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America's Opioid Crisis: Status, Solutions and Next Steps

April 12, 2018

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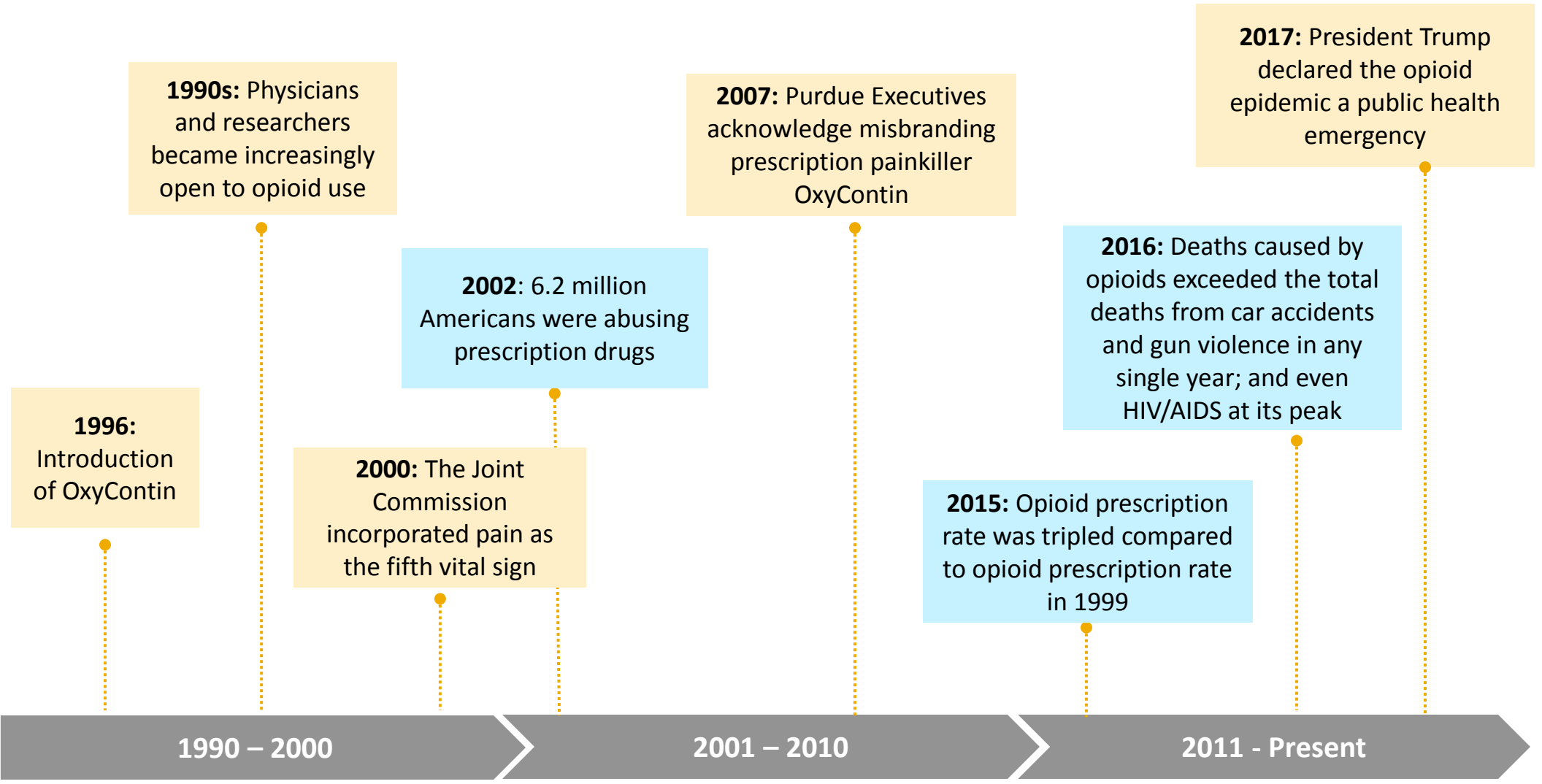
Agenda

- Genesis of the Crisis
- Response by State and Local Governments
- Response by the Federal Government
- Provider and Insurer Perspectives
- Life Sciences Industry Perspective
- Hypothetical

Genesis of America's Opioid Crisis



Response of State Governments

Through legislations and executive orders, most states have established programs designed to prevent new addictions, treat the addicted, and support their recovery.

Gubernatorial Opioid Task Force

Many governors have established task forces to ensure inter-agency coordination, engage community stakeholders, collect and analyze data, and review state laws, policies and procedures**.**

Greater Restrictions on Opioid Prescribing and Use of Prescription Drug Monitoring Programs

Forty-four states have created prescription drug monitoring databases (PDMDs), and most states have adopted laws that limit opioid prescribing.

Expanding Treatment, Including Access to Medication-Assisted Treatment

States looking for ways to promote MAT, but supply continues to remain a challenge, as does strengthening treatment capacity more broadly.

Civil Litigation by Local, State, and Tribal Governments

- Cases Filed by Municipalities, Counties, and Tribes
  - Hundreds of plaintiffs have filed suits against manufacturers, distributors, and pharmacies
  - Some cases focus on more on manufacturers, some on distributors, but all entities in the distribution chain have been named. (e.g., Seattle has sued only manufacturers while the counties of West Virginia have sued distributors and pharmacies)
  - Cases have been filed in state courts, federal court, and even tribal court
- Removal to Federal Court and Consolidation
  - Many (but not all) of the cases filed in state court have been removed to federal court, on the grounds that claims or defenses rely on the federal Controlled Substances Act or on the theory of federal officer removal
  - Some plaintiffs have fought removal because most cases removed to federal court are being consolidated in the Northern District of Ohio
  - Federal cases continue to be consolidated and new cases continue to be filed

Civil Litigation by Local, State, and Tribal Governments: Theories and Defenses

- Negligence and Negligence Per Se Allegations
  - Duty of Care – Plaintiffs claim the monitor-and-report requirement imposed on manufacturers, distributors, and pharmacies under the Controlled Substances Act ("CSA") creates a duty of care to patients, or that such a duty exists independently
  - Breach – Defendants did not monitor or report suspicious orders and, therefore, were negligent in breaching that duty
  - Causation – Diversion of opioids was a foreseeable cause of defendants' negligent failure to report and monitor
  - Damages – Cities, counties and tribes were damaged by having to pay for health care and law enforcement as a result
- Negligence and Negligence Per Se Defenses
  - The CSA does not create a private right of action
  - A valid prescription written by a licensed physician breaks the chain of causation
  - The costs of government are not recoverable as damages under the Free Public Services Doctrine

Civil Litigation by Local, State, and Tribal Governments: Theories and Defenses

- Nuisance Allegations – Defendants' actions created "an unreasonable interference with a right common to the general public." Restatement (Torts) 821(B)
  - West Virginia counties passed an ordinance declaring the opioid epidemic a public nuisance, relying on state public nuisance law used originally for dumps, in 2017
  - Under a nuisance theory, defendants are liable for the cost of abating the nuisance. Plaintiffs allege that means enough money to combat the epidemic entirely.
- Nuisance Defenses
  - Defendants claim there is no common right – no public land that has been dumped on, no lake that has been poisoned.
  - Defendants claim that passing the ordinance was a means of evading the "common right" requirement and therefore constitutes bootstrapping.
  - Defendants also cite the Free Public Services Doctrine

Civil Litigation by Local, State, and Tribal Governments: Theories and Defenses

- Consumer Protection Claims
  - Numerous state consumer protection statutes grant a private right of action against companies engaged in deceptive business practices.
    - Plaintiffs claim that manufacturers made false or misleading statements regarding:
      - The risks of addiction to opioids
      - The effectiveness of opioids
      - The safety of opioids
    - Typically these claims are aimed at manufactures only, even if others have been sued.
- Potential Consumer Protection Defenses
  - Most statutes require consumer-facing statements – statements to doctors and trade groups are not actionable
  - The statements made were truthful
  - The Free Public Services Doctrine is applicable to all city and county cases

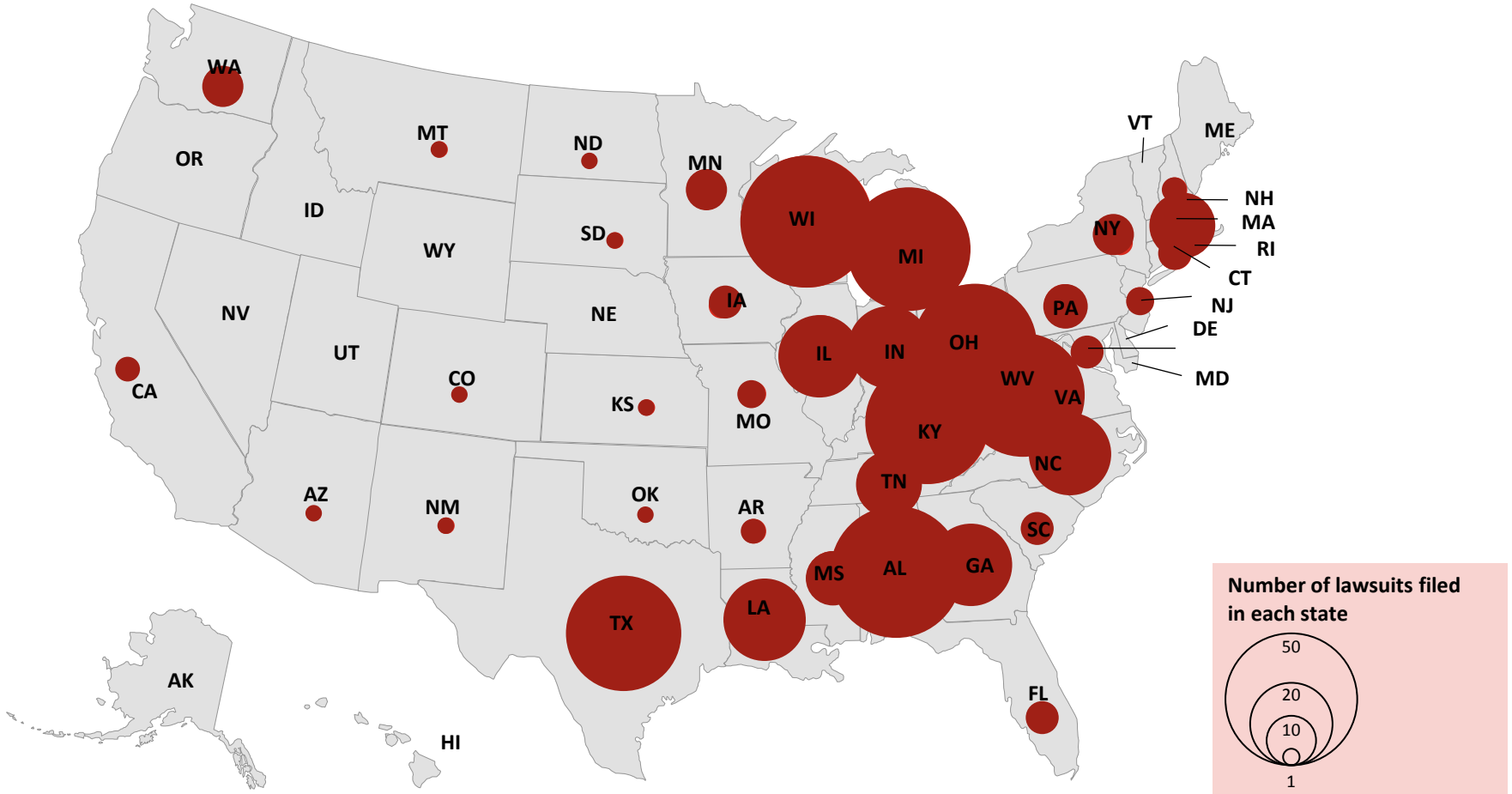
Civil Litigation by Local, State, and Tribal Governments: Theories and Defenses

- Common Law Fraud Claims
  - Allege that Plaintiffs made false statements about the risk of addiction and effectiveness of opioids, calculated to deceive
  - Allege that states and counties incurred costs of medications that should not have been prescribed, in addition to costs of treatment
- Medicaid Fraud claims
  - Brought under state Medicaid Fraud statutes (for example, Sec. 2913.40(B) of the Ohio Revised Code) by AGs
  - Allege that Defendants marketed opioids deceptively by making false statements
  - Allege that Medicaid departments reimbursed unnecessary opioid prescriptions
- Potential Fraud Defenses
  - Fraud must be pled with particularity
  - Fraud requires specific intent to deceive
  - Free Public Services doctrine may also apply

Civil Litigation by Local, State, and Tribal Governments: MDL

Multi-District Litigation (MDL)

- On December 5, 2017, sixty-two cases brought by cities, counties, and states were consolidated in the Northern District of Ohio.
- Since then, more than 387 additional cases have been added to the multidistrict litigation.



