is a table produced by the FDA of opioid products currently on the market, and the company that developed the product. The list is current December 2017.

**Figure 9: Brand Name Opioids and Sponsors**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Avinza Morphine sulfate extended-release capsules</td>
<td>Pfizer</td>
</tr>
<tr>
<td>2</td>
<td>Butrans Buprenorphine transdermal system</td>
<td>Purdue Pharma</td>
</tr>
<tr>
<td>3</td>
<td>Dolophine Methadone hydrochloride tablets</td>
<td>Roxane</td>
</tr>
<tr>
<td>4</td>
<td>Duragesic Fentanyl transdermal system</td>
<td>Janssen Pharmaceuticals</td>
</tr>
<tr>
<td>5</td>
<td>**Embeda Morphine sulfate and naltrexone extended-release capsules</td>
<td>Pfizer</td>
</tr>
<tr>
<td>6</td>
<td>Exalgo Hydromorphone hydrochloride extended-release tablets</td>
<td>Mallinckrodt</td>
</tr>
<tr>
<td>7</td>
<td>Kadian Morphine sulfate extended-release capsules</td>
<td>Actavis</td>
</tr>
<tr>
<td>8</td>
<td>MS Contin Morphine sulfate controlled-release tablets</td>
<td>Purdue Pharma</td>
</tr>
<tr>
<td>9</td>
<td>Nucynta ER Tapentadol extended-release oral tablets</td>
<td>Janssen Pharmaceuticals</td>
</tr>
<tr>
<td>10</td>
<td>Opana ER Oxymorphone hydrochloride extended-release tablets</td>
<td>Endo Pharmaceuticals</td>
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<tr>
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<td>OxyContin Oxycodone hydrochloride controlled-release tablets</td>
<td>Purdue Pharma</td>
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<tr>
<td>12</td>
<td>*Palladone Hydromorphone hydrochloride extended-release capsules</td>
<td>Purdue Pharma</td>
</tr>
</tbody>
</table>

*No longer being marketed, but is still approved.

**Not currently available or marketed due to a voluntary recall, but is still approved.
Figure 10: Pharmaceutical Industry Lobbying Expenses, 2014-2015

Figure 10 represents the total lobbying contributions larger than $5,000 on behalf of the pharmaceutical industry related to the proposed Ensuring Patient Access and Effective Drug Enforcement Act from 2014-2016. As the figure shows, pharmaceutical industry expenditures amounted to more than $102 million. Pharmaceutical researchers, manufacturers, and distributors have exponential resources to advocate for or against a piece of legislation that may affect their overall business practice. Considering the above expenditures are for a single piece of legislation, pharmaceutical companies likely have an overwhelming influence on Capitol Hill, and therefore throughout the country. Furthermore, Figure 11 depicts public political contributions by pharmaceutical companies and distributors to singular candidates and political parties. Companies like Pfizer, who contributed nearly $1 million, exposes the extensive capital pharmaceutical companies are willing to spend to ensure a specific candidate or party’s success. In many cases, these political successes are advantageous to achieving each company’s goals and objectives.
<table>
<thead>
<tr>
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<th>To Candidates and Parties</th>
<th>To Outside Spending Groups</th>
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<td>$365,337</td>
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<td>16</td>
<td>McKesson Corp</td>
<td>$372,154</td>
<td>$371,899</td>
<td>49.8%</td>
</tr>
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</table>

Figure 11: Pharmaceuticals/Health Products: Top Contributors to Federal Candidates, Parties, and Outside Groups Election Cycle 2018  

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4 LOCAL LENS: ALLEGHENY COUNTY

In 2016, it was estimated that more than 2.1 million people living in the U.S. had a substance use disorder involving prescription opioids, and 948,000 others had a substance use disorder involving heroin.99 Through the course of 2016, there were 42,249 fatalities that involved opioids, which is about five times higher than observed in 1999.100 Of these fatalities, 17,087 were due to prescription opioids and 15,469 were due to heroin. From 2015 to 2016, Pennsylvania’s drug overdose death rate increased by 44.1%.101 Pennsylvania had the fourth highest drug-related death rate of 37.9 per 100,000 residents in 2016.102

Opioid overdose fatalities are not only growing statewide and nationally, but fatalities continue to rise in Allegheny County as well. In 2016, 617 fatal overdoses occurred in Allegheny County, a rate of 50.45 per 100,000 people.103 Further, 72.1 opioid prescriptions were written per 100 people, out of an estimated 1.23 million residents. This translates to 886,830 opioid prescriptions written just in Allegheny County.

A CDC analysis of overdose trends show “two distinct but interconnected trends” are propelling the current national opioid overdose crisis: “a 17-year increase in [fatalities] from prescription opioids, and a recent surge in illicit opioid overdoses driven mainly by heroin and illegally-made fentanyl.”104 The proceeding analysis is dedicated to determining whether these trends are occurring in Allegheny County, and to characterize overdose drug trends specific to Allegheny County.

4.1 Statistics

To analyze the impact of accidental overdose fatalities in Allegheny County, we compared fatal accidental overdose incident vital statistics collected by the Office of the Medical Examiner from years 2016 and 2017 in Allegheny County, Pennsylvania.105 2017 data extends only to October 23, 2017. Therefore, the 2017 dataset is evaluated as a sample population rather than a comprehensive population of all fatal overdoses in 2017. It should be noted the total fatal overdoses in 2016 statistic varies between sources. For this analysis, we consider the medical examiner approximation to be accurate.

Between January 1, 2016 and December 31, 2016, a total of 617 fatal overdoses occurred in Allegheny County. The following zip codes represent the highest concentration of decedent zip code fatalities: 15210 with 32 overdose fatalities, 15212 with 27 overdose fatalities, and 15136 with 24 overdose fatalities.

Between January 1, 2017 and October 23, 2017, a total of 542 fatal overdoses occurred in Allegheny County. The following zip codes represent the highest concentration of decedent zip code fatalities: 15212 with 26 overdose fatalities, 15210 with 24 overdose fatalities, and 15136 with 24 overdose fatalities. A full list of decedent zip code fatalities for 2016 and 2017 can be found in Appendix 11.1
Figure 12: 2016 Decedent Zip Code Fatal Overdoses with Number of Fatalities ≥ 10
The demographics of fatal overdoses are relatively consistent from 2016 to 2017. In 2016, approximately 30.0% of fatalities were female, 185 out of 617. Approximately 70.0% of fatalities were males, 432 out of 617. In 2017, approximately 29.0% of fatalities were female, 157 out of 542. Approximately 71.0% of fatalities were males, 385 out of 542. In the county, females represent approximately 51.7% of the population and males 48.3% of the population. Therefore, males are at a significantly higher risk of fatal overdose than females in Allegheny County. In 2016, 520 fatalities were white, accounting for 84.3% of all fatal overdoses. Ninety-three fatalities were black, accounting for 15.1% of all fatal overdoses. In 2017, 469 fatalities were white, accounting for 86.5% of all fatal overdoses. Sixty-nine fatalities were black, accounting for 12.7% of all fatal overdoses. In 2016, 80.5% of the county’s population was white, and 13.7% of the population was black. The racial makeup in Allegheny County was proportional to fatal opioid-related overdoses categorized by race; thus, race is not a determinant of fatal opioid overdoses.
4.2 Drugs Defined

To better understand the primary drugs discussed in this section, we provide a brief overview of their scheduling based on the Controlled Substances Act and the FDA, drug characteristics, and use behavior.

4.2.1 Cocaine

Cocaine is a Schedule 2 stimulant narcotic with “strong addictive potential.” Cocaine originates from Bolivia, Peru, and Columbia, and is derived through chemical transformations from coca leaves. Currently 90% of all cocaine that enters the U.S. comes from Columbia. Cocaine can be snorted in powder form, injected in liquid form after dissolved in water, or smoked in ‘crack’ cocaine form. Further, ‘speedballing’ is a method of combining and snorting cocaine with an opiate. Cocaine users “typically binge on the drug until they are exhausted or run out of cocaine.”

4.2.2 Heroin

Heroin in a Schedule 1 opiate with a high potential for abuse. Heroin is derived from morphine, which is naturally occurring and extracted from the poppy plant. Poppy plants are harvested globally, heralding from “Mexico, South America, Southwest Asia (Afghanistan and Pakistan), and Southeast Asia (Thailand, Laos, and Myanmar (Burma)).” Heroin is produced in two forms: white or brown powder, and black tar heroin. Drug users inject, smoke, or snort heroin for an instantaneous high. Heroin is highly addictive with evidence of both psychological and physical dependence. As use increases, the user develops a tolerance to the drug. Effects of heroin use include: a “surge of euphoria… drowsiness, respiratory depression, constricted pupils, nausea, a warm flushing of the skin, dry mouth, and heavy extremities.” Effects of a heroin overdose include: “slow and shallow breathing, blue lips and fingernails, clammy skin, convulsions, coma, and possible death.”
4.2.3 Fentanyl

Fentanyl is a Schedule 2 potent synthetic opioid used by the healthcare industry as an analgesic, painkiller, and anesthetic. Fentanyl is “approximately 100 times more potent than morphine and 50 times more potent than heroin” as a painkiller. Although legal fentanyl is approved by the Food and Drug Administration (FDA), illicit fentanyl is “diverted via theft, fraudulent prescriptions, and illicit distribution by patients, physicians, and pharmacists,” and clandestinely produced. Clandestinely produced fentanyl is “sold alone or in combination with heroin and other substances and has been identified in counterfeit pills, mimicking pharmaceutical drugs such as oxycodone.” Fentanyl is “injected, snorted/sniffed, smoked, taken orally by a pill or tablet, spied onto blotter paper,” or absorbed through gel skin patches. Fentanyl is approximately “50-100 times more potent than morphine” and “30-50 times more potent than heroin.” A lethal dose of fentanyl is estimated to be 2-3 milligrams, inducing “respiratory depression, arrest and possibly death.” For reference, 5-7 grains of salt are equivalent to 2-3 milligrams of fentanyl (see Figure 15).

