

Focus on the Opioid Epidemic – Enforcement and Prevention

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The Opioid Crisis At-A-Glance

- Since 1999, the number of prescription opioid overdoses in the U.S. have **quadrupled**, as have the sales of these prescription drugs according to the CDC.
- 80% of heroin addiction starts with prescription drug addiction.
- In 2014, almost 2 million Americans abused or were dependent upon prescription opioids.
- From 2013 to 2015, NJ doctors were paid \$1.67M+ by pharma marketing fentanyl. In the same time period, fentanyl deaths in NJ increased from 42 in 2014 to 417 in 2015.

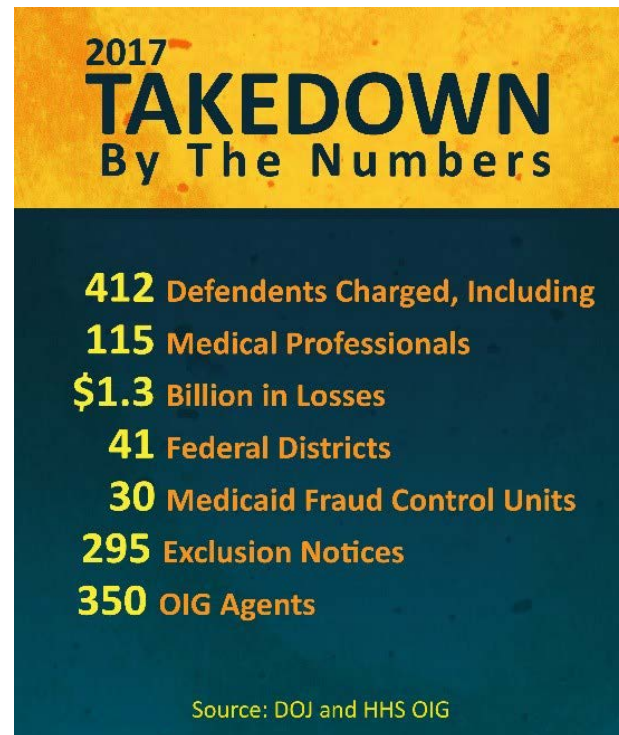
Each day, more than
1,000
PEOPLE

are treated in
emergency departments for not using prescription opioids as directed.



Opioids and the Trump Administration

- DOJ announces charges against over 400 people for \$1.3 billion in health care fraud (07/13/17)
 - “Largest ever health care fraud enforcement action” by the Medicare Fraud Strike Force.
 - Allegedly billed Medicare for \$164 million in fraudulent claims.
 - 295 individuals (including 57 doctors, 162 nurses, and 36 pharmacists) were served with exclusion notices by HHS-OIG for conduct related to opioid diversion and abuse.



Opioids and the Trump Administration

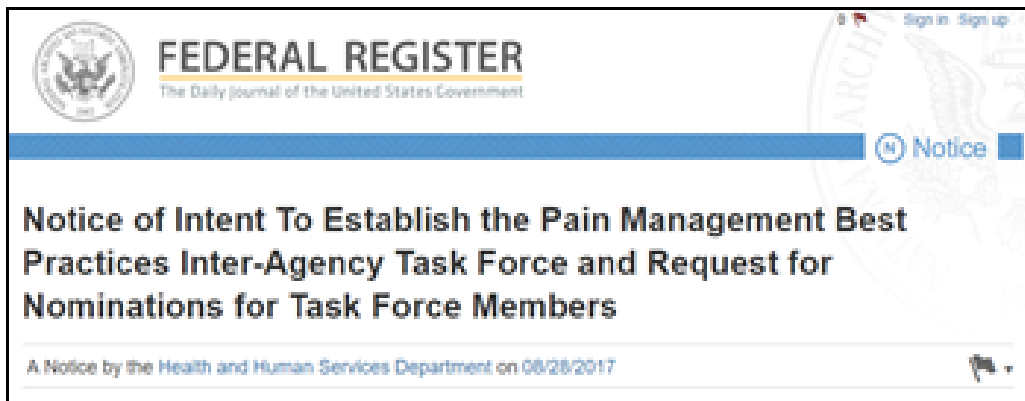
■ DOJ Forms Opioid Fraud And Abuse Detection Unit (08/2/17)

