View from the Trenches: The Government's Opioid Fraud and Abuse Initiatives

Disclaimer

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* Ms. Ben-David's comments today represent her personal opinions; they do not reflect the opinions or positions of the United States Department of Justice. Likewise, the written materials for this panel were not produced or approved by the United States Department of Justice.

Introduction

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- How the crisis developed and has evolved
- Federal statutes & regulations
- Current enforcement initiatives
- Federal responses to the crisis
- State opioid initiatives
- How to avoid liability

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How the Opioid Crisis Has Developed & Evolved

How the Crisis Developed and Has Evolved

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- First wave of opioid epidemic began in **1991** when deaths involving opioids began to rise following increase in prescribing of opioid medication for pain mgmt.
  - Pharma companies begin promoting use of opioids in patients with non-cancer related pain despite data regarding risks
  - Pharma companies reassure prescribers that risk of addiction to prescription opioids was very low
  - By 1999, 86% of patients using opioids were using them for non-cancer patients

How the Crisis Developed and Has Evolved

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- Second wave of opioid epidemics started around **2010** with rapid increase in deaths from heroin abuse.
  - As early efforts to decrease opioid prescribing began to take effect, making prescription opioids harder to obtain, focus turned to cheaper, more widely-available heroin
  - Deaths due to heroin-related overdose increased by nearly 300% from 2002 to 2013
  - Approx. 80% of heroin users admitted to misusing prescription opioids before turning to heroin

How the Crisis Developed and Has Evolved

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- Third wave of epidemic began in **2013** as increase in deaths related to synthetic opioids like fentanyl.
  - Sharpest rise in drug-related deaths occurred in 2016 with over 20,000 deaths from fentanyl and related drugs
  - Increase in fentanyl deaths has been linked to illicitly manufactured fentanyl (as opposed to diverted medical fentanyl) used to replace or adulterate other drugs of abuse

How the Crisis Developed and Has Evolved

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294 Citing Articles

TO THE EDITOR

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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2 References

How the Crisis Developed and Has Evolved

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2016 Review Article
Nora Volkow, M.D.
Thomas McLellan, PhD

Source of the Opioid Epidemic

More than 30% of Americans have some form of acute or chronic pain.[1-3] Among older adults, the prevalence of chronic pain is more than 40%.[2] Given the prevalence of chronic pain and its often disabling effects, it is not surprising that opioid analgesics are now the most commonly prescribed class of medications in the United States.[3] In 2014 alone, U.S. retail pharmacies dispensed 245 million prescriptions for opioid pain relievers.[4,5] Of these prescriptions, 65% were for short-term therapy (<3 weeks),[6] but 3 to 4% of the adult population (9.6 million to 11.5 million persons) were prescribed longer-term opioid therapy.[7] Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable.[8]

However, two major facts can no longer be questioned. First, opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions. More than a third (37%) of the 44,000 drug-overdose deaths that were reported in 2013 (the most recent year for which estimates are available) were attributable to pharmaceutical opioids; heroin accounted for an additional 19%. At the same time, there has been a parallel increase in the rate of opioid addiction, affecting approximately 2.5 million adults in 2014.[9] Second, the major source of diverted opioids is physician prescriptions.[10,11] For these reasons, physicians and medical associations have begun questioning prescribing practices for opioids, particularly as they relate to the management of chronic pain. Moreover, many physicians admit that they are not confident about how to prescribe opioids safely,[12] how to detect abuse or emerging addiction, or even how to discuss these issues with their patients.[13]

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Federal Statutes & Regulations

The Anti-Kickback Statute

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- Prohibits **knowingly & willfully** paying, offering, soliciting or receiving remuneration in return for referral
- **Criminal**, civil & administrative remedies (including damages + penalties + exclusion)
- Predicate to FCA liability
- Safe Harbors & exceptions similar to Stark exceptions (space & equipment rental, personal services & mgmt. contracts, sale of practice, bona fide employment, physician recruitment, etc.)
- Applies to **all** federal healthcare programs
- "One Purpose" rule

The Anti-Kickback Statute

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- **2016:** Ill. psychiatrist pleads guilty to receiving kickbacks from two pharma. companies in exchange for prescribing opioids. Sentenced to 9 months.
  - Remuneration under sham "consulting agreement"
  - Defendant also agreed to restitution of $600K

The False Claims Act ("FCA")

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- Prohibits, among other things:
  - Knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval
  - Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government
    - Retention of overpayment
    - 60-day rule
- *Qui tam* actions

The False Claims Act ("FCA")

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- Consequences of violating: Treble damages, per-claim penalties (b/t $10,957 and $21,916), exclusion.
- "Knowing" and "knowingly" includes actual knowledge, deliberate ignorance, or reckless disregard. **No proof of specific intent to defraud required**.