Figure 15: Lethal Dose of Fentanyl

4.2.4 Non-Pharmaceutical Fentanyl/Synthetic Opioids

Non-Pharmaceutical fentanyls, also referred to as illicit synthetic opioids, are Schedule 1 opioids synthesized in laboratories and function like natural opioids, such as morphine or codeine, to “produce analgesic effects.” Certain synthetic opioids are FDA approved, such as fentanyl and methadone. Non-pharmaceutical opioids are clandestinely produced and trafficked. Though illicit synthetic opioids have existed in the market since the late 1970s, there was a significant re-emergence in 2013 causing the development of new compounds, increased production, and, as a result, an increase of overdoses. Examples of illicit synthetic opioids include: 4-fluoroisobutyryl fentanyl, 3-methylfentanyl, U-47700, acetyl fentanyl, acryl-fentanyl, beta-hydroxythiofentanyl, butyryl fentanyl, carfentanil, furanyl fentanyl, para-fluorobutyryl fentanyl/FBIF, and p-fluoroisobutyryl. As mentioned above, “speedballing” has transitioned to combining cocaine and illicit synthetic opioids. Further, “fentanyl and fentanyl-related substances have been combined with heroin and other synthetic opioids, such as U-47700, to create a deadly opioid mix called ‘Grey Death,’ due to the unique grey, concrete colored appearance.” Abuse of illicit synthetic opioids in users mirrors heroin abuse and prescription opioid analgesics.
4.2.5 Carfentanil

Carfentanil is a Schedule 2 opioid, legally used in veterinary medicine as a “tranquilizing agent for elephants and other large mammals.” Illicit carfentanil is grouped under the overall category of illicit synthetic opioid. Estimated to be 10,000 times more potent than morphine, the lethal dose of carfentanil in the average human is undetermined. Much like fentanyl, carfentanil can either be inhaled or absorbed through the skin in the form of “powder, blotter paper, tablets, and spray.” 116

4.3 Drug Analysis

Of 617 fatal overdoses in 2016, the 6 most prevalent drugs in fatal overdoses were fentanyl, heroin, cocaine, alcohol, alprazolam (Xanax), and oxycodone (OxyContin). Of 542 fatal overdoses in 2017, the 6 most prevalent drugs in fatal overdoses were fentanyl, heroin, cocaine, alcohol, alprazolam (Xanax), and despropionyl fentanyl 4-ANPP.

Of 617 fatal overdoses in 2016, 379 cases, 61.43%, had fentanyl present at time of death. Heroin was present in 298 cases, approximately 48.3%. Cocaine was present in 205 cases, approximately 33.23%. Alcohol was present in 140 cases, approximately 22.69%. Alprazolam, brand name Xanax, was present in 101 cases, approximately 16.37%. Oxycodone (OxyContin), was present in 56 cases, approximately 9.08%.

Of 542 fatal overdoses in 2017, 394 cases, 72.69%, had fentanyl present at time of death. Heroin was present in 201 cases, approximately 37.08%. Cocaine was present in 194 cases, approximately 35.79%. Alcohol was present in 116 cases, approximately 21.4%. Alprazolam (Xanax), was present in 75 cases, approximately 13.84%. Despropionyl Fentanyl 4-ANPP, was present in 39 cases, approximately 7.2%.

We compared absolute count drug trends by calculating the difference of the overall drug percentage prevalence between 2016 and 2017. Fatal overdoses with fentanyl present increased by 11.26% from year 2016 to 2017. Fatal overdoses with heroin present decreased by 11.22% from year 2016 to 2017. Zero fatal overdoses with despropionyl fentanyl 4-ANPP present occurred in 2016. In contrast, 39 fatal overdoses with despropionyl fentanyl 4-ANPP present occurred in 2017. Despropionyl fentanyl 4-ANPP had the 6th highest concentration of fatalities in 2017, behind fentanyl, heroin, cocaine, ethanol, and alprazolam (Xanax).

4.3.1 Trends

The vast majority of fatal overdoses had more than one identified drug present at time of death. Drug combinations present in overdose cases provides crucial information that reveals larger drug use trends in Allegheny County. To analyze paired drug use trends, we used Chi-Square tables to measure and compare proportions of drug presence. We analyzed the following drug combination pairs: fentanyl and cocaine, fentanyl and heroin, fentanyl and carfentanil, and fentanyl, cocaine, and carfentanil.

It is important to note that 1 out of 5 fatal overdoses that occur in the U.S. do not specify a “specific drug listed on the death certificate” as cause of death. Further, it is difficult for medical examiners to ascertain which drug is the target cause of death when multiple drugs are present.117
4.3.2 Cocaine and Fentanyl

Of 617 total fatal overdoses in 2016, fentanyl was present in 379 fatalities and not present in 238 fatalities. Of 617 total fatal overdoses, cocaine was present in 205 fatalities, and not present in 412 fatalities. A total of 124 fatalities contained both cocaine and fentanyl, representing 32.72% of all 379 fatalities containing fentanyl. In comparison, the 124 fatalities containing both cocaine and fentanyl represents 60.49% of all 205 fatalities containing cocaine. That is, just under two-thirds of all cocaine fatalities in 2016 had fentanyl present.

Of 542 total fatal overdoses in 2017, fentanyl was present in 394 fatalities and not present in 148 fatalities. Of 542 total fatal overdoses, cocaine was present in 194 fatalities, and not present in 348 fatalities. A total of 142 fatalities contained both cocaine and fentanyl, representing 36.04% of all 394 fatalities containing fentanyl. In comparison, the 142 fatalities containing both cocaine and fentanyl represents 73.20% of all 194 fatalities containing cocaine. Accordingly, just under three-fourths of all cocaine fatalities in 2017 had fentanyl present.
From 2016 to 2017, the proportion of fatalities with cocaine and fentanyl present out of all fentanyl fatalities increased by only 3.32%. However, there was a 12.71% increase in the proportion of fatalities with cocaine and fentanyl present out of all cocaine fatalities. This data reflects that cocaine use is positively trending toward association with fentanyl. This poses dyer implications because the “estimated lethal dose” for cocaine is 1.2 grams, and “addicts may tolerate up to 5 grams daily.” In comparison, “the estimated lethal dose of fentanyl in humans is 2mg.” If drug users or dealers are increasingly cutting cocaine with fentanyl, the drug combination becomes exponentially more lethal. Furthermore, illicit drug dealers run the risk of unintentional contamination of cocaine with fentanyl. If contaminated product is sold unknowingly, users will be naïve to the appropriate non-lethal dosage.

**Figure 17.1: Chi Square Fentanyl/Heroin 2016**

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<th>Heroin 0: No</th>
<th>Heroin 1: Yes</th>
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<td>194</td>
<td>379</td>
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<td>Total</td>
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**Figure 17.2: Chi Square Fentanyl/Heroin 2017**

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<td>394</td>
</tr>
<tr>
<td>Total</td>
<td>341</td>
<td>201</td>
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</table>
4.3.3 Fentanyl and Heroin

Of 617 total fatal overdoses in 2016, fentanyl was present in 379 fatalities and not present in 238 fatalities. Of 617 total fatal overdoses, heroin was present in 298 fatalities, and not present in 319 fatalities. A total of 194 fatalities contained both heroin and fentanyl, representing 51.19% of all 379 fatalities containing fentanyl. In comparison, the 194 fatalities containing both heroin and fentanyl represents 65.10% of all 298 fatalities containing heroin.

Of 542 total fatal overdoses in 2017, fentanyl was present in 394 fatalities, and not present in 148 fatalities. Of 542 total fatal overdoses, heroin was present in 201 fatalities, and not present in 341 fatalities. A total of 147 fatalities contained both heroin and fentanyl, representing 37.31% of all 394 fatalities containing fentanyl. In comparison, the 147 fatalities containing both heroin and fentanyl represents 73.13% of all 201 fatalities containing heroin.

From 2016 to 2017, the proportion of fatalities with heroin and fentanyl present out of all heroin fatalities increased by 8.03%. However, there was a 13.88% decrease in the proportion of fatalities with heroin and fentanyl present out of all fentanyl fatalities. As previously mentioned, all fatal overdoses with heroin present fell 11.22% from 2016 to 2017. Despite experiencing less fatalities with heroin present in 2017, fatalities with both heroin and fentanyl present increased by 8.03%. These patterns reveal an increasing pairing of fentanyl and heroin in drug use where heroin is present. While heroin and fentanyl fatalities decreased by 13.88% out of the total number of fatalities with fentanyl present in 2017, total fatalities with fentanyl present increased by 11.26% from 2016 to 2017. Overall, more heroin is being used with fentanyl, and more fentanyl is being used without heroin. This trend could mean that fentanyl is increasingly being used with other illicit drugs, or independently.

Figure 18: Chi Square Carfentanil/Fentanyl 2017

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<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>148</td>
<td>394</td>
<td>542</td>
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</table>
4.3.4 Carfentanil- 3 Variable Analysis

In 2016, carfentanil was not present in any fatal overdose. In 2017, 19 fatalities occurred with carfentanil present. Because carfentanil was not present in 2016, we conducted a 3-variable analysis for cocaine, fentanyl, and carfentanil for 2017.

Of 542 total fatal overdoses, carfentanil was present in 19 fatalities; carfentanil was present without cocaine and fentanyl in 5 fatalities, carfentanil and cocaine were present without fentanyl in 0 fatalities, carfentanil and fentanyl were present without cocaine in 7 fatalities, and all three drugs were present in 7 fatalities.

Fentanyl was present in 14 total fatalities, accounting for 73.68% of all 19 fatalities with carfentanil present. No cocaine fatalities occurred with carfentanil present and not fentanyl. Therefore, all fatalities with cocaine and carfentanil present also had fentanyl present. We can assume cocaine is always used with both fentanyl and carfentanil when carfentanil is present.

Carfentanil fatal overdoses occur in two distinct time periods in 2017. These two time periods will be referred to as Period 1 and Period 2. Period 1 includes carfentanil fatalities between April 4, 2017 to May 4, 2017, comprising 7 of 19 fatalities. Period 2 includes carfentanil fatalities between August 6, 2017 to August 28, 2017, comprising 11 of 19 fatalities. The drug composition in fatal overdoses were unique among Period 1 and Period 2 samples. We identified 3 possible outliers determined by death date, age, and/or drug combination.

During Period 1, 6 of the 7 fatalities had both heroin and para-fluorobutyryl fentanyl/FBIF (synthetic fentanyl) present. We consider the 50-year-old fatality on April 22, 2017 an outlier, because only carfentanil was present at death. During Period 2, 10 of the 11 fatalities had either cocaine and fentanyl present, or fentanyl present. Of 11 fatalities, 9 had fentanyl present; 7 had both fentanyl and cocaine present, 2 had fentanyl present but not cocaine, and 0 had cocaine present but not fentanyl. Thus, 63.6% of all carfentanil fatalities had both cocaine and fentanyl present, and 81.8% of all carfentanil fatalities had fentanyl present. We consider the 1-year-old fatality on August 6, 2017 an outlier due to age. We also consider the 44-year-old fatality on August 22, 2017 an outlier, because only carfentanil and alcohol were present at death.
Since there were no 2016 carfentanil instances, the 19 fatalities in 2017 do not indicate a statistically significant trend of carfentanil use. Rather, we assume there were two infiltrations of drugs laced with carfentanil in April and August of 2017. However, the appearance of carfentanil in 2017 with no previous history of carfentanil in Allegheny County is a concern. Furthermore, carfentanil appears in two different and distinct drug combinations at two points in time. If these instances signify a future trend toward cutting multiple drugs with carfentanil, this will have major fatal implications.

4.4 Summary

In summary, drug use behavior and trends in Allegheny County changed significantly between January 1, 2016 and October 23, 2017. Fatal overdoses with fentanyl present increased 11.26%, whereas fatal overdoses with heroin present decreased 11.22%. Highly lethal synthetic fentanyls, with little to no presence in 2016, occur at significant rates in 2017. For instance, carfentanil was present in 19 fatalities, and despropionyl fentanyl 4-ANPP was present in 39 fatalities in 2017. Neither synthetic opioids were present in any fatal overdose in 2016.

