

Confronting the Opioid Epidemic

Communication (03/29/2018) from the County Attorney, requesting authorization to expend funds of up to \$25,000.00 for Special Counsel services to represent the County of Kaua'i in pursuing opioid litigation against the manufacturers and distributors of opioid pain medications, and related matters.

* Used with permission of Napoli Shkolnik, PLLC

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

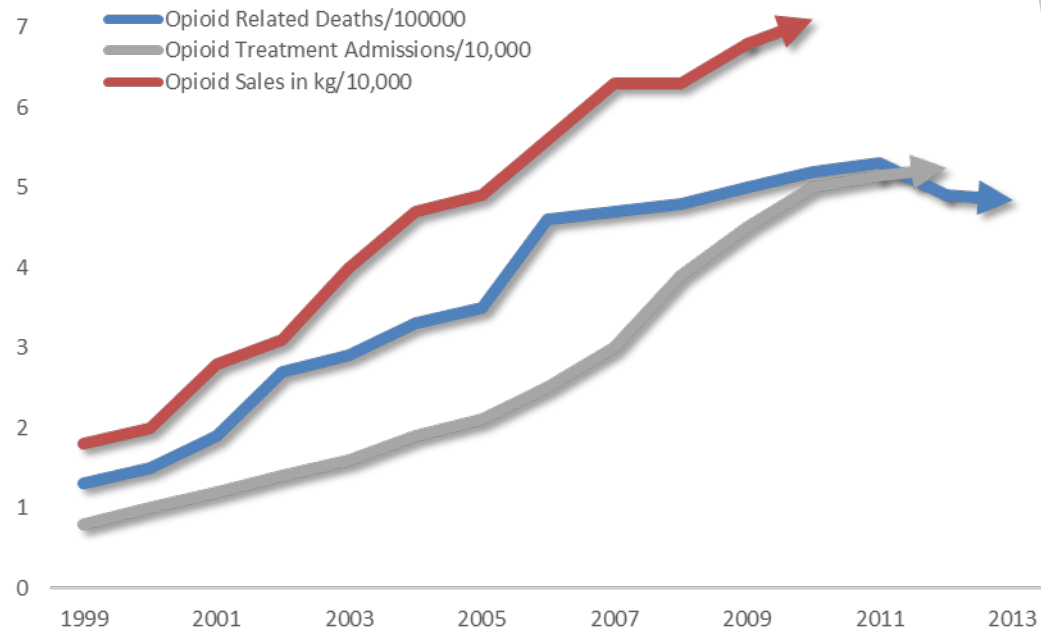
The Opioid Epidemic

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.



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 July 10, 2017. ICD-10 Codes: X40-X44, X60-X64, X85, and Y10-Y14

Opioid sales, opioid treatment admissions, and opioid-related deaths. Sources: CDC Wonder, 2015; DEA ORCOS, 2015; TEDS, 2015

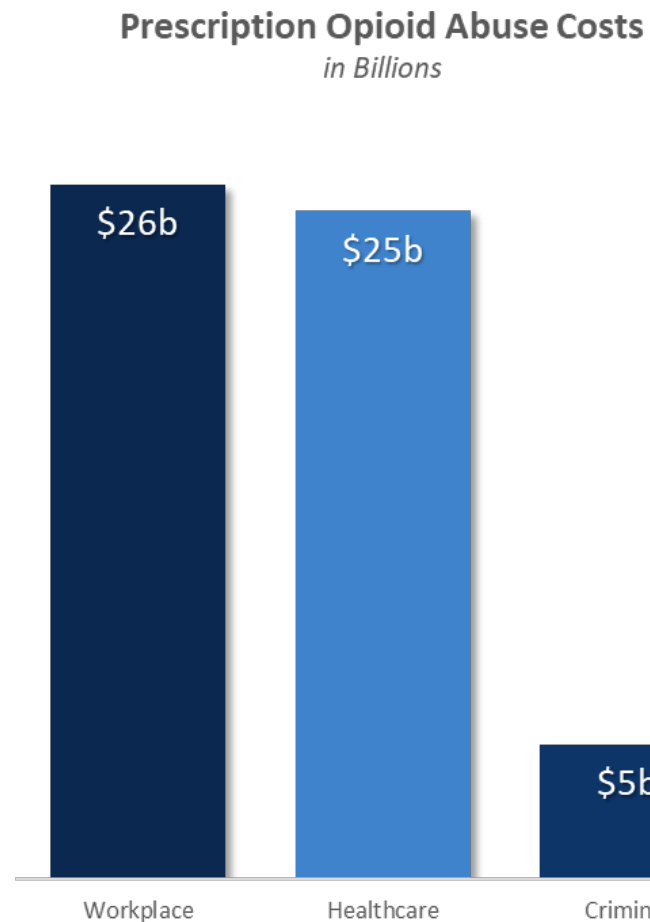
The Opioid Epidemic

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



Source: CDC, Prescription Drug Overdose data.

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. Jayaraman 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. Compton 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/NEJMra1508490

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)

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

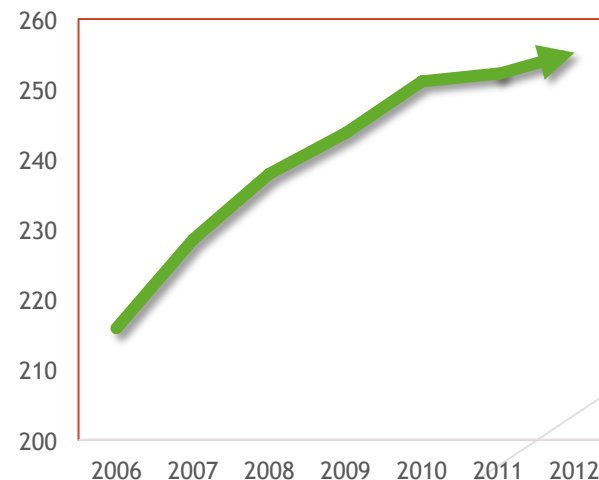
Surge in prescriptions may be traced back to under treatment of chronic pain in the 1980s and 1990s

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

Total Prescribed Opioids in the US²
(2006-2012 in Millions)



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.

