

DEA DISTRIBUTOR CONFERENCE



DEA – Mobile Field Office
FBI – Mobile Field Office
United States Attorney's Office – Southern District of Alabama



May 11, 2016 - Indianapolis, Indiana

// UNCLASSIFIED / FOIA EXEMPT //

PRESENTATION FORMAT

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- **DEA Diversion Perspective on Drug Distribution**
 - ⊗ Kevin Downey, DEA Diversion Investigator
- **Case Study**
 - ⊗ Michael Burt, DEA Special Agent
- **Criminal Prosecution of Diversion Offenses**
 - ⊗ Deborah Griffin, Assistant United States Attorney
 - ⊗ Christopher Bodnar, Assistant United States Attorney

STANDARD DISCLAIMER

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The views expressed in this presentation do not necessarily reflect the official views of the Drug Enforcement Administration, the Federal Bureau of Investigation, or the U.S. Department of Justice.

POSSIBLE DEGREES OF ACTIONS

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· How Do We Go From:

- ⊗ **Inspection**
- ⊗ **Administrative Actions (LOA, MOA)**
- ⊗ **Civil Penalties and Fines**
- ⊗ **Criminal Prosecution**

CRIMINAL INVESTIGATIONS

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- .. Criminal investigations may begin at either the Distributor level or may result in the Distributor being identified during a separate investigation.
- .. What is the Difference?
 - ⊗ Fines
 - ⊗ Registration
 - ⊗ Potential Imprisonment

RED FLAGS OF DIVERSION

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- Receiving the same Controlled Substances from different Distributors;
 - Doctors may have multiple Registrations, even at the same location.
- Receiving Controlled Substances in amounts excessive to the type of practice or area of the country served;
- Receiving Controlled Substances in amounts and types that are outside the scope of the practice.
 - Weight loss clinic receiving hydromorphone, oxycodone, fentanyl, etc.

RED FLAGS OF DIVERSION

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- .. Doctors prescribing Controlled Substances off-label;
- .. Purchasing large amounts of Controlled Substances versus Non-Controlled Substances;
- .. Prescriptions being filled by multiple patients who live in different states from the practice;

RED FLAGS OF DIVERSION – ONE DOCTOR

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- Number 1 Purchaser in the State
 - 2014
 - n Oxycodone
 - n Morphine
 - n Fentanyl

RED FLAGS OF DIVERSION – ONE DOCTOR

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- .. One Doctor was also one in the **Top 10** in the entire United States for the purchase of **multiple** Schedule II Controlled Substances

WHAT CAN YOU DO

- .. DUE DILIGENCE
- .. Ask Questions, then ask more questions
- .. Take Photos
- .. Observe
- .. Have a **GOOD SOP** in place
- .. Don't be afraid to deny shipment

TYPES OF QUESTIONS

- .. How many patients/customers
- .. How many Doctors dispense?
- .. Only Distributor?
- .. Patients/Customers from out of state?
- .. Type of Practice
- .. Discuss excessive purchase



POTENTIAL CONSEQUENCES

Pharmaceutical Distributor in FL

- Defendant should have been aware clinics were unlawfully distributing/dispensing C.S. w/o a legitimate medical necessity & outside the usual and customary scope of medical practice.
- No due diligence
- Failed to file suspicious order reports
 - Suspicious size, unusual frequency and orders deviating from a normal pattern