The proportion of fatalities with cocaine and fentanyl present out of all fentanyl fatalities increased by 3.32%, whereas the proportion of fatalities with cocaine and fentanyl present out of all cocaine fatalities increased by 12.71%. This reflects an increasing co-occurrence of cocaine and fentanyl when cocaine is involved in drug use. However, this does not imply a co-occurrence of cocaine and fentanyl when fentanyl is involved in drug use.

The proportion of fatalities with heroin and fentanyl present out of all heroin fatalities increased by 8.03%, whereas the proportion of fatalities with heroin and fentanyl present out of all fentanyl fatalities decreased by 13.88%. This reflects an increasing co-occurrence of heroin and fentanyl when heroin is involved in drug use. However, the data reflects a decreasing co-occurrence of heroin and fentanyl when fentanyl is involved in drug use. Overall, more heroin is being used with fentanyl, and more fentanyl is being used without heroin. This trend could mean that fentanyl is increasingly being used with other illicit drugs, or independently.

According to the DEA Philadelphia Field Division (PFD), “the increase in cocaine/fentanyl combination samples may be attributed to a trend wherein heroin is supplanted by fentanyl in the illicit drug supply.” DEA laboratory-analyzed drug seizure trends show a “112 percent increase in cocaine/fentanyl combination exhibits” and a “corresponding decrease in cocaine/heroin combination samples” between 2016 and 2017. Furthermore, the DEA identified 214 seizures containing cocaine and fentanyl, representing “less than 1 percent of the total cocaine exhibits analyzed and reported in Pennsylvania for 2015 through 2017.” Of the 214 seizures identified, Allegheny County had the highest number of submissions per county, with 40 in total.

The DEA laboratory system identified “230 [seized] identifications of fentanyl, fentanyl-related substances, and other synthetic opioids” during the first quarter of 2017. Of the 230 seized drug incidents, 58% identified fentanyl, 26% identified the fentanyl-related substance furanyl-fentanyl, and 61% identified heroin in combination with fentanyl. Other prominent indications were “U-47700, alprazolam, ketamine, and cocaine.” In Allegheny County, fatal overdoses with fentanyl present are increasing, as well as co-occurrences of fentanyl with fentanyl-related substances, and synthetic opioids. Several synthetic opioids and fentanyl-related substances debuted in Allegheny County fatal overdoses in significant quantities in 2017. Allegheny County data suggests fatal overdoses by these new and lethal substances will continue to rise into the future.
### Figure 20: Carfentanil Fatal Overdose Drug Profiles 2017

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<th>Combined OD2</th>
<th>Combined OD3</th>
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<tr>
<td>4/5/17</td>
<td>Alprazolam</td>
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<td>Fentanyl</td>
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<td>Fentanyl</td>
<td>Heroin</td>
<td>Para-Flurobutyryl Fentanyl/FIBF</td>
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<td>Heroin</td>
<td>Oxazepam</td>
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<td>Heroin</td>
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<tr>
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<tr>
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<td>Cocaine</td>
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<td></td>
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<tr>
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<td>Cocaine</td>
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<td>Cocaine</td>
<td>Fentanyl</td>
<td>Para-Flurobutyryl Fentanyl/FIBF</td>
<td>Para-Flurofentanyl</td>
<td></td>
</tr>
</tbody>
</table>
5 ECONOMICS OF OPIOIDS

5.1 Cost of Opioid Use Overdose Treatment

The National Institutes of Health (NIH) estimated the total economic burden of “fatal overdose and abuse and dependence of prescription opioids” in the U.S. to be $78.5 billion in 2013. Over one third, $28.9 billion, accounts for “increased healthcare and substance abuse treatment costs.” Further, one quarter, approximately $19.6 billion, was allotted “by the public sector in health care, substance abuse treatment, and criminal justice costs.”

Cost estimates from the U.S. Department of Defense for treatment outline treatment costs according to medication assisted treatment types. Methadone, including drug and “[daily] integrated psychosocial and medical support services” costs approximately “$126.00 per week or $6,552.00” annually per patient. Buprenorphine treatment “for a stable patient” provided in an opioid treatment program, including drugs and two appointments weekly costs approximately “$115.00 per week or $5,980.00” annually. Naltrexone treatment provided in an opioid treatment program, “including drug, drug administration, and related services” costs approximately “$1,176.00 per month or $14,112.00” annually. Comparatively, annual healthcare expenditures per patient for diabetes mellitus treatment cost $3,560.00 per year, and kidney disease treatment cost $5,624.00 per year.

According to a cohort study conducted by the Center for Healthcare Delivery Science at Beth Israel Deaconess Medical Center in Boston, the average cost per intensive care unit (ICU) overdose-related admission totaled $92,408 in 2015. That figure increased by 58 percent in 5 years, from $58,517 in 2009. However, this figure is dependent upon the individual services provided for each patient per ICU visit. The study further expressed that of ICU patients, approximately 10 percent “required mechanical ventilation,” 7 percent required noninvasive ventilation, and 4 percent required vasopressors. Furthermore, “critically ill patients required renal replacement therapy 37 percent more often in 2015 than in 2009.” Overdose patients admitted to the ICU “had several comorbidities associated [with] their hospitalization.” Simultaneous comorbidities require additional treatment, thus increasing associated costs. Among all overdose patients admitted to the ICU, 25 percent “experienced aspiration pneumonia, 6 [percent] had septic shock, 15 percent had rhabdomyolysis, and 8 percent experienced anoxic brain injury.”

The average additional costs to each comorbidity include: mechanical ventilation at a median cost of between $17,000 and $24,000; pneumonia at an average cost of $30,280 per case, and septic shock with an average cost to treat of $43,566 in Pennsylvania. Each comorbidity estimate has variable costs depending on the extent of the injury.

5.2 Hospitalization Admittance-Mortality Rates

Modeled by the Beth Israel Deaconess Medical Center study, opioid ICU admission rates “increased 34 [percent], from 44 per 10,000 to 59 per 10,000” between 2009 and 2015. The study collected data regarding “22,783,628 hospital admissions and 4,145,068 ICU admissions” from 162 hospitals in 44 states from January 1, 2009 to September 31, 2015. Approximately 18 percent of patients were insured by Medicaid. A total of 21,705 hospital admissions required intensive unit care involving overdose, or “an average of 52.4 admissions for overdose per 10,000 ICU admissions.” Between 2009 and 2015, the incidence of opioid overdose ICU admittance consistently increased every month and every year. The mean increase was 0.6 percent per month.

The mortality rate of overdose ICU patients was 7.3 percent on average. However, the mortality rate peaked at 9.81 percent in 2015. The monthly mortality of opioid-related overdose ICU admissions “increased at a rate of 0.5 percent per month.” Between January 2009 and September 2015, “there was an estimated doubling of ICU [fatalities] from opioid overdoses.” Furthermore, ICU patients increasingly required significant “intense care, as reflected by the use of more renal replacement therapy at
significantly higher costs.” In a state level analysis, the rates of ICU admissions for overdose in Pennsylvania “nearly doubled” between 2009 and 2015.

Overall, the incidence and mortality of overdose ICU patients in the U.S. is significantly increasing. Researchers, including the Associate Medical Director of the ICU at Beth Israel Dr. Jennifer P. Stevens, claim, “overdose patients are arriving in worse shape, requiring longer stays and a higher level of treatment.”

5.3 Opioid-Related Hospitalization Rates

The graphs below illustrate the U.S. national opioid-related hospitalization rate of inpatient stays compared to Pennsylvania rates. Data is divided into 4 quarters and reflected as a rate per 100,000 people. The national rate for opioid-related hospitalization inpatient stays was 284 per 100,000 people in quarter 4 of 2015. The Pennsylvania rate for opioid-related hospitalization inpatient stays was 353 per 100,000 people in quarter 4 of 2015. More recent data shows Pennsylvania’s quarter 3 of 2016 rate increased to 377 per 100,000 people in just 9 months. Although there is no data available for national rates in 2016, in all likelihood Pennsylvania will continue to exceed national rates.

In Pennsylvania, there were 1,524 heroin-related overdose hospital admissions in 2016. Further, approximately 3 percent of the heroin-related hospital admission patients had “at least one additional admission” relating to a heroin overdose within the year. In Pennsylvania, there were 1,775 prescription opioid-related hospital admissions in 2016. Identical to heroin-related readmission, 3 percent of prescription opioid-related hospital admission patients had “at least one additional hospital admission” within the year. Allegheny County totaled 362 opioid-related overdose hospitalizations in 2016. This figure is comprised of 179 heroin-related overdose hospitalizations, and 183 prescription opioid-related hospitalizations. Overall, there were 34.9 opioid overdose-related hospitalizations per 100,000 Allegheny County residents. Allegheny County’s rate is slightly higher than the statewide rate of 31.1 opioid overdose-related hospital admissions per 100,000 Pennsylvanians.

Figure 21.1: U.S. National: Opioid-Related Hospital Use- Rate of Inpatient States per 100,000 Population

<table>
<thead>
<tr>
<th>Year</th>
<th>Quarter</th>
<th>Rate per 100,000</th>
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</thead>
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<td>3</td>
<td>254</td>
</tr>
<tr>
<td>2015</td>
<td>4</td>
<td>284</td>
</tr>
</tbody>
</table>
Figure 21.2: Pennsylvania: Opioid-Related Hospital Use- Rate of Inpatient Stays per 100,000 Population

Pennsylvania: Opioid-Related Hospital Use- Rate of Inpatient Stays per 100,000 Population

<table>
<thead>
<tr>
<th>Year</th>
<th>Quarter</th>
<th>Rate per 100,000</th>
</tr>
</thead>
<tbody>
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<td>357</td>
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<tr>
<td>2016</td>
<td>3</td>
<td>377</td>
</tr>
</tbody>
</table>

Figure 22.1: U.S. National: Opioid-Related Hospital Use

Source: Agency for Healthcare Research and Quality (AHRQ), Healthcare Cost and Utilization Project (HCUP), National (Nationally) Inpatient Sample (NIS), 2000-2015 (all available data as of 12/19/2017). Inpatient stays include those admitted through the emergency department.
Neonatal Abstinence Syndrome Hospitalizations

Neonatal Abstinence Syndrome (NAS) has become increasingly problematic among maternal drug users. NAS is defined as the “result of the sudden discontinuation of fetal exposure to substances that were used or abused by the mother during pregnancy.” Neonates experience symptoms of withdrawal upon birth as a result of either licit or illicit maternal drug use. Withdrawal as a result of “prolonged maternal opioid use” is characterized in neonates as “severe and intense.” Though NAS is rarely fatal, symptoms can cause “significant illness” involving “the central and autonomic nervous systems [and] gastrointestinal tract.” If withdrawal symptoms become severe, the neonate is treated with pharmaceutical therapy, specifically opioids or morphine. This often leads to prolonged treatment and extended hospital stays.\textsuperscript{132}

In fiscal years (FY) 2016 - 2017, 3,883 neonates were born with NAS and required hospital stay in Pennsylvania. This accounts for a rate of 15.0 per 1,000 neonate stays statewide. In Allegheny County, 399 neonates were born with NAS and required hospital stay, a rate of 15.6 per 1,000 neonate stays. Several neighboring counties have comparatively higher NAS rates, such as Greene County with 76.0 per 1,000 neonate stays. In just FY 2017, there were 1,912 “NAS-related neonate stays,” and 3,289 overarching cases of maternal substance use in Pennsylvania. Approximately 58 percent of neonates associated with maternal substance use were diagnosed with NAS.\textsuperscript{133}

In FY 2017, the average NAS neonate hospital stay was 17.1 days, approximately 5 times longer than the average stay of 3.5 days for non-NAS neonates. This equates to an additional 26,018 extra hospital stay days for NAS neonates, totaling 5.5 percent of all neonate hospital stays. Furthermore,
additional complications co-occur in NAS neonates at elevated rates than non-NAS neonates such as, “low birth weight, prematurity, difficulty feeding, and respiratory distress.” Refer to Figure 23 for specific rates for FY 2017.