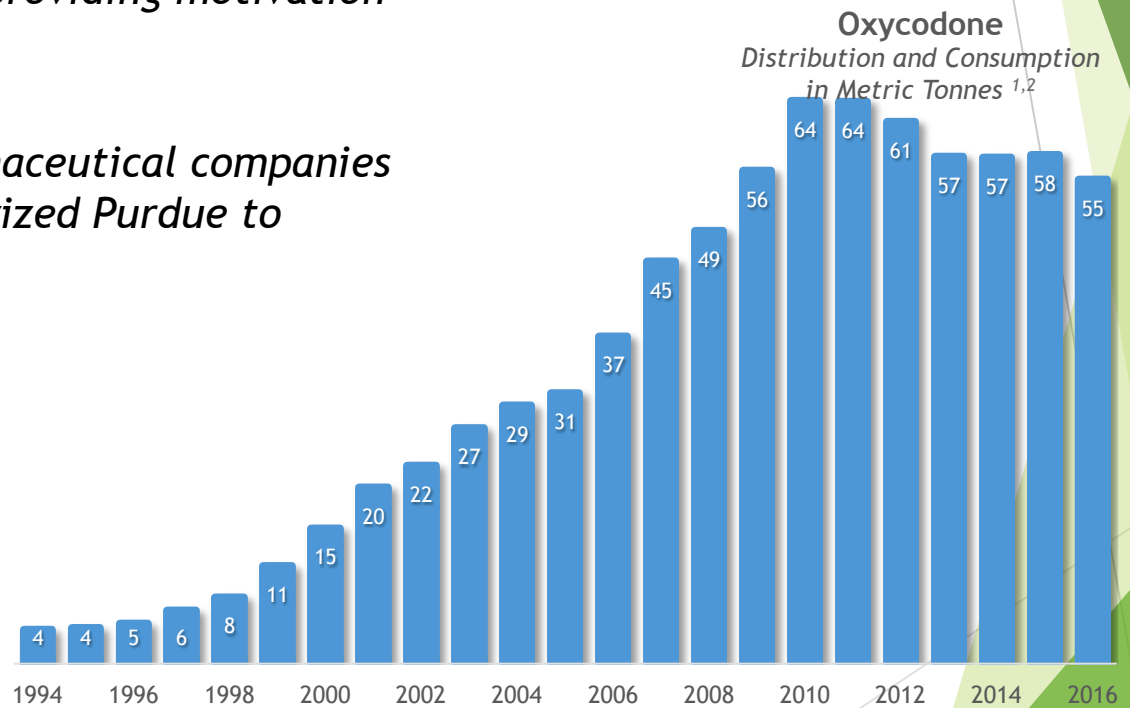
Source for all prescribing data: QuintilesIMS Transactional Data Warehouse (TDW) 2006-2016. Accessed at <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>

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.

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 abuse and misuse, with tragic public health consequences.”*

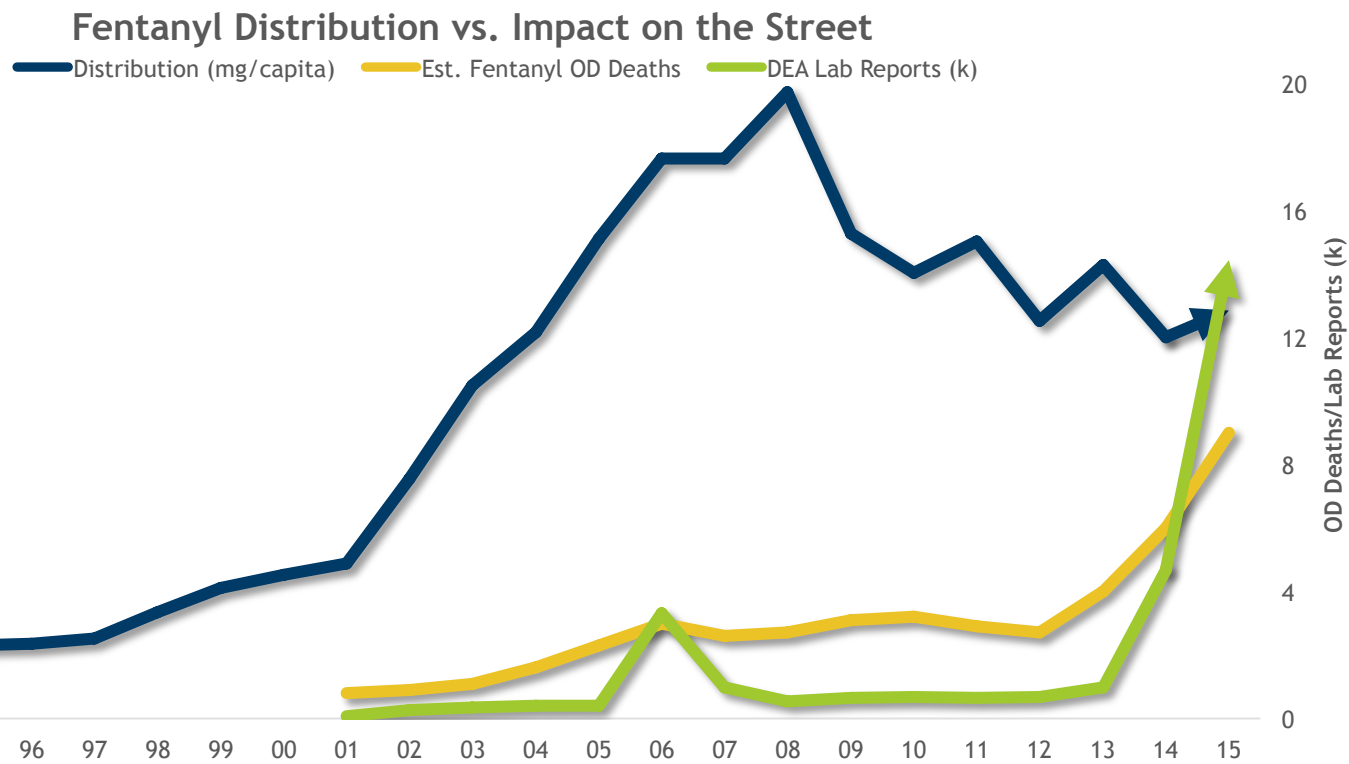


*Sarpawari, Michael S. Sinha, Aaron S. Kesselheim, “The Opioid Epidemic: Fixing a Broken Pharmaceutical Market”, Harvard Law & Policy Review, Volume 11, Number 2 (Summer, 2017): pp. 463-484.

¹US 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.
²International 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



Source 1: 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, 3-21-17

Source 2: US Department of Justice. Automation of Reports and Consolidated Orders System (ARCOS). Springfield, VA: US Department of Justice, Drug Enforcement Administration; 2017.

Source 3: International Narcotics Control Board; World Health Organization population data By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2017

Source 4: Drug Enforcement Administration, Diversion Control Division. (2017). NFLIS Brief: Fentanyl, 2001-2015. Springfield, VA: U.S. Drug Enforcement Administration.