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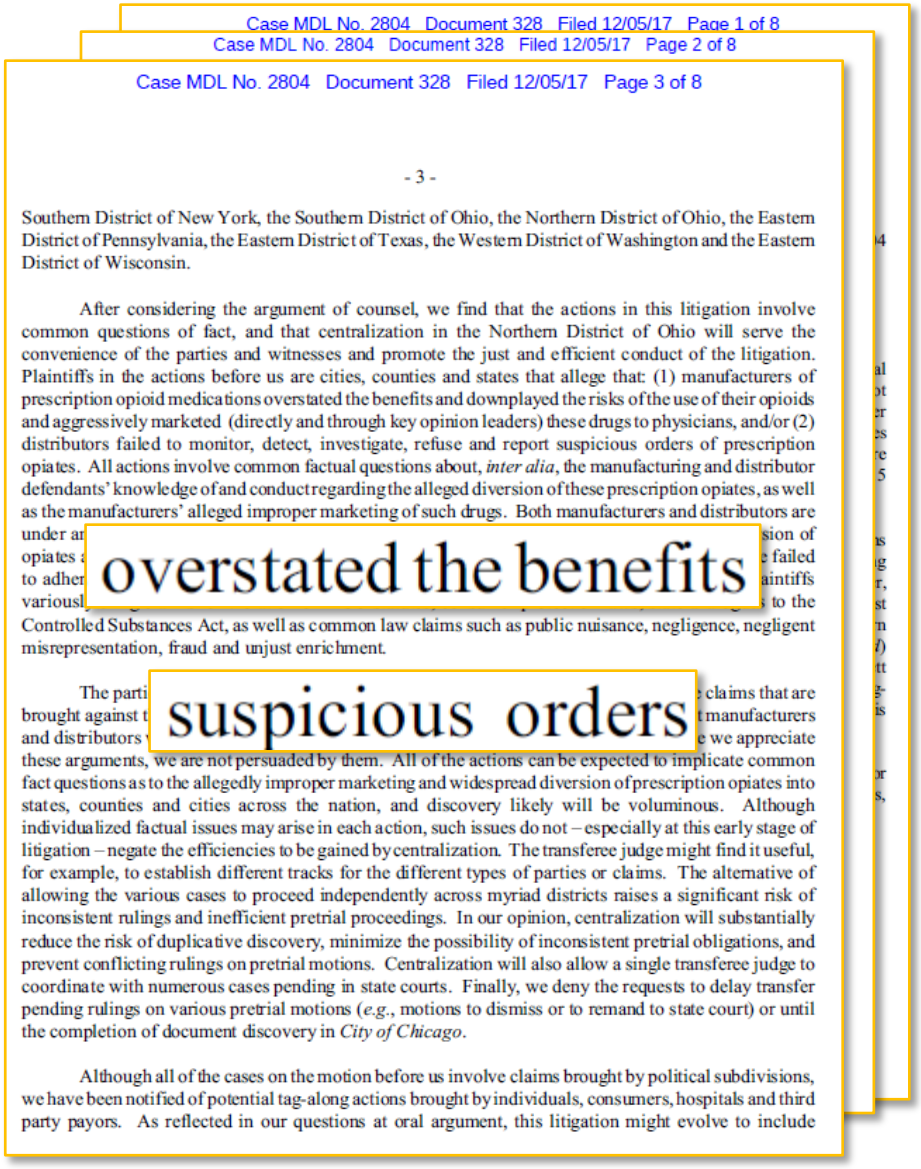
Claims in the Multi-District Litigation

- Cases have different legal theories, but share common issues of fact
- States and counties allege that manufactures and distributors "overstated the benefits and downplayed the risks"
- Further claim that defendants failed to monitor "suspicious orders of prescription opiates" – often alleging violations of the CSA
- Standard for MDL is common issue of fact, so most if not all cases will "tag along" to join the consolidated cases



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Southern District of New York, the Southern District of Ohio, the Northern District of Ohio, the Eastern District of Pennsylvania, the Eastern District of Texas, the Western District of Washington and the Eastern District of Wisconsin.

After considering the argument of counsel, we find that the actions in this litigation involve common questions of fact, and that centralization in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Plaintiffs in the actions before us are cities, counties and states that allege that: (1) manufacturers of prescription opioid medications overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians, and/or (2) distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates. All actions involve common factual questions about, *inter alia*, the manufacturing and distributor defendants' knowledge of and conduct regarding the alleged diversion of these prescription opiates, as well as the manufacturers' alleged improper marketing of such drugs. Both manufacturers and distributors are under ar sion of opiates a failed to adher aintiffs variousl to the Controlled Substances Act, as well as common law claims such as public nuisance, negligence, negligent misrepresentation, fraud and unjust enrichment.

overstated the benefits

The parti claims that are brought against t manufacturers and distributors we appreciate these arguments, we are not persuaded by them. All of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation, and discovery likely will be voluminous. Although individualized factual issues may arise in each action, such issues do not – especially at this early stage of litigation – negate the efficiencies to be gained by centralization. The transferee judge might find it useful, for example, to establish different tracks for the different types of parties or claims. The alternative of allowing the various cases to proceed independently across myriad districts raises a significant risk of inconsistent rulings and inefficient pretrial proceedings. In our opinion, centralization will substantially reduce the risk of duplicative discovery, minimize the possibility of inconsistent pretrial obligations, and prevent conflicting rulings on pretrial motions. Centralization will also allow a single transferee judge to coordinate with numerous cases pending in state courts. Finally, we deny the requests to delay transfer pending rulings on various pretrial motions (*e.g.*, motions to dismiss or to remand to state court) or until the completion of document discovery in *City of Chicago*.

suspicious orders

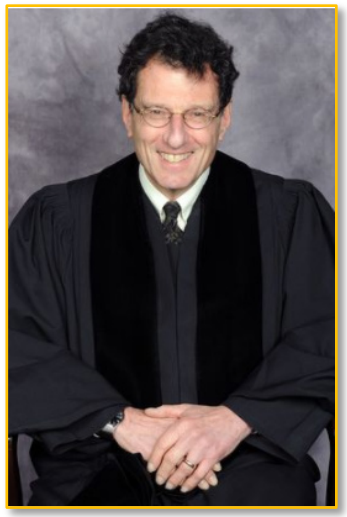
Although all of the cases on the motion before us involve claims brought by political subdivisions, we have been notified of potential tag-along actions brought by individuals, consumers, hospitals and third party payors. As reflected in our questions at oral argument, this litigation might evolve to include

Civil Litigation by Local, State, and Tribal Governments

- Cherokee Nation sought relief in Tribal Court
  - Filed in Tribal Court in April 2017
  - Federal Court held that non-tribal defendants cannot be sued in tribal court in January 2018
  - Re-filed in state court – Defendants have removed to federal court and seek to join the MDL
  - The tribe has moved to remand to state court
- Additional Tribal Suits
  - New tribal cases are being filed in federal court, some affirmatively seeking to join the MDL
  - Over a dozen tribes have brought suit to date
  - Tribes have been particularly hard hit by the opioid crisis

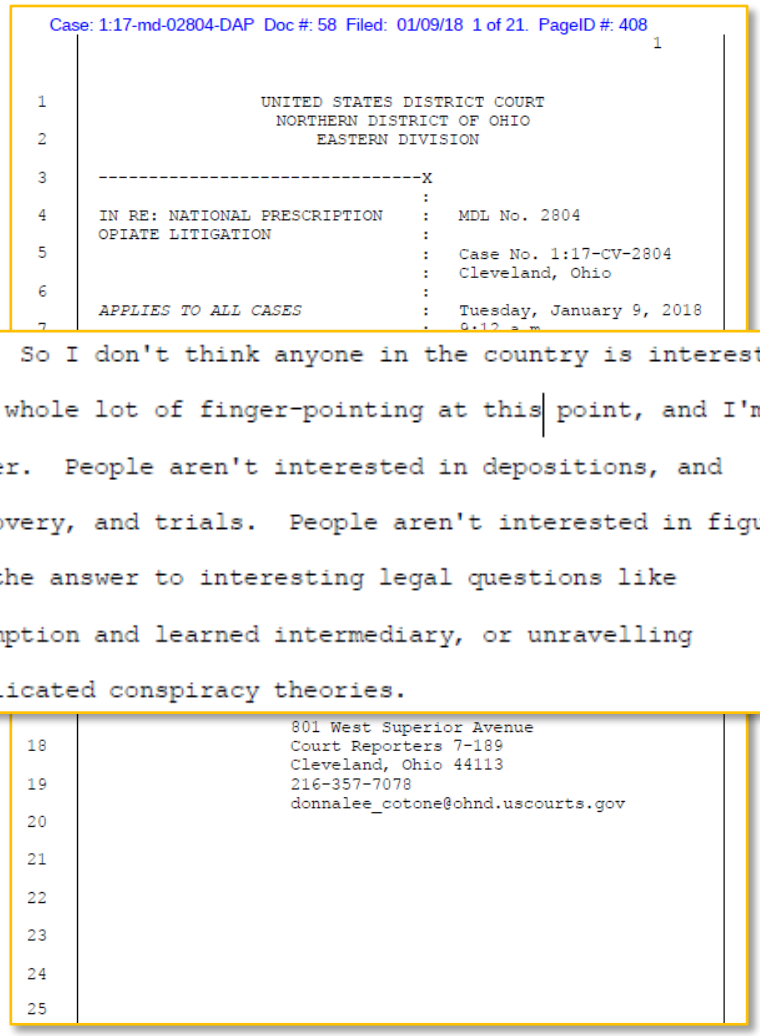
Attorney General Todd Hembree, Cherokee Nation

- Status of the Multi-District Litigation



The Hon. Dan Polster
ND-Ohio

  - Hon. Dan Polster has set an aggressive timetable
  - Suggested a resolution will involve more than a financial settlement, said "my objective is to do something meaningful to abate this crisis and to do it in 2018."
  - Suggested calling in Attorneys General and inviting the involvement of anyone who is "necessary"
  - Conference held on March 6, 2018; "settlement conference" set for May 10, 2018



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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION : MDL No. 2804
: Case No. 1:17-CV-2804
: Cleveland, Ohio
APPLIES TO ALL CASES : Tuesday, January 9, 2018

So I don't think anyone in the country is interested in a whole lot of finger-pointing at this point, and I'm not either. People aren't interested in depositions, and discovery, and trials. People aren't interested in figuring out the answer to interesting legal questions like preemption and learned intermediary, or unravelling complicated conspiracy theories.