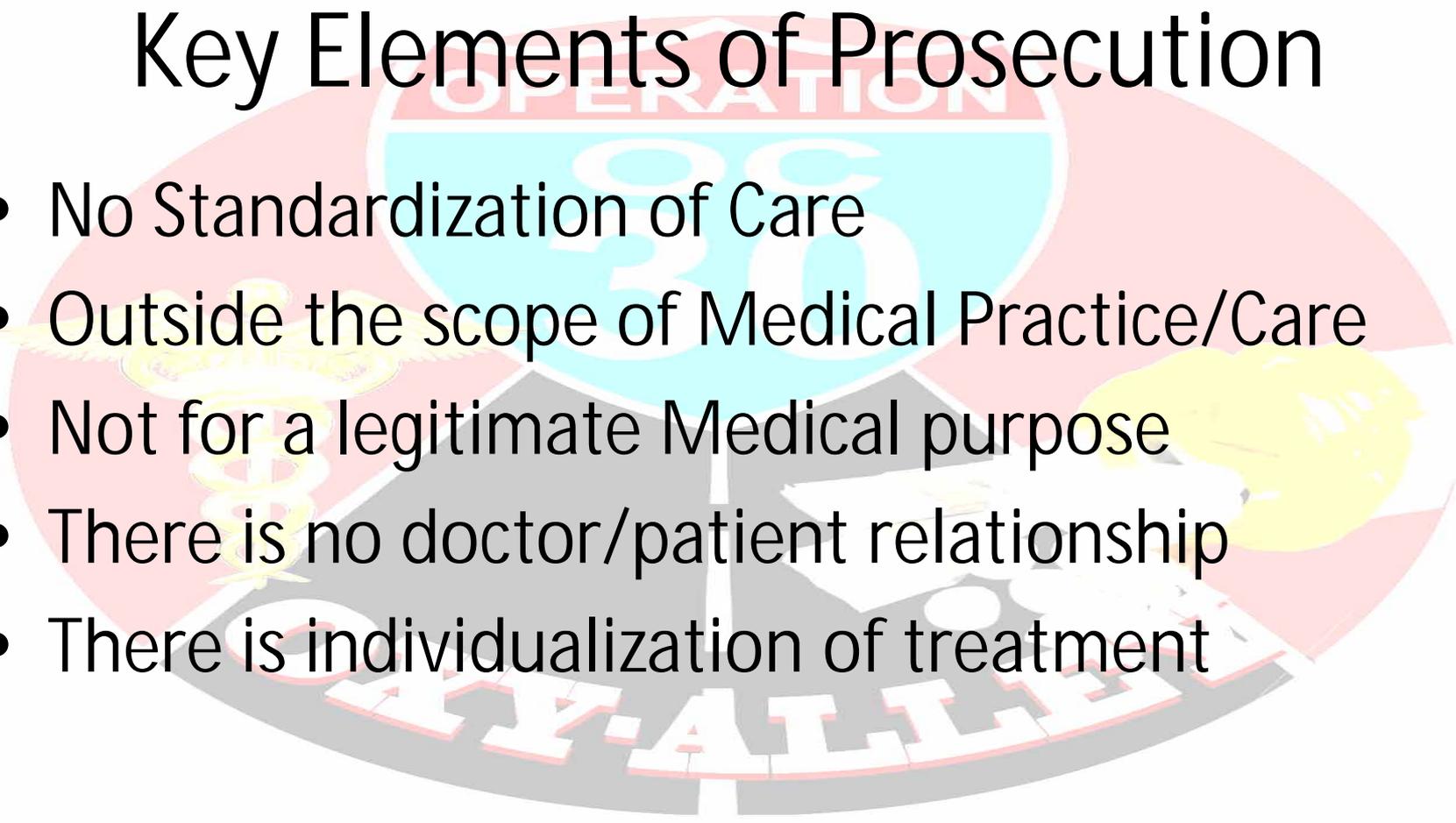
Pharmaceutical Distributor

- June 2009 Letter of Admonition issued by DEA citing 11 violations of Federal regulations
- August 2009 – Briefed by DEA personnel regarding due diligence and filling suspicious orders for C-II's. Ignored warning and notices by DEA to exercise due diligence and suspicious orders for C-II's
- Hired a pain physician to inspect the pain clinic operated by the target of investigation

Pharmaceutical Distributor

- Distributor was told by the physician that the pain clinic was filthy, dispensed enormous amounts of C-II's and appeared to be a "pill-mill"
- After meeting and counseling, DEA tracked over one million Oxycodone pills (through ARCOS) to the South FL pain clinic
- The distributor was charged with:
 - Title 18 USC, Section 1341 - Mail Fraud
 - Title 18 USC, Section 1343 - Wire Fraud

Key Elements of Prosecution

The background features a large, semi-transparent graphic. At the top, the word 'OPERATION' is written in a red, sans-serif font. Below it, the number '30' is displayed in a large, light blue, stylized font. At the bottom, the word 'WY-ALLIE' is written in a white, sans-serif font with a red outline. To the left of the text is a yellow caduceus symbol. The entire graphic is set against a light pink and white background.

