



DEA National Conference

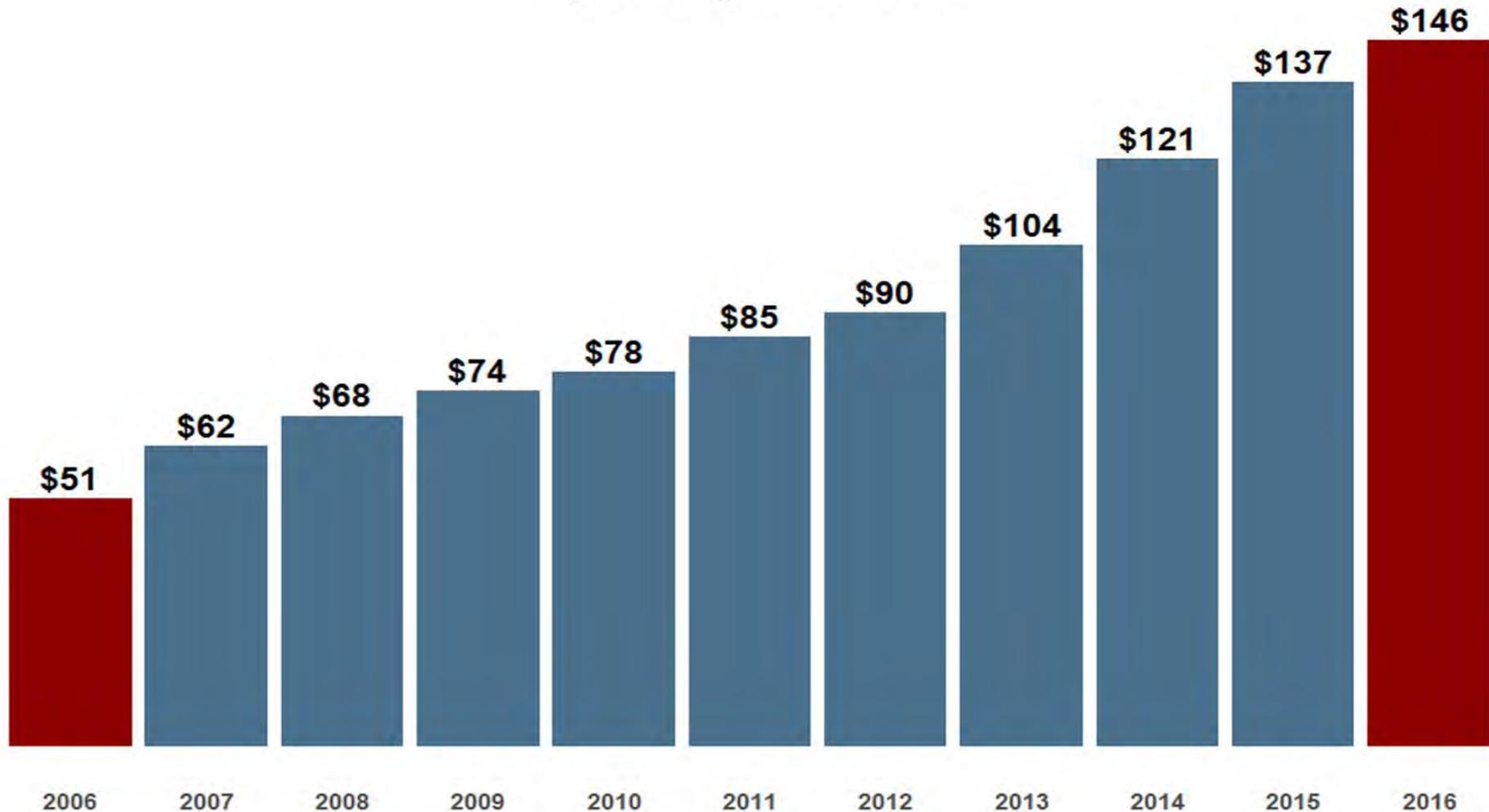
Current & Emerging Threats

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Spending for Part D Drugs 2006-2016

Spending in Billions



Opioid Costs



White House: Economic cost of opioid crisis about \$504B

BY RACHEL ROUBEIN - 11/19/17 09:55 PM EST

97 COMMENTS

278 SHARES



Just In...