Source 5: National Center for Health Statistics, Centers for Disease Control and Prevention

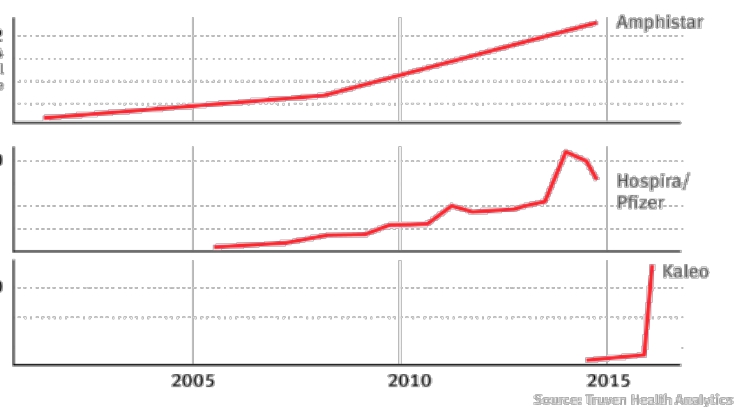
The Opioid Epidemic

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

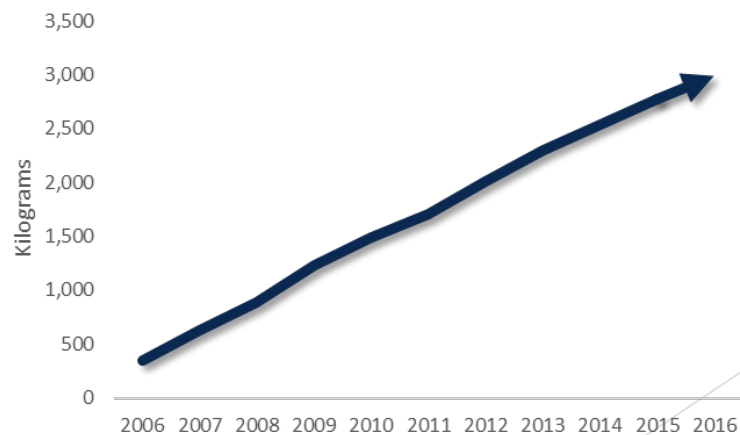
- First responders, law enforcement or others are being trained how to administer Buprenorphine/Naloxone (Narcan), the lifesaving antidote which is used to block the effects of opioids, especially in overdose
- The increasing demand Narcan has led to pharmaceutical companies drastically increasing the 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.



Source: Truven Health Analytics

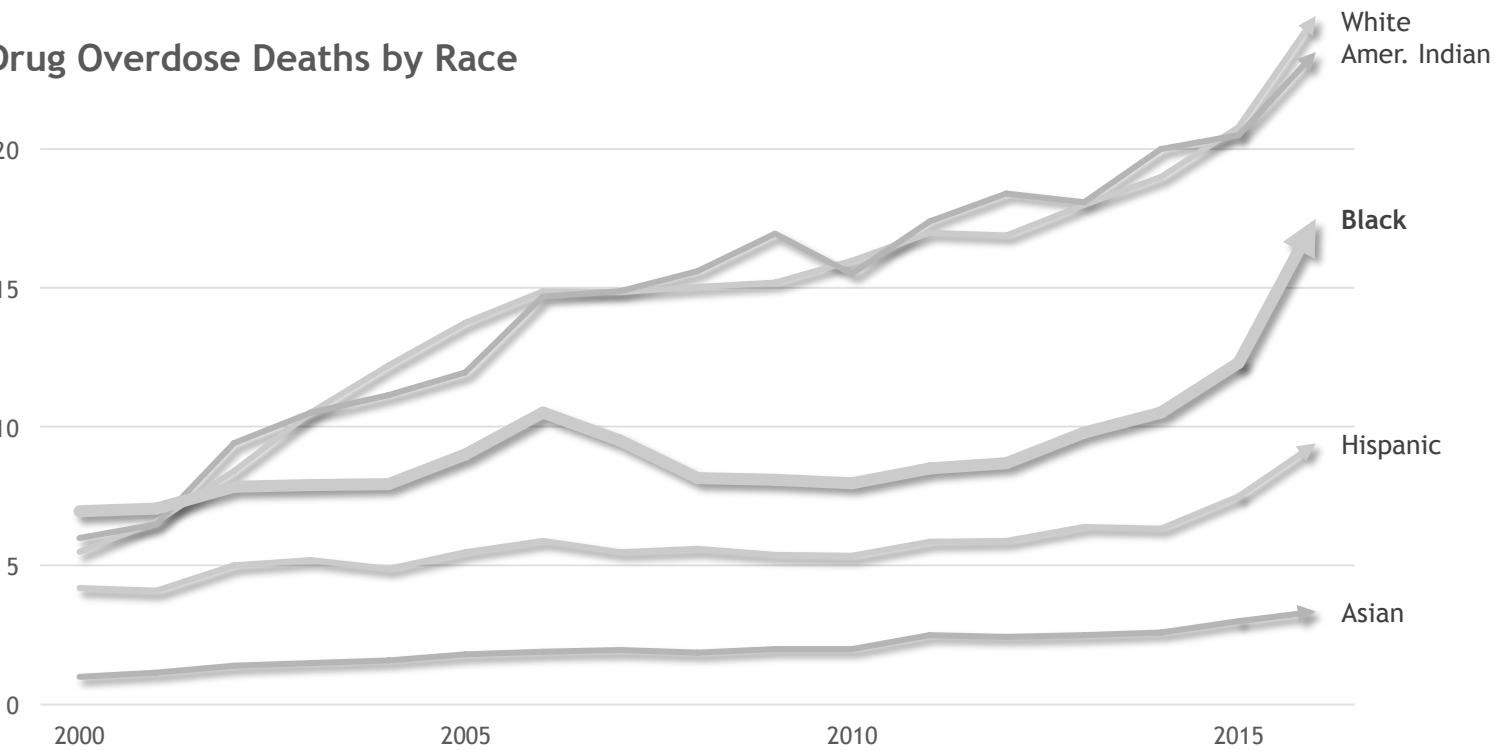
Annual Narcan Distribution in kg¹



The Opioid Epidemic

Statistics show that all ethnic groups are a victim to this crisis, contrary to the common perception that the opioid epidemic is primarily a white, rural problem.