- Creation of 12 Atty Team.
- Use data analytics to pinpoint suspicious prescribers.
- Select districts in FL, MI, AL, TN, KY, PA, OH, CA, NC, W.VA, NV, MD.
- **No NJ or New England AUSAs**

■ Pain Management Best Practices Inter-Agency Task Force (08/28/17)

- HHS task force to develop best practices for prescribing pain medication and managing chronic and acute pain. Authorized under the Comprehensive Addiction and Recovery Act of 2016

- Representatives from the HHS, VA, DOD, and the Office of National Drug Control Policy
- Pain management, addiction, mental health, and recovery experts, also sought



Opioids – Recent OIG Work Plan Items

- **Controls Over Opioid Treatment Programs (August 2017)**

Whether a State agency is effectively monitoring its opioid treatment programs' services and medications in accordance with federal guidelines for opioid treatment programs

- **Opioid Treatment Program Services (July 2017)**

Whether selected State agencies complied with certain Federal and State requirements when claiming Medicaid reimbursement for OTP services

- **Data Brief: Excessive Use of Opioids in Medicare Part D (June 2017)**

Identified prescribers who have questionable opioid prescribing patterns



Opioids – More Federal Involvement

DEA

- Proposed 20% reduction in the number of controlled substances (including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, meperidine and fentanyl) manufactured in 2018

NIDA

- Working with researchers to better understand pain pathways and develop new treatments
- Partnering with industry on early-phase development of treatments
- Leading the Interagency Pain Research Coordinating Committee

CDC

- Guidelines recommending lowering the amount of opioid medications prescribed for pain management
- Training

FDA

- Incentivizing development of new pain treatments
- REMS and associated education
- Safety labeling changes

Opioids – New Jersey’s Response

- Governor Chris Christie, Chair of the President's Commission on Combating Drug Addiction and the Opioid Crisis.
- NJ Facing Addiction Task Force.
- New NJ legislation curbs initial opioid prescriptions to a five-day supply (most stringent limit in U.S.).
- Mandated coverage of inpatient and outpatient treatment for drug addiction.



ENFORCEMENT BACKGROUND:

The Players: Federal and State

- Federal Entities/Individuals:

- U.S. Department of Justice (USAOs and DEA)
- U.S. Department of HHS, Office of Inspector General
- Law Enforcement: FBI, HHS-OIG, IRS-CI, OPM-OIG, and other federal government agencies' OIGs
- CMS: Recovery Audit Contractors (RACs) and ZPICs (Zone Program Integrity Contractors (ZPICs))
- U.S. Department of Justice- Compliance Counsel

- State Entities:

- Medicaid Fraud Control Unit (MFCUs)
- Board of Medical Examiners
- NJ Division of Consumer Affairs – Pain Management Council



ENFORCEMENT BACKGROUND:

Civil False Claims Act—31 U.S.C. § 3729 et. seq.

Prohibits

- Filing, or *causing* to be filed ...
- “False or fraudulent” claims

Knowing

Requires:
Actual knowledge of
falsity, or
Deliberate ignorance, or
Reckless disregard of truth
or falsity.

Intent

“Intent to defraud” not
required
Filing claims with “reckless
disregard” of their truth or
falsity is sufficient

ENFORCEMENT BACKGROUND:

Civil False Claims Act—31 U.S.C. § 3729 et. seq.

- Liability
 - 3X Damages
 - Penalties: \$10,957-\$21,916 (per claim) (eff: 2/3/17)
 - *Potential exclusion consequences*
- False statements in support of a claim also triggers liability
- Materiality is key issue
- Anti-kickback Statute as a predicate for FCA liability
- 60 days to return “known” overpayment- Reverse False Claims Act liability

ENFORCEMENT BACKGROUND:

OIG Exclusion Authority -- Administrative

- §§1128 and 1156 of the Social Security Act.
- Effect of Exclusion:
 - No Federal health care program payment may be made for items or services:
 - Furnished by an excluded individual.
 - Directed or prescribed by an excluded individual, where person furnishing the item or service knew or had reason to know of the exclusion.