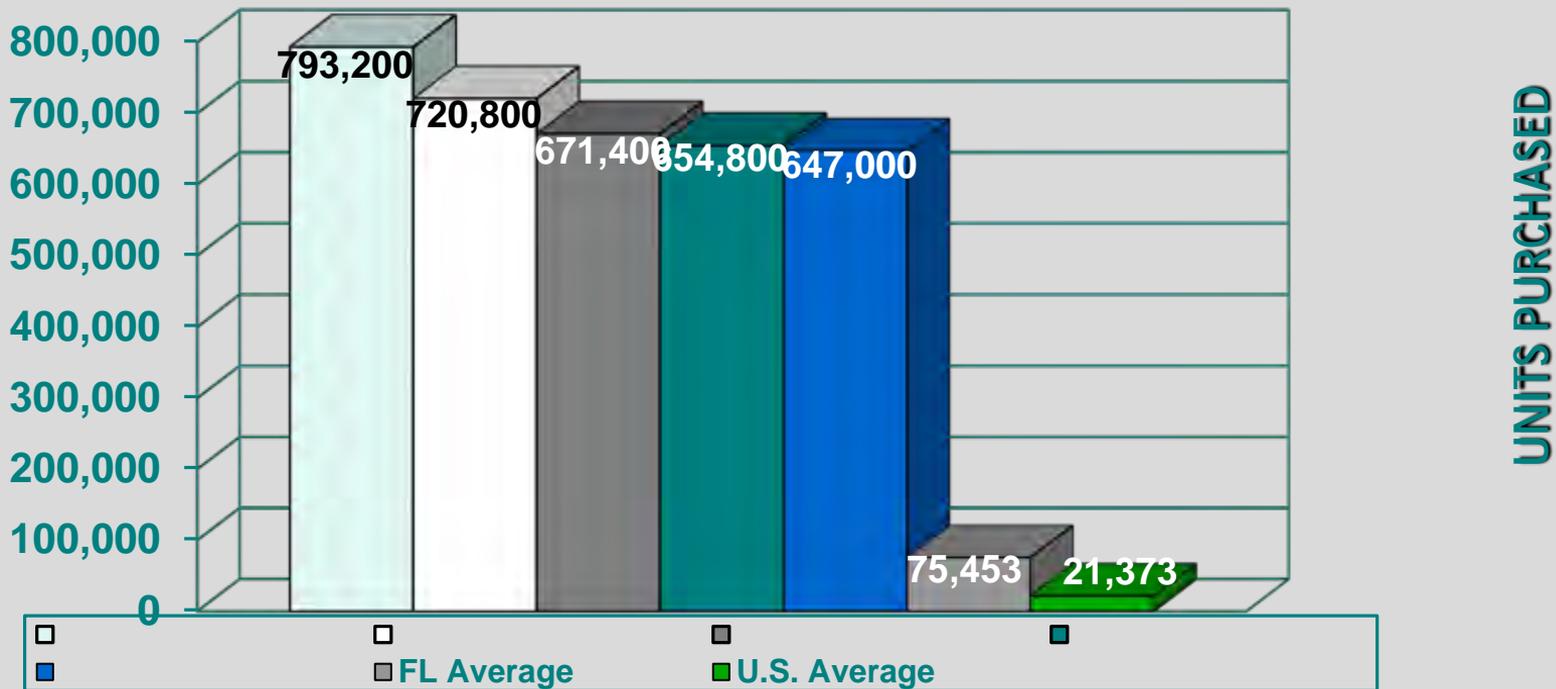
- No Standardization of Care
- Outside the scope of Medical Practice/Care
- Not for a legitimate Medical purpose
- There is no doctor/patient relationship
- There is individualization of treatment

The Holy Trinity

- The Holy Trinity is a drug regimen that included at least:
 - An **Opioid** (Oxycodone, Hydrocodone, Methadone, Vicodin, Percocet)
 - A **Benzodiazepine** (Xanax, Valium, Klonopin)
 - A **Carisoprodol** (Soma)