FCA Common Focus Areas

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- Overprescribing opioids
- Medically unnecessary urine drug screenings
- Relationships with pharma. companies / outside laboratories
- Overutilization of ancillary services

False Claims Act

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- **August 2018:** Ohio physician sued under FCA for overprescribing opioids. Suit also alleges that defendant received kickbacks from phama. company in exchange for prescribing opioids.
  - Govt. also sought temporary restraining order under Controlled Substances Act barring physician from writing prescriptions.

Controlled Substances Act

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- Controlled Substances Act contains numerous requirements and regulations governing prescribers. Violations can lead to civil monetary penalties, suspension of registration, and imprisonment.

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Current Enforcement Initiatives

Current Enforcement Initiatives

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- **July 2017:** National healthcare fraud takedown
  - Over 400 charged
  - Over 1/3 related to prescribing opioids & other dangerous narcotics

Current Enforcement Initiatives

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- **August 2017:** DOJ Announces Opioid Fraud & Abuse Detection Unit
  - Use of data to identify & prosecute individuals that are contributing to opioid epidemic
    - Outlier physicians
    - Patient deaths w/in 60 days of opioid RX
    - Avg. age of prescriptions
    - Outlier pharmacies
  - 12 AUSAs for 3 year term
  - MDFL, EDMI, NDAL, EDTN, DNEV, EDKY, DMD, WDPA, SDOH, EDCAL, MDNC, SDWV

Current Enforcement Initiatives

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- **September 2017:** 41 State AGs announce joint investigation of manufacturers & distributors of opioids.
- **January 2018:** AG Sessions announces DEA surge to focus on pharmacies and prescribers who dispense unusual or disproportionate amount of drugs.
- **February 2018:** New Jersey AG announces creation of new office within AG Office dedicated exclusively to opioid issues.

Current Enforcement Initiatives

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- **February 27, 2018:** DOJ announces creation of **Prescription Interdiction & Litigation (PIL) Task Force**.
  - PIL will "aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufactures and distributors."
  - PIL will use all criminal & civil tools available to hold distributors such as **pharmacies, pain mgmt. clinics, drug testing facilities, and individual physicians** accountable for unlawful actions.

Current Enforcement Initiatives

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- **Individual US Attorney's Offices get involved:**
  - **April 6, 2018:** USA Bill Powell (NDWV) announces creation of **Health Care Crimes Task Force,** which will investigate and prosecute opioid diversion, healthcare fraud, and other illegal activities in healthcare field.
    - Taskforce comprised of USAO, HHS-OIG, DEA, FBI, DCIS, WV Insurance Commission Fraud Unit, and W.V. MFCU.
- **DEA Surge:**
  - DEA announces that during 45-day period in Feb. and March 2018, DEA surfed its enforcement and administrative resources to identify & investigate prescribers and pharmacies that dispensed disproportionately large amounts of drugs.
  - DEA used agents, investigators, and analysts to analyze 80 million transaction reports from DEA-registered manufacturers and distributors, as well as reports submitted on suspicious orders and drug thefts and information shared from agency partners.
  - Reported results include 28 arrests, 54 other enforcement actions including search warrants and administrative inspection warrants, and 283 administrative actions of other types (including inspections, letters of admonition, memoranda of agreement/understanding, surrenders for cause of DEA registrations, orders to show cause, and immediate suspension orders).

Current Enforcement Initiatives

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- **June 2018:** DOJ announces largest HCF enforcement action in DOJ history:
  - 601 individuals charged, including 165 doctors, nurses and other licensed medical professional
  - 162 defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics
  - Thirty state MCFUs participated in takedown
  - Since July 2017, 2700 individuals excluded (587 for opioid diversion and abuse)

Current Enforcement Initiatives

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- **State criminal cases:**
  - **February 2016:** California general practitioner found guilty of **second-degree murder** and sentenced to 30 years to life in prison for deaths of three patients who fatally overdosed on opioids and other dangerous drugs. **According to DA's press release, this is the first such conviction in the country.**
  - **May 2016:** Georgia psychiatrist charged with murder for deaths of three patients allegedly related to overprescribing of hydrocodone, oxycodone, methadone, fentanyl, and amphetamines.
  - **June 2017:** Oklahoma physician charged with 5 counts of second-degree murder based on opioid deaths. According to medical examiner's report, "[e]ach of the individuals was prescribed an excessive amount of medication the same months of their deaths which were all the result of multi-drug toxicity."

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Federal Responses to Opioid Crisis

Federal Responses to the Crisis

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- CDC Guidelines (**March 2016**)
  - Nonpharmalogic therapy and nonopioid pharmalogic therapy preferred. Consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to patients.
  - Before starting opioid therapy, establish treatment goals with all patients & consider how opioid therapy will be discontinued if benefits do not outweigh risks.
  - Before starting and periodically during opioid therapy, discuss with patients known risks & realistic benefits.