Drug Overdose Deaths by Race

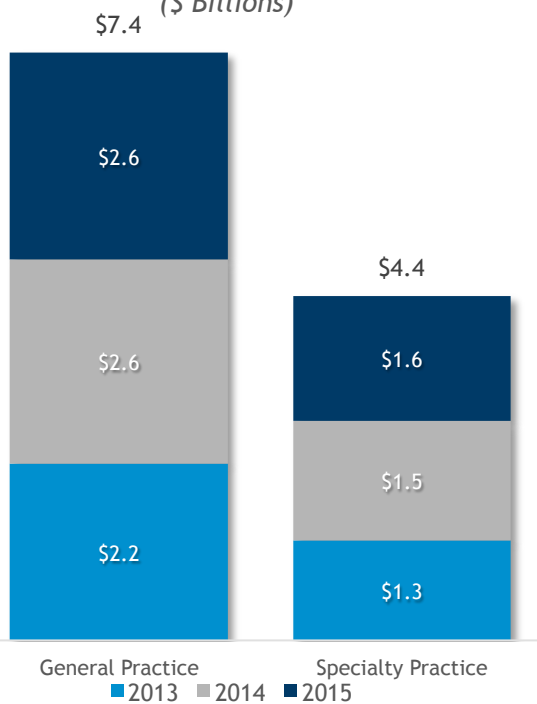


<https://www.nytimes.com/interactive/2017/12/22/upshot/opioid-deaths-are-spreading-rapidly-into-black-america.html>
National Center for Health Statistics, Centers for Disease Control and Prevention

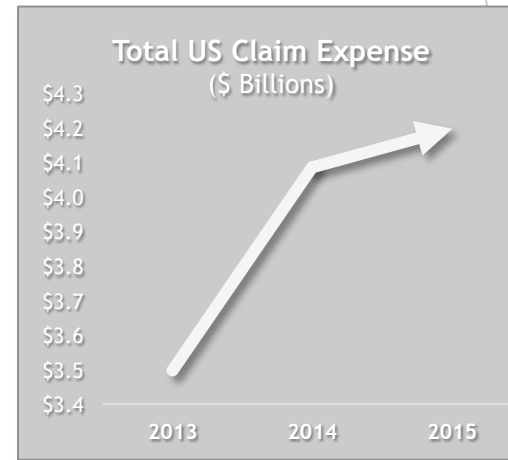
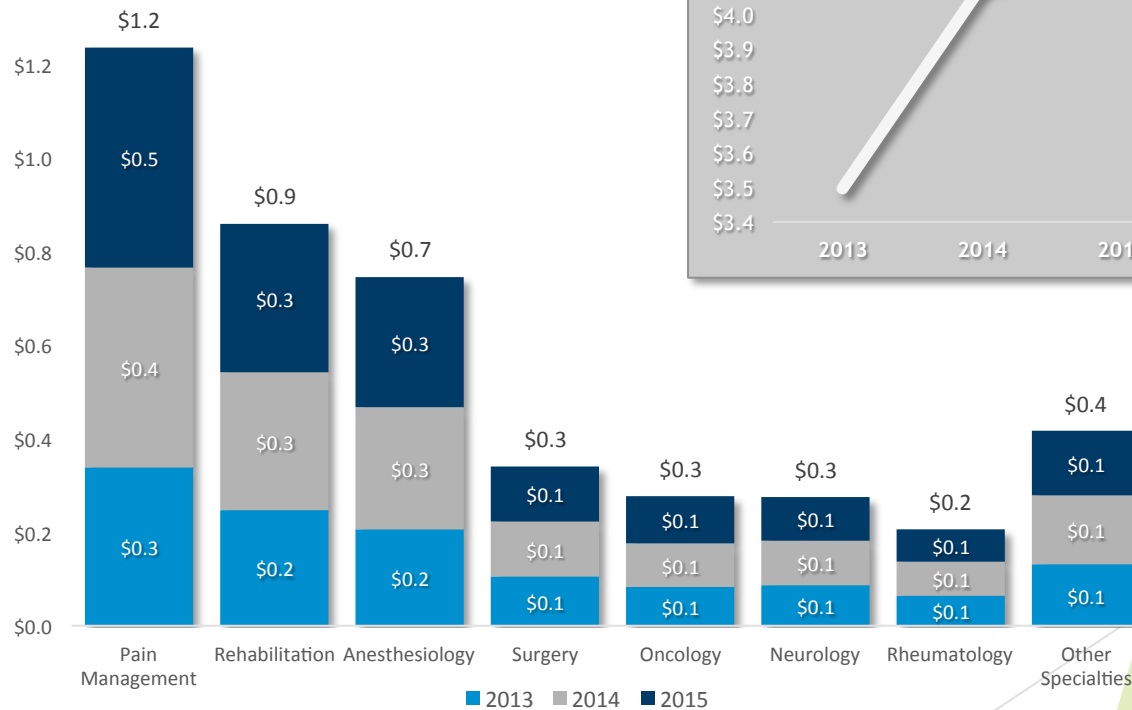
The Opioid Epidemic

Medicare Part D Prescription Claim Costs on the Rise¹

Claim Expense by Practice
(\$ Billions)

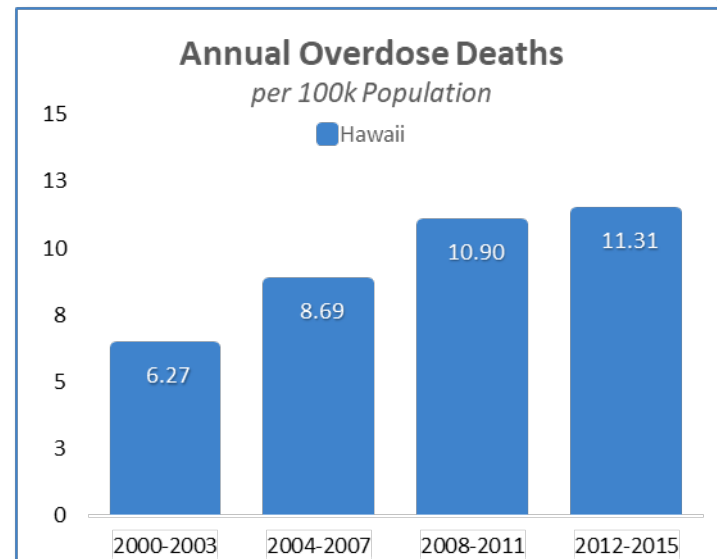
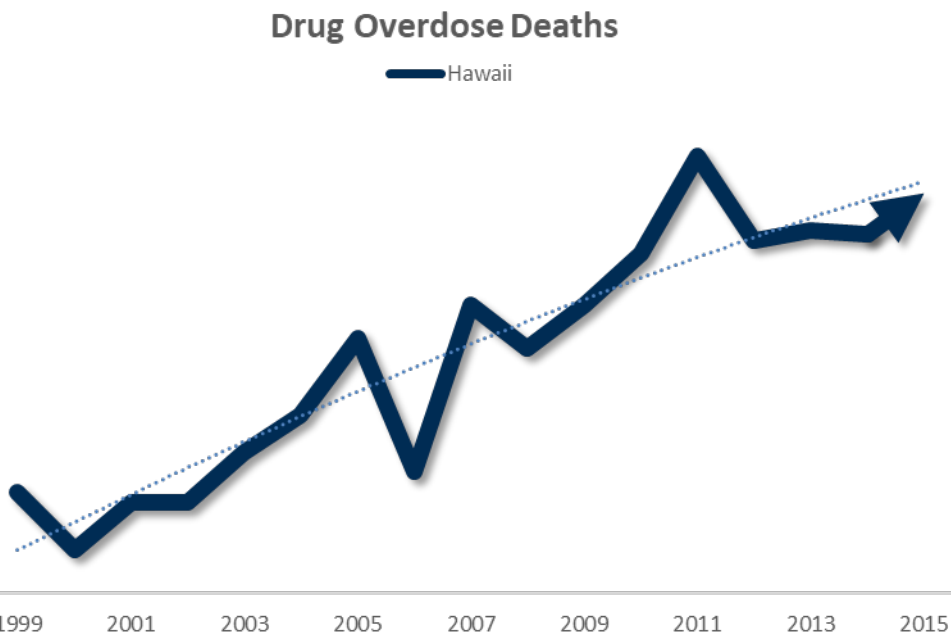