ENFORCEMENT BACKGROUND:

OIG Exclusion Authority

Mandatory exclusion

bases include:

Convictions of various crimes related to provision of services under Medicare/Medicaid or healthcare fraud.

Permissive exclusion bases include:

- Engaging in fraud, kickbacks or other prohibited activities.
- Performance of unnecessary or substandard services.
- License revocation/suspension.
- Conviction relating to obstruction of investigation.
- Entities controlled by a sanctioned individual.
- Conviction of certain misdemeanors and other crimes.

ENFORCEMENT BACKGROUND:

Civil Monetary Penalty Actions

- Affirmative fraud litigation.
- Standard
 - Actual knowledge
 - Deliberate indifference
 - Reckless disregard
- 6 year S.O.L.
- Often spin off, or companion to pending FCA investigation/case.

Recent Enforcement Examples

Federal Civil Settlements and Exclusion

- **CleanSlate Addiction Treatment Centers Settle Allegations of Unlicensed Prescribing and Improper Billing (11/22/16)**
 - \$750,000 civil settlement (FCA and CSA) to resolve allegations that the two companies, which together operate opioid addiction treatment centers in multiple states, improperly prescribed drugs for opioid addiction treatment and improperly billed Medicare.

- **New York Physician Agrees to Another Voluntary Exclusion (5/17/17)**
 - In connection with the resolution of his FCA liability, Dr. Michael Esposito agreed to be excluded again from participation in all Federal health care programs for 15 years.
 - OIG's investigation revealed that despite previously having been excluded for five years beginning December 2016, he forged another physician's signature on prescriptions, including opioids, in order to obtain medications for himself and another person.
 - Dr. Esposito also presented claims for payment to Medicare for services that he furnished, ordered, and prescribed to Medicare beneficiaries while excluded.

Recent Enforcement Examples

Federal Civil Settlements Cont'd

■ **Mallinckrodt Pharmaceuticals (07/11/17)**

- \$35 million settlement under the Controlled Substances Act to resolve allegations that the company failed to report signs that large quantities of its highly addictive oxycodone pills were diverted to the black market in Florida.
- Requires company to track drugs through the supply chain to consumers.

■ **Pain Management Group, P.C. (July, 2017)**

- Settlement resolves allegations that PMG caused the submission of false claims to Medicare and TennCare for non-Food & Drug Administration approved pharmaceuticals.

Recent Enforcement Examples

Federal Criminal Prosecutions

- ***U.S. v. Ludwikowski***, Crim. No. 16-513 (D.N.J. Nov. 28, 2016)
 - The owner of two pharmacies was convicted of illegally distributing and dispensing oxycodone and maintaining a drug-involved premises.
 - Ludwikowski and another pharmacist reached an agreement with a physician to “steer” patients to Ludwikowski’s pharmacies.
 - From 3/08 – 8/13, Ludwikowski and his employee knowingly distributed and dispensed controlled substances to individuals, including addicts, who presented phony prescriptions. They also ignored concerns raised by an employee who pointed out an obviously altered prescription. Customers who used the fraudulent prescriptions generally paid in cash and provided gifts to the two employees. In some instances, these customers filled fraudulent prescriptions multiple times a week.

Recent Enforcement Examples

Federal Criminal Prosecutions

- ***U.S. v. Evans & Devido***, Crim. No. 15-00015 (S.D. Tex. July 26, 2016)
 - A doctor and a pharmacist conspired to distribute oxycondone and hydrocondone that were then sold on the street. Dr. Evans faces up to life in prison.
- ***U.S. v. Williams, et al.*** (S.D. Tex. April 3, 2017)
 - A physician, pharmacist, and recruiter were imprisoned for dispensation and distribution conspiracy of oxycondone to those who did not need prescriptions for a legitimate medical reason.
- ***U.S. v. Fernandez*** (S.D. Fla. July 12, 2017)
 - A licensed physician prescribed controlled substances to patients and patient recruiters knowing that they did not have a medical need for them in a classic “pill mill.” Many of the patients who received prescriptions were never examined by Fernandez.

