

Confronting the Opioid Epidemic

Communication from the Department of the Corporation Counsel,
relating to potential litigation against the manufacturers, distributors,
and retailers of opioid pain medications, and related matters.

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The Opioid Epidemic Nationally

In 2015, over 300 million prescriptions were written for opioids, which is more than enough to give every American adult their own bottle of pills.¹

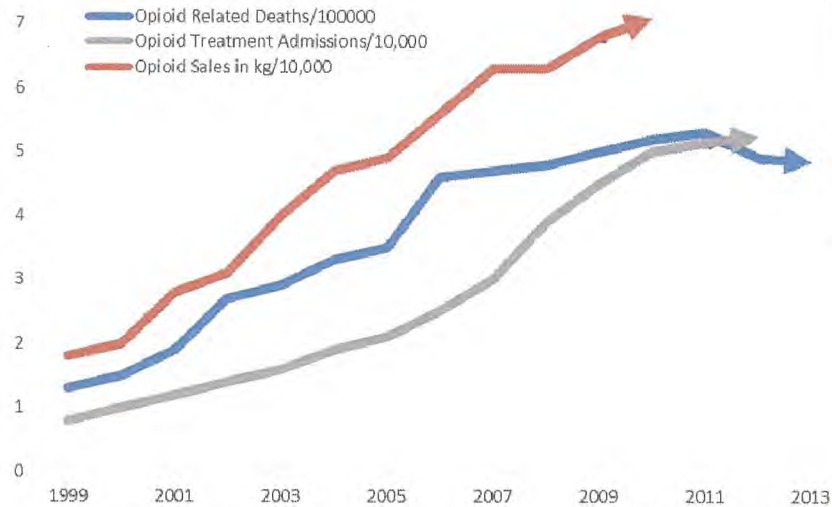
- **Hydrocodone** (e.g., Vicodin)
- **Oxycodone** (e.g., OxyContin)
- **Oxymorphone** (e.g., Opana)
- **Methadone** (especially when prescribed for pain)

(1) Ameet Sarpatwari, Michael S. Sinha, Aaron S. Kesselheim, "The Opioid Epidemic: Fixing a Broken Pharmaceutical Market", Harvard Law & Policy Review, Volume 11, Number 2 (Summer, 2017): pp. 463-484

The Opioid Epidemic

Parallels of Opioid Sales with Opioid Treatment and Deaths

- Opioids have claimed 175,000 lives from 1999-2013.
- In 2013 alone, 16,235 deaths attributed to opioid overdoses.
- From 1999 to 2010, a 4-fold increase in opioid sales paralleled a more than 4-fold increase in prescription opioid overdose deaths.



(1) Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on Jul 26, 2017. ICD-10 Codes: X40-X44, X60-X64, X85, and Y10-Y14

(2) Opioid sales, opioid treatment admissions, and opioid-related deaths. Sources: CDC Wonder, 2015; DEA ARCOS, 2015; TEDS, 2015

The Opioid Epidemic

Costs of the Opioid Epidemic

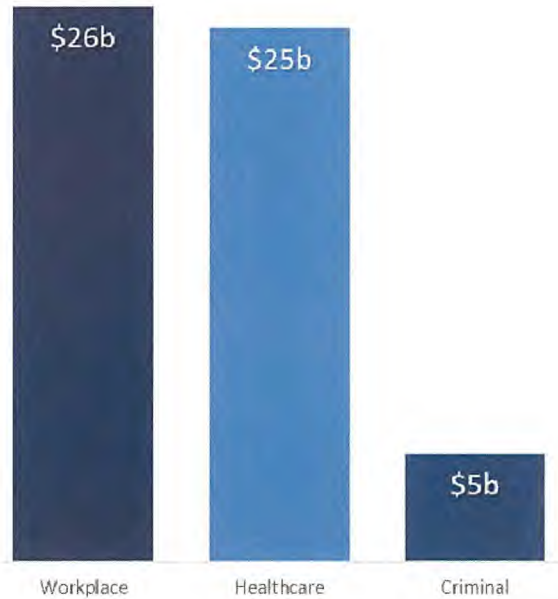
- ▶ In the United States, prescription opioid abuse costs are about **\$55.7 billion annually**¹

Of this amount:

- ▶ 46% is attributable to workplace costs (e.g., lost productivity): **\$26 Billion**
- ▶ 45% to healthcare costs (e.g., abuse treatment): **\$25 Billion**
- ▶ 9% to criminal justice costs: **\$5 Billion**

(1) Data Source: CDC, Prescription Drug Overdose data.

Prescription Opioid Abuse Costs
in Billions



The Opioid Epidemic

Studies Show: Heroin Use is Tied to Prescription Opioid Abuse

- ◇ Prescription opioid abuse precedes heroin use by an average of 2 years¹
- ◇ Frequent prescription opioid users are more likely to switch to heroin²
- ◇ Abuse of prescription opioids has been associated with a 40-fold increased risk of dependence on or abuse of heroin²

*Fundamentally, prescription opioids and heroin are each elements of a larger epidemic of opioid-related disorders and death. Viewing them from a unified perspective is essential to improving public health. The perniciousness of this epidemic requires a multipronged interventional approach that engages all sectors of society³.
(Compton, et al, 2016)*

(1) Suryaprasad AG, White JZ, Xu F, et al. Emerging epidemic of hepatitis C virus infections among young nonurban persons who inject drugs in the United States, 2006-2012. Clin Infect Dis. 2014;59(10):1411-1419.