Figure 23- Co-occurring Complications and Rates Among NAS-Neonates vs Non-NAS- Neonates in Pennsylvania, 2017

<table>
<thead>
<tr>
<th>Complication</th>
<th>NAS Newborn Stays</th>
<th>All Other Newborn Stays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low birth weight</td>
<td>15.7%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Prematurity</td>
<td>14.8%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Difficulty feeding</td>
<td>14.9%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>24.0%</td>
<td>9.3%</td>
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</table>

According to the National Institute on Drug Abuse, the average cost of stay for one NAS-neonate is $66,700 based on the national average of 16.9 hospital stay days. Comparatively, the average cost of stay for one non-NAS neonate is $3,500 based on the national average of 2.1 hospital stay days. These estimates are based on nationwide cost of treatment in 2012. In Pennsylvania, an estimated $14.1 million was spent on NAS-related hospital payments in FY 2017. Further, Medicaid was the primary payer in 86.9 percent of NAS-neonate hospital stays.

6 APPROACHES AND OUTCOMES IN OTHER JURISDICTIONS

6.1 Global

The U.S. is far from the only country experiencing rampant opioid use. Other countries, including Portugal, Switzerland, and Australia have previously experienced or are currently seeing the same widespread use of opioids. There were more than 100,000 Portuguese, or approximately 1 percent of the total population, addicted to drugs in 1999. In response to drug use in Portugal, the government decriminalized all drug use, meaning drug use and possession was still illegal, but the act no longer fell within the criminal law framework. It should be noted that decriminalization and depenalization are two different concepts; decriminalization may still entail a penalty like mandated treatment, whereas depenalization means drug use and possession still fall within the criminal law framework but with other penalties. By 2012 the number of high-risk opioid users in Portugal dropped to between 27,000 and 33,000 individuals. The success is due largely to the public health officials that can order drug abusers found with less than a 10 day supply of drugs on them into treatment. Treatment is extensive in Portugal, including physical activities and job training programs, and many are successful in securing a job after treatment. Medicated assisted treatment is an option as well, with mobile clinics to accommodate job schedules of those in need. All of this- the treatment, medication, job training, and more- is all paid for by the government. The payoff is significant though as nearly all drug use, regardless of the drug, has declined.

In Zurich, Switzerland there is a park by the main train station named Platzspitz, once referred to as “Needle Park” by the New York Times, and it was home to around 3,000 drug addicts daily in 1992. Between 1975 and 1992, the number of drug addicts in Switzerland increased from 3,000 to 30,000
individuals, and drug-related fatalities increased by twelvefold. Much like Portugal, Switzerland adopted similar drug policies and also instituted heroin prescription programs, and overdose rates also declined significantly. The United Kingdom has a similar program where individuals are given a small daily dose of heroin as a mechanism to enter treatment. Other countries around the world, including Ecuador, Uruguay, Czech Republic, Croatia, Argentina, the Netherlands, Australia, and Mexico have all instituted similar drug policies involving non-enforcement, decriminalization, or depenalization, and each country has seen a decline in overdose rates since instituting the policies.

Alternatively, there are a number of countries, including China and Russia, that pursue harsh criminal sentences for drug users, distributors and the like. The notion of harsh punishments is not the approach embraced by the international community though, as evidenced by the discussions at the 2016 United Nations General Assembly on the World Drug Problem. Rather, the overall trend is shifting towards treatment-centered programs.

6.2 National

Nationally, there are varying results regarding drug-related fatalities. Fatalities are decreasing or plateauing in some states, while others are increasing. Data collected by the CDC show that predominantly east coast states have seen statistically significant increases in drug-related overdose mortality rates (see Figure 24). Figure 24 depicts the states with a significant increase in red.

At the end of 2017, Massachusetts released a brief finding the number of fatal opioid-related overdoses decreased 10 percent during the same January to September timeframe between 2016 and 2017. Other states observing a decrease in fatal opioid-related overdoses include California and Colorado. The reason for declining rates is uncertain at this time, but it is suggested the legalization of recreational marijuana may contribute to the declining rates. Studies suggest opioid-related fatalities have declined in Colorado since the legalization of marijuana, and other states believe that may be true as well. As such, states seeking to decriminalize, and in some cases legalize, certain drugs model the European and overall international approach to addressing the opioid crisis.

Many counties and states are also seeking legal action against many of the pharmaceutical companies, pharmacies, and physicians whom they believe are responsible for instigating the opioid crisis. There are presently no judgments as most lawsuits were dismissed or settled, and we explore the overall legal climate in Section 7.

Figure 24: Statistically Significant Drug Overdose Death Rate Increase in U.S. 2015-2016
6.3 Local

The Pennsylvania Legislature enacted Act 319 in 2014 to address the growing number of fatalities related to opioid drugs. The relevant provision of Act 319, titled Drug Overdose Response Immunity, serves two main purposes. First, it allows first responders to administer naloxone. Second, it allows other individuals to administer naloxone to someone in need and will be provided immunity from prosecution for administering the naloxone. Naloxone is a drug that acts as an antidote for opioids, and it is used when an individual overdoses. The drug is capable of blocking opioid receptor sites in the body, effectively nullifying the opioid in the individual’s system.

In May 2015, Dr. Karen Hacker, the Director of the Allegheny County Health Department, issued a standing order for the county regarding naloxone. The standing order “allows any licensed pharmacy in the county, which chooses to participate, to dispense naloxone to individuals at risk of a heroin or opioid-related overdose, or those who may witness one.” The intent of the standing order is to make naloxone readily available and prevent opioid-related fatalities in the county. Moreover, the immunity protection of Act 319 further promotes using naloxone regardless of an individual’s current state.

The standing order has not decreased the number of opioid-related fatalities though. The order was issued in May 2015. In Allegheny County, there were 352 opioid-related fatalities in 2015. There were 558 opioid-related fatalities in 2016. While the preceding figures do not capture naloxone use, the increased number of opioid-related fatalities indicates the availability of naloxone has not reduced the number of fatalities in the county. However, if naloxone was not widely available and used, there would likely be more opioid-related fatalities in the county each year.

7 LEGAL ANALYSIS

7.1 Theories of Liability

Through our approach, we identified five main theories of liability that were consistently used by municipalities, counties, and states in their complaints under parens patriae authority. Parens patriae “refers traditionally to [the] role of state as sovereign and guardian of persons under legal disability. It is a concept of standing utilized to protect those quasi-sovereign interests such as health, comfort and welfare of the people. …” The theories of liability we identified are (i) public nuisance; (ii) fraud; (iii) consumer protection concerning deceptive acts or practices; (iv) unjust enrichment; and (v) racketeering. All theories but racketeering are based on state law so there may be some variation between jurisdictions, but states generally have similar laws defining the theories of liability. Racketeering actions fall under a federal statute, the Racketeer Influenced and Corrupt Organizations Act.

For purposes of this analysis, Pennsylvania state laws and judicial decisions, as well as federal judicial decisions from primarily the Third Circuit were used as a foundation for legal definitions and elements necessary for a successful action. Furthermore, the theories below are discussed generally as the facts applied are available to the public or hypothetical, and we are not privy to the requisite information needed to provide a proper legal analysis. Lastly, the number of cases that have gone to trial where a judgment has been rendered is negligible. Therefore, the application of these theories has not been discussed by the courts. Yet as such, there is a high level of uncertainty on how a court would rule on the law and facts of our case and others like it.
There are also other theories of liability discussed among attorneys, academics, and legal scholars as part of the ongoing strategy development in opioid litigation. Theories include conspiracy, negligence, strict products liability, and criminal prosecution. The preceding theories were not discussed at length because we felt the five discussed below were the stronger options, but that does not mean they are not viable claims.

It should also be mentioned that all, or most, claims have a statute of limitations, meaning a party has to bring a claim within a certain period of time or else they will likely be barred from doing so. Statute of limitations is also an affirmative defense so if the county were to bring an action outside of the determined timeframe, the defendants could raise statute of limitations as a defense and the claim would likely be dismissed. As such, the county should be cognizant on when the clock starts for purposes of statute of limitations.

The reason for providing a legal analysis is twofold. Initially, we believed there were parallels between what is happening now throughout the country with prescription opioids and the continuous litigation and the effects of tobacco in the 1990s and the excessive litigation then. However, there were a few distinctions between tobacco and prescription opioids that led us to conclude an agreement like the Master Settlement Agreement (MSA) between states and the tobacco industry would be unlikely for states and the pharmaceutical industry.

Tobacco and prescription opioids vary in a few ways. First, while tobacco and cigarettes are a legal product in the United States, there is no medical use for the product. In contrast, there is a medical use for prescription opioids. There was also evidence that the tobacco industry knew their products were addictive, yet the information was concealed from the public. The concealment and misrepresentation of tobacco was therefore a large factor leading to the MSA. Because we do not think an agreement like the MSA is feasible in the current environment, we shifted our objective and continued the legal analysis to offer plausible strategies for the county as part of a larger, statewide initiative to come to an agreement independently with the pharmaceutical industry.

7.1.1 Public Nuisance

Nuisance is a common law doctrine typically associated with property law, but in certain situations, it can be applied to a community at large under the theory of public nuisance. A public nuisance is an unreasonable and substantial interference with the public’s common rights, and the public nuisance causes an injury. Moreover, a public nuisance can be “[a] condition dangerous to health, offensive to community moral standards ... [and it] is a behavior which unreasonably interferes with the health, safety, peace, comfort, or convenience of the general community.”\(^\text{163}\) When bringing a public nuisance claim, the nuisance affects “rights enjoyed by citizens as part of [the] public and must affect a considerable number of people or an entire community or neighborhood.”\(^\text{164}\) Public nuisance may also involve the violation of a state statute, but Pennsylvania does not provide a statute in which there would be a violation for this particular case, thus we rely on common law public nuisance.

Pennsylvania has adopted the Restatement (Second) of Torts for public nuisance for the elements necessary for a successful public nuisance claim.

