Morgan Lewis

FAST BREAK

DEA Enforcement

Jake Harper and John Pease

May 18, 2023

Presenters

Tesch Leigh West

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Agenda

- **DEA Enforcement Overview**
  - Regulated entities
  - Enforcement activities
  - Coordination with federal and state authorities
- **Common Diversion Scenarios**
  - Hospitals
  - Medical groups and offices
  - Post-acute care settings
- **Collateral Consequences and Actions for Providers**
  - Reporting and HR issues
  - Follow-up from federal and state authorites

DEA ENFORCEMENT OVERVIEW

What is the DEA?

- The Drug Enforcement Administration (DEA) is part of the U.S. Department of Justice
- Established in 1973 to enforce the Controlled Substances Act (CSA), which had been passed in 1971
- The mission of the DEA is two-fold:
  - To enforce all laws related to the growing, manufacture, and distribution of controlled substances
  - To create policy related to controlling and limiting the availability of illicit drugs and scheduled substances in various markets
- Currently led by Administrator Anne Milgram

Who is Regulated by the DEA?

- The DEA's authority, for most regulatory activity, is keyed to being a DEA "registrant," which are entities that are required by law to register with the federal government to prescribe, manufacture, possess or dispense controlled substances. DEA registrants include the following types of entities:
  - Pharmaceutical manufacturers
  - Drug distributors and reverse distributors
  - Hospitals
  - Substance abuse treatment programs
  - Practitioners (physicians, NPs, PAs)
  - Pharmacies
  - Certain research programs
  - Importers/exporters

Who is Regulated by the DEA?

- Healthcare practitioners and entities are subject to DEA registration requirements because they "dispense" controlled substances.
  - DEA takes a broad view of this term and includes controlled substance storage and prescribing as elements of dispensing controlled substances

- In effect, this interpretation means that all hospitals and virtually all healthcare practitioners will be dispensing controlled substances

- At the same time, there are some provider types, such as post-acute care programs, that neither store nor prescribe controlled substances, even if they are routinely interacting with these kinds of medications
  - Hospice and home health agencies do not need to register with the DEA since these entities do not prescribe (in the case of hospice, their medical directors, with separate DEA registrations, actually prescribe) and do not store controlled substances at their offices

DEA Oversight and Enforcement Activities

- DEA utilizes two standard processes to enforce the CSA

Criminal Enforcement

- DEA agents work with law enforcement partners to investigate and prosecute instances of drug diversion and drug trafficking activities
- DEA investigates wide spectrum of potential drug diversion schemes, from international cartels to physicians inappropriately prescribing

Surveying

- DEA utilizes surveyors to analyze and inspect DEA registrants to ensure they have adequate controls over controlled substances
- DEA undertakes site visits and other inspection activity to assess the physical security and processes of DEA registrants, especially those that store or directly use controlled substances

DEA Coordination

- DEA coordinates its activities with other federal law enforcement partners and works closely with state authorities to investigate and prosecute instances of drug diversion
  - In instances where an individual is not a DEA registrant *(e.g.,* a nurse), DEA still coordinates with specialized local resources to investigate diversion activity
  - May also work with local police depending on the type of matter
    - DEA has established at least 271 state and local Task Forces that utilize joint federal and state funding to employ officers and agents
  - DEA investigators work closely with United States Attorneys offices to make prosecution decisions and bring matters involving misuse of controlled substances
  - DEA also utilizes Special Response Teams for high-risk tactical operations

COMMON DIVERSION SCENARIOS

Hospitals

- $1.9 million settlement after a hospital self-reported that an employee had stolen 17,846 doses of controlled substances over the course of at least a year
  - Fine was based on the hospital system's alleged non-compliance with recordkeeping and drug transfer processes
- $4.36 million settlement after a hospital system experienced two instances of diversion from a pharmacy technician and nurse
  - The pharmacy technician found a loophole in the automated dispensing system enabling her to withdraw controlled substances under codes that were no longer valid
  - The nurse replaced vials of fentanyl and hydromorphone with saline and diverted the controlled substances
  - Fine was based on the hospital system's alleged ineffective controls and procedures to guard against diversion, actual filling of suspicious orders, and failure to maintain readily retrievable records of controlled substances

Physicians

- Physician took bribes from drug manufacturer in exchange for prescribing fentanyl; prescribed so often he ranked highest in state in net sales of fentanyl
- Pain management physician prescribed oxycodone and other drugs to a 17 year-old patient for no legitimate medical need; the patient later overdosed
- Physician with clinic located in a nail salon and medi-spa prescribed hydrocodone and oxycodone for no legimate medical purpose; did not conduct reasonable assessment of patients and viewed as "churning" prescriptions
- Physician wrote medically unnecessary prescriptions for Adderall, fentanyl, hydrocodone, and other opioids in exchange for cash payments of between $100 and $300; he did not accept insurance.