(2) Jones CM, Logan J, Gladden RM, Bohm MK. Vital signs: demographic and substance use trends among heroin users - United States, 2002-2013. Morbidity and Mortality Weekly Report (MMWR). Atlanta, GA: Centers for Disease Control and Prevention; 2015.

(3) Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H. N Engl J Med 2016; 374:154-163 January 14, 2016 DOI: 10.1056/NEJMr1508490

The Opioid Epidemic

1 in 12 Doctors Being Paid by Pharmaceuticals Marketing Opioids

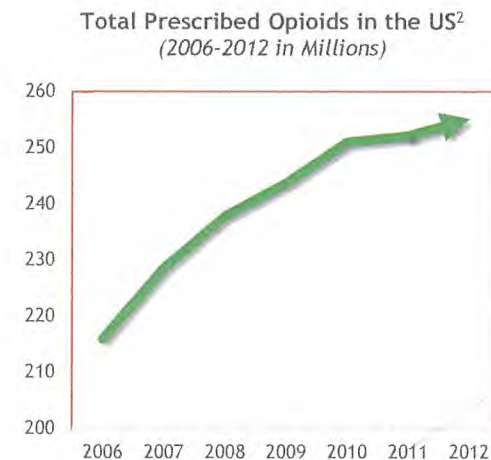
- ◇ **1 in 12 Doctors Being Paid by Pharmaceuticals Marketing Opioids:¹**
 - ◇ From 2013 to 2015 - more than **375,000** non-research opioid-related payments were made to more than **68,000** physicians, totaling more than **\$46 million**
- ◇ **The Top 1% of Physicians Received 83% of the Payment**
- ◇ **Family and General Practice Physicians received the most payments (almost 1 in 5)**

(1) Scott E. Hadland, Maxwell S. Krieger, Brandon D. L. Marshall, "Industry Payments to Physicians for Opioid Products, 2013-2015", American Journal of Public Health 107, no. 9 (September 1, 2017): pp. 1493-1495.
DOI: 10.2105/AJPH.2017.303982
PMID: 28787210

The Opioid Epidemic

Over Prescription of Opioids a 'Fundamental Cause'

- ◇ Opioid prescriptions rose 104% from 2000 to 2010¹
- ◇ 300 million prescriptions for opioids were written in 2015 alone
 - ◇ More than one for every US adult
- ◇ Surge in prescriptions may be traced back to under treatment of chronic pain in the 1980s and 1990s
- ◇ Many prominent physicians urged usage of opioids for pain - some stating that the risk of misuse and addiction was low
- ◇ 1995 - Purdue Pharma received FDA approval for extended release OxyContin
- ◇ Intensive marketing and limited policing of fraudulent activity leads to 'blockbuster' success for Purdue, OxyContin and other major opioids



(1) Ameet Sarpatwari, Michael S. Sinha, Aaron S. Kesselheim, "The Opioid Epidemic: Fixing a Broken Pharmaceutical Market", Harvard Law & Policy Review, Volume 11, Number 2 (Summer, 2017): pp. 463-484.

(2) Source for all prescribing data: QuintilesIMS Transactional Data Warehouse (TDW) 2006-2016. Accessed at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>

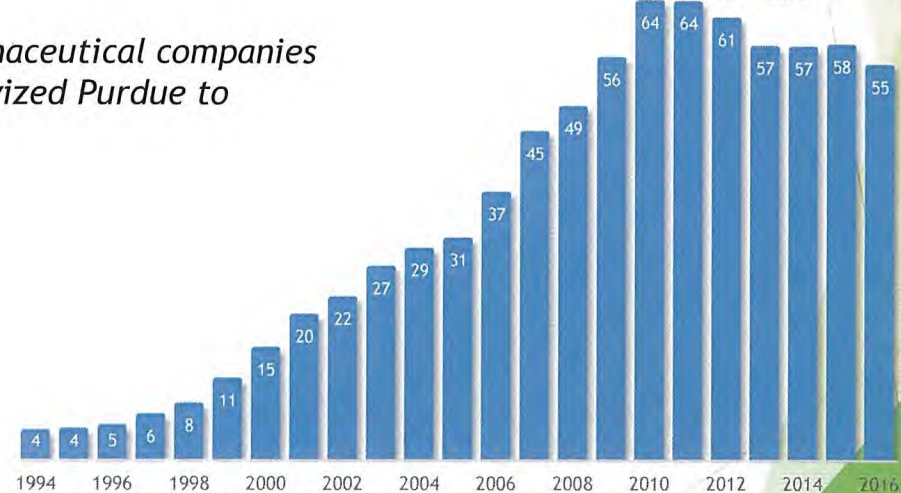
The Opioid Epidemic

The OxyContin Blockbuster

“Purdue’s success was attributable in part to low patenting standards that enabled the company to secure and extend market exclusivity for extended-release oxycodone, providing motivation for its aggressive marketing.