1. The public nuisance is an unreasonable interference with a right common to the general public.
2. Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:
a. Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience; or

b. Whether the conduct is proscribed by a statute, ordinance or administrative regulation; or

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

Richard Ausness from the University of Kentucky College of Law discussed in *The Role of Litigation in the Fight Against Prescription Drug Abuse* that *parens patriae* lawsuits using a public nuisance liability theory is likely one of the most successful actions a state can bring. Additionally, a recent judgment from a California appellate court supports the theory of public nuisance in industries that typically have a lot of power, like the paint and pigment industry. The judgment was for the state of California and ordered the defendants, ConAgra Grocery Products and Sherwin-Williams Company, to pay $600 million for their role in promoting paint with lead for interior residential use. The Supreme Court of California recently denied appeal as well. Therefore, the established record of a public nuisance claim against big industry companies is beneficial for current opioid litigation.

A number of counties in Pennsylvania have alleged public nuisance in their complaints. Nearby Beaver County filed a lawsuit against leading pharmaceutical manufacturers and distributors in October 2017 alleging public nuisance due to the defendants’ activities. As the complaint states:

The activities of the Defendants that created a public nuisance worked an obstruction or injury to Beaver County and its residents, producing a material annoyance, inconvenience, discomfort, and/or hurt on the County and its residents by causing them to suffer actual damages directly caused by Defendants’ deceptive, negligent, and/or unlawful behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue. Defendants’ conduct was willful, wanton, and malicious and was directed at the public generally.

Beaver County’s essential argument is that because of the defendants’ actions, the county and its residents suffered because public resources were expended at a great cost to the public. While some of the defendants’ activities are not definitive and only mechanisms like discovery or voluntary sharing would support the alleged activities, the Beaver County complaint is illustrative of a public nuisance claim in the context of opioid litigation. As such, Allegheny County would likely have similar allegations to Beaver County. Evidence to support a public nuisance claim may include records showing an oversaturation of prescription drugs in the local market, adverse public health outcomes and increased public expenditures on the various departments addressing public health and opioid-related issues.

### 7.1.2 Fraud

Black’s Law Dictionary defines fraud as “[a]n intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right; [a] false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives and
is intended to deceive another so that he shall act upon it to his legal injury. There are five elements that must be established for a successful claim of fraud in Pennsylvania. The elements are “[1] a misrepresentation, [2] a fraudulent utterance thereof, [3] an intention to induce action thereby, [4] justifiable reliance thereon and [5] damage as a proximate result.”

For a successful fraud claim, Allegheny County would need to establish the above five elements. Both Beaver and Luzerne Counties have alleged fraud and misrepresentation in their complaints against pharmaceutical companies. Evidence to support fraud claims may include false statements made by the defendants about prescription opioids, the defendants knowingly made the false statements in order to sell the opioids, and the addictive nature of opioids was concealed. The court has also stated that "[c]oncealment can be a sufficient basis for finding that a party engaged in fraudulent conduct, provided that the other requisite elements of fraud are established.” Consequently, documentation supporting the defendants’ knowledge of the addictive nature of opioids yet persistent misrepresentation and hiding of the fact in conjunction with the remaining elements would be sufficient.

One particular element of fraud that may present a challenge to the county is justifiable reliance. As stated by Beaver County, “[g]iven the incredible resources Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants’ misrepresentations and omissions… .” While the burden to establish justifiable reliance is high, there may be evidence that will likely meet this burden. For instance, a recent report published by the U.S. Senate Homeland Security & Governmental Affairs Committee found that 5 opioid pharmaceutical companies paid 14 advocacy groups $9 million between 2012 and 2017, and the advocacy groups often promoted pro-opioid agendas. With the consistent pro-opioid messaging, it may be established that the county, among others, justifiably relied on the defendants misrepresentations, and thus be successful in a claim for fraud.

Further supporting a claim of fraud, The Purdue Frederick Company, Inc. and three top level executives, including President and Chief Operating Officer Michael Friedman, Executive Vice President and Chief Legal Officer Howard Udell, and former Executive Vice President for Worldwide Medical Affairs Dr. Paul Goldenheim, pleaded guilty to felony and misdemeanor misbranding of OxyContin with the intent to defraud and mislead in May 2007. Together, Purdue and the executives will pay $634,515,475 in fines with Purdue paying approximately $600 million of the total amount. Presently, this plea agreement is the largest judgment rendered among the opioid litigation, and unlike other settlement agreements regarding this issue, this plea agreement actually entailed finding Purdue and its executives guilty. Moreover, this plea agreement further supports fraud, unjust enrichment, and consumer protection violations as viable claims.

7.1.3 Consumer Protection

The Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPCPL) was enacted in 1968 after the Federal Trade Commission (FTC) encouraged states to pass their own legislation mirroring the Federal Trade Commission Act (FTCA), which was enacted in 1914. The UTPCPL also encompasses parts of the Federal Lanham Trademark Act of 1946 (Lanham Act). Both the FTCA and Lanham Act address consumer fraud and protect consumers from unfair business practice. Historically, only the Pennsylvania Attorney General or a district attorney could bring an action under the UTPCPL as long as it was “in the public interest,” but a change in 1976 allowed for private action. The UTPCPL defines “unfair or deceptive acts or practices,” and the relevant provision of the definition is the final “catchall” provision, which includes “engaging in any other fraudulent or deceptive conduct which
creates a likelihood of confusion or of misunderstanding.” The Pennsylvania Legislature amended the UTPCPL to include this catchall provision in 1996, and it has caused some confusion among the courts.

Presently, it is unclear whether common law fraud needs to be established to have a successful action under the UTPCPL. The Pennsylvania courts are split on the interpretation of the “catchall” provision, and only time will tell which interpretation prevails. The Pennsylvania Supreme Court and the Third Circuit have interpreted the provision to mean common law fraud needs to be established whereas the appellate courts have interpreted the provision more loosely and have not required that all common law fraud elements be met in order to be successful. In our present case, we have a preference for the court’s interpretation of the provision in Bennett v. A.T. Masterpiece Homes, as it is more lenient and favorable regarding the inducement by pharmaceutical companies. Specifically, common law fraud necessitates that the justifiable reliance element be met, and is typically a barrier for plaintiffs to overcome. The distinction between proving reliance and causation is difficult, however, “causation does not require reliance,” and is thus an easier burden to meet.

Ultimately, a UTPCPL claim relies on evidence pertaining to advertising and marketing strategy, distribution of educational materials and other publications, misleading and deceptive statements, financial support to physicians, and sponsored Continuing Medical Education sessions. The nature of the advertisement is pertinent and there is likely a stronger argument regarding the misrepresentation of the addictiveness of the opioids. Beaver County, as well as others, allege the preceding actions as support for consumer protection and fraud claims, and it follows that Allegheny County and the rest of the state would too.

7.1.4 Unjust Enrichment

The doctrine of unjust enrichment is the “[g]eneral principle that one person should not be permitted unjustly to enrich himself at the expense of another.” For a successful unjust enrichment claim, three elements must be met. The elements are “benefits conferred by plaintiff, appreciation of such benefits by defendant, and acceptance and retention of such benefits under such circumstances in which it would be inequitable for defendant to retain the benefit without payment of value.” For a successful claim, there would need to be evidence that the county or state granted a benefit to the defendants, the defendants received and appreciated the benefits, and the defendants kept the benefit despite being inequitable.

The application of unjust enrichment to the present case would mean the pharmaceutical industry benefited financially to the detriment of others due to their practices. In other words, the pharmaceutical industry financially profited from prescription opioid sales while states and counties were expending resources trying to reduce the impact and adverse outcomes. As alleged by Beaver County and other similar counties, the defendants “profited and benefited from opioid purchases made” by the “expected and intended result of their conscious wrongdoing.” Moreover, it was “expected that defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.” Consequently, the defendants’ wrongdoing led to the expenditure of public resources “without receiving any of the purported benefits deceptively promoted.”
7.1.5 Racketeering

The common definition of racketeering is “the act or practice of making money through dishonest or illegal activities.” Racketeering claims arise under a federal statute, the Racketeer Influenced and Corrupt Organizations Act (RICO Act), which was codified as part of the Organized Crime Control Act of 1970 to address long-term, organized crime in interstate commerce in the U.S. Under the RICO Act, there are both civil remedies and criminal penalties. For a successful RICO claim, there must be “(a) a culpable “person” who (b) willfully or knowingly (c) commits or conspires to the commission of “racketeering activity” (d) through a “pattern” (e) involving a separate “enterprise” or “association in fact,” and (f) an effect on interstate or foreign commerce.” RICO claims are extensive and with the exception of Luzerne County, Pennsylvania, we have found no other claims concerning the opioid litigation, though that may change in the future. Civil remedies for a successful claim are abundant because the RICO Act permits treble damages. Treble damages are “[d]amages given by statute in certain cases, consisting of the single damages found by the jury, actually tripled in amount.” Therefore, the judgment in a successful RICO claim may be significant.

Presently, a RICO claim relies on the fact that prescription opioid manufacturers and primarily distributors knowingly and unlawfully repeatedly increased the volume of opioid pills in the market, specifically to areas with an unreasonable risk of diversion, and thus constitutes racketeering activity. An unreasonable risk of diversion may be established by evaluating the number of pills distributed to a certain market while considering the demographic of that market. For example, investigative journalist Eric Eyre uncovered that in Kermit, West Virginia, a town of 392 people, almost 9 million pills infiltrated the town during a 2-year period. This equates to nearly 11,480 pills per person per year or about 31 pills per person per day. Comparatively, the average person would take 2 to 4 pills per day depending on the prescription yet there was enough in Kermit for 31 pills per day. It is highly unlikely everyone in Kermit had a prescription for opioids. Thus, it is unreasonable that the opioid distributors consistently delivered that obscene number of pills to the town. Eyre further uncovered that between 2007 and 2012, 780 million hydrocodone and oxycodone pills were distributed throughout the state. Eyre’s work earned him a Pulitzer Prize for his journalism. To date, West Virginia is the only state whose prescription opioid distribution information is public. Therefore, evidence like the distribution information from West Virginia would help establish that the pharmaceutical industry knew an excessive number of opioid pills were distributed to areas with an unreasonable risk of diversion.

In Luzerne County’s complaint, it alleged that “[f]or over a decade, the RICO Defendants [the major opioid pharmaceutical companies] aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers.” While this is just a piece of a more extensive RICO allegation, it illustrates the essential argument Luzerne County has put forth. Moreover, nearly all RICO claims will be filed in a federal court or removed to federal court because it involves a federal statute. As such, Allegheny County, as well as others, will want to consider the implications of state court over federal court and vice versa.
7.2 Previous and Ongoing Strategies

7.2.1 Settlements

Our search also led us to a number of settlement agreements between pharmaceutical manufacturers and distributors and individuals and government entities. Specifically, we reviewed and analyzed a settlement agreement between Kentucky and Purdue Pharma, its subsidiaries, Abbott Laboratories, and Abbott’s subsidiaries. Kentucky commenced action in 2007, and Kentucky, Purdue, and Abbott reached a settlement agreement in December 2015. The settlement agreement resolved all claims that were or could have been brought against Purdue and Abbott in the initial action.