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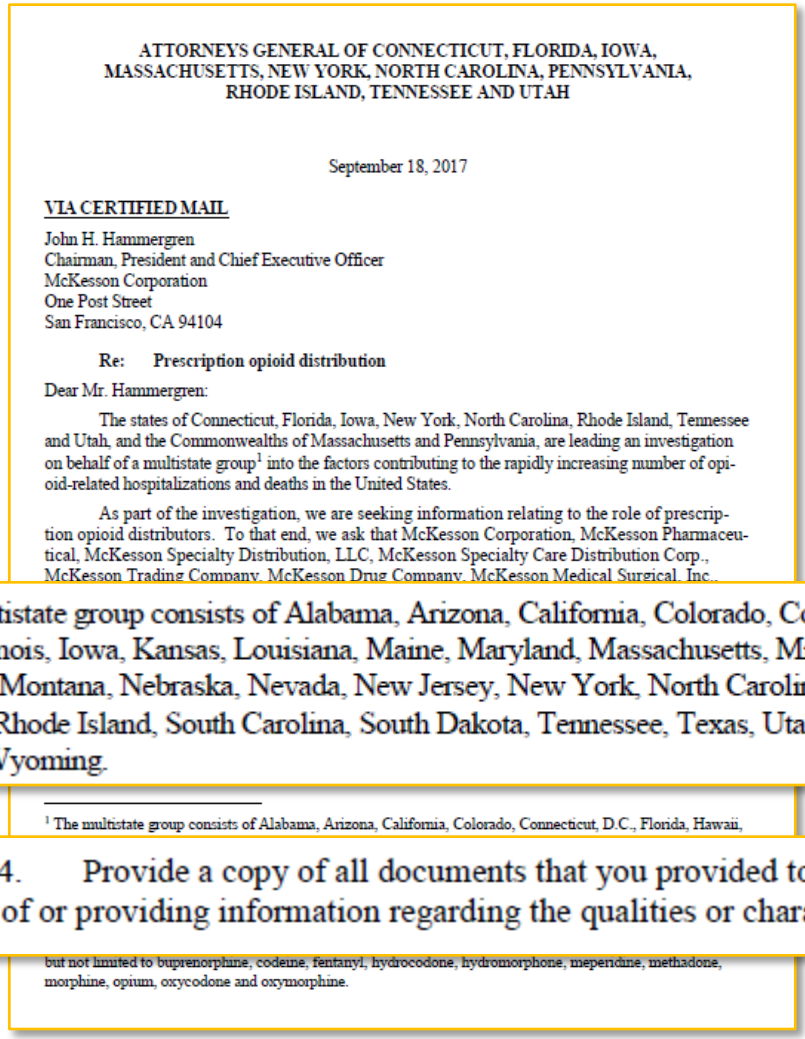
Civil State Attorneys General

State AG Working Group

- In September 2017, 41 attorneys general announced they had requested information and documents from manufacturers and distributors.
- As of April 5, 17 states have filed opioid-related lawsuits, some in federal court (in the MDL) and some in state courts.



ATTORNEYS GENERAL OF CONNECTICUT, FLORIDA, IOWA, MASSACHUSETTS, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, RHODE ISLAND, TENNESSEE AND UTAH

September 18, 2017

VIA CERTIFIED MAIL

John H. Hammergren
Chairman, President and Chief Executive Officer
McKesson Corporation
One Post Street
San Francisco, CA 94104

Re: Prescription opioid distribution

Dear Mr. Hammergren:

The states of Connecticut, Florida, Iowa, New York, North Carolina, Rhode Island, Tennessee and Utah, and the Commonwealths of Massachusetts and Pennsylvania, are leading an investigation on behalf of a multistate group[1] into the factors contributing to the rapidly increasing number of opioid-related hospitalizations and deaths in the United States.

As part of the investigation, we are seeking information relating to the role of prescription opioid distributors. To that end, we ask that McKesson Corporation, McKesson Pharmaceutical, McKesson Specialty Distribution, LLC, McKesson Specialty Care Distribution Corp., McKesson Trading Company, McKesson Drug Company, McKesson Medical Surgical, Inc.,

[1] The multistate group consists of Alabama, Arizona, California, Colorado, Connecticut, D.C., Florida, Hawaii,

but not limited to buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, opium, oxycodone and oxymorphine.

[1] The multistate group consists of Alabama, Arizona, California, Colorado, Connecticut, D.C., Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wyoming.

34. Provide a copy of all documents that you provided to any customer promoting the ordering of or providing information regarding the qualities or characteristic of any opioid.

Criminal Cases: State Attorneys General and Local DAs

- Criminal cases on the local level have included cases against healthcare providers
  - Stan Xuhui Li – Queens doctor specializing in pain management convicted after trial on charges of manslaughter, criminal sale of a controlled substance, scheme to defraud, grand larceny, falsifying business records, offering a false instrument for filing. Sentenced to 10 2/3 to 20 years in December 2014.
  - Hsiu-Ying "Lisa" Tseng – Los Angeles doctor found guilty of three counts of murder after an eight-week trial, stemming from claims that she ignored multiple calls that patients had died from overdoses. Sentenced to thirty years in prison in February 2016.
  - Craig Gialanella – Essex County doctor charged by New Jersey Attorney General with second-degree distribution of narcotics in July 2017 for taking money from a trafficking ring to write bogus prescriptions. The case came from a tip from a pharmacist. New Jersey's Prescription Monitoring Program (PMP) revealed that during 2016 alone, Dr. Gialanella wrote over 400 prescriptions providing access to approximately 50,000 oxycodone pills.

Federal Government's Responses to the Opioid Crisis

Trump Administration and Congress scrambling to support states and communities in need, mitigate harm, and promote sound prevention and treatment policies

- President Trump declared the opioid crisis a public health emergency on Oct 26, 2017 and has proposed increased federal spending, but critics say effort requires better coordination
  - ❑ FY 2018 omnibus appropriation bill included almost $4 billion for federal agencies and states; President has proposed $10 billion for FY 2019 but spending priorities unclear
- The Senate HELP Committee and House Energy and Commerce Committee are actively considering legislative packages for approval before July 4th recess
  - ❑ Expanded HHS role on prescribing practices and treatment priorities
  - ❑ Substantial new resources to states for immediate needs (e.g., naloxone) and longer term capacity-building (e.g., treatment and recovery)
- HHS Secretary Azar is taking on broader leadership role with key staffing changes
  - ❑ Strategic policy and coverage initiatives in Medicare and Medicaid
  - ❑ Coordination across multiple federal agencies working on prevention, pain management, access to treatment, and data reporting

Medicare

The Centers for Medicare and Medicaid Services (CMS) adopted an opioid overutilization monitoring policy for its Medicare prescription drug program ("Part D") in 2013. Recent Medicare Part C and D Call Letter & Final Rule updated the policy.

- Limit initial opioid prescription fills for the treatment of acute pain (opioid naïve) to no more than a 7 days supply
- Leverage and expand CMS' OMS to identify beneficiaries at significant risk (using high levels of opioids from multiple prescribers and pharmacies) - 90 MME and either 3+ Prescribers **and** 3+ Pharmacies **OR** 5+ Prescribers
  - Sponsors review these cases and perform case management with the beneficiaries' prescribers
  - Excludes buprenorphine for MAT
- Implement CARA drug management program in 2019 within the OMS process
  - Ability to "lock-in" at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies and apply beneficiary-specific point-of-sale (POS) claim edits

Medicare (continued)

- Real-time safety edits at POS to proactively engage both patients and prescribers about overdose risk and prevention (chronic opioid overuse)
- Opioid care coordination triggers pharmacist to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that specifically states that the prescriber has been consulted
- Includes high risk beneficiaries who take opioids and "potentiator" drugs (soft safety edits to alert the pharmacist)
  - Opioid + gabapentin/pregabalin
  - Concurrent use of opioids and benzodiazepines
- Beneficiaries exempted from drug management program include 1) those who have elected to receive hospice care, palliative or end-of-life care 2) residents of LTC facilities or another facility where drugs are dispensed through a single contract pharmacy 3) those being treated for cancer-related pain

Goal: further reduce the number of beneficiaries who may potentially misuse or overdose on opioids while still having access to important treatment options

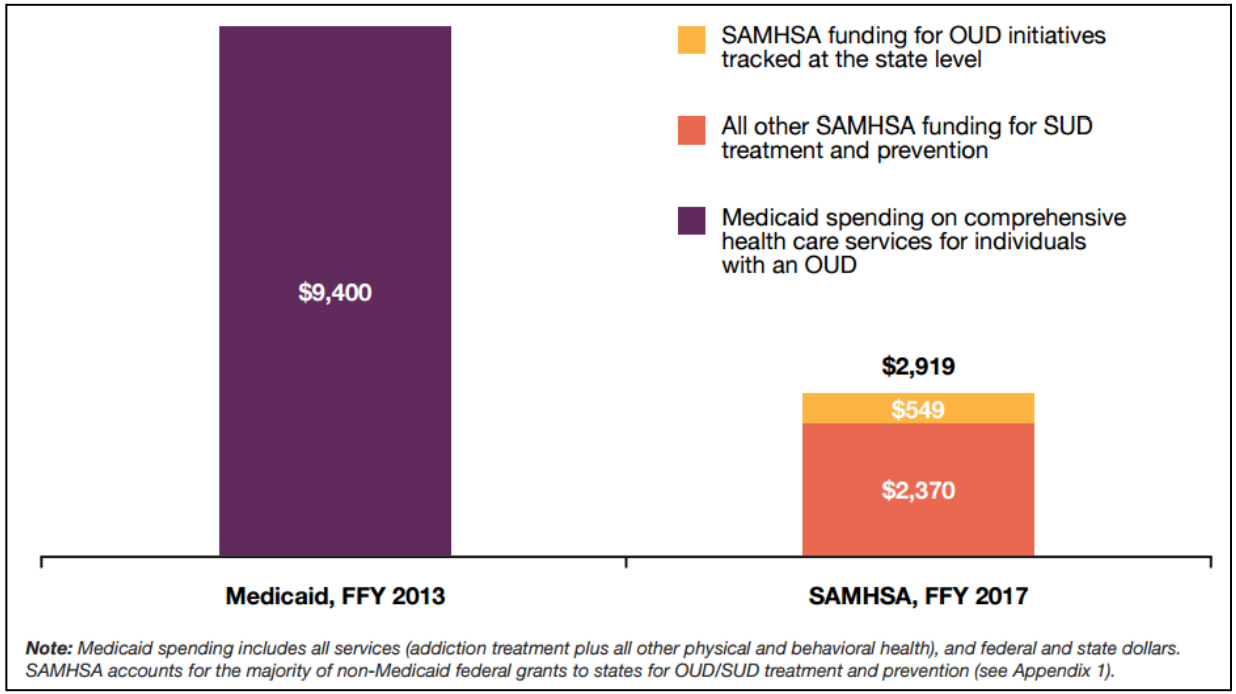
Medicaid

Even prior to expansion (FFY 2013), Medicaid spent $9.4B in federal and state dollars on comprehensive health care services for 636,000 individuals with an OUD