*A history of tepid enforcement against pharmaceutical companies engaging in illegal marketing further incentivized Purdue to make false claims about the safety and effectiveness of the drug. Both practices helped drive opioid overuse and misuse, with tragic public health consequences.”**

Oxycodone
Distribution and Consumption
in Metric Tonnes ^{1,2}



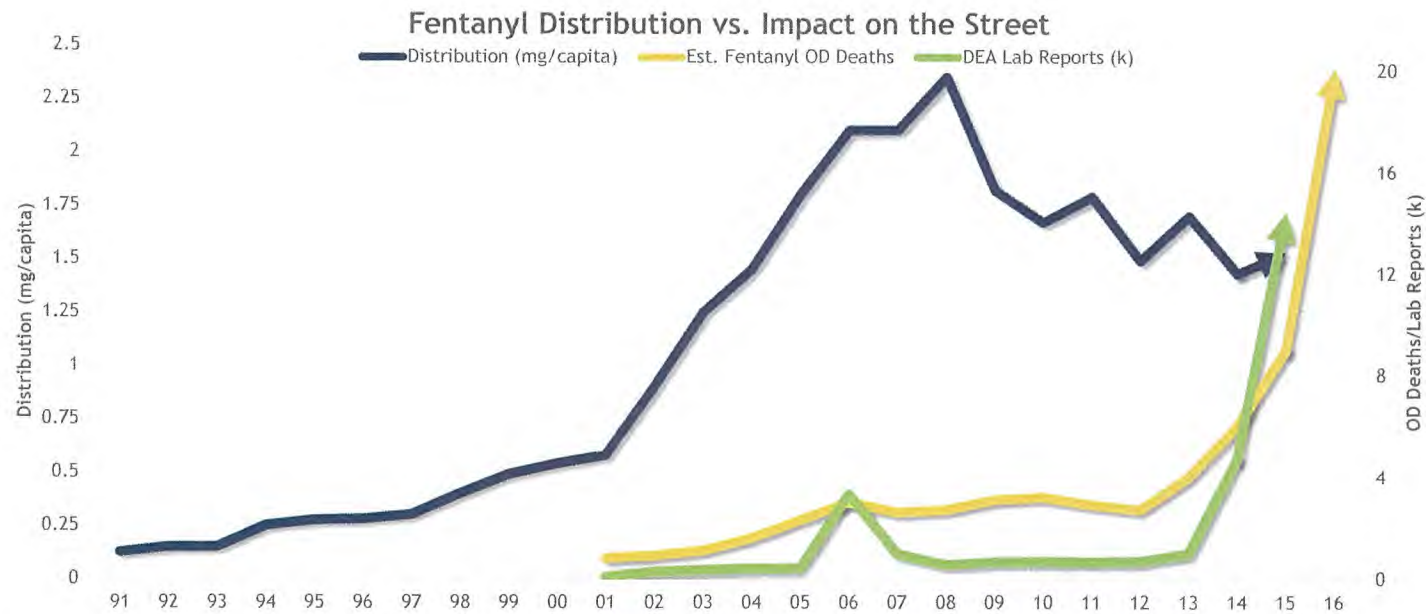
*Ameet Sarpatwari, Michael S. Sinha, Aaron S. Kesselheim, “The Opioid Epidemic: Fixing a Broken Pharmaceutical Market”, Harvard Law & Policy Review, Volume 11, Number 2 (Summer, 2017): pp. 463-484.

(1) US Department of Justice. Automation of Reports and Consolidated Orders System (ARCOS). Springfield, VA: US Department of Justice, Drug Enforcement Administration; 2017. Available at <http://www.deadiversion.usdoj.gov/arcos/index.html>. Accessed July 25, 2017.

(2) International Narcotics Control Board; World Health Organization population data By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2017

The Opioid Epidemic

Fentanyl & The Next Wave of the Opioid Epidemic



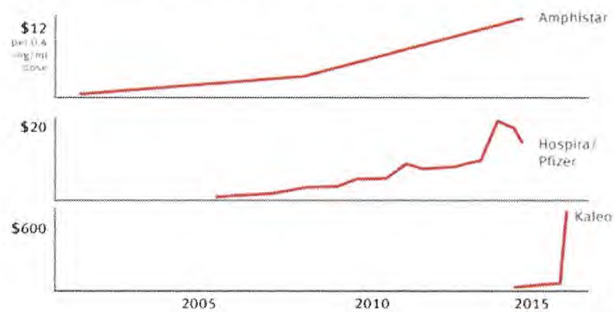
(1) Fentanyl: The Next Wave of the Opioid Crisis, Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, United States House of Representatives, 115th Congress, 1st Session, 3-21-17
(2) Data Source: US Department of Justice. Automation of Reports and Consolidated Orders System (ARCOS). Springfield, VA: US Department of Justice, Drug Enforcement Administration; 2017.
(3) Data Source 2: International Narcotics Control Board; World Health Organization population data By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2017
(4) U.S. Drug Enforcement Administration, Diversion Control Division. (2017). NFLIS Brief: Fentanyl, 2001-2015. Springfield, VA: U.S. Drug Enforcement Administration.
(5) Source: National Center for Health Statistics, Centers for Disease Control and Prevention