By entering into this agreement, Kentucky and all its counties and political subdivisions released any and all claims pertaining to the “covered conduct” defined in the agreement, which includes all conduct that would resemble or even remotely resemble wrongful or liable conduct in the opioid crisis. Moreover, Kentucky released any and all claims pertaining to the “covered conduct” and is not permitted to bring an action for conduct occurring before the settlement agreement date. Therefore, any subsequent action brought by Kentucky, its counties, and political subdivisions has to be in regards to facts and matters after the settlement agreement, which is December 18, 2015. Unfortunately, the time prior to 2016 is a significant period for opioid litigation, and Kentucky is now unable to file a new lawsuit for any conduct prior to December 2015. Further, Purdue expressly denied liability for all allegations. Finally, the agreement stipulated that the payment, $24 million, was to be placed in a restricted fund and the money can only be used in matters related to addiction prevention and treatment.

This particular settlement in Kentucky demonstrates the current events in opioid litigation. As initially mentioned, nearly all cases pertaining to the opioid crisis have either been dismissed or eventually settled. Thus, agreements like the one in Kentucky are common throughout the country.

7.2.2 Multidistrict Litigation

In 1968, Congress created the Judicial Panel for Multidistrict Litigation “to avoid duplication of discovery, to prevent inconsistent pretrial rulings, and to conserve the resources of the parties, their counsel and the judiciary.” The panel is comprised of 7 federal judges, and the panel determines if federal cases in different districts involving one or more common questions of fact should be coordinated or consolidated to a single district to promote judicial efficiency, economy, and fairness. In December 2017, the panel coordinated all pending federal cases pertaining to the opioid crisis to one district court, the Northern District of Ohio, under Judge Dan Polster. The description of the Opioid Multidistrict Litigation (MDL) states “Plaintiffs allege that the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain, and distributors failed to properly monitor suspicious orders of those prescription drugs—all of which contributed to the current opioid crisis.” Presently, there are hundreds of federal cases in the Opioid MDL, and there have been three conferences and hearings with counsel from both the plaintiffs and defendants since January 2018.

Judge Polster initiated the Opioid MDL by discussing his overall objective to work collaboratively with both parties to “dramatically reduce the number of opioids that are being disseminated, manufactured, and distributed. … Because sadly, everyday more and more people are being addicted, and they need treatment.” Judge Polster’s approach to achieve this objective is a bit untraditional because he would like to not litigate the case and point fingers at the guilty parties.
Rather, he wants to find solutions through extensive discovery, and he is prepared to involve any individual or entity necessary to find solutions. The MDL garners much publicity, and while it is not the only legal action, the size alone is shaping the present legal climate concerning opioids.

There are both positives and negatives to the MDL. The sheer number of cases involved amass to enormous resources available as well as privilege to the discovery, which would benefit the county and state tremendously. Alternatively, there may be different agendas for the parties involved and deter some municipalities, counties, and states from joining. It is true all plaintiffs want to abate this issue, but the means of doing so may differ, whether it is recouping past public expenditures or seeking damages for addiction treatment and further prevention. Thus, there are many factors to consider for any party looking to initiate litigation.

8 DAMAGES

The White House Council of Economic Advisers (CEA) recently expanded on a number of estimates by economists to include mortality and non-mortality costs of the opioid crisis. Mortality costs include an extensive analysis of cost to society. Non-mortality costs include health care and substance abuse treatment, criminal justice, and lost productivity costs. CEA estimates mortality costs were $431.7 billion and non-mortal costs were $72.3 billion for a total of $504 billion in 2015. We acknowledge that this is an estimate and a difficult number to accurately compute due to the numerous factors and high variability among individuals as well as states and counties. Thus, $504 billion is a preferred estimate, but may not be inclusive of every necessary cost and is therefore preliminary. We review these costs to further depict the magnitude of the issue and provide an initial starting place to determine the necessary resources to abate the opioid crisis.

8.1 Mortality Costs

Calculating mortality cost presents a challenge because there is no single way to put a monetary value on an individual’s life. The federal government frequently uses the “value of statistical life” (VSL), which is a calculation to monetarily quantify an individual’s life. The government uses VSL’s when drafting and implementing policies and regulations to determine the amount an individual is willing to pay to reduce the risk of death, but it still varies widely across departments. For example, the U.S. Department of Transportation uses $9.6 million as the median VSL, while the Environmental Protection Agency uses $10.1 million, and the Department of Health and Human Services uses $9.4 million (all in 2015 dollars). VSL’s typically have a low, central, and high value, and all are used to develop a range. Moreover, mortality cost estimates may control for age because VSL does vary within an individual’s own life based on a risk analysis. Therefore, the VSL estimate will be controlled to account for the age variation. We acknowledge that VSL’s are not necessarily an accurate representation for the entire population, but it is commonly used for these types of estimates, and thus a component of our general damages analysis.

In 2015, there were 33,091 officially reported opioid-related overdoses in the U.S., and most fatalities occurred in individuals between 25 and 55 years old. The overall mortality rate in the U.S. was 10.3 fatalities per 100,000, but the mortality rate for the 25-55 population was between 16.1 to 22.0 fatality per 100,000 in 2015. When calculating, the CEA adjusted for underreporting of fatal overdoses,
which was approximately 24 percent. Therefore, the total number of 2015 opioid-related overdoses was 41,033 when accounting for underreporting.\(^{209}\)

The CEA estimates that fatal opioid-related overdoses cost $431.7 billion in 2015. This number controls for age and also includes the likely underreported opioid-related fatal overdoses. Below is a table with the additional ranges based on the low, central, and high VSL values.

**Figure 25.1: Estimated Cost of Opioid-Involved Overdose Deaths in 2015 by VSL Assumption** \(^{210}\)

<table>
<thead>
<tr>
<th>VSL Assumption</th>
<th>Estimated Cost of Fatalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age-dependent</td>
<td>$431.7 billion</td>
</tr>
<tr>
<td>Low</td>
<td>$221.6 billion</td>
</tr>
<tr>
<td>Middle</td>
<td>$393.9 billion</td>
</tr>
<tr>
<td>High</td>
<td>$549.8 billion</td>
</tr>
</tbody>
</table>

### 8.2 Non-Mortality Costs

Non-mortality costs are comprised of health care and substance use treatment programs, criminal justice, and lost productivity costs. Criminal justice costs include costs associated with police protection, judicial and legal services and fees, corrections, and intergovernmental expenditures at the federal, state, and local levels. CEA expanded on previous research to estimate the total non-mortality prescription opioid and heroin-related costs to be $72.3 billion in 2015.\(^{211}\) This estimation was calculated using an average cost of $30,000 per individual based on 2013 data, which estimated health care and substance use treatment to be $29.4 billion, criminal justice to be $7.8 billion, and lost productivity to be $20.8 billion.\(^{212}\) The 2015 non-mortality cost was then estimated using the average cost per individual and the total number of people with an opioid disorder in the U.S., which was 2.4 million people.

The American Enterprise Institute (AEI) recently released a report that further analyzed the White House CEA findings to account for geographic disparities, and produced state-level data on the overall cost of the opioid crisis in 2015. AEI found non-mortality costs per capita and mortality costs per capita for each state. In Pennsylvania, AEI estimates the non-mortality cost per capita to be $205 and the mortality cost per capita to be $1,945. Mortality costs in AEI’s report are inclusive of the same CEA components – health care and substance use treatment programs, criminal justice, and lost productivity costs.\(^ {213}\)

**Figure 25.2: Estimated Cost of the Opioid Crisis in 2015 by VSL Assumption** \(^{214}\)

<table>
<thead>
<tr>
<th>VSL Assumption</th>
<th>Fatality Costs</th>
<th>Non-fatality Costs</th>
<th>Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age-dependent</td>
<td>$431.7 billion</td>
<td>$72.3 billion</td>
<td>$504.0 billion</td>
</tr>
<tr>
<td>Low</td>
<td>$221.6 billion</td>
<td>$72.3 billion</td>
<td>$293.9 billion</td>
</tr>
<tr>
<td>Middle</td>
<td>$393.9 billion</td>
<td>$72.3 billion</td>
<td>$466.2 billion</td>
</tr>
<tr>
<td>High</td>
<td>$549.8 billion</td>
<td>$72.3 billion</td>
<td>$622.1 billion</td>
</tr>
</tbody>
</table>
8.3 **Health Care Costs**

Independently, we analyzed the health care costs associated with hospital admissions for a prescription opioid or heroin-related overdose. It is estimated that the average hospital stay for a patient admitted to the ICU for a drug-related overdose is $92,400. This estimate is based on a comprehensive analysis of hospital admissions throughout the country conducted by Beth Israel Deaconess Medical Center in Boston.\(^{215}\) In 2016, 362 people were admitted to hospitals in Allegheny County for a prescription opioid or heroin-related overdose. On average, there is also a 3 percent readmission rate among those hospitalized for a prescription opioid or heroin-related overdose within that same year. Therefore, the total number of hospitalizations in Allegheny County in 2016 was approximately 373 individuals. Specifically, there were 183 prescription opioid-related overdose admissions and 179 heroin-related overdoses. There were approximately 11 additional people readmitted in the same year for a drug-related overdose. Based on the number of hospitalizations in Allegheny County in 2016, the estimated hospitalization cost was $34,465,200.\(^{216}\)

In 2016, 3,299 people were admitted to hospitals in Pennsylvania for a prescription opioid or heroin-related overdose. Accounting for the 3 percent readmission rate, the total number of hospitalizations in Pennsylvania in 2016 was approximately 3,398 individuals. Specifically, there were 1,775 prescription opioid-related overdose admissions and 1,524 heroin-related overdoses. There were approximately 99 additional people readmitted in the same year for a drug-related overdose. Based on the number of hospitalizations in Pennsylvania in 2016, the estimated hospitalization cost was $313,975,200.\(^{217}\)

**Figure 26: Pennsylvania and Allegheny County Estimated Health Care Costs 2016**

<table>
<thead>
<tr>
<th>Allegheny County(^{218})</th>
<th>Prescription Opioid</th>
<th>Heroin</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># of admissions</td>
<td>183</td>
<td>179</td>
<td>362</td>
</tr>
<tr>
<td>Cost</td>
<td>$16,909,200</td>
<td>$16,539,600</td>
<td>$33,448,800</td>
</tr>
<tr>
<td>3% readmission rate, # of admissions</td>
<td>5.49</td>
<td>5.37</td>
<td>10.86 =&gt; 11</td>
</tr>
<tr>
<td>Readmission cost</td>
<td></td>
<td></td>
<td>$1,016,400</td>
</tr>
<tr>
<td>Total cost</td>
<td></td>
<td></td>
<td>$34,465,200</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pennsylvania</th>
<th>Prescription Opioid</th>
<th>Heroin</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># of admissions</td>
<td>1,775</td>
<td>1,524</td>
<td>3,299</td>
</tr>
<tr>
<td>Cost</td>
<td>$164,010,000</td>
<td>$140,817,600</td>
<td>$304,827,600</td>
</tr>
<tr>
<td>3% readmission rate, # of admissions</td>
<td>53.25</td>
<td>45.72</td>
<td>98.97 =&gt; 99</td>
</tr>
<tr>
<td>Readmission cost</td>
<td></td>
<td></td>
<td>$9,147,600</td>
</tr>
<tr>
<td>Total cost</td>
<td></td>
<td></td>
<td>$313,975,200</td>
</tr>
</tbody>
</table>
There are limitations to this calculation as the hospital admission numbers are not inclusive of individuals treated in the emergency department, received naloxone, or fatally overdosed. Additionally, the estimated cost of treatment was based on ICU admissions and may not be wholly indicative of the demands and care of Allegheny County residents. Therefore, the health care cost is a baseline and there are likely additional costs that were not a factor in our calculation.