NAFTA promotes U.S. manufacturing in the food and agriculture sector

OPINION — 6M 5S AGO

GOP leaders need to get serious about our massive debt problem

OPINION — 16M 4S AGO





Patient Violence

- Physician killed in Indiana by patient
- Angry Florida patient bites off physician's finger for not prescribing drugs
- Explosive behavior
- Tires slashed, cars keyed
- Hard to put genie back in bottle



Newest OEI Report



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

HHS OIG Data Brief • OEI-02-17-00250

Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing

Key Takeaways:

- ✓ *One in three Medicare Part D beneficiaries received a prescription opioid in 2016*
- ✓ *About 500,000 beneficiaries received high amounts of opioids*

Opioid abuse and overdose deaths are at epidemic levels in the United States. In 2015, the number of opioid-related deaths exceeded 33,000 for the first time.¹ Nearly half of these deaths involved prescription opioids.

Opioids include narcotics intended to manage pain from surgery, injury, or illness. They can create a euphoric effect, which makes them vulnerable to



Use of MED in Compliance, Prosecutions and Investigations

- The Ninth Circuit Court of Appeals stated that Morphine Equivalent Dose can be used in court to show usual course of medicine for Title 21 charges against a medical doctor when it is part of the state medical board's policies.
- *“MED is a standard tool used to calculate the overall strength of opioid narcotics. The Model Policy is nationally and locally recognized as reflecting the relevant, usual course of professional practice. Testimony revealed that Idaho adopted the Model Policy in part because of concerns over Idaho's opioid epidemic. Accordingly, this expert testimony was not only helpful to the jury, but was necessary to assess whether Minas's actions were criminal; and, therefore, the district court properly admitted the testimony”*





President Announcement

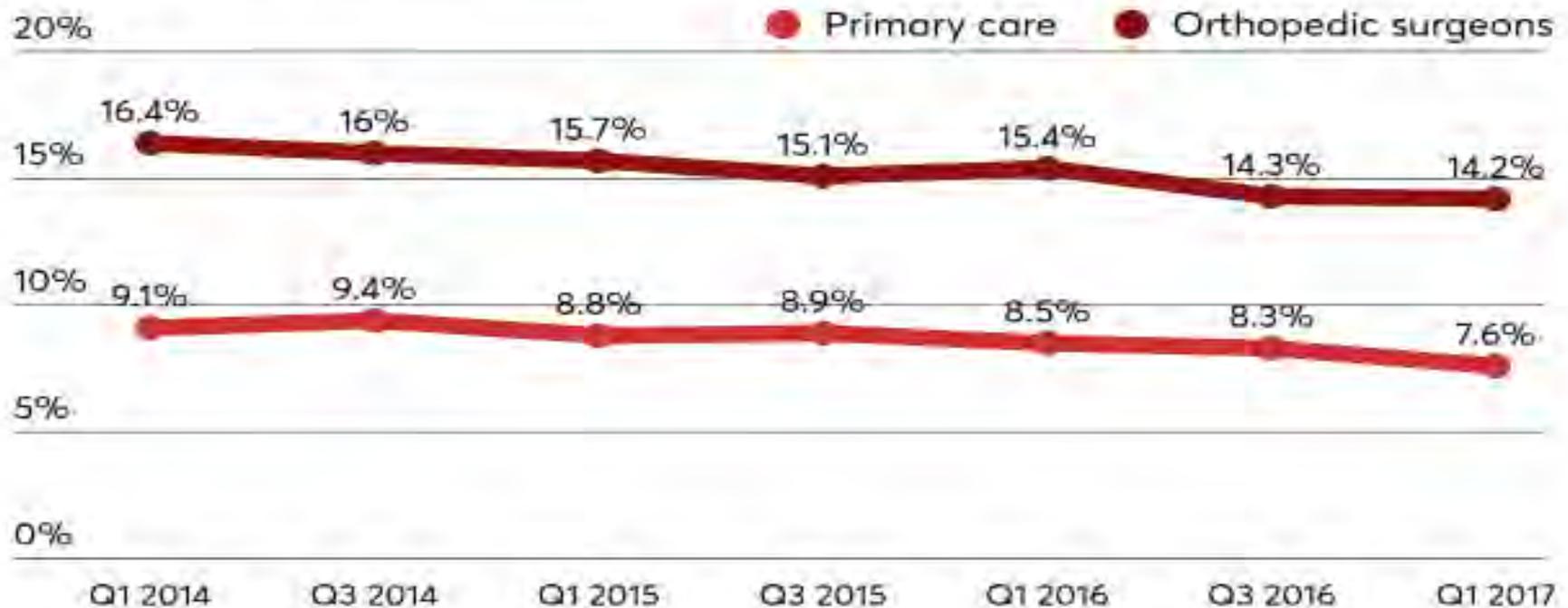
- Public Health Emergency, not National Disaster declaration
- No Stafford Act (used for short term problems)
- No standing emergency fund
- Expand access to telemedicine in rural areas, improve movement grant money and shift some federal grants
- Latitude on how current money is spent
- Refocuses Public Health Service employees