The Opioid Epidemic

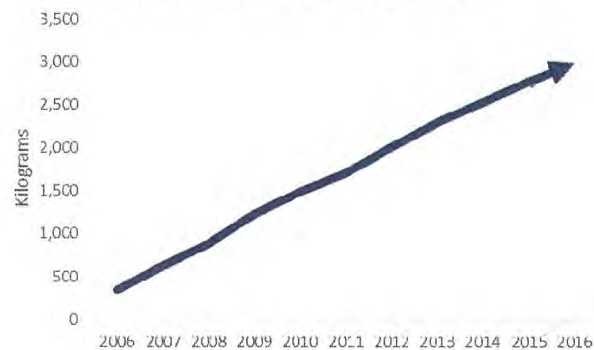
Taxpayers Footing the Bill - Naloxone Costs & Distribution

- ◇ State, County and City programs to help individuals battling opioid abuse are needed, but can also further enable the opioid epidemic
 - ◇ First responders, law enforcement or others are being trained how to administer Buprenorphine/Naloxone (Narcan), the lifesaving antidote which is used to block the effects of opioids, especially in overdose
 - ◇ The increasing demand Narcan has led to pharmaceutical companies drastically increasing the price
 - ◇ Taxpayer funds are used to pay for Narcan, while both prices and pharmaceutical profits are sharply on the rise

Between 2005 - 2015 pharmaceutical companies have drastically increased prices for naloxone products. Prices continue to rise today.



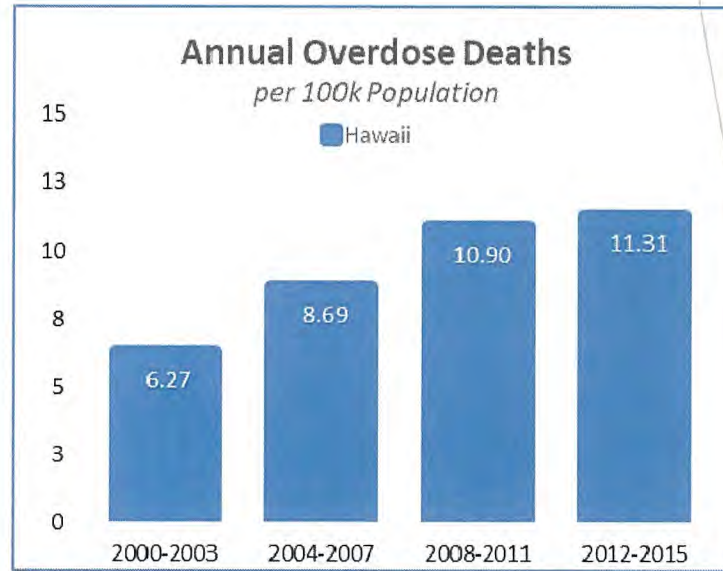
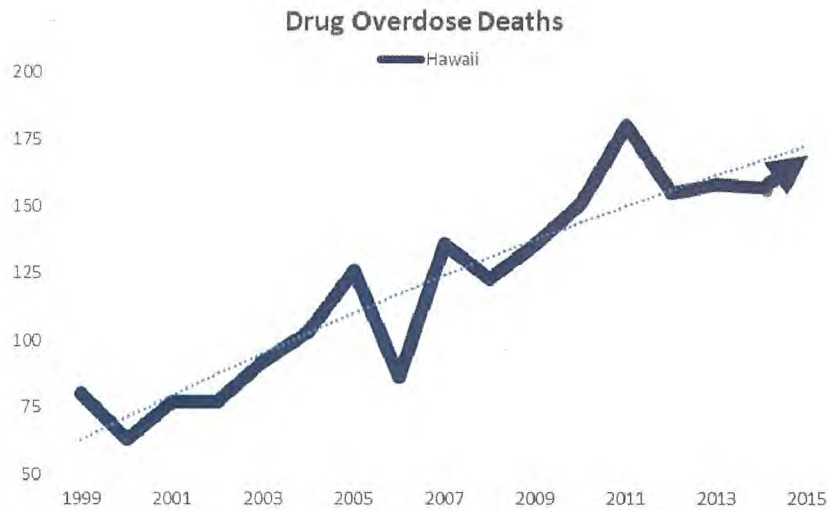
Annual Narcan Distribution in kg¹



Opioids Impacts on Maui County



Drug Overdose Deaths in State of Hawaii



◇ Hawaii overdose death rates, despite occasional variation are trending significantly upward and increasing by nearly double from 1999 to 2015

*Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on Jul 26, 2017. ICD-10 Codes: X40-X44, X60-X64, X85, and Y10-Y14