Additional health care costs that should be highlighted include the cost of Neonatal Abstinence Syndrome (NAS). As previously mentioned NAS pertains to neonates who experience symptoms of withdrawal upon birth as a result of either licit or illicit maternal drug use. In Allegheny County, there were 399 babies born with NAS between 2016 and 2017. The average cost of treatment for a neonate with NAS is $66,700. The total cost of treating neonates with NAS between 2016 and 2017 in Allegheny County was $26,613,300. In the state of Pennsylvania, the total cost of treating neonates with NAS in 2017 was $127,530,400.219

As previously stated, we provide these numbers as a starting place. As such, we did not aggregate the total costs because it is incomplete. Further, we do not have the resources to conduct a complete economist analysis.

9 SUMMARY

We have established the history of opioid use around the world and this country. There were periods of steady and drastic increase of opioid use and now a transition to illicit synthetic opioids like heroin and fentanyl. The impact on human life by drug-related overdoses is astounding; in 2016 there were 64,070 fatal drug-related overdoses nationally, 4,627 in Pennsylvania, and 617 locally in Allegheny County. Moreover, it is estimated that the national economic impact of this crisis is $504 billion. Consequently, the magnitude of this issue is significant and must be addressed.

Our analysis supports a proposal to bring the pharmaceutical industry into negotiations to help mitigate the issue rather than engage in extended, uncertain, and expensive litigation. By collaborating across the various sectors, the resources necessary to provide treatment and programs for substance use can be allocated to the appropriate entities. Therefore, Section 10 discusses our recommendations for Allegheny County to address the opioid crisis plaguing the country and community. The recommendations will not only help those with substance use, but will further promote and address the goals of the Child Death Review Team, because this issue affects every population. In response to the question “Want to solve the opioid crisis,” Eliza Wheeler of the Harm Reduction Coalition in San Francisco states: “here you go: safer drugs, safer places to use drugs, safer ways to use drugs, better treatment, more of it, more naloxone for people who use drugs, more harm reduction, no more incarceration, no more racist, murderous drug policy, no more drug war, eradicate poverty, make a world people want to live in.”220 While this is a tall order, we collectively have to start somewhere, and this analysis is our contribution.


10 RECOMMENDATIONS

Our research has led to the following conclusion: Allegheny County should work in collaboration with the Attorney General of the Commonwealth of Pennsylvania and the other departments and counties to persuade the numerous stakeholders that litigation is expensive, time consuming, and not results-driven, and therefore must come to an agreement to combat the opioid crisis. Primary stakeholders include the pharmaceutical manufacturers and distributors we have identified in this report, but this is by no means an exhaustive list.

Support for an agreement of this magnitude is predominantly for economical and efficiency reasons. Based on our analysis of the economic impact of the opioid crisis across the country and in Allegheny County, at minimum $504 billion is necessary to compensate municipalities, counties, and states for past public expenditures and future costs associated with public and private health care costs, programs, and overall society. The rationale is balanced with resolving, or at least effectively addressing, the issue as soon as possible because each day brings additional fatal overdoses. New lawsuits are also filed each day, further burdening the judicial system, limiting government resources, as well as the primary stakeholder's resources. Therefore, it is in the best interest of every party involved to reallocate financial resources and effort from litigation toward a proactive solution by coming to an agreement.

Our rudimentary health care cost estimate totaled over $313 million for the state of Pennsylvania alone, not accounting for all other contributing costs. To effectively address the opioid crisis in Allegheny County and Pennsylvania as a whole, substantially more funding is necessary to provide the requisite care moving forward as this issue is ongoing, and there will be residual effects for years to come.

Upon execution of the agreement, a fund can then be established and used for drug-related treatment and programs. Consequently, we have identified the following areas where resources will be most impactful and address the goals of the Child Death Review Team.

- Adequate numbers of social workers and behavioral health providers must be available in all hospital based obstetrical clinics to meet the psychosocial needs of patients
  - Extend to all family members
- Improve identification coordination between those likely to identify children at risk
- Provide universal access to naloxone and overdose prevention education
- Improve access to treatment, support groups and other counseling programs
- Provide education about:
  - Utilization of medication-assisted treatment (MAT)
  - Potential high-risk periods
  - Increasing prevalence of fentanyl in most drugs
- Provide funding to schools so they can:
  - Train staff and students about overdose risks and the use of naloxone hydrochloride (i.e. Narcan)
  - Perform evidence-based screening procedures for unhealthy substance use such as SBIRT
  - Deliver/coordinate evidence-based prevention/educational activities
• Invest in treatment programs and monitoring the prescribing of medication which may lead to addiction
• By investing in treatment programs and monitoring the prescribing of medications which may lead to addiction, the demand for illegal drugs in Allegheny County, especially the demand for opiates, will decrease

Secondary recommendations include:
• Reassess Pennsylvania's PDMP and make it integration-friendly with electronic medical records systems to ensure efficiency
• Ensure all physicians licensed and practicing in Pennsylvania are registered with the PDMP
## 11 APPENDIX

### 11.1 Tables

Table 1. 2016 Decedent Zip Code Fatal Overdoses with Number of Fatalities > 10

<table>
<thead>
<tr>
<th>Zip Code</th>
<th>Cities</th>
<th>Boroughs</th>
<th>Townships</th>
<th>Neighborhoods</th>
<th>No. Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>15210</td>
<td>Pittsburgh</td>
<td>Baldwin, Mount Oliver</td>
<td></td>
<td>Allentown, Arlington, Arlington Heights, Beltzhoover, Bon Air, Brookline, Carrick, Knoxville, Mount Oliver, Mount Washington, Mt Oliver, Overbrook, Saint Clair, Southside Flats, Southside Slopes</td>
<td>32</td>
</tr>
<tr>
<td>15212</td>
<td>Pittsburgh</td>
<td>Reserve, Ross</td>
<td></td>
<td>Allegheny Center, Allegheny West, Brighton Heights, California-Kirkbride, Central Northside, Chateau, East Allegheny, Fine View, Herrs Island, Marshall-Shadeland, North Shore, Northview Heights, Perry North, Perry South, Spring Garden, Spring Hill-City View, Strip District, Summer Hill, Troy Hill</td>
<td>27</td>
</tr>
<tr>
<td>15136</td>
<td>Pittsburgh</td>
<td>McKees Rocks</td>
<td>Kennedy, Robinson, Stowe</td>
<td></td>
<td>24</td>
</tr>
<tr>
<td>15132</td>
<td>McKeesport</td>
<td>Port Vue, Versailles, White Oak/ North Versaille</td>
<td>North Versailles</td>
<td></td>
<td>19</td>
</tr>
<tr>
<td>15236</td>
<td>Pittsburgh</td>
<td>Baldwin, Brentwood, Jefferson Hills, Pleasant Hills, West Mifflin, Whitehall</td>
<td>South Park</td>
<td></td>
<td>17</td>
</tr>
<tr>
<td>15206</td>
<td>Pittsburgh</td>
<td></td>
<td>Penn Hills</td>
<td>Bloomfield, East Liberty, Friendship, Garfield, Highland Park, Homewood North, Homewood West, Larimer, Lincoln-Lemington-Belmar, Morningside, Point Breeze, Shadyside, Stanton Heights</td>
<td>16</td>
</tr>
<tr>
<td>15226</td>
<td>Pittsburgh</td>
<td>Dormont</td>
<td>Baldwin, Mount Lebanon</td>
<td>Beechview, Beltzhoover, Bon Air, Brookline, Carrick, Mount Washington, Overbrook</td>
<td>15</td>
</tr>
<tr>
<td>15227</td>
<td>Pittsburgh</td>
<td>Baldwin, Brentwood, Whitehall</td>
<td></td>
<td>Carrick, Overbrook</td>
<td>14</td>
</tr>
<tr>
<td>15146</td>
<td>Trafford</td>
<td></td>
<td>Monroeville, Murrysville (municipalities)</td>
<td></td>
<td>13</td>
</tr>
<tr>
<td>15216</td>
<td>Pittsburgh</td>
<td>Dormont</td>
<td>Mount Lebanon, Scott</td>
<td>Banksville, Beechview, Bon Air, Brookline, Duquesne Heights, Mount Washington, Ridgmont</td>
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<tr>
<td>15205</td>
<td>Pittsburgh</td>
<td>Crafton, Green Tree, Ingram, Pennsbury Village, Thornburg</td>
<td>Collier, Kennedy, Robinson</td>
<td>Crafton Heights, East Carnegie, Fairywood, Oakwood, Westwood, Wind Gap</td>
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<tr>
<td>15219</td>
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<td></td>
<td>Bedford Dwellings, Bluff, Central Business District, Crawford Roberts, Elliot, Middle Hill, Mount Washington, Oakland, Polish Hill, South Shore, Southside Flats, Strip District, Terrace Village, Upper Hill, West End, West Oakland</td>
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<tr>
<td>15211</td>
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<td></td>
<td>Allentown, Beltzhoover, Duquesne Heights, Mount Washington, South Shore, West End</td>
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</tr>
<tr>
<td>Zip Code</td>
<td>Cities</td>
<td>Boroughs</td>
<td>Townships</td>
<td>Neighborhoods</td>
<td>No. Deaths</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------</td>
<td>------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------</td>
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<tr>
<td>15212</td>
<td>Pittsburgh</td>
<td>Reserve, Ross</td>
<td></td>
<td>Allegheny Center, Allegheny West, Brighton Heights, California-Kirkbride, Central Northside, Chateau, East Allegheny, Fine View, Herrs Island, Marshall-Shadeland, North Shore, Northview Heights, Perry North, Perry South, Spring Garden, Spring Hill-City View, Strip District, Summer Hill, Troy Hill</td>
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<tr>
<td>15210</td>
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<td>Baldwin, Mount Oliver</td>
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<td>Allentown, Arlington, Arlington Heights, Beltzhoover, Bon Air, Brookline, Carrick, Knoxville, Mount Oliver, Mount Washington, Mr Oliver, Overbrook, Saint Clair, Southside Flats, Southside Slopes</td>
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<tr>
<td>15136</td>
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<td>15272</td>
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<td>Carrick, Overbrook</td>
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<td>Churchill, Plum, Wilkinsburg</td>
<td>Penn Hills, Wilkins</td>
<td>East Hills, Lincoln-Lemington, Belmar</td>
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<tr>
<td>15216</td>
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<td>Dormont</td>
<td>Mount Lebanon, Scott</td>
<td>Banksville, Beechview, Bon Air, Brookline, Duquesne Heights, Mount Washington, Ridgemont</td>
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</tr>
<tr>
<td>15205</td>
<td>Pittsburgh</td>
<td>Crafton, Green Tree, Ingram, Pennsby Village, Thornburg</td>
<td>Collier, Kennedy, Robinson</td>
<td>Crafton Heights, East Carnegie, Fairywood, Oakwood, Westwood, Wind Gap</td>
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<tr>
<td>15120</td>
<td>McKeesport</td>
<td>Port Vue, Versailles, White Oak/ North Versaille</td>
<td>North Versailles</td>
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<tr>
<td>15120</td>
<td>Pittsburgh</td>
<td>Homestead, Munhall,</td>
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<td>Lincoln Place</td>
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</table>