Opioid Prescribing Decreasing

Docs prescribe fewer opioids

Percentage of orders for addicting pain meds fall



OTC 45 States





Amazon Pharmaceuticals

- Amazon moving towards online pharmacy
- Online pharmaceuticals can be multi-billion dollar business
- Reportedly hired someone to create PBM
- History of entering complicated markets (computers-90% CE growth 2015, clothing)
- Death sentence for small independent pharmacies?





Amazon Prime Air

- Drone delivery in 30 minutes or less
- Awaiting FAA regulatory support
- Signature mechanism CII?
- Small geography trial in UK underway





CONTROLLED DRUGS





Fentanyl

- Schedule II Controlled
- TIRF only for cancer breakthrough patients
- Also comes in a patch (used as black market currency)
- Also clandestine lab fentanyl
- 100X more potent than morphine





Lethal Injections

- Problems obtaining pentothal
- Will try **IV fentanyl**
- Nevada and Nebraska
- Combined with diazepam, cisastracurium (not pancuronium), potassium





Opana

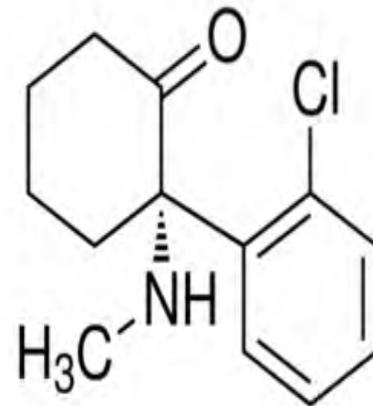
- CII oxymorphone
- Implicated in HIV outbreak in Indiana
- Weak abuse deterrent
- Endo withdrew application for abuse deterrent labeling 8/2016 due to lack of positive data
- FDA terminated 2017



Esketamine

Transformational Potential Therapy for Major Depression in Phase 2 Development with FDA Fast Track Designation

- S-ketamine has greater binding affinity than R-ketamine
- 33%-40% less drug required than racemic mixture
- Esketamine early results are promising
- **Intranasal**
 - Less invasive, outpatient access, higher patient and prescriber acceptance
 - Deliver optimal dose rapidly to reach target
 - Misuse mitigation plan
- **Robust portfolio of targets for severe mood disorders**
 - Oral NR2B antagonist
 - Suite of glutamatergic agents
 - Disease-modifying agents



• HCl



Ketamine Isomers

- Mood disorders huge and growing
- Massive market share available
- IV ketamine found to have great utility treating depression
- No drug company wants ketamine; off-patent
- Esketamine, Arketamine, others
- Currently used as dissociative anesthetic (and date rape drug)





Isomer Games

- Esketamine more potent, less effective than arketamine for depression
- Isomers: Claritin>Clarinx,
Prilosec>Nexium, Albuterol>Xopenex





Potentiators

- Drug recipes that aggregate drugs that in combination enhance the euphoria
- May be another controlled drug but often are non-controlled drugs (OIG purview)
- Pushes patients over edge to respiratory arrest/death
- Hundreds of potentiators in thousands of combinations
- Large financial exposure to Medicare program





Polypharmacy Cocktails Potentiators

- Abilify + Seroquel Snort (“jailhouse heroin”)
- Oxycodone + Flexeril + Xanax (Holy Trinity)
- Soma + Codeine (“Soma Coma”)
- Gabapentin + oxycodone (OH, KY, VA PDMP)
- Gabapentin + Tegretol (Morontin)
- Seroquel + Zyprexa + Ativan + ETOH + Cocaine
- HIV Protease Inhibitors + Percocet
- Caffeine + ETOH + Eyeball