The Maui News

Opioid overdose deaths doubled over past 16 years

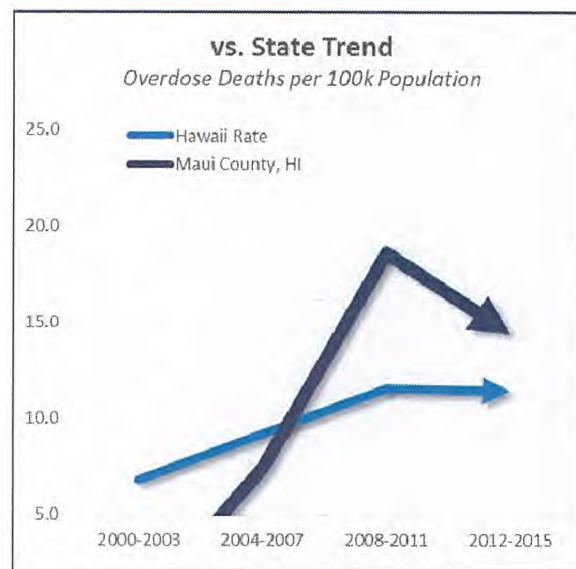
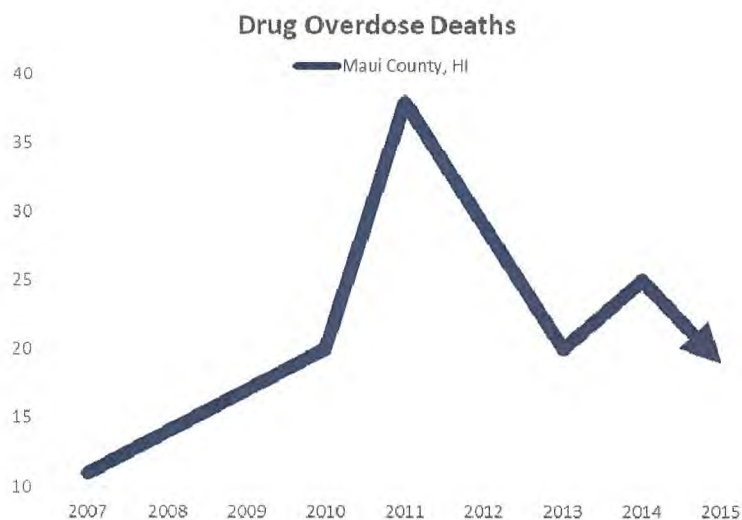


Opioid overdose deaths have more than doubled in Hawaii, from 25 in 2000 to 59 in 2016. The pain relievers have contributed to about 40 percent of drug overdose deaths statewide over the past decade. -- AP photo

Source: The Maui News, 07/23/17

From 2010-2014, “[t]he average number of annual opioid overdose deaths in Maui County was 26 . . . making up 18 percent of all the opioid overdose deaths in Hawaii. The county averaged the highest annual rate of opioid overdose deaths per 100,000 residents in Hawaii at 17.5.”

Drug Overdose Deaths in Maui County

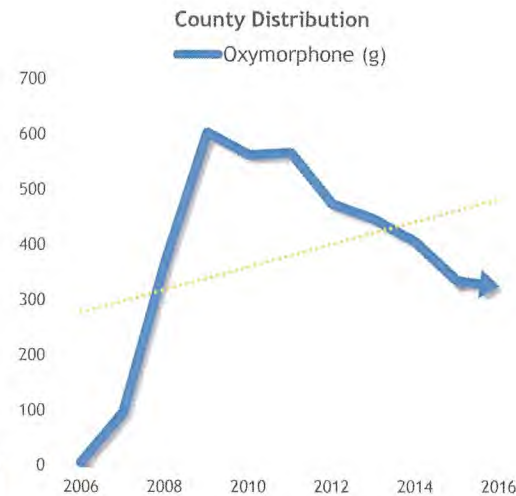
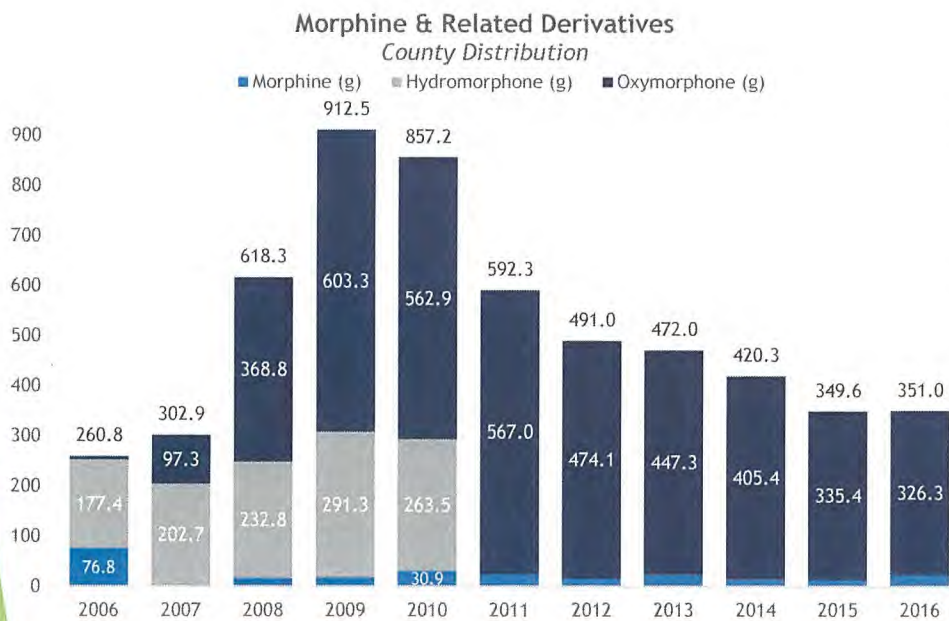