Claim Expense by Specialty Practice Area
2013-2015 in \$ Billions



Opioids in Hawaii

Drug Overdose Deaths in Hawaii



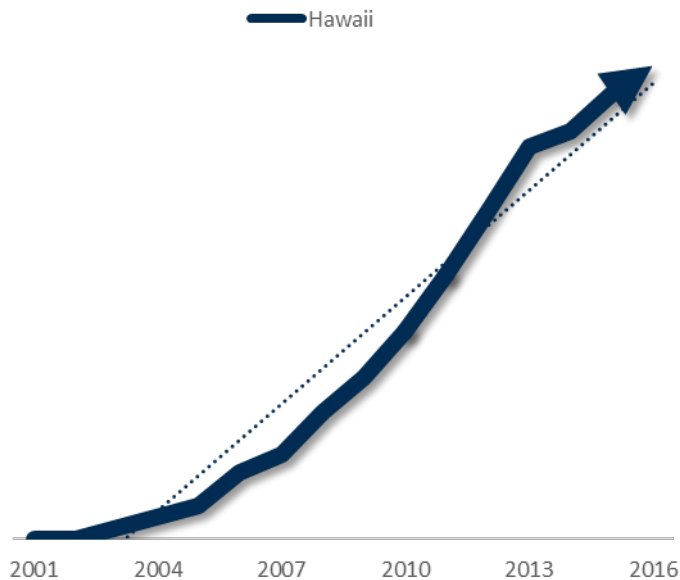
Hawaii overdose death rates, despite occasional variation are trending significantly upward and increasing by nearly double from 1999 to 2015

*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

Dispensed Opioids in Hawaii

Methadone, Naloxone & Buprenorphine Distribution

Naloxone & Buprenorphine Distribution
Rate of Grams per 100k Population



Methadone Distribution
Kilograms Distributed



Reliance or usage of methadone has declined by more than a third since 2006

The increased distribution of Naloxone/Buprenorphine is indicative of the striking growing demand for overdose prevention as has been seen all across the nation

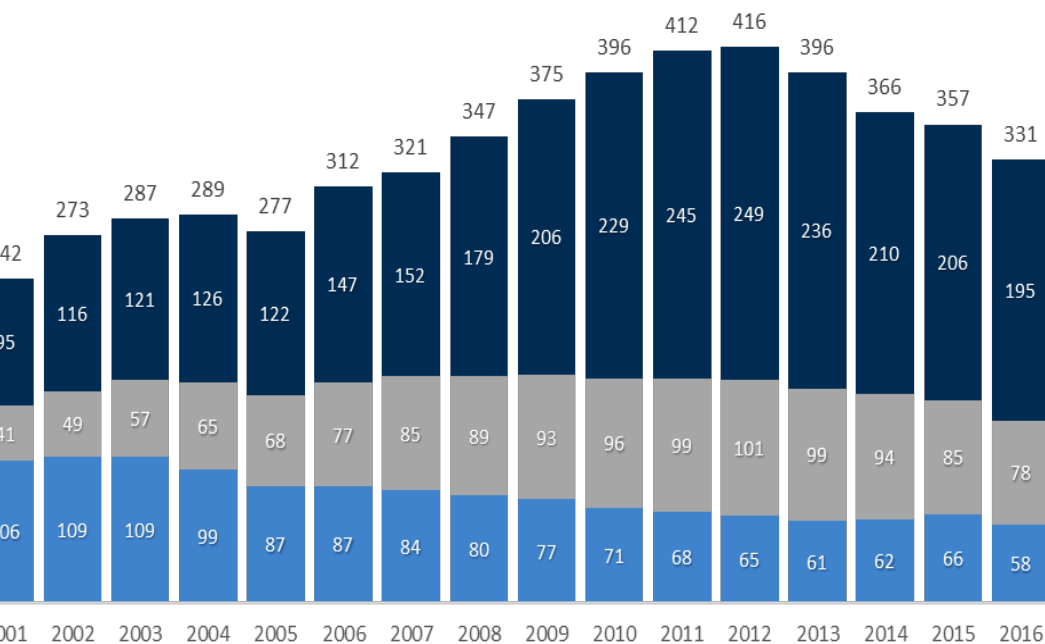
Dispensed Opioids in Hawaii

Distribution of Codeine & Related Synthetics

Codeine & Related Synthetics

Kilograms Distributed

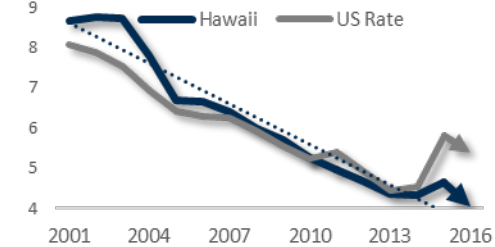
■ Codeine ■ Hydrocodone ■ Oxycodone



Similar to national trends, Hydrocodone and Oxycodone distribution peaked in 2011/2012 in Hawaii whereas Codeine values have decreased steadily and significantly since 2001