The largest sources of OUD funding in 2017 included:

- **$500M**: Opioid State Targeted Response to the Opioid Crisis (SAMHSA)
- **$40.8M**: Prevention for States Program (CDC)
- **$12M**: First Responders (SAMHSA)
- **$4.2M**: Pain Management Collaboratory (NIH)
- **$25M**: Targeted Capacity Expansion Medicaid Assisted Treatment (MAT) – Prescription Drug and Opioid Addiction (SAMHSA)

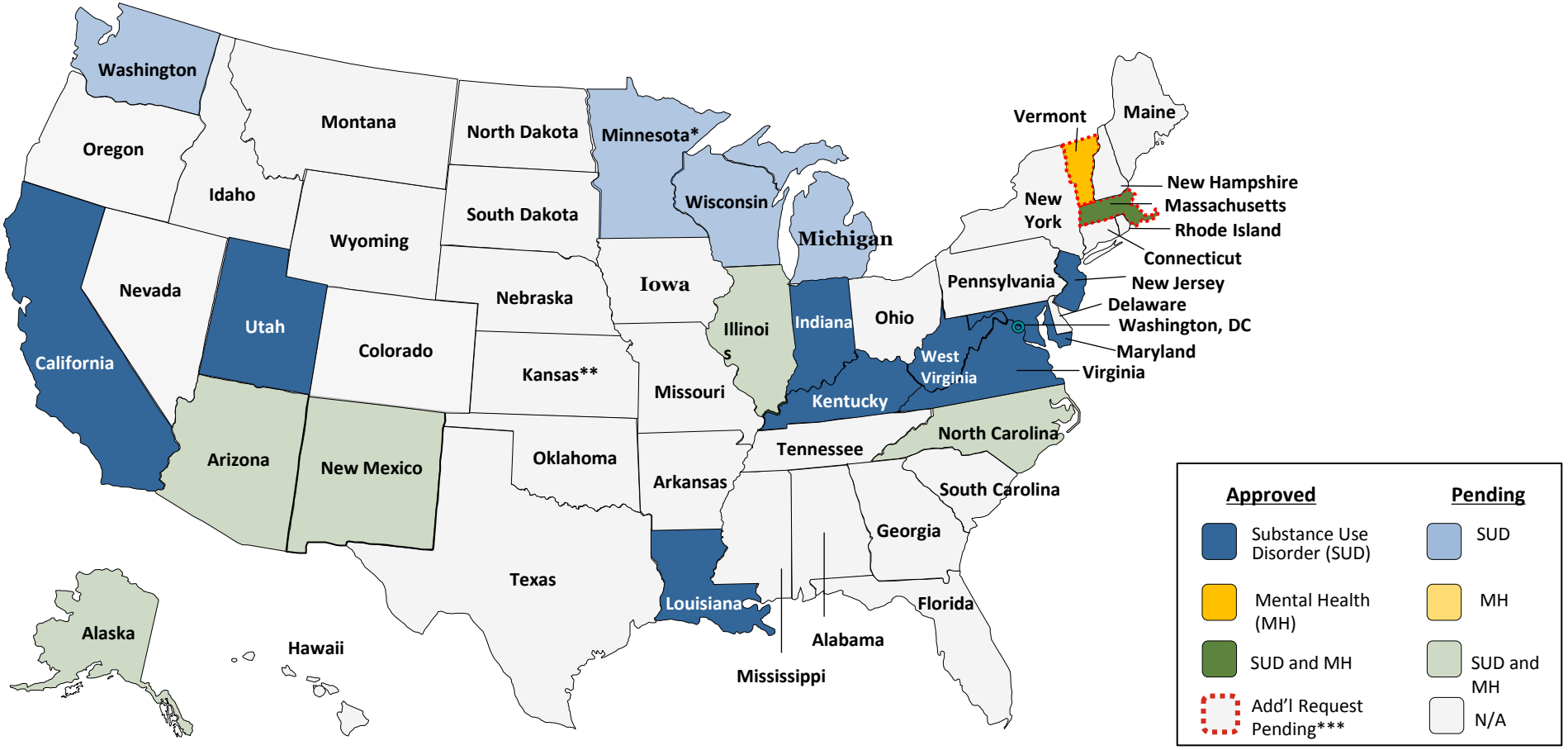
Medicaid Spending for People with an OUD Compared to Non-Medicaid Federal Grants to States for OUD/SUD Treatment and Prevention (in millions)



Note: *Medicaid spending includes all services (addiction treatment plus all other physical and behavioral health), and federal and state dollars. SAMHSA accounts for the majority of non-Medicaid federal grants to states for OUD/SUD treatment and prevention (see Appendix 1).*

Institutions for Mental Disease (IMD) Exclusion Waiver

CMS has continued to use its 1115 waiver authority to provide federal Medicaid matching funds for the cost of serving people in residential settings, including IMD. To date, 20 States Have Approved or Pending Waivers of the IMD Exclusion.



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Many Federal Agencies Are Responding to the Opioid Crisis

HHS Secretary Alex Azar manages many agencies with expertise to support states and other stakeholders in responding to the opioid crisis

CDC – Centers for Disease Control and Prevention

- Publish treatment guidelines, including 2016 guidelines for pain management that promote non-pharmacological and non-opioid options, and limit opioid prescriptions based on patient needs
- Produce data studies on overdose deaths and other public health trends

FDA

- Use data analytics to rationalize prescribing
- Enhance state prescription drug monitoring programs (PDMPs) with electronic medical records and e-prescribing
- Packaging and disposal standards
- Commissioner Gottlieb recently challenged on-line providers to redirect fentanyl searches to treatment options

SAMHSA – Substance Abuse and Mental Health Services Administration – www.samhsa.gov

- Distribute grant funding to support capacity-building at state and local level
- Serve as clearinghouse for local treatment options
- Promote access to medication assisted treatment (MAT)
- Support distribution of naloxone and training of first responders to reduce overdose deaths

NIH – National Institutes of Health

- Partner with innovator companies to facilitate development of new treatments for pain, addiction, and overdose reversal
- Work with Veterans Administration on pain management in military and for veterans

- Key Statutory Provisions:
  - **Part D – Offenses and Penalties**
    21 USC §842. Prohibited acts B (in part)
    (a) Unlawful acts

    It shall be unlawful for any person—
    (1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;
    (2) **who is a registrant to distribute or dispense a controlled substance not authorized by his registration** to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;
    (3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;
    (4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;
    (5) **to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter** or subchapter II of this chapter;

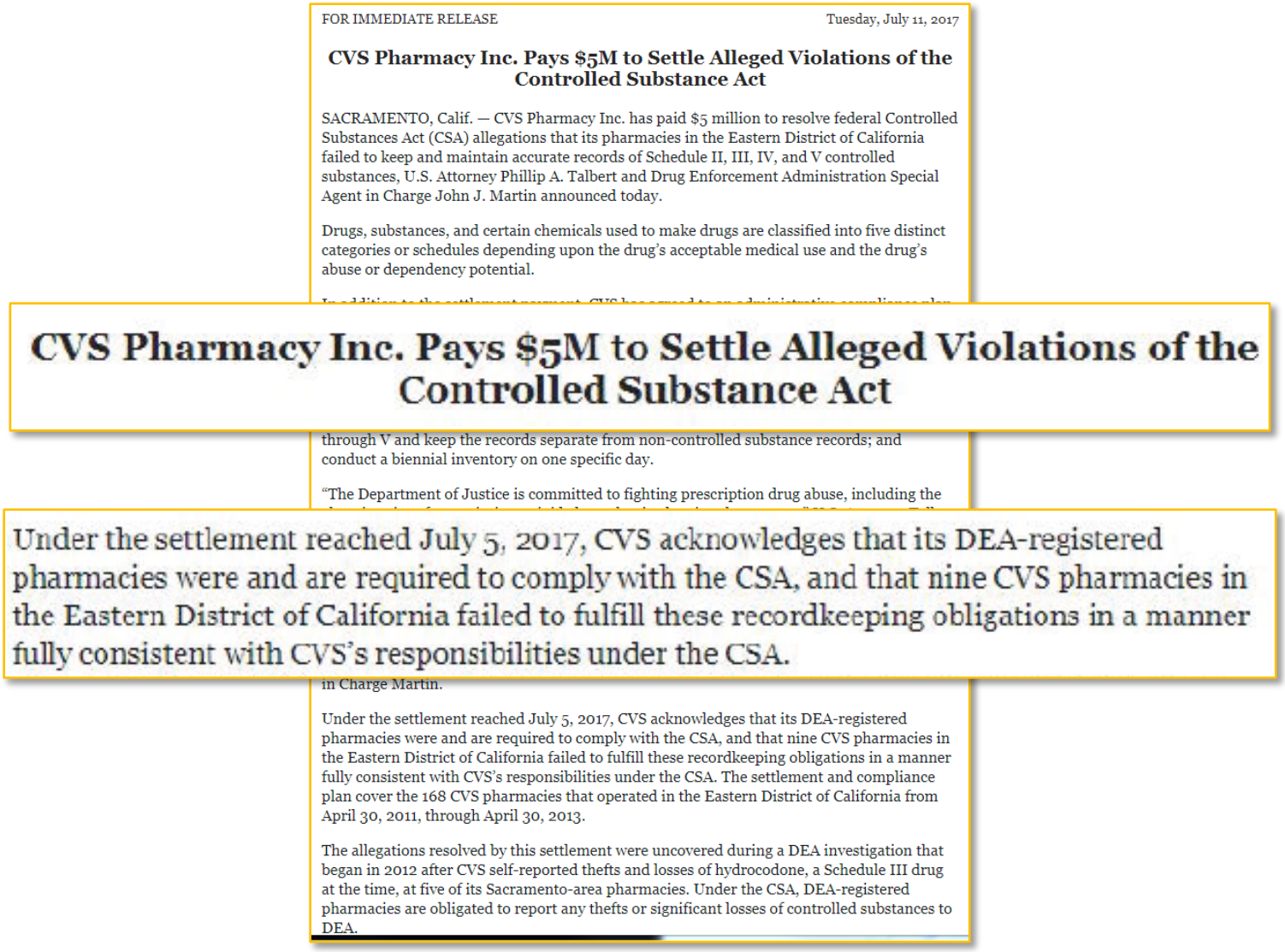
Administrative CSA Record Keeping Cases

- Key Statutory Provisions (continued)
  - **21 CFR 1300 et. Seq. — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES §1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs (in part)**

    (a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.
    (b) **The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency**.

- Violations punishable by administrative sanctions, including suspension and revocation, and civil penalties up to $25,000 for each violation; “knowing” violations can bring criminal penalties, including imprisonment and fines.

Administrative CSA Record Keeping Cases



FOR IMMEDIATE RELEASE

Tuesday, July 11, 2017

CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act

SACRAMENTO, Calif. — CVS Pharmacy Inc. has paid $5 million to resolve federal Controlled Substances Act (CSA) allegations that its pharmacies in the Eastern District of California failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances, U.S. Attorney Phillip A. Talbert and Drug Enforcement Administration Special Agent in Charge John J. Martin announced today.

Drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential.

CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act

through V and keep the records separate from non-controlled substance records; and conduct a biennial inventory on one specific day.