- ◇ Peaking in 2011, the overdose death rate in Maui County has since a sharp decline since then, while still remaining higher than the 2007 figures
- ◇ The overdose death rate in Maui county has been consistently greater than the statewide rate since 2007

*Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2015 on CDC WONDER Online Database, released December, 2016. Data are from the Multiple Cause of Death Files, 1999-2015, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on Jul 26, 2017. ICD-10 Codes: X40-X44, X60-X64, X85, and Y10-Y14

Dispensed Opioids in Maui County

Morphine & Related Derivatives



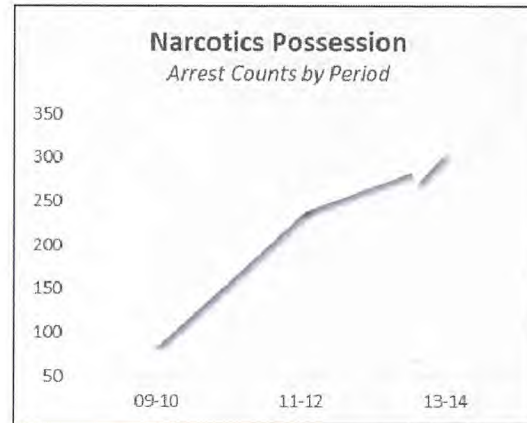
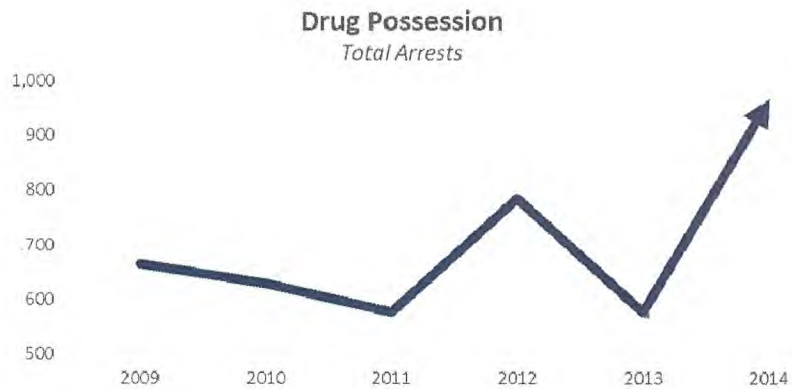
Oxymorphone distribution increased drastically from 2006 to 2009 and has steadily reduced since

Distribution levels for Morphine and related derivatives, Oxymorphone and Hydromorphone had peak levels in 2009, with reported volumes of Hydromorphone stopping abruptly in 2011

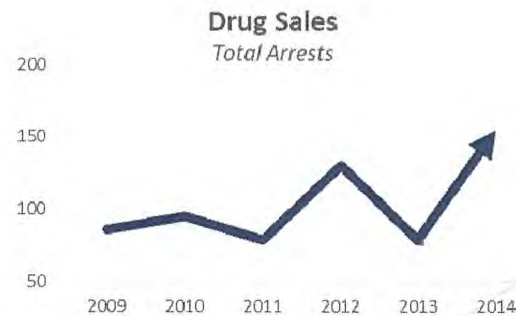
US Department of Justice. Automation of Reports and Consolidated Orders System (ARCOS). Springfield, VA: US Department of Justice, Drug Enforcement Administration; 2017. Available at <http://www.deadiversion.usdoj.gov/arcos/index.html>. Accessed July 25, 2017. Allocations of distributions at City and County level calculated using 2010 Census population within 3-digit ZIP Codes.