Table 2. 2017 Decedent Zip Code Fatal Overdoses with Number of Fatalities ≥ 10
<table>
<thead>
<tr>
<th>Zip Code</th>
<th>City</th>
<th>Neighborhoods</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>15221-22</td>
<td>Pittsburgh</td>
<td>Braddock Hills, Churchill, Edgewood, Forest Hills, Swissvale, Wilkinsburg</td>
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</tr>
<tr>
<td>15206</td>
<td>Pittsburgh</td>
<td>Penn Hills</td>
<td>12</td>
</tr>
<tr>
<td>15108</td>
<td>Coraopolis</td>
<td>Findlay, Kennedy, Moon, North Fayette, Robinson</td>
<td>12</td>
</tr>
<tr>
<td>15122-22</td>
<td>Munhall, Pleasant Hills, West Mifflin, Whitaker</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>
Figure 27: Fatal Overdoses in Allegheny County by Drug and Count January 1, 2016 - October 23, 2017
11.2 Methods

11.2.1 Literature Review

The information used in this report was put together from government sources, like the CDC, NIH and other entities within the Department of Health and Human Services. For Allegheny County drug-specific death rates, information was obtained from Allegheny County’s Medical Examiner. There was also an extensive literature review performed of peer reviewed scientific journals that allowed for the determination of current costs and approaches that are being accrued and employed in the opioid crisis. A web-based search was done to find all journalistic reporting completed to uncover the true nature of the opioid crisis, including the book Dreamland: A True Tale of America’s Opioid Epidemic by Sam Quinones. This was utilized for background in the opioid crisis, reporting in the current extent of the crisis, and the numbers who have died because of it, trends in drug use, Medicaid information, global and national trends to approaching treatment and the economic toll that this crisis has extracted on our country.

Legal research was conducted by performing a general web search for past and ongoing litigation regarding opioids. This led to countless news articles in both local and national publications about rising overdose rates and actions municipalities, states, and others have taken to address this issue. The general web search resulted in identifying more than a dozen states and their respective attorney generals that have filed a lawsuit against the leading opioid manufacturers and distributors. Consequently, we were able to search online court dockets based on the state and date of filing found in recent news articles.

We also used the two online legal databases to research national law reviews to obtain a preliminary perspective on the overall opioid litigation occurring throughout the United States. To access the dockets, we utilized two online legal databases, LexisNexis and Westlaw. From there, we specified what state docket we wanted to query, followed by “Purdue” in the search bar, and narrowed the search results to the general time frame the lawsuit was filed by the state. We chose to search “Purdue” because all actions we encountered had listed Purdue as a defendant. As such, it was an easier way to narrow the results and identify the leading case filed by the states. This process was repeated for each state identified in the initial web search as states that filed complaints.

We also found many complaints were filed in federal court so we then conducted a general search in federal court dockets, or narrowed the scope of search if the appropriate federal court was identified. Upon doing this, we found almost all ongoing litigation addressing the opioid crisis, which is more than 400 cases, were consolidated by the judicial panel to form the opioid multidistrict litigation (MDL) at the end of 2017. Judge Dan Aaron Polster of the United States District Court Northern District of Ohio is overseeing the MDL. Each MDL is given a specific master docket number, and each order pertaining to the MDL is publically available through the Northern District of Ohio’s website. From there, we were able to review the various court documents pertaining to the MDL. Additionally, there were a number of settlement and plea agreements found in our preliminary research that we then researched further using the legal databases.

11.2.2 Statistical Methods

Visit the following website: https://catalog.data.gov/dataset/allegheny-county-fatal-accidental-overdoses
Click on file links.

2017- Click on URL link: https://data.wprdc.org/dataset/7fb0505e-8e2c-4825-b22c-4fbe8fe8010/resource/2d963e35-4f69-495e-985e-55acd72c87ca/download/crimelabaccidentaldrugdeathsextract2017.csv
2016- Click on URL link: https://data.wprdc.org/dataset/7fb0505e-8e2c-4825-b22c-4fbee8fc8010/resource/386ca0ed-717d-46d3-8ed2-da37553ee6d1/download/crimelabaccidentaldrugdeathsextract2016.csv

These links open into data file format. Copy all data from file.

Open Excel document.
Create 6 separate pages within 1 Excel file by pressing the “+” sign. Paste the 2017 data into an excel sheet.
After data is pasted, click “Data” tab.
Click “Text to Columns…”
Select “Delimited- Characters such as commas or tabs separate each field”. Click “Next”. Select “Comma” as the Delimiter. Click “Next.” Select General as the Column Data Format. Click “Finish”

Organizing Data: All functions performed on Mac computer
The data file drug list is organized into groups titled Combined OD1, Combined OD2, Combined OD3, Combined OD4, Combined OD5, Combined OD6, Combined OD7. In order to use the data file in STATA software, the data must be organized by individual drug and coded in binary. The following steps were taken to organize the data.
Create a Pivot Table for Each data file Sheet. Highlight all data from 2016. Click the “Data” tab and select “Summarize with PivotTable.” Select “Okay”.
Click “Combined OD1” from Field Names and drag to “Rows” box. The resulting table will list all drugs listed in the Combined OD1 column in alphabetical order. In the original data entry sheet, create a new column for each listed drug in alphabetical order. The columns will descend from column H to column BY for year 2016. The columns will descend from column H to column CA for year 2017. Once all drugs have been allotted a column from the Combined OD1 field group, deselect “Combined OD1” from Field Names. Complete this process for Combined OD2, Combined OD3, Combined OD4, Combined OD5, Combined OD6, and Combined OD7. Create only 1 column for each drug.

Return to the data sheet with newly created drug columns. Select the “Sort & Filter” button. Select “Filter.” Select the downward facing arrow next to “Combined OD1” column header. In the drop-down menu, unselect the box next to “Select All.” Going in reverse alphabetical order, look through the drop-down menu for the last drug column header (for year 2016, this is Zolpidem). If the drug is listed on the drop-down menu, select the corresponding box. All incidences of the drug in Combined OD1 group will be filtered and listed in the Excel sheet. Under the corresponding drug header in the drug column, type a “1” in the appropriate box to indicate the drug was present in the overdose. Complete this process for Combined OD2, Combined OD3, Combined OD4, Combined OD5, Combined OD6, and Combined OD7 for every drug. Once the drug column has been completed, highlight the completed drug column and right click. Select “Hide.” Complete this process for every drug column until reaching the first listed drug, column H.
Once all drug incidence coding is completed, unhide all columns. Right click on the hidden columns and select “Unhide.” Continue unhiding columns until all columns are listed.
Under each drug column, type a “0” in all empty boxes to indicate the drug was not present in the overdose. The resulting product is a list of overdose deaths coded in binary, indicating if each drug was present or not present in the overdose.

Analyzing Data: All functions performed on Mac computer.
Create a Pivot Table for Each data file Sheet. Highlight all data from 2016. Click the “Data” tab and select “Summarize with PivotTable.” Select “Okay”.

Count Death Time:
Click “Death Time” from Field Names and drag to “Rows” box. Click Death Time from field names and drag to “Values” box. Right click on “Sum of Death Time” in the Values box and select “Field Settings.”
Click “Summarize by”, then “Count.” Select “Okay”. The resulting data is the number of overdose deaths by Time of Death. Once data is collected, unselect the Death Time Field in the Field Name box.

**Count Decedent Zip:**
Click “Decedent Zip” from Field Names and drag to “Rows” box. Click Decedent Zip from field names and drag to “Values” box. Right click on “Sum of Decedent Zip” in the Values box and select “Field Settings.” Click “Summarize by”, then “Count.” Select “Okay”. The resulting data is the number of overdose deaths by decedent zip code in each Allegheny County zip code. Once data is collected, unselect the Decedent Zip Field in the Field Name box.

**Count Age:**
Click “Age” from Field Names and drag to “Rows” box. Click Age from field names and drag to “Values” box. Right click on “Sum of Age” in the Values box and select “Field Settings.” Click “Summarize by”, then “Count.” Select “Okay”. The resulting data is the number of overdose deaths by age. Once data is collected, unselect the Age Field in the Field Name box.

**Count Sex:**
Click “Sex” from Field Names and drag to “Rows” box. Click “Sex” from field names and drag to “Values” box. Right click on “Sum of Sex” in the Values box and select “Field Settings.” Click “Summarize by”, then “Count.” Select “Okay”. The resulting data is the number of overdose deaths by gender. Once data is collected, unselect the Sex Field in the Field Name box.

**Count Race:**
Click “Race” from Field Names and drag to “Rows” box. Click “Race” from field names and drag to “Values” box. Right click on “Sum of Race” in the Values box and select “Field Settings.” Click “Summarize by”, then “Count.” Select “Okay”. The resulting data is the number of overdose deaths by race. Once data is collected, unselect the Race Field in the Field Name box.

**Count Death by Drug:**
Click appropriate drug name from Field Names and drag to “Rows” box. Click appropriate field names and drag to “Values” box. Right click on “Sum of appropriate drug” in the Values box and select “Field Settings.” Click “Summarize by,” then “Count.” Select “Okay.” The table will indicate the number of deaths with the appropriate drug present under Row Label “1.” The number of deaths without the appropriate drug present will be the Count under Row Label “0.”

**Chi-Square Analysis:**
Using the Count data by drug calculated in excel, create a Chi-Square table using the calculated drug totals.
12 REFERENCES

13 Stolberg (pp. 8-31).
14 Stolberg (pp. 50-53).
15 Stolberg (pp. 35).
16 Stolberg (pp. 54-55, 35, 56).
17 Stolberg (pp. 203).
23 Quinones (pp. 124-5).
24 Quinones (pp. 124-5).
25 Quinones (pp. 138).
26 Stolberg (pp. 204).


34 The Food and Drug Administration. (2017).


International Trade Administration. (2016).


Complaint at 2, County of Beaver v. Purdue Pharma L.P.