"The Department of Justice is committed to fighting prescription drug abuse, including the

Under the settlement reached July 5, 2017, CVS acknowledges that its DEA-registered pharmacies were and are required to comply with the CSA, and that nine CVS pharmacies in the Eastern District of California failed to fulfill these recordkeeping obligations in a manner fully consistent with CVS's responsibilities under the CSA.

in Charge Martin.

Under the settlement reached July 5, 2017, CVS acknowledges that its DEA-registered pharmacies were and are required to comply with the CSA, and that nine CVS pharmacies in the Eastern District of California failed to fulfill these recordkeeping obligations in a manner fully consistent with CVS's responsibilities under the CSA. The settlement and compliance plan cover the 168 CVS pharmacies that operated in the Eastern District of California from April 30, 2011, through April 30, 2013.

The allegations resolved by this settlement were uncovered during a DEA investigation that began in 2012 after CVS self-reported thefts and losses of hydrocodone, a Schedule III drug at the time, at five of its Sacramento-area pharmacies. Under the CSA, DEA-registered pharmacies are obligated to report any thefts or significant losses of controlled substances to DEA.

Administrative CSA Record Keeping Cases

Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations

Mallinckrodt LLC, a pharmaceutical manufacturer and one of the largest manufacturers of generic oxycodone, agreed to pay $35 million to settle allegations that it violated certain provisions of the Controlled Substances Act (CSA) that are subject to civil penalties, Attorney General Jeff Sessions of the Justice Department and Acting Administrator Chuck Rosenberg of the Drug Enforcement Administration (DEA) announced today.

This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere. The settlement also addressed violations in the company's manufacturing batch records at its plant in Hobart, New York. Both sets of alleged violations impact accountability for controlled substances, and the compliance terms going forward are designed to help protect against diversion of these substances at critical links in the controlled substance supply chain.

"In the midst of one of the worst drug abuse crises in American history, the Department of Justice has the responsibility to ensure that our drug laws are being enforced and to protect the American people," said Attorney General Sessions. "Part of that mission is holding drug manufacturers accountable for their actions. Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. Thanks to the hard work of our

Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations

accountable."

The government alleged that Mallinckrodt failed to design and implement an effective system to detect and report

In addition to the significant monetary penalty, this settlement includes a groundbreaking parallel agreement with the DEA, as a result of which the company will analyze data it collects on orders from customers down the supply chain to identify suspicious sales.

The government also alleged that Mallinckrodt violated record keeping requirements at its manufacturing facility in upstate New York. Among other things, these violations created discrepancies between the actual number of tablets manufactured in a batch and the number of tablets Mallinckrodt reported on its records. Accurate reconciliation of records at the manufacturing stage is a critical first step in ensuring that controlled substances are accounted for properly through the supply chain.

In addition to the significant monetary penalty, this settlement includes a groundbreaking parallel agreement with the DEA, as a result of which the company will analyze data it collects on orders from customers down the supply chain to identify suspicious sales. The resolution advances the DEA's position that controlled substance manufacturers need to go beyond "know your customer" to use otherwise available company data to "know your customer's customer" to protect these potentially dangerous pharmaceuticals from getting into the wrong hands. DEA's Memorandum of Agreement with Mallinckrodt also sets forth specific procedures it will undertake to ensure the accuracy of batch records and protect loss of raw product in the manufacturing process.

Administrative CSA Record Keeping Cases

FOR IMMEDIATE RELEASE Tuesday, January 17, 2017

McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs

McKesson Corporation (McKesson), one of the nation's largest distributors of pharmaceutical drugs, agreed to pay a record $150 million civil penalty for alleged violations of the Controlled Substances Act (CSA), the Justice Department announced today.

McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs

the government alleged again that McKesson failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers – i.e.,

The government's investigation developed evidence that even after designing a compliance program after the 2008 settlement, McKesson did not fully implement or adhere to its own program. In Colorado, for example, McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious, all connected to one instance related to a recently terminated customer.

terms for the next five years. Among other things, McKesson has agreed to specific, rigorous staffing and organizational improvements; periodic auditing; and stipulated financial penalties for failing to adhere to the compliance terms. Critically, the settlement will require McKesson to engage an independent monitor to assess compliance – the first independe monitor of its kind in a CSA civil penalty settlement.

This was a multi-district investigation that involved the following DEA Field Divisions: Boston Field Division, Chic Division, Denver Field Division, Detroit Field Division, Miami Field Division, Newark Field Division, San Francisc Division, St. Louis Field Division, and Washington District Office. The following U.S. Attorney's Offices participate case: Central District of California, Eastern District of California, District of Colorado, Middle District of Florida, Ea District of Kentucky, Northern District of Illinois, District of Massachusetts, Eastern District of Michigan, District o Nebraska, District of New Jersey, Northern District of West Virginia, and Western District of Wisconsin.

U.S. Attorneys' Offices for the District of Colorado and the Northern District of West Virginia, along with DEA Offic Counsel and Diversion Control Division, led the civil settlement negotiations. DEA's Denver, Detroit and Miami Fi Divisions, and its Washington Division Office, led the administrative and civil investigation. The Criminal Division's Narcotic and Dangerous Drug Section (NDDS) also coordinated and assisted in negotiating certain portions of the settlement. Assistant United States Attorneys Amanda Rocque (Colorado) and Alan McGonigal (NDWV) represented the United States in the civil penalty investigations and negotiations. Associate Chief Counsel Lee Reeves and Senior Attorneys Dedra Curteman, Dana Hill and Krista Tongring represented DEA in the investigations and negotiations. Trial Attorneys Harry Matz and Kirtland Marsh were involved for NDDS.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

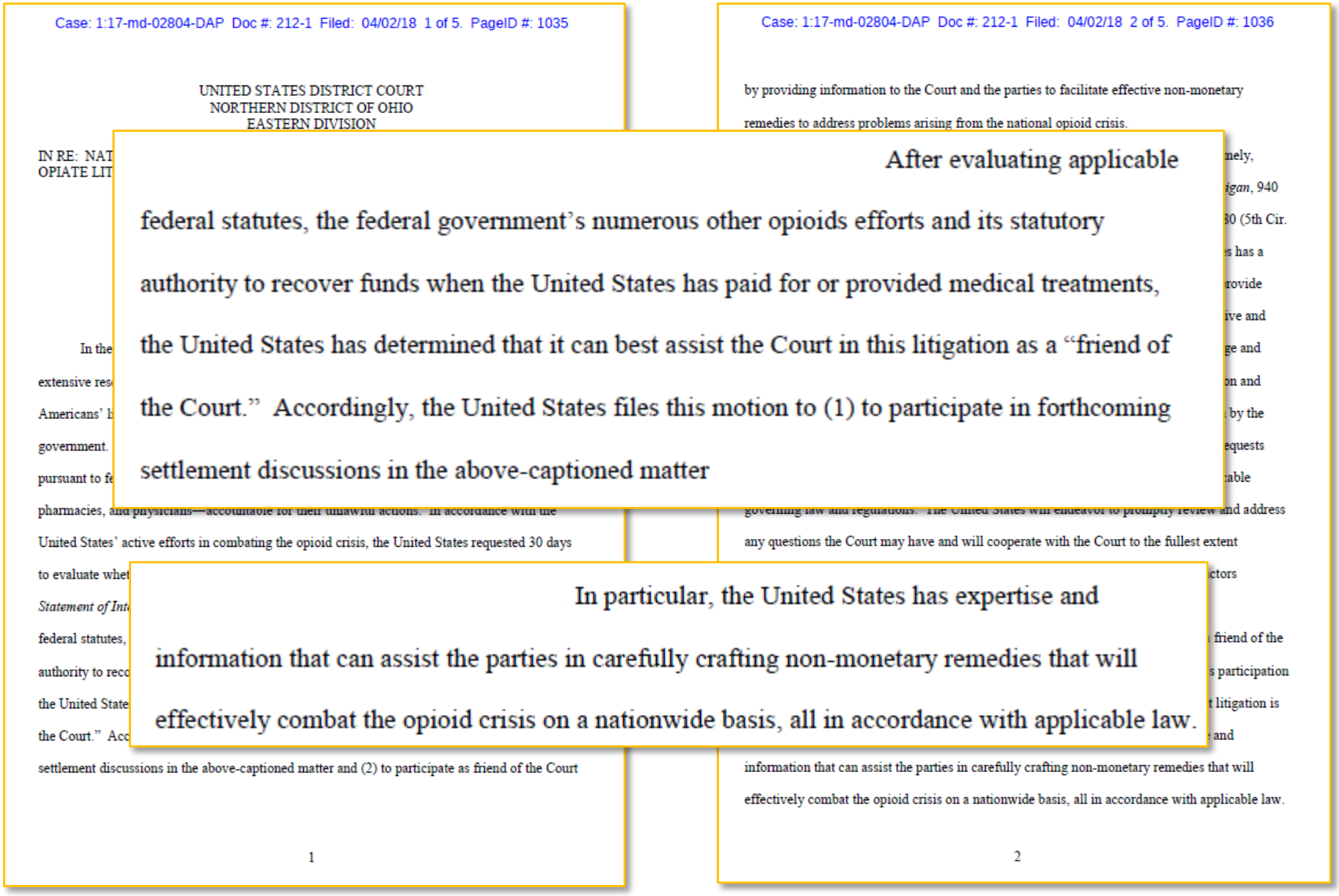
b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format ders System ("ARCOS") data is llowing web address: The files shall be due by the ndar month's report. This report ARCOS data in the time arties agree that the report does s compliance with recordkeeping licable implementing not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

5

U.S. Files Motion to Participate in Settlement in MDL



Case: 1:17-md-02804-DAP Doc #: 212-1 Filed: 04/02/18 1 of 5. PageID #: 1035

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NAT
OPIATE LIT

In the
extensive res
Americans' l
government.
pursuant to fe
pharmacies, and physicians—accountable for their unlawful actions. In accordance with the
United States' active efforts in combating the opioid crisis, the United States requested 30 days
to evaluate whet
Statement of Int
federal statutes,
authority to reco
the United State
the Court." Acc
settlement discussions in the above-captioned matter and (2) to participate as friend of the Court

1

Case: 1:17-md-02804-DAP Doc #: 212-1 Filed: 04/02/18 2 of 5. PageID #: 1036

by providing information to the Court and the parties to facilitate effective non-monetary remedies to address problems arising from the national opioid crisis.

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governing law and regulations. The United States will endeavor to promptly review and address
any questions the Court may have and will cooperate with the Court to the fullest extent
ctors
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t litigation is
and
information that can assist the parties in carefully crafting non-monetary remedies that will effectively combat the opioid crisis on a nationwide basis, all in accordance with applicable law.