Drug Offenses in Maui County

Narcotics and Synthetics - Possession and Sales Arrests



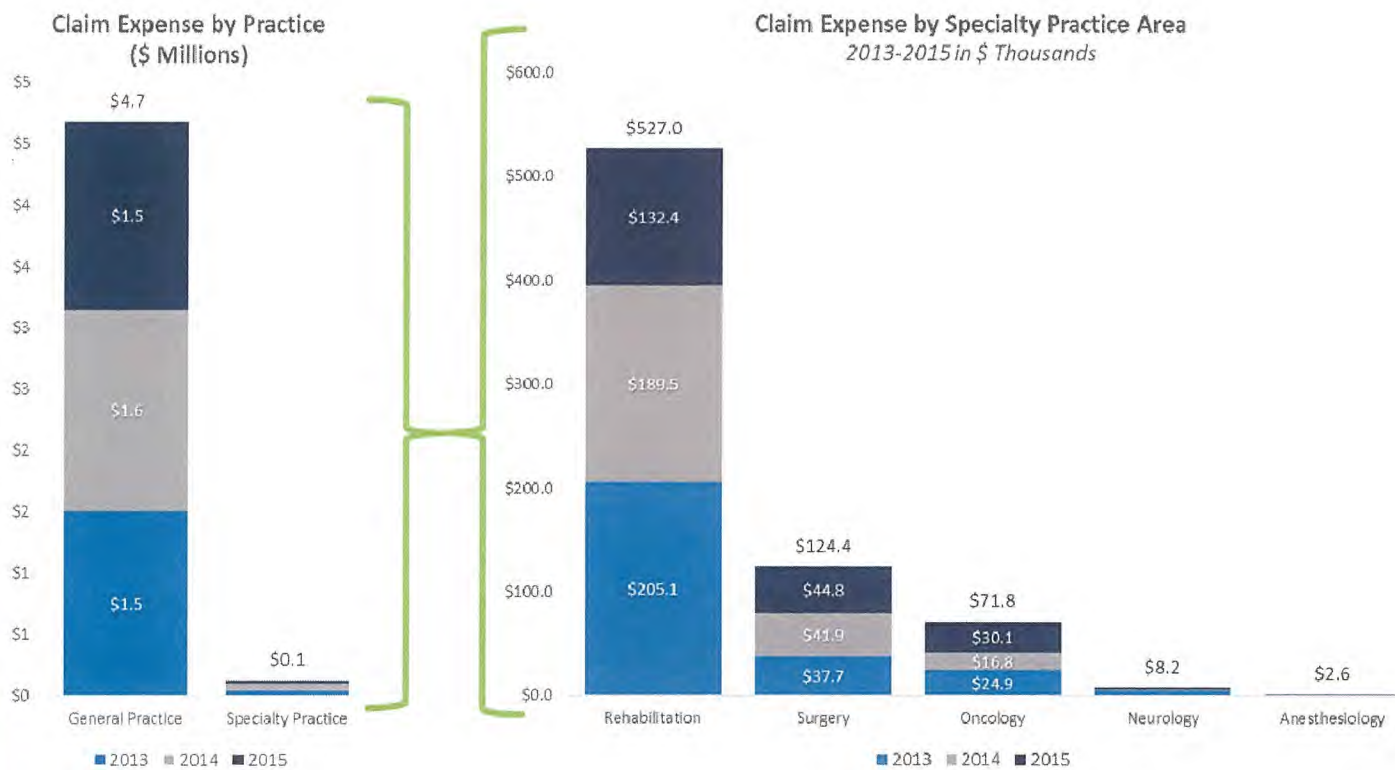
- ◇ Drug possession arrests in Maui County varied each year, but saw a dramatic increase in 2014
- ◇ Drug sales arrests in saw a similar increase in 2014
- ◇ Narcotics possession arrests, specifically, saw a three-fold increase from 2009 to 2014



Data Source: United States Department of Justice. Office of Justice Programs. Federal Bureau of Investigation. Uniform Crime Reporting Program Data: County-Level Detailed Arrest and Offense Data, 2009-2014. ICPSR34582-v2. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2014-06-13. <https://doi.org/10.3886/ICPSR34582.v2>

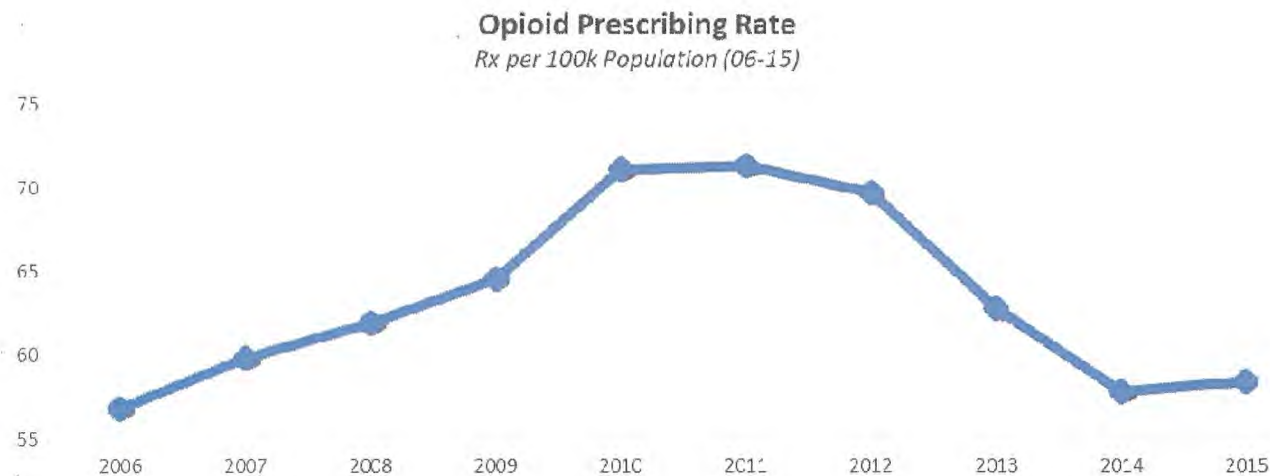
Dispensed Opioids in Maui County

Medicare Part D Prescription Claims by Specialty



Data Source: Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use File (PUF). Centers for Medicare & Medicaid Services (CMS)
 General Practice coded Specialties: Emergency Medicine, Family Practice, Family Medicine, General Practice, Internal Medicine, Pediatric Medicine, Physician Assistant