When these drugs are combined the synergistic effect causes respiratory depression

Comparison of 2009 Purchases of Oxycodone by Practitioners at Pain Clinic





Options for Criminal Prosecution

Potential Drug Charges

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.. Drug Distribution Charges

- ⊗ Substantive Drug Distribution - 21 U.S.C. § 841(a)
- ⊗ Conspiracy to Distribute Drugs - 21 U.S.C. § 846
- ⊗ Registrants - 21 U.S.C. § 843

PROHIBITIONS ON REGISTRANTS

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· 21 U.S.C. § 843 – Unlawful Acts

- ✧ It is unlawful for any person knowingly or intentionally – who is a registrant to distribute a Schedule I or II Controlled Substance in the course of his legitimate business, except pursuant to an order or an order form as required by 21 U.S.C. § 828

PROHIBITIONS ON REGISTRANTS

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· 21 U.S.C. § 843 – Unlawful Acts

- ✧ It is unlawful for any person knowingly or intentionally – to use in the course of the manufacturing, distribution, or dispensing of a Controlled Substance, or to use for the purpose of acquiring or obtaining a Controlled Substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person.

PROHIBITIONS ON REGISTRANTS

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· 21 U.S.C. § 843 – Unlawful Acts

- ✧ It is unlawful for any person knowingly or intentionally – to furnish false or fraudulent material, information in, or omit from any application, report, record or other document required to be made, kept, or filed.

POTENTIAL PENALTIES FOR 843 VIOLATIONS

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- **Criminal Penalties Can Include:**
 - ⊗ Up to 4 years in prison per Count
 - ⊗ 3 years of supervised release
 - ⊗ \$250,000 fine for individuals
 - ⊗ Potentially larger fines for corporations

POTENTIAL FRAUD CHARGES

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.. General Fraud Charges:

- ⊗ Wire Fraud – 18 U.S.C. § 1343
- ⊗ Mail Fraud – 18 U.S.C. § 1341
- ⊗ **NOTE:** The wire and mail communication itself need not be fraudulent

.. Healthcare Fraud Charges:

- ⊗ Healthcare Fraud – 18 U.S.C. § 1347
- ⊗ Healthcare Fraud Conspiracy – 18 U.S.C. § 1349

ELEMENTS OF CRIMINAL FRAUD VIOLATIONS

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- 1) The defendant knowingly devised or participated in a scheme to defraud, or to obtain money or property by using false pretenses, representations, or promises;
- 2) The false pretenses, representations, or promises were about a material fact;
- 3) The defendant acted with the intent to defraud; and
- 4) Use of interstate wire (wire fraud) or mail (mail fraud).

ELEMENTS OF CRIMINAL FRAUD CONSPIRACY

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- 1) Two or more persons, in some way or manner, agreed to try to accomplish as common and unlawful plan to commit fraud; and
- 2) The defendant knew the unlawful purpose of the plan and willfully joined in it.

POTENTIAL PENALTIES FOR FRAUD VIOLATIONS

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- **Criminal Penalties Can Include:**
 - ⊗ Up to 20 years in prison
 - ⊗ 5 years of supervised release
 - ⊗ \$250,000 fine for individuals
 - ⊗ Potentially larger fines for corporations

POTENTIAL KICKBACK VIOLATIONS

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Violations of the Anti-Kickback Statute

- ✧ Knowingly and willfully offering, paying, soliciting, or receiving **ANY** remuneration (does not have to be money);
- ✧ Remuneration offered, paid, solicited, received, **AT LEAST IN PART**, to induce or in exchange for some medical good or service; and
- ✧ Good or service paid for, **AT LEAST IN PART**, by a federal healthcare program

KNOW THE SAFE HARBOR PROVISIONS!
42 C.F.R. § 1001.952

POTENTIAL PENALTIES FOR KICKBACK VIOLATIONS

30

- **Criminal Penalties Can Include:**
 - ⊗ Up to 5 years in prison
 - ⊗ 3 years of supervised release
 - ⊗ \$250,000 fine for individuals
 - ⊗ Potentially larger fines for corporations