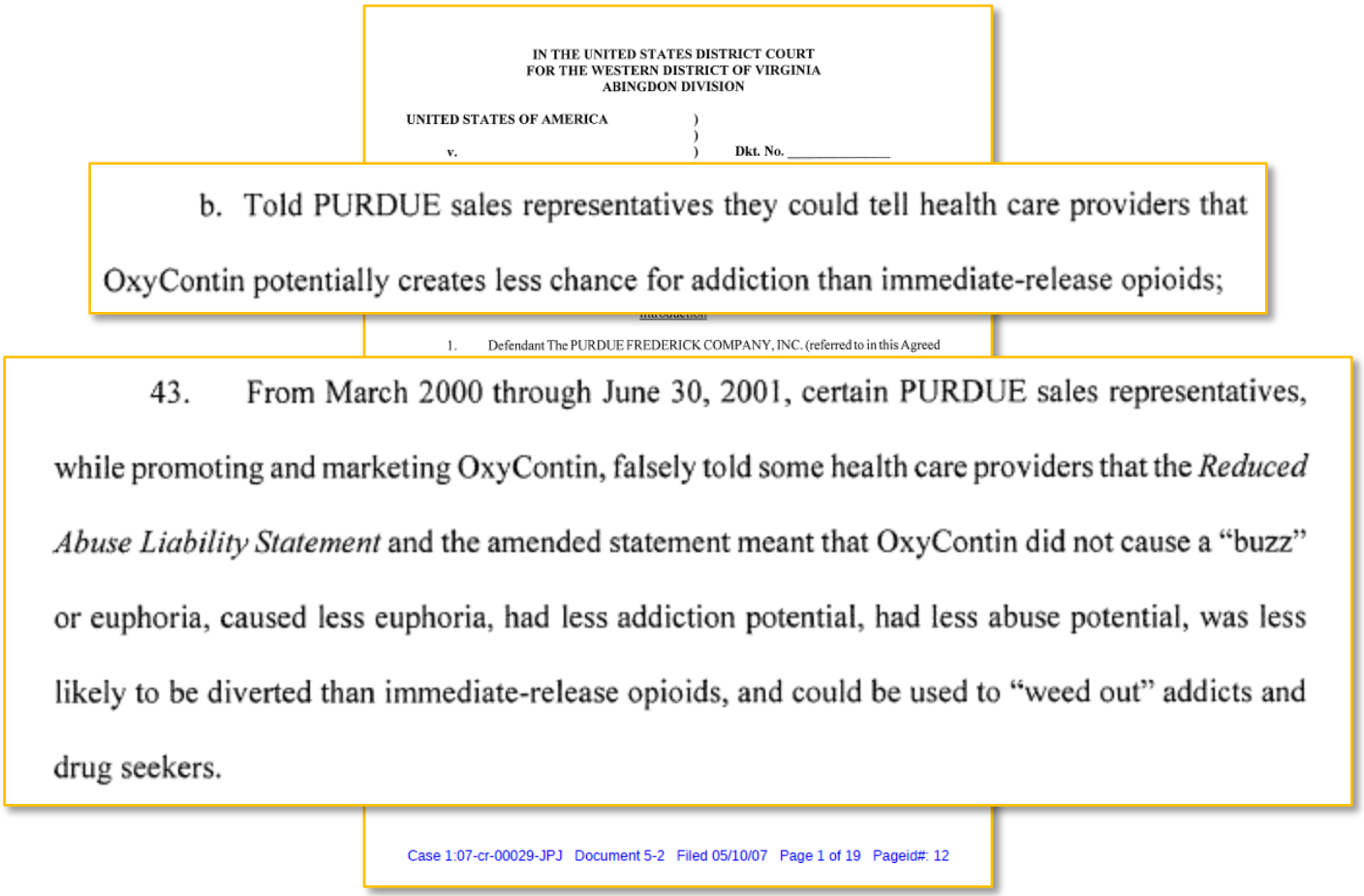
2

After evaluating applicable federal statutes, the federal government's numerous other opioids efforts and its statutory authority to recover funds when the United States has paid for or provided medical treatments, the United States has determined that it can best assist the Court in this litigation as a "friend of the Court." Accordingly, the United States files this motion to (1) to participate in forthcoming settlement discussions in the above-captioned matter

In particular, the United States has expertise and information that can assist the parties in carefully crafting non-monetary remedies that will effectively combat the opioid crisis on a nationwide basis, all in accordance with applicable law.

Federal Criminal Cases: In the Beginning There Was Purdue

- In 2007, The Purdue Frederick Company, Inc. and three executives pleaded guilty, respectively, to misbranding OxyContin with intent to defraud and misbranding



IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA)
)
v.) Dkt. No. _____

b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

1. Defendant The PURDUE FREDERICK COMPANY, INC. (referred to in this Agreed

43. From March 2000 through June 30, 2001, certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* and the amended statement meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

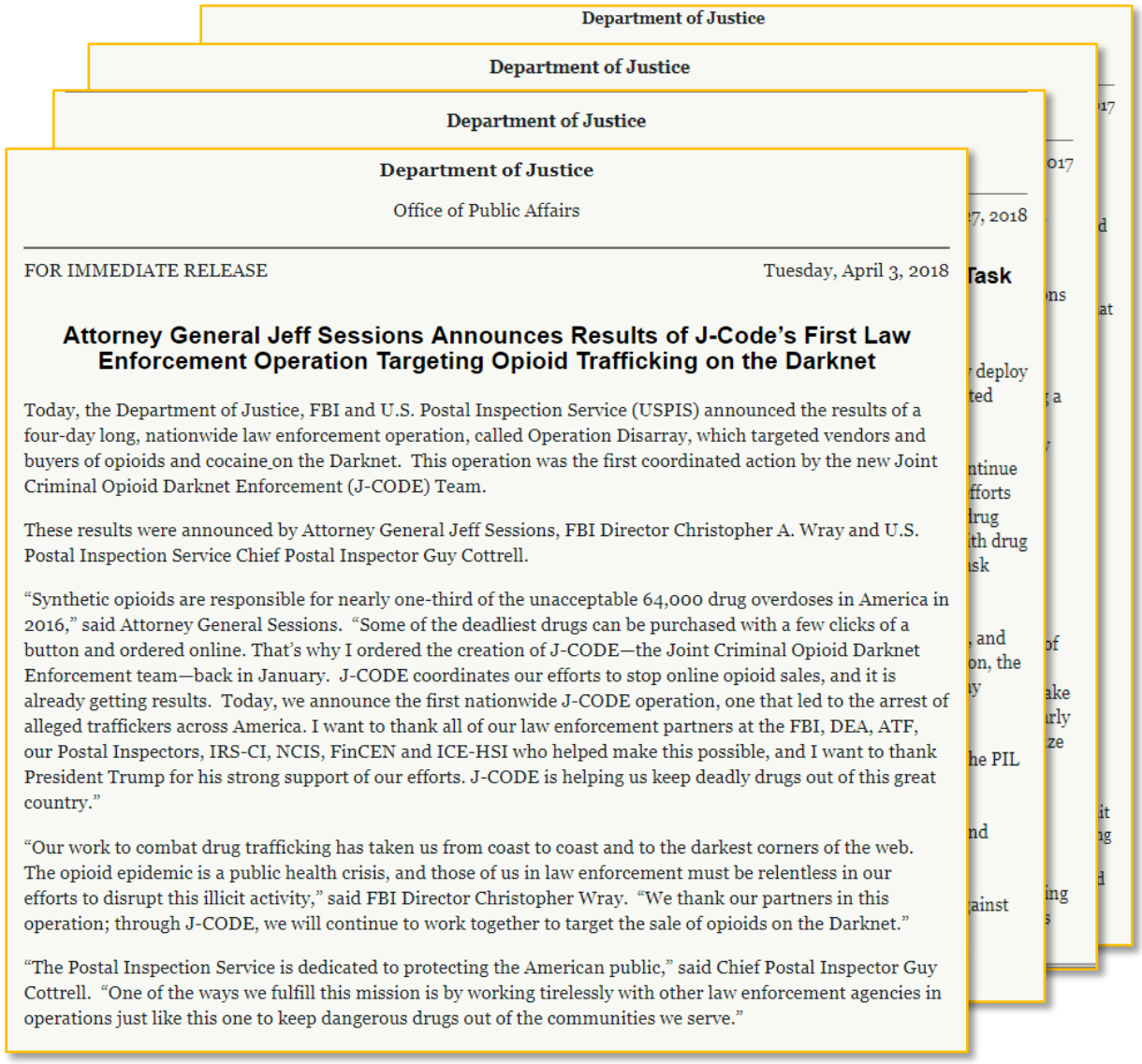
Case 1:07-cr-00029-JPJ Document 5-2 Filed 05/10/07 Page 1 of 19 Pageid#: 12

Federal Criminal Cases

- On July 13, 2017, Attorney General Sessions announced that 412 defendants across 41 districts would be charged with health care fraud, and that 120 defendants were charged for distributing opioids. Doctors Charged or Investigated
- Subsequent convictions and Investigations
  - On February 27, 2018, Charles Gartland pleaded guilty to health care fraud and obtaining a controlled substance by deception in the Middle District of Pennsylvania
  - On March 29, 2018, Gazelle Craig and Shane Faithful were found guilty by a federal jury of conspiracy to distribute and unlawfully distributing controlled substances by a federal jury in Houston
  - In November 2017, the DEA raided the office and home of Forest Tennant, California pain specialist featured as “doctor of last resort” and advocate of using opioids

DOJ Initiatives

- August 2, 2017 – Opioid Fraud and Abuse Detection Unit
- November 29, 2017 – Opioid Coordinator for Each U.S. Attorney's Office
- February 27, 2018 – Prescription Interdiction and Litigation Task Force
- Joint Criminal Opioid Darknet Enforcement (J-CODE) announced first arrests in April 2018.



Department of Justice

Department of Justice

Department of Justice

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, April 3, 2018

Attorney General Jeff Sessions Announces Results of J-Code's First Law Enforcement Operation Targeting Opioid Trafficking on the Darknet

Today, the Department of Justice, FBI and U.S. Postal Inspection Service (USPIS) announced the results of a four-day long, nationwide law enforcement operation, called Operation Disarray, which targeted vendors and buyers of opioids and cocaine on the Darknet. This operation was the first coordinated action by the new Joint Criminal Opioid Darknet Enforcement (J-CODE) Team.

These results were announced by Attorney General Jeff Sessions, FBI Director Christopher A. Wray and U.S. Postal Inspection Service Chief Postal Inspector Guy Cottrell.

"Synthetic opioids are responsible for nearly one-third of the unacceptable 64,000 drug overdoses in America in 2016," said Attorney General Sessions. "Some of the deadliest drugs can be purchased with a few clicks of a button and ordered online. That's why I ordered the creation of J-CODE—the Joint Criminal Opioid Darknet Enforcement team—back in January. J-CODE coordinates our efforts to stop online opioid sales, and it is already getting results. Today, we announce the first nationwide J-CODE operation, one that led to the arrest of alleged traffickers across America. I want to thank all of our law enforcement partners at the FBI, DEA, ATF, our Postal Inspectors, IRS-CI, NCIS, FinCEN and ICE-HSI who helped make this possible, and I want to thank President Trump for his strong support of our efforts. J-CODE is helping us keep deadly drugs out of this great country."

"Our work to combat drug trafficking has taken us from coast to coast and to the darkest corners of the web. The opioid epidemic is a public health crisis, and those of us in law enforcement must be relentless in our efforts to disrupt this illicit activity," said FBI Director Christopher Wray. "We thank our partners in this operation; through J-CODE, we will continue to work together to target the sale of opioids on the Darknet."

"The Postal Inspection Service is dedicated to protecting the American public," said Chief Postal Inspector Guy Cottrell. "One of the ways we fulfill this mission is by working tirelessly with other law enforcement agencies in operations just like this one to keep dangerous drugs out of the communities we serve."