Federal Responses to the Crisis

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- CDC Guidelines (**March 2016**)
  - When starting opioid therapy, prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
  - When opioids are started, prescribe lowest effective dosage. Carefully reassess evidence of individual benefits and risks when considering increasing dosage.
  - When opioids used for acute pain, prescribe lowest effective dose of immediate-release opioids and prescribe no greater quantity than needed for expected duration of pain severe enough to require opioids. 3 days or less will often be sufficient, more than 7 days rarely needed.
  - Evaluate benefits & harms with patients within 1-4 weeks of starting opioid therapy for chronic pain or dose escalation. Evaluate benefits 7 harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harm of continued use, reduce dose or taper and discontinue.

Federal Responses to the Crisis

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- 21st Century Cures Act (**December 2016**)
  - Authorized $6.3 billion in funding, including $1 billion to help states fight opioid epidemic ($500 million in each of 2017 and 2018)
  - Cures Act has numerous aims, including:
    - Expand access to and better coordinate mental health ("MH") and substance use disorder ("SUD") care, especially in underserved areas
    - Integrate MH and primary care programs
    - Create and maintain real-time State databases of MH and SUD beds
  - **April 2017**: Tom Price announced $485 million in grants to be issued to States and territories
  - Money to be used to improve State PDMPs, abuse prevention efforts, practitioner training, access to treatment

Federal Responses to the Crisis

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- DATA 2000 – amended in 2016 to permit physicians who have prescribed buprenorphine to 100 patients for at least a year to increase limit to 275 patients
- **June 2017**: FDA asked Endo International to withdraw its long-lasting Opana ER from market; thinks benefits no longer outweigh risks of abuse
- **September 2017**: FDA acted against 500+ websites illegally selling unapproved versions of opioids and other drugs

Federal Responses to the Crisis

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- Commission on Opioids (**March 2017**)
  - Chaired by Gov. Christie
  - August 1 draft report urged Pres. Trump to declare a national public health emergency to unlock emergency funding, expand treatment
  - Trump stated his intent to issue declaration on August 10; did so on October 26
  - Commission's final report issued **November 1, 2017**

Federal Responses to the Crisis

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- Commission's Report contains 56 recommendations, including
  - Block grant federal funding to states for opioid programs
  - Roll out SBIRT to adolescents in school starting in middle school
  - Develop model statutes and policies for patient informed consent process before issuing opioid prescriptions for chronic pain
  - More education and training for prescribers, pharmacists
  - Enhance and require use of PDMPs, including establishing data-sharing hub; increase e-prescribing
  - CMS should remove all pain survey questions from patient satisfaction surveys
  - CMS should modify payment policies that discourage non-opioid pain treatments
  - Enhance federal sentencing penalties for fentanyl trafficking

Federal Responses to the Crisis

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- Opioid Commission recommendations
  - Payors should remove reimbursement and policy barriers to SUD treatment, like patient limits, prior authorizations, and fail-first protocols
  - Enable DOL to fine insurers and funders who violate Mental Health Parity Act
  - Use medication-assisted treatment for pre-trial detainees; establish drug courts in all 93 federal judicial districts
  - HHS should develop new guidance for EMTALA compliance for stabilizing SUD patients
  - Offer employers and EAPs information to address employee SUDs
  - Fast-track (a) research into pain management, overdose medications and prevention and treatment of SUDs, and (b) FDA review of SUD-prevention technology

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State Opioid Initiatives

State opioid initiatives

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- **Florida HB21:** Effective 7/1/18:
  - Prescriber or dispenser must verify patient's identity and consult PBMP prior to prescribing/dispensing controlled substances
  - Provider must record dispensing of opioid into PDMP no later than close of next business day

State opioid initiatives

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- **Arkansas:** New state regulations finalized in July 2018:
  - Require physicians to explore alternative treatments when prescribing daily doses of 50 morphine mg equivalents for chronic pain
  - Require physicians to avoid raising a patient's dosage over 90 morphine mg equivalents per day and "carefully justify a decision" for such a high dosage when prescribed
  - Limits opioid prescriptions for acute maim to 7 day supply

State opioid initiatives

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- **Arizona:** Sen. Bill 1001, requirements effective April 2018:
  - For new prescriptions, 5 day limit for initials fills on opioid prescriptions for patients who have not had opioid prescription filled in prior 60 days
  - For new prescriptions, dosage limit of 90 morphine mg equivalents per day for patients who haven't received opioid prescription in past 60 days
  - Dispensers must check PDMP prior to dispensing opioid prescription
  - Prescribers can no longer be able to dispense opioids directly to patient
  - Prescribers of controlled substances will be required to take continuing education related to opiods

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Defense Perspective: How to Avoid Liability

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Questions?