Recent Enforcement Examples

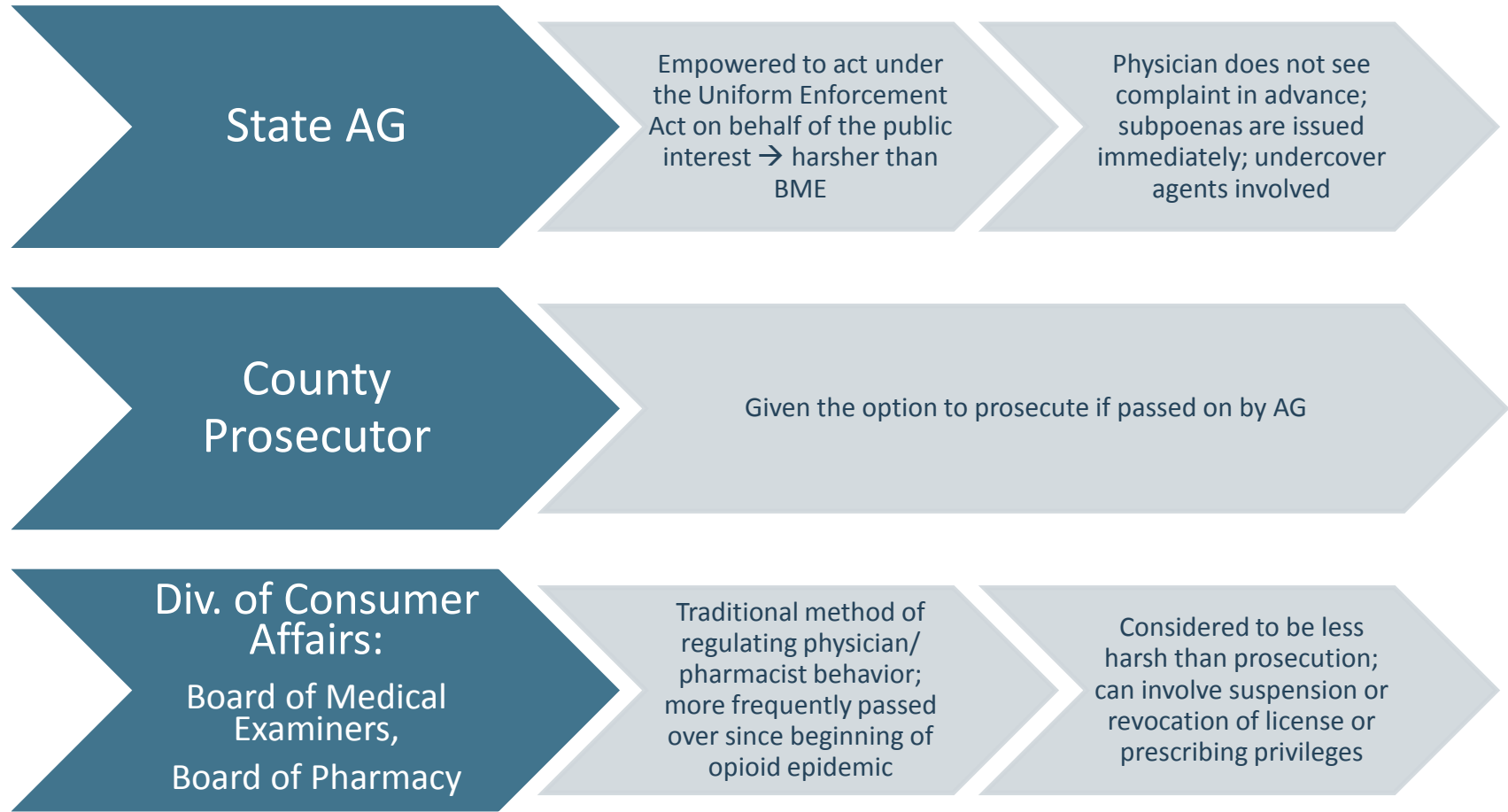
FBI Seizure

■ Alpha Bay (July 2017)

- Alpha Bay is the largest darknet marketplace for illegal drugs, particularly heroin and fentanyl. Sales have been linked to multiple overdose death in the U.S.
- Alpha Bay had operated for more than two years and had transactions exceeding \$1 billion. Joint action by FBI, DEA and European authorities
- The site's creator and administrator were arrested and their assets were seized, as well as millions of dollars in cryptocurrency.