DOJ Initiatives: Data Analytics

- Using Data Analytics to Support Federal Enforcement
  - Attorney General Sessions, January 30, 2018
    - "DEA collects some 80 million transaction reports every year from manufacturers and distributors of prescription drugs. These reports contain information like distribution figures and inventory. DEA will aggregate these numbers to find patterns, trends, statistical outliers—and put them into targeting packages."
  - Acting Assistant AG Ken Blanco on May 18, 2017:
    - "data from CMS has become a key part of our investigations because it permits us to focus on the most aggravated cases and to identify quickly emerging schemes and new types of Medicare fraud. Access to CMS billing data in close to real time permits us to remain a step ahead. We have the opportunity to halt schemes as they develop. This cutting-edge method has truly revolutionized how we investigate and prosecute healthcare fraud."
  - Andrew Weissmann, Chief, Fraud Section, DOJ, Oct. 25, 2016:
    - "Data isn't everything, but in terms of getting leads, data is fantastic and unique…HHS and DOJ have gotten better at how we use data…[Both agencies] have Ph.D.s. on staff to mine data to find links and leads. We can take data and make it incredibly granular, breaking it down by state and city."

DOJ Initiatives: Data Analytics

- DEA Data – Manufacturers must report transactions to the DEA under 21 U.S.C. § 827(d)(1). Some data has been released, showing:
  - 780 million opioid doses in West Virginia from 2007-2012
  - 20.8 million doses to one town with a population of 2,900
  - This system, called ARCOS, is already playing a role in the MDL, and is likely to play a role in federal enforcement
- CMS data can be used to identify fraud through predictive modeling.
  - Section 4241 of the Small Business Jobs Act (2010) requires HHS to use predictive modeling to find fraud
  - CMS uses predictive modeling, including building profiles, to support its Fraud Prevention System on all Medicare fee-for-service claims
  - Leads are generated that trigger administrative actions before payment is released—moving away from "pay and chase" model

DOJ Initiatives: Data Analytics

- Building a case through Data Analytics
  - Identify outliers – registrants that are billing, prescribing, or dispensing at higher rates than peers or population suggests is reasonable
  - Once an outlier is identified, use traditional investigative methods, either covertly or overtly, to find improper relationships, collusion or illegal activity
- Courts have a mixed response to statistical sampling establishing guilt
  - *U.S. ex rel. Martin v. Life Care Centers of America, Inc.* (E.D. Tenn. 2014)
    - Court allowed expert testimony to establish liability for all claims (400 random samples used to establish that more than 154,000 claims were false)
  - Since *Life Care*, some courts have allowed statistical sampling to establish liability
  - But other courts have since rejected statistical sampling to establish liability, requiring individual proof per patient. See *U.S. ex rel. Wall v. Vista Hospice Care, Inc.* (N.D. Tex. 2016) and *U.S. ex rel. Paradies v. AseraCare, Inc.* (D. Ala. 2016).

The Future: The DEA Surge

- DEA will use every criminal, civil, and regulatory tool possible to target, prosecute and shut down individuals and organizations responsible for the illegal distribution of addictive and potentially deadly pharmaceutical controlled substances. We must stop the loss of our loved ones to these drugs.

– April 2, 2018, Acting DEA Administrator Robert W. Patterson

- Our country is in the midst of a drug abuse crisis, enabled and worsened by rampant drug trafficking and prescription drug diversion. This surge of resources by the Drug Enforcement Administration will help us make more arrests, secure more convictions, and reduce the number of diverted or unnecessary prescription drugs causing addiction and overdose.

– January 31, 2018, Attorney General Jeff Sessions

The DEA Surge

- For 45 days in February and March 2018, the DEA surged its enforcement and administrative resources to identify and investigate prescribers and pharmacies that dispensed disproportionately large amounts of drugs.
- The DEA analyzed
  - 80 million transaction reports from DEA-registered manufacturers and distributors,
  - reports submitted on suspicious orders and drug thefts
  - information shared by federal partners, such as the Department of Health and Human Services
- Resulting in…
  - 28 arrests
  - 54 other enforcement actions
    - search warrants
    - administrative inspection warrants

The DEA Surge

- Results (continued)
  - 283 administrative actions
    - scheduled inspections
    - letters of admonition
    - memoranda of agreement/understanding
    - surrenders for cause of DEA registrations
    - orders to show cause
    - immediate suspension orders (the immediate revocation of registrations)

The Future: FCA and Other Traditional Routes of Attack

THE UNITED STATES DEPARTMENT of JUSTICE

Home » Office of Public Affairs » News

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Friday, September 8, 2017

Galena Biopharma Inc. to Pay More Than $7.55 Million to Resolve Alleged False Claims Related to Opioid Drug

providing more than 85 free meals to doctors and staff from a single, high-prescribing practice; paying doctors $5,000, and speakers $6,000, plus expenses, to attend an "advisory board" that was partly planned, and attended, by Galena sales team members and paying approximately $92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce the owners to prescribe Abstral. The United States also contends that Galena paid doctors to refer patients to the company's RELIEF patient registry study, which was nominally designed to collect data on patient experiences with Abstral, but acted as a means to induce the doctors to prescribe Abstral. Galena has not marketed any pharmaceutical drug since the end of 2015.

Two of the doctors who received remuneration from Galena were tried, convicted and later sentenced to prison in the U.S. District Court for the Southern District of Alabama following a jury trial of, among other counts, offenses relating to their prescriptions of Abstral. Galena cooperated in that prosecution.

The settlement resolves a lawsuit filed by relator Lynne Dougherty under the whistleblower provisions of the False Claims Act, which permit private parties to file suit on behalf of the United States and obtain a portion of the government's recovery. As part of today's resolution, Ms. Dougherty will receive more than $1.2 million. The matter remains under seal as to allegations against entities other than Galena.

The settlement is the result of a coordinated effort by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the District of New Jersey, with assistance from the Department of Health and Human Services Office of Counsel to the Inspector General, and the Food and Drug Administration Office of Criminal Investigations' Metro Washington Field Office.

The claims settled by this agreement are allegations only; there have been no admissions of liability by Galena.

Galena Biopharma Inc. to Pay More Than $7.55 Million to Resolve Alleged False Claims Related to Opioid Drug

Galena Biopharma Inc. (Galena) will pay more than $7.55 million to resolve allegations under the civil False Claims Act that it paid kickbacks to doctors to induce them to prescribe its fentanyl-based drug Abstral, the Department of Justice announced today.

The Future: It's Not Your Father's Purdue Pharma Case Anymore

United States Department of Justice — Offices of the United States Attorneys

THE UNITED STATES ATTORNEY'S OFFICE

BOSTON – The founder and majority owner of Insys Therapeutics Inc., was arrested today and charged with leading a nationwide conspiracy to profit by using bribes and fraud to cause the illegal distribution of a Fentanyl spray intended for cancer patients experiencing breakthrough pain.

U.S. Attorneys » District of Massachusetts » News

Department of Justice

U.S. Attorney's Office

charged with RICO

FOR IMMEDIATE RELEASE — Thursday, October 26, 2017

including conspiracy to commit mail and wire fraud and conspiracy to violate the Anti-Kickback Law.

Defendant and other executives allegedly bribed doctors and pharmacists to prescribe fentanyl spray meant for breakthrough cancer pain

BOSTON – The founder and majority owner of Insys Therapeutics Inc., was arrested today and charged with leading a nationwide conspiracy to profit by using bribes and fraud to cause the illegal distribution of a Fentanyl spray intended for cancer patients experiencing breakthrough pain.

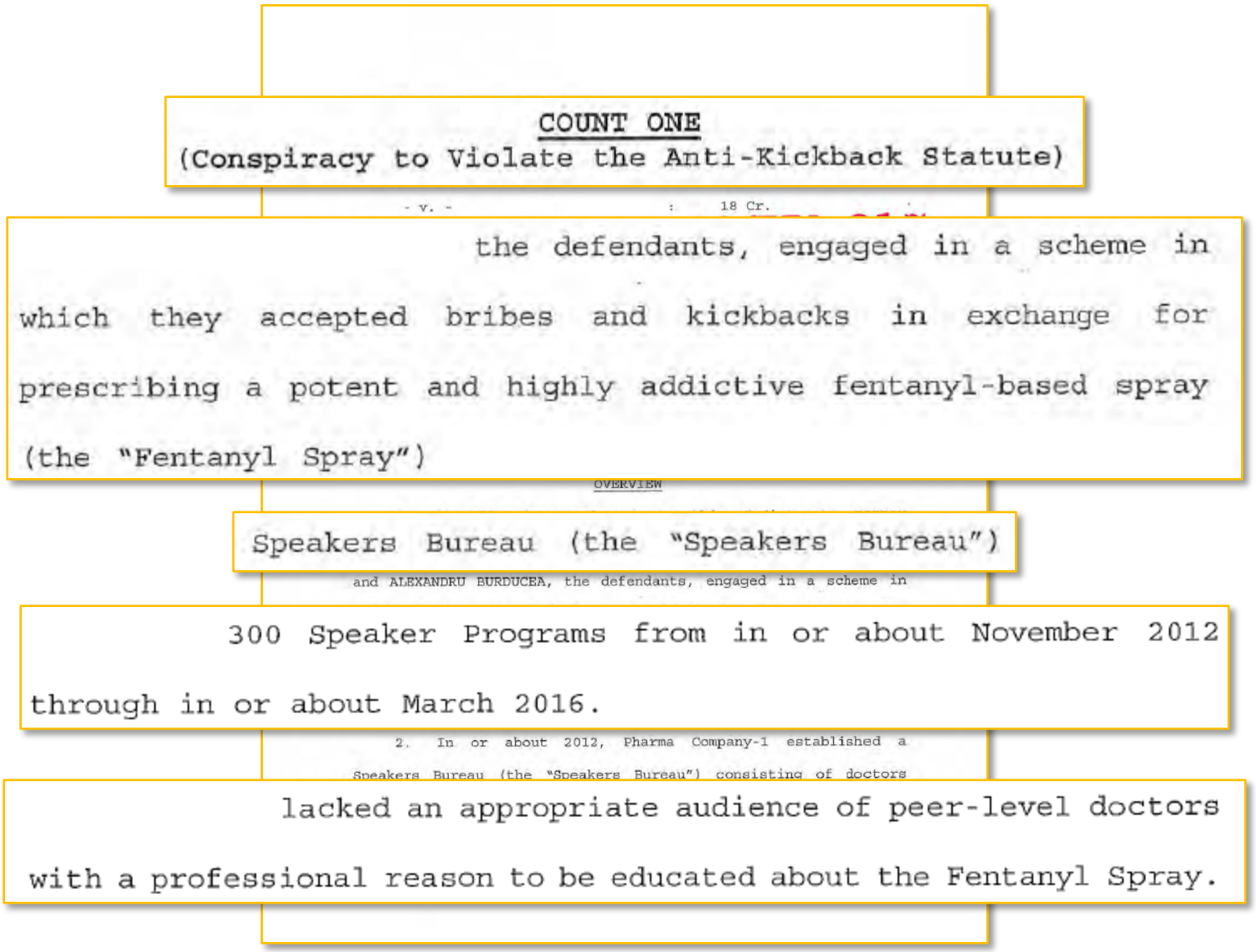
John N. Kapoor, 74, of Phoenix, Ariz., a current m… CEO … Board of Directors of Insys, was arrested this morning in Arizona and charged with RICO conspiracy, as well as other felonies, including conspiracy to commit mail and wire fraud and conspiracy to violate the Anti-Kickback Law. Kapoor, the former Executive Chairman of the Board and CEO … Vice President of Sales; …x today. He will appear in U.S. District Court in Boston at a later …

The superseding indictment, un… …llegations against several former Insys executives and ma… National Director of Sales …016.