Dispensed Opioids in Maui County Prescription Rate



- ◇ Opioid prescribing rates per 100k population in Maui county saw a sharp increase from 2006 through 2010, followed by a return to pre-2007 levels in 2014

Source for all prescribing data: QuintilesIMS Transactional Data Warehouse (TDW) 2006-2016. Accessed at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>

The Maui News

MPD first to get outfitted with antidote for opioid overdoses

Naloxone nasal spray can save lives



Source: The Maui News,
05/23/18

Heather Lusk, executive director of the CHOW Project, shows the Narcan nasal spray now in the hands of Maui police officers. The spray form of naloxone counteracts the life-threatening effects of an opioid overdose. CHOW stands for Community Health Outreach Work, a program funded by the state Department of Health. CHOW Project photo

- 200+ MPD Patrol Officers received training
- Naloxone utilized once already to save a life

Why Should Maui County File a Lawsuit?

County Cause of Action is Preferable to Waiting for the State

- ◇ It appears that the effects of the opioid epidemic have been felt at the Maui County level
- ◇ Counties may have experienced financial costs that are separate and distinct from the State
- ◇ The goal of a lawsuit on behalf of the County individually would be to leave the power of accepting a settlement and distribution of any recovery to the County, as opposed to giving control to the State

Why Should Maui County File a Lawsuit?

Previous Manufacturer or Distributor Fines

Previous Significant Fines

Purdue
\$635 M

For OxyContin

◇ **Purdue:**

- ◇ \$634.5 Million - Fined (2007) for claiming the drug was less addictive and less subject to abuse

◇ **McKesson**

- ◇ \$150 Million - Fined (2017) for failure to report suspicious orders of drugs

McKesson
\$150 M

◇ **Cardinal Health**

- ◇ \$44 Million - Fined (2016) for failure to report suspicious orders of drugs

**Cardinal
Health**
\$44 M

◇ **Amerisourcebergen**

- ◇ \$16 Million - Fined (2016) for failure to report suspicious orders of drugs

Amerisourceberge
\$16 M

Why Should Maui County File a Lawsuit?

Previous Manufacturer or Distributor Settlements

Substantial Settlements Underway

◇ Purdue:

- ◇ **\$24 Million - (2013)** Settlement with State of Kentucky, accused of misleading the public about the addictiveness of OxyContin
- ◇ **\$4 Million - (2013)** Settlement with Pike County, KY, accused of misleading the public about the addictiveness of OxyContin

- ◇ Galena Biopharma - **\$7.5 Million** - (2017) Resolved settlement paid kickbacks to doctors in exchange for prescribing fentanyl-based Abstral

- ◇ Teva - **\$1.6 Million** - (2017) Santa Clara and Orange County, California alleging misleading marketing practices

- ◇ Endo - **\$200,000** - (2016) Settlement w/ NY State for misleading marketing around the risks associated with Opana ER

Purdue
\$24 M

For OxyContin

Settlement with
State of
Kentucky

Purdue
\$4 M

For OxyContin

Settlement with
Pike County, KY

Galena
\$7.5 M

For Paid
Kickbacks to
Doctors

Teva
\$1.6 M

Settlement with
Two Counties in
California

Endo
\$200k

Settlement w/
State of New York

Defendants

▶ Manufacturers and marketers of prescription opioids include:

- **Purdue Pharma;**
 - Purdue Pharma L.P.;
 - Purdue Pharma Inc.;
 - Purdue Frederick Company, Inc.;
- **Teva Pharmaceuticals USA, Inc.;**
 - Cephalon, Inc.;
- **Johnson & Johnson;**
 - Janssen Pharmaceuticals, Inc.;
 - Janssen Pharmaceutical, Inc. n/k/a Janssen Pharmaceuticals, Inc.;
 - Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.;
- **Endo Health Solutions Inc.;**
 - Endo Pharmaceuticals, Inc.;
- **Insys Therapeutics**
- **Allergan plc f/k/a Actavis plc;**
 - Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.;
 - Watson Laboratories, Inc.; and
 - Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

• Distributors of prescription opioids include:

- McKesson Corporation;
- Cardinal Health Inc.; and
- Amerisource Drug Corporation

Claims

- ▶ Violations of Consumer Protection Act/Fair Business Practices
- ▶ Violations of State Controlled Substances Act
- ▶ Public Nuisance
- ▶ Negligence
- ▶ Fraud
- ▶ Unjust Enrichment

Claims as to the Manufacturers

- ▶ Falsely and fraudulently marketing opioids pain medications as safe and non-addictive
- ▶ Failing to perform proper long term studies regarding the effects of their drugs
- ▶ Generally, creating a false perception of the safety and efficacy of opioids in the medical community

Claims as to the Distributors

- ▶ Defendants' conduct in failing to report suspicious orders as required by law
- ▶ Defendants' conduct in dispensing, supplying and/or selling prescription opioids without adequate safeguards to prevent diversion
- ▶ Conduct proximately caused injury to the County and its citizens