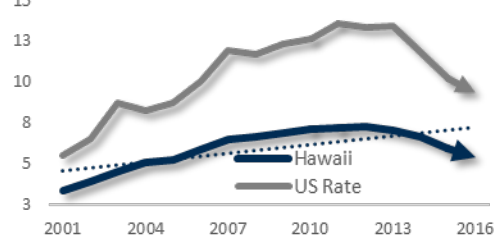
Codeine Distribution

Rate of Kilograms per 100k Population



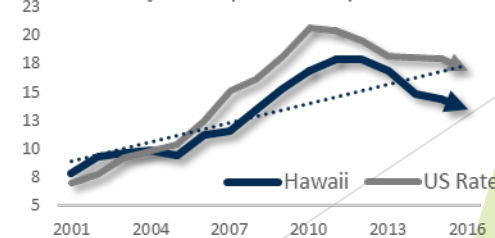
Hydrocodone Distribution

Rate of Grams per 100k Population



Oxycodone Distribution

Rate of Grams per 100k Population



Department of Justice. Automation of Reports and Consolidated Orders System (ARCOS). Springfield, VA:

Department of Justice, Drug Enforcement Administration; 2017. Available at <http://www.deadiversion.usdoj.gov/arcos/index.html>. Accessed July 25, 2017.

Opioids in Kauai County

Dispensed Opioids in Kauai County

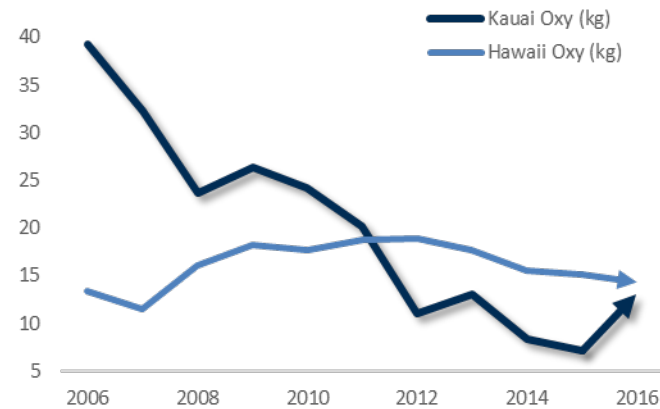
Codeine & Related Synthetics

Codeine & Related Synthetics
County Distribution

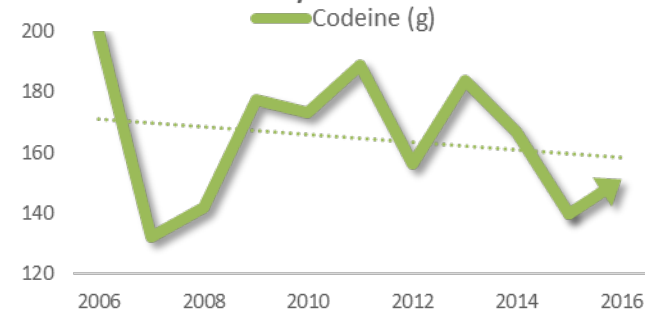
Codeine (g) Oxycodone (g)



Oxycodone Distribution per 100k Population



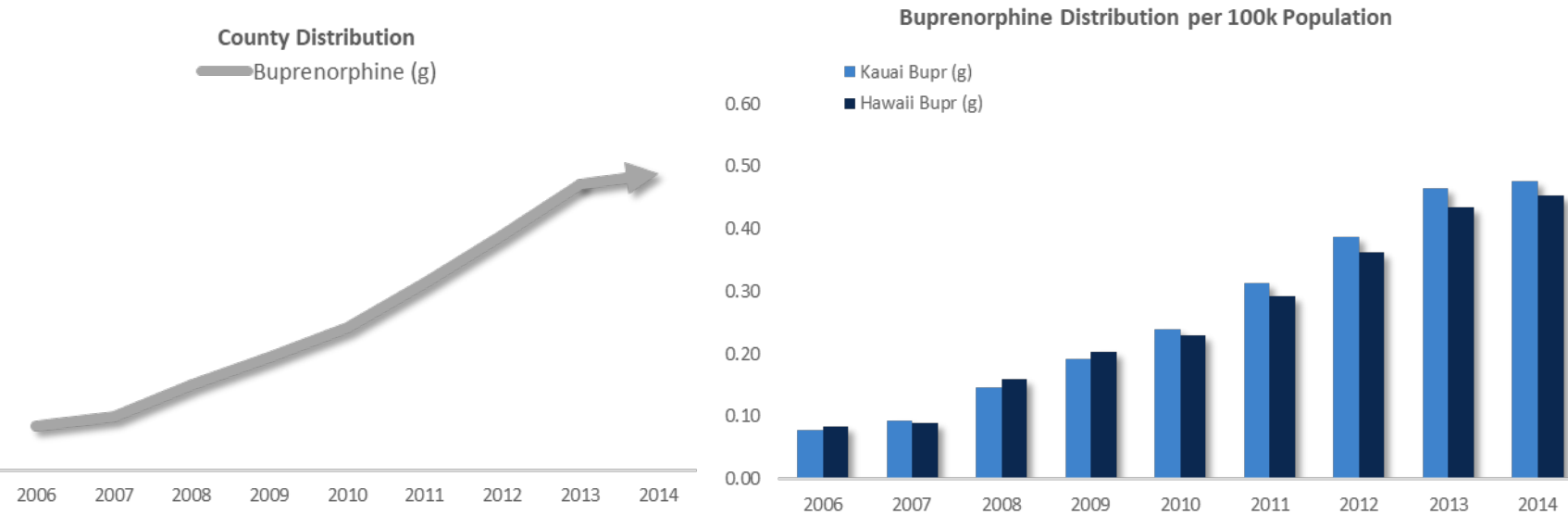
County Distribution



Codeine and Oxycodone distribution varied over 2006-2016, with Oxycodone distribution rates starting significantly higher than state average, and ending in 2016 at similar rate