The superseding indictment charges that Kapoor; Michael L. Babich, 40, of Scottsdale, Ariz., former CEO and President of the com… …les; Richard M. Simon, 46, of Seal B… Vice President of Managed Markets …rectors Sunrise Lee, 36, of Bryant City, Mich., and Joseph A. Rowan, 45, of Panama City, Fla., and former Vice President of Managed Markets, Michael J. Gurry, 53, of Scottsdale, Ariz., conspired to bribe practitioners in various states,

conspired to bribe practitioners in various states, many of whom operated pain clinics, in order to get them to prescribe a fentanyl-based pain medication.

The Future: It's Not Your Father's Purdue Pharma Case Anymore



COUNT ONE
(Conspiracy to Violate the Anti-Kickback Statute)

- v. - : 18 Cr.

the defendants, engaged in a scheme in which they accepted bribes and kickbacks in exchange for prescribing a potent and highly addictive fentanyl-based spray (the "Fentanyl Spray")

OVERVIEW

Speakers Bureau (the "Speakers Bureau")

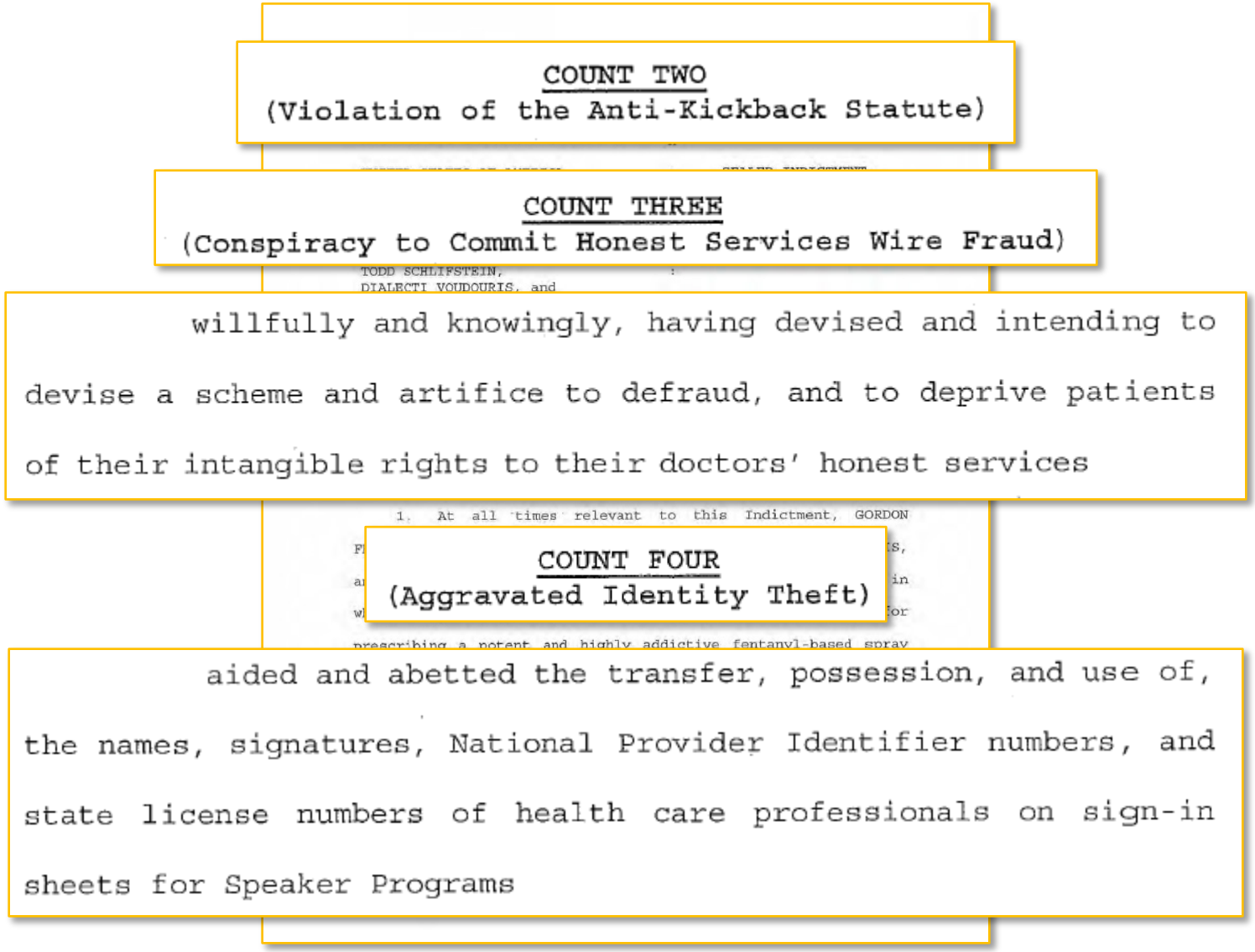
and ALEXANDRU BURDUCEA, the defendants, engaged in a scheme in

300 Speaker Programs from in or about November 2012 through in or about March 2016.

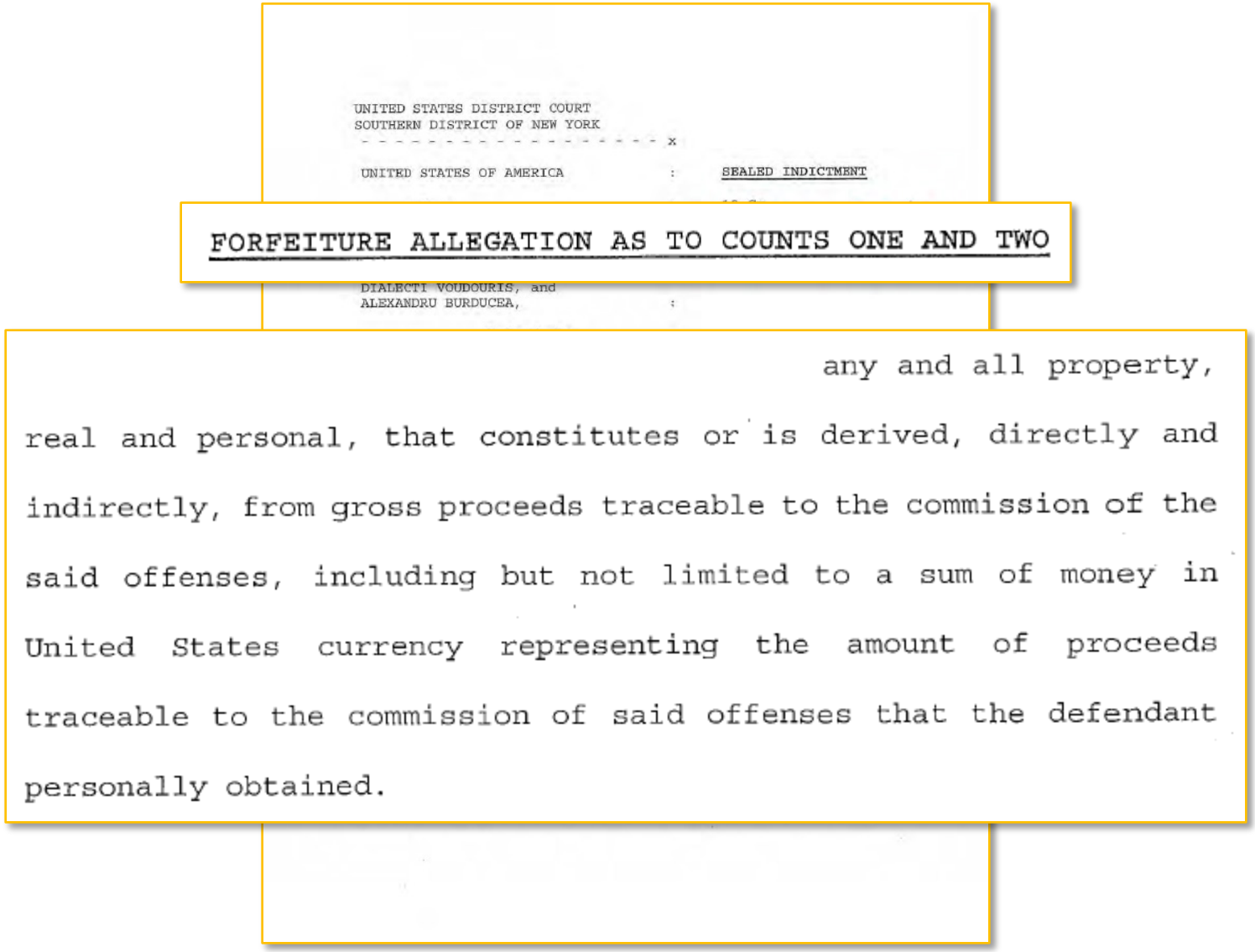
2. In or about 2012, Pharma Company-1 established a Speakers Bureau (the "Speakers Bureau") consisting of doctors

lacked an appropriate audience of peer-level doctors with a professional reason to be educated about the Fentanyl Spray.

The Future: FCA and Other Traditional Routes of Attack



The Future: FCA and Other Traditional Routes of Attack



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA : SEALED INDICTMENT

FORFEITURE ALLEGATION AS TO COUNTS ONE AND TWO

DIALECTI VOUDOURIS, and
ALEXANDRU BURDUCEA,

any and all property, real and personal, that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the said offenses, including but not limited to a sum of money in United States currency representing the amount of proceeds traceable to the commission of said offenses that the defendant personally obtained.

Providers Face Prescribing and Treatment Challenges

States have been active in regulating prescribing practices;
full continuum of treatment options has been slower to develop

Prescriptions	Treatment
➢ Strict limits on duration and dosages	➢ Shortages of naloxone and medication-assisted treatment (MAT)
➢ Mandated participation in Prescription Drug Monitor Programs	➢ Mental health parity, complementary therapies still developing
➢ Continued education standards	➢ Limited support services for treatment and recovery
➢ Danger of over-reaction	➢ Payment reform could create flexibility

Insurers Have Wide Range of Roles

Prevention

- Education about evolving best practices in pain management
- Dashboards to measure and share comparative opioid prescribing rates
- Formulary changes to favor non-opioid pain medications and restrict access to high-dose formulations

Monitoring

- Early detection and appropriate follow up for outlier prescribers
- Pharmacy lock-ins for patients using multiple prescribers
- Support enhanced information-sharing through Prescription Drug Monitoring Programs

Treatment

- Expansion of behavioral health and related services for patients with chronic pain or substance use disorders
- Bundled payments and other incentives to promote innovative treatments
- Network adequacy plan to identify and fill service gaps

Treatment

- Co-prescribing and other policies that expand access to naloxone
- Alternative payment models that encourage services for patients with acute needs (*e.g.*, justice-involved populations, infants with neonatal abstinence syndrome)

Pharmaceutical Manufacturers	Other Stakeholders
➢ Developing new medications ▪ Non-addictive pain medication ▪ Treatment for Opioid Use Disorder ➢ Revising marketing policies for existing pain medications ➢ Implementing appropriate monitoring to identify/prevent abuse ➢ Responding to overwhelming swell of litigation	**Pharmacy Chains** ➢ Implementing anti-diversion policies **Pharmacy Benefit Managers** ➢ More aggressive opioid utilization management

Hypothetical

- You are the Chief Compliance Officer at a pharmaceutical company that manufactures opioids and your head of marketing comes to you with data reflecting significantly increased number of scripts being written over the last few months by several thought leaders in the opioid space.
  - Are you legally obligated to do anything?
  - Even if not legally obligated, is there anything you may want to think about doing?
  - What initiatives has Medicare and certain Medicaid/States come up with that would assist a Compliance Officer?

QUESTIONS?