Local Enforcement Possibilities



Recent Enforcement Examples

State Criminal Enforcement Action – New Jersey

- ***N.J. v. Kang***, Docket No. 17-03-00037-S (N.J. Sup. Ct. Mar. 1, 2017)
 - Dr. Byung Kang was charged with strict liability for drug-induced death, money laundering, conspiracy, and illegally distributing oxycodone and xanax. Kang allegedly prescribed oxycodone to a patient he knew was abusing the drug, and the patient later fatally overdosed on pills he prescribed.

- ***N.J. v. Beecher***, Docket No. 16-08-00129-S (N.J. Sup. Ct. Aug. 2016)
 - Dr. George Beecher was charged with conspiring with a drug dealer to operate a ring that distributed oxycodone and xanax pills with a street value of over \$1 million. He was charged with first-degree strict liability for a drug-induced death in the death of a ring member's son.

- ***N.J. v. Evans, et al.*** (N.J. Sup. Ct. Jan. 2015)
 - Dr. Eugene Evans was sentenced to five years in prison for conspiring with a drug dealer to illegally distribute thousands of high-dose oxycodone pills. Evans allegedly issued prescriptions for thousands of 30 milligram tablets of oxycodone in the names of individuals he never examined, treated or even met. Eight other defendants pleaded guilty for their roles in the drug ring.

Recent Enforcement Examples

Action by NJ Board of Medical Examiners and Board of Pharmacy for Improper Prescribing

■ 2016 Action Against Physicians

- 8 license revocations
- 5 long-term suspensions
- 1 voluntary retirement
- 17 temporary license suspensions and other cessations of practice and/or prescribing privileges

- 6 other licensed professionals (PA, chiropractor, pharmacist, pharmacy technician, social worker and a hearing aid dispenser) were disciplined for alleged improper prescription, distribution, or diversion of narcotics

■ *In the Matter of the NJ Prescription Blank Vendor Authorization Issued to Downtown Printing Center*

(May 9, 2016)

- The Division of Consumer Affairs terminated a printing company's authority to print prescription blanks for physicians after the Division found the company failed to follow security requirements and issued 25,000 blanks to unauthorized individuals.

- NJ has not released up to date numbers for 2017, but there have been actions against at least four practitioners regarding controlled substances.

Frequent Federal Criminal Statutes

- Federal Controlled Substances Act, 21 U.S.C. § 846, 841
- Healthcare fraud, insurance fraud, wire fraud
- Internet prescribing, unlawful practice of medicine, professional misconduct, indiscriminate prescribing, diversion of narcotics
- Murder or prescribing leading to the death of an individual
- Involuntary manslaughter
- Falsifying business records, forgery, failure to maintain adequate records
- Tax evasion, tax fraud, money laundering
- Conspiracy and aiding and abetting

How does the Government prove these cases?

Government Investigative Tactics

- Informants/proffers
- Undercover agents seeking prescriptions
- Review of medical records
- Expert review of charts
- Recorded calls
- Interviews with employees/former employees/beneficiaries
- Review of financial records (follow the money trail.....)
- Search warrants – e-mails, cloud storage, physical premises (office/home)
- Seizure warrants – cars, watches, jewelry, boats, etc.

How does the Government prove its case?

Government Investigative Tactics Cont'd

Data Analytics: looking for outliers

- Metrics focus on patterns in billing data that resemble known examples of fraud – red flags for further investigation
 - Non-painmanagement physicians prescribing opioids
 - Prescriber/Beneficiary/Pharmacy states are all different
 - Lack of recorded medical justification for controlled substances
 - Similar quantities and dosages prescribed to all patients
 - Prescriber writes a greater number of prescriptions than others similarly situated or in much higher doses
 - Influx of patients who travel great distances
 - Volume of prescriptions

ENFORCEMENT BACKGROUND:

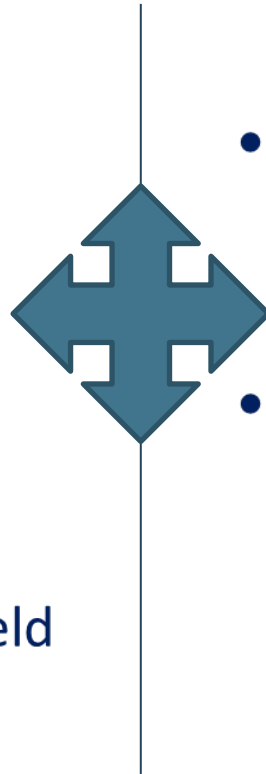
INDIVIDUAL ACCOUNTABILITY - THE YATES MEMO – WHAT IS IT?

- First issued on September 9, 2015.
- Referred to informally as the Yates Memo because it is a policy pronouncement made by the then-Deputy Attorney General Sally Quillian Yates.
- Constitutes new guidelines for Department of Justice attorneys' handling corporate investigations and prosecutions.
- Traditionally, a corporation's cooperation with the federal government's investigation may be factored into how to resolve the case. U.S. Attorney's Manual, § 9-28.700.
- Corporations act through individuals and so investigating the conduct of individuals is the logical means of learning the facts and extent of corporate misconduct and individual misdeeds.
- The Yates Memo sets forth the Department's commitment to seeking individual accountability for corporate wrongdoing.

WHY THE INTEREST IN INDIVIDUAL ACCOUNTABILITY?

Purposes Served

- Future illegal activity is deterred.
- Forcing change in corporate behavior.
- The proper parties are held responsible for their actions.



Overall Benefit

- Builds public confidence in the justice system.
- Corporate investigations are handled consistently across sectors further inspiring public confidence.