Dispensed Opioids in Kauai County

Buprenorphine Distribution

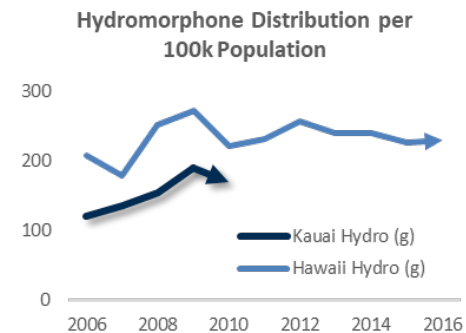
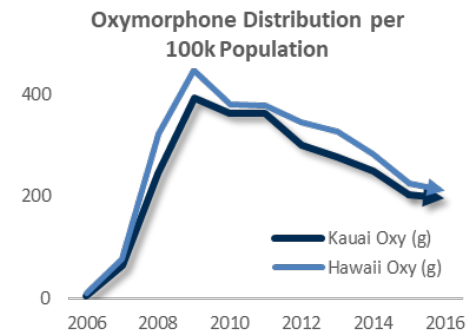
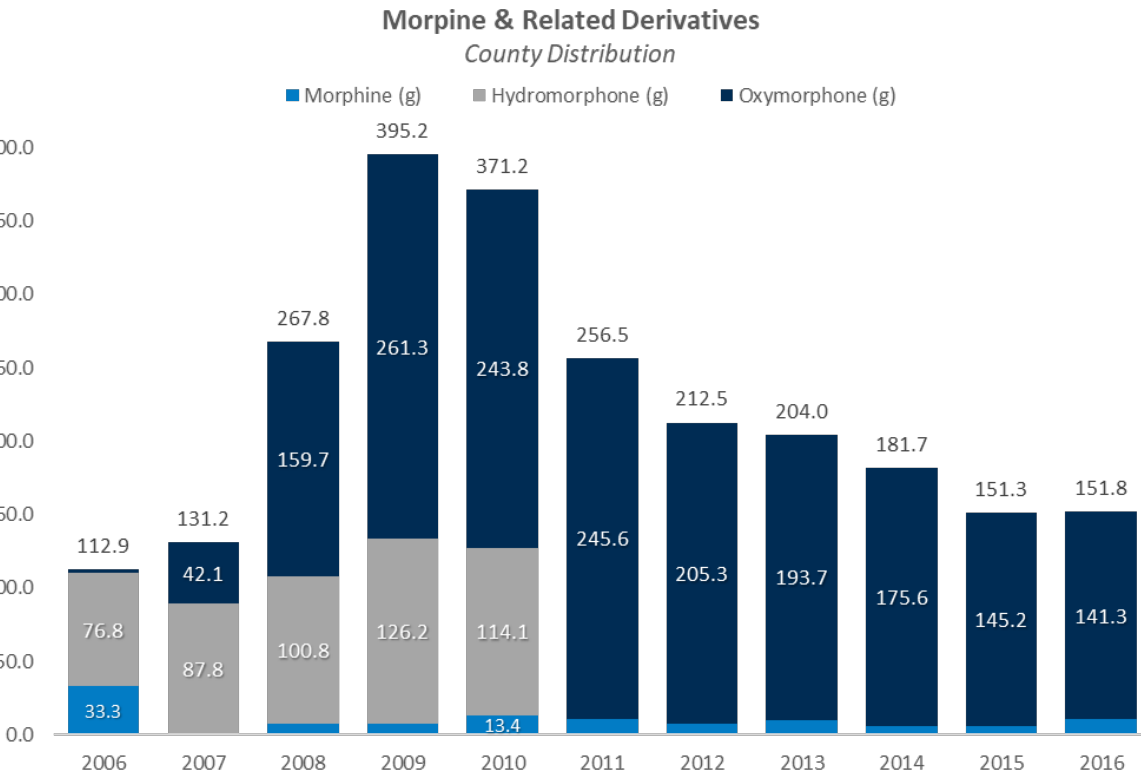


The increased distribution of Naloxone/Buprenorphine in Kauai County is consistent with the state and is indicative of the striking and growing demand for overdose prevention

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 data within 3-digit ZIP Codes.

Dispensed Opioids in Kauai County

Oxymorphone Distribution



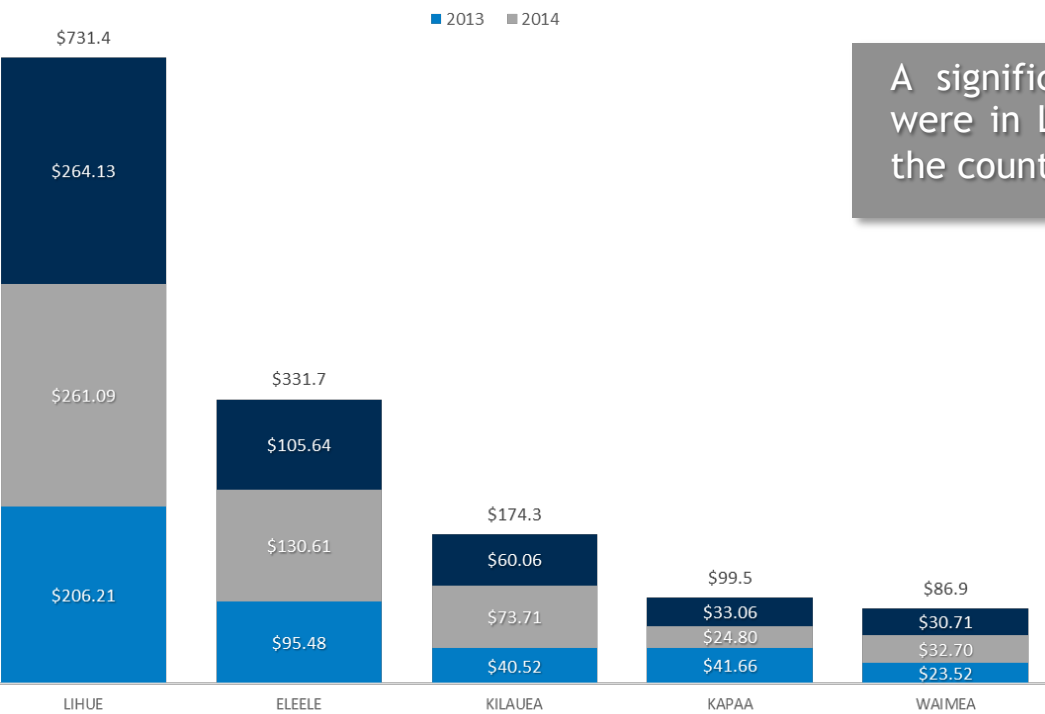
Oxymorphone distribution trends in Kauai County have been largely similar to statewide, peaking in 2011

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.