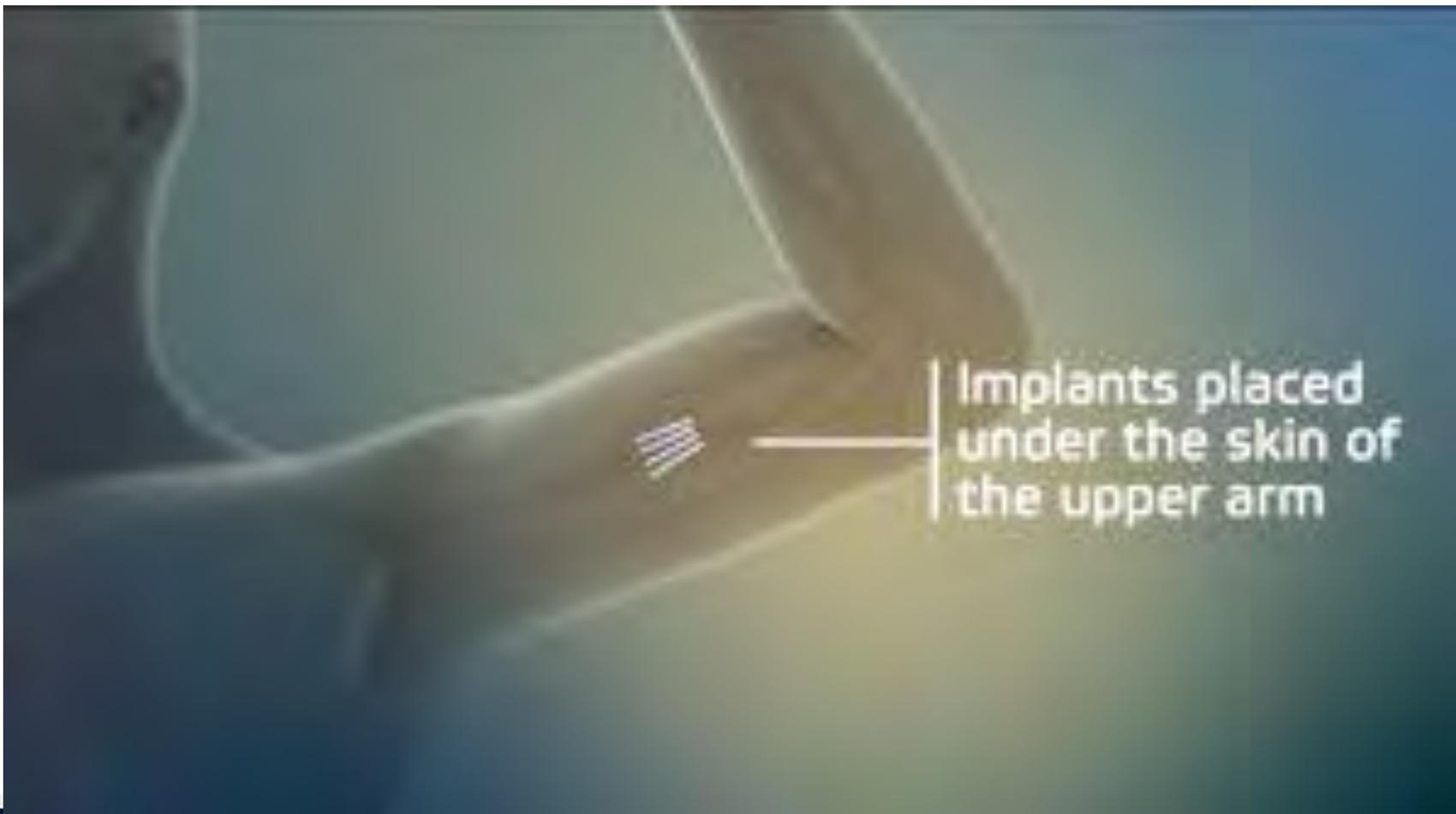
Buprenorphine

- Double edged sword
- Used for addiction to block opioid receptor sites which blocks the high
- Is an opiate and can be abused (solubilized)
- Popular for diversion and mobile bupe clinics
- Causing death in opiate-naïve patients and children





Probuphine





Sublocade

- Manufacturer Indivior
- Once monthly depot injection
- Will be available early 2018