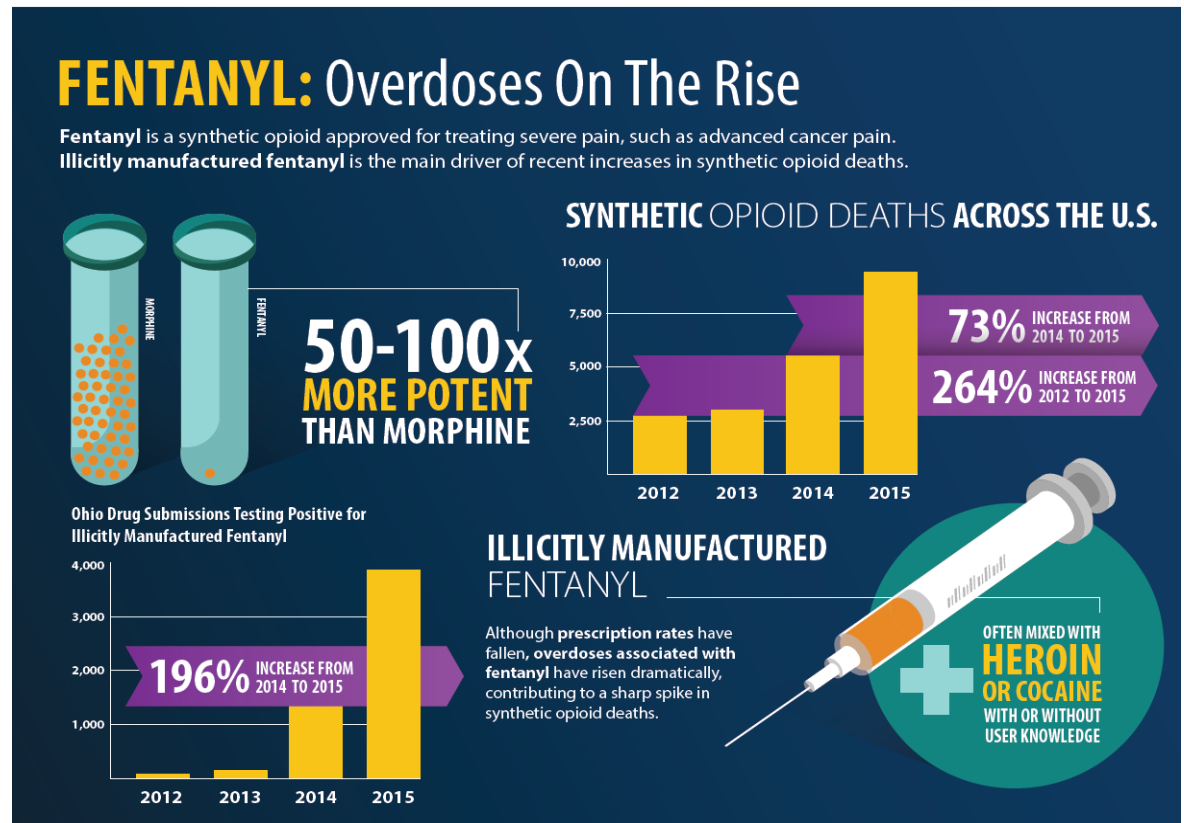
Yates Memo Guidance

The Six Key Points to Understand

- Eligibility for cooperation credit means that corporations must provide the DOJ all relevant facts about individuals involved in corporate misconduct;
- Focus on individuals from start of criminal and civil investigation;
- Criminal and Civil DOJ attorneys will be in routine communication with each other;
- No corporate resolution should provide protection from criminal or civil liability for any culpable individuals;
- Corporate cases should not be resolved without a clear plan to resolve related individual cases; and
- Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based upon factors beyond the ability to pay money to the Government.

Opioid Enforcement Trends: Focus on Fentanyl

- Government is using:
 - Civil settlements
 - Criminal prosecutions
 - License suspensions, revocations, and other disciplinary actions
- Investigations involve a host of players: DOJ; HHS-OIG; FBI; DEA; State AGs, county prosecutors, and state boards of medical examiners



Insys Therapeutics, Inc.

U.S. v. Babich et al., Crim. No. 16-10343 (D. Mass. Dec. 6, 2016)

- Six former executives are accused of bribing doctors to prescribe a spray version of fentanyl, Subsys, intended as a last resort to treat breakthrough cancer pain, often to patients without cancer.
- Insys managers allegedly paid medical practitioners to speak at sham events where their primary goal was to prescribe Subsys. If the practitioners didn't write enough prescriptions, Insys would reduce their number of paid speaking events.

FENTANYL

Known as Subsys, Duragesic, and Abstral.

Fentanyl is a strong prescription pain medicine that contains an opioid (narcotic). It is used to manage breakthrough pain in cancer patients.

WARNING:

- May be habit forming.

State Action Regarding Subsys

- **Illinois:** Illinois Attorney General filed a lawsuit against Insys for deceptively marketing and selling Subsys to physicians treating non-cancer patients for off-label uses like back and neck pain in August 2016. the AG alleges that Insys illegally marketed its painkiller to doctors who prescribed high volumes of opioid drugs instead of focusing its marketing on oncologists.
- **New Jersey:** Investigations into the off-label prescribing of Subsys by doctors who were prescribing the drug beyond its federally-approved use as a cancer pain medication. Three doctors have been disciplined since the investigation began in October 2016.
 - Dr. Matalon had her license suspended on 10/31/16 for indiscriminately prescribing fentanyl to patients, one of whom died.
 - Dr. Patharkar agreed on 11/22/16 to forever cease practicing medicine in NJ.
 - Dr. Sun agreed on 1/5/17 to temporarily suspend his license.
- **New Hampshire:** New Hampshire Attorney General found that Insys held sham speaker engagements to provide payments to induce prescribers to write Subsys prescriptions. Some of these speaking programs did not include anyone who could actually prescribe the drug. Insys was required to pay \$2.9M for violations of the Consumer Protection Act and \$.5M to the New Hampshire Charitable Foundation.

Galena Biopharma, Inc. Settlement

District of New Jersey, Sept. 8, 2017

- More than \$7.55 million civil False Claims Act settlement to resolve allegations that Galena paid physicians kickbacks in exchange for prescribing high volumes of Fentanyl-based drug, Abstral.
- Alleged improper payments for “advisory board” participation and incentive agreements.
- Allegedly involved 2 physicians who were convicted of running a “pill mill” who were sentenced to 20+ years in prison in S.D. Alabama.





QUESTIONS