Dispensed Opioids in Kauai County

Medicare Part D Prescription Claims by City

Medicare Part D - Prescription Claim Expense
2013-2015 by City in \$ Thousands



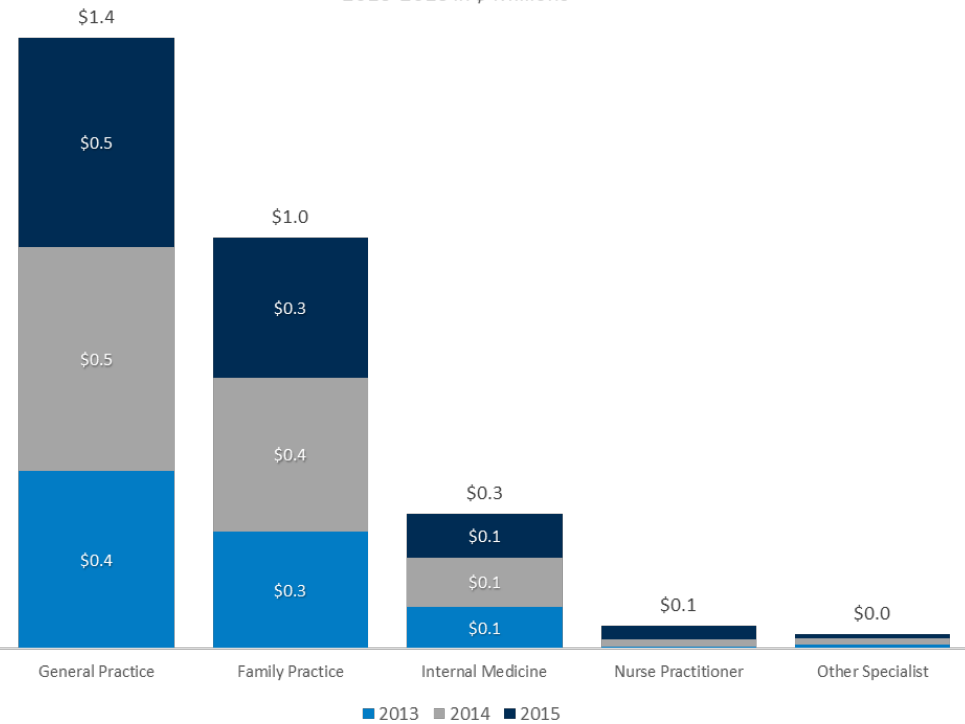
A significant majority of claim expenses were in Lihue and Eleele with over 70% of the county-wide total

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

Dispensed Opioids in Kauai County

Medicare Part D Prescription Claims by Specialty

Claim Expense by Specialty Practice Area
2013-2015 in \$ Millions



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

Why Kauai County?

Why Should Kauai County File a Lawsuit?

County Cause of Action is Preferable to Waiting for the State

We believe that the effects of the opioid epidemic have been felt strongly at the County level

Counties have experienced significant 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 Kauai 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

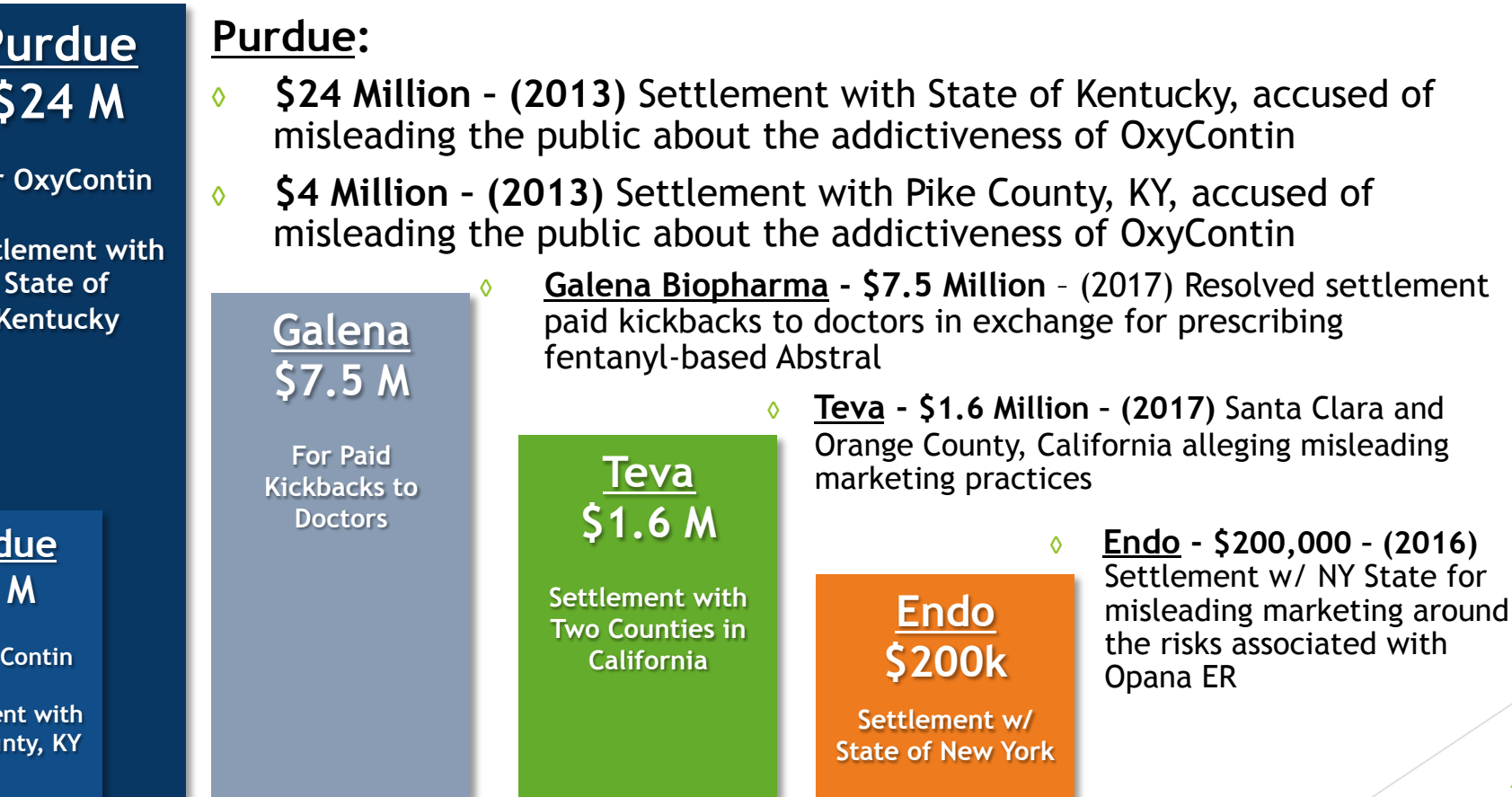
- ◇ **Amerisourcebergen**
 - ◇ \$16 Million - Fined (2016) for failure to report suspicious orders of drugs

Amerisourcebergen
\$16 M

Why Should Kauai County File a Lawsuit?

Previous Manufacturer or Distributor Settlements

Substantial Settlements Underway



Causes of Action

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

Relief Sought

Civil Penalties

Treble damages

Compensatory damages

Punitive damages

Attorneys' fees and costs

Working Together To Fight the Opioid Epidemic