Post-Acute Care

- New Mexico hospice nurse pled guilty after hospice reported suspicious behavior, including that patients' medications could not readily be reconciled and that the nurse was picking up patient prescriptions at Federal Express instead of them going directly to the patient – 42,150 mgs of oxycodone had been diverted
- Indiana hospice nurse indicted for medical fraud after a pharmacist found concerning narcotic prescriptions filled by the nurse for hospice patients in long term care facilities – all prescriptions except hydrocodone and zolpidem were filled by the mail order pharmacy, while these were filled at local grocery and drug stores. The nurse then did not deliver the medications to patients.
- Three nurses in a hospital-based hospice and home health program were indicted for initially taking a deceased patient's unused medication for their own use and then switching a patient's stronger morphine prescription with a less potent form; after this was identified, the hospital undertook an investigation that revealed numerous instances of drug diversion by the trio

COLLATERAL CONSEQUENCES AND ACTIONS FOR PROVIDERS

Reporting Requirements

- DEA registrants have specific reporting requirements to the DEA when controlled substances are lost or stolen
  - This must be done promptly and accurately and can result in follow-up from DEA
- In addition, state bureaus of narcotics and state licensing boards also may have reporting requirements in certain scenarios
  - Most "unprofessional conduct" provisions in state practice acts make drug diversion a form of unprofessional conduct and may also require that other licensees report instances of unprofessional conduct that they are aware of
- Certain states may also expect reporting to other authorities, such as the state survey agency, state authority for elder abuse, or local law enforcement
- It is important to promptly analyze the facts of each case to determine what reporting may be appropriate and in what time frames

HR and Vendor Issues

- Suspected diversion activity may result in HR issues, including employee suspension and termination, discretionary drug testing requests, and contract termination
  - Most allegations of diversion should be carefully but quickly analyzed to determine relevant individuals' level of culpability
- There may also be need to interact with vendors, such as external pharmacies, to assist with the investigation, but such vendors may also have potential exposure from DEA non-compliance allegations
- It is therefore critical to involve both HR and compliance/legal personnel in evaluating and reporting a suspected case of diversion

Follow-up Activity after Reporting

- In the event an entity reports a matter of suspected diversion, anticipate that there will be follow-up investigation from several potential government authorities
  - For DEA registrants, the DEA may conduct survey and investigative activity related to the diversion scheme (in order to prosecute the accused individual) as well as the organization's processes to assess compliance with the CSA
  - For non-DEA registrants, while the DEA may not directly investigate the entity, it may investigate related personnel, such as prescribers
  - In both instances, relevant state medical and nursing boards, as well as state survey agencies, may conduct investigations into the reported activity. Some states have designated investigators for board activity while others utilize their state bureau of investigations to analyze possible criminal and civil liability
- In most instances, cooperation with investigations may be a helpful tool to avoid additional consequences

Biography

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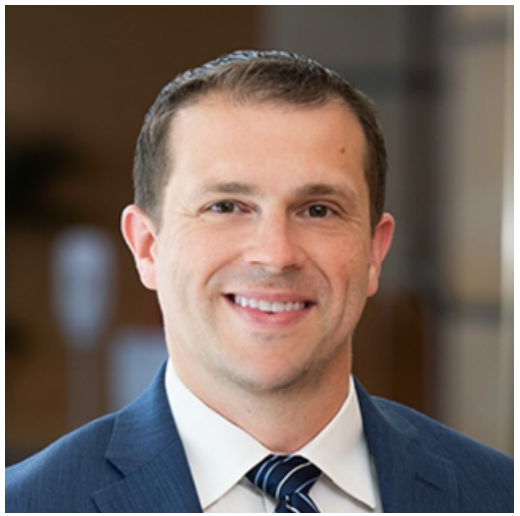
With more than 30 years of experience as a federal prosecutor, defense attorney, and in-house counsel specializing in complex criminal and civil investigations and trials, John Pease represents clients in a host of civil and criminal white collar litigation and government investigations matters, including Foreign Corrupt Practices Act (FCPA) and False Claims Act (FCA) litigation. While serving as an Assistant US Attorney for the Eastern District of Pennsylvania from 1997 to 2013, John also served as Chief of the Government and Health Care Fraud Section in the Criminal Division, leveraging his healthcare fraud and FCA litigation experience and leading a number of nationwide investigations and prosecutions involving global pharmaceutical and medical device manufacturers, defense contractors, and healthcare providers. In that role, John also worked closely with FBI and DEA to investigate and prosecute physicians, pharmacists, nurses and other health care providers who diverted controlled substances for illicit purposes.

Biography



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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Biography

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Tesch Leigh West helps clients navigate a variety of federal and state regulatory issues, including Medicare, Medicaid, and managed care coverage, compliance, and reimbursement. She provides guidance related to financing the non-federal share of Medicaid payments and represents states and providers challenging CMS disallowances. Tesch has performed compliance reviews for health plan risk adjustment programs, reviewed contract agreements between MCOs and downstream entities, and analyzed state licensure, supervision, and scope of practice issues. She reviews healthcare compliance programs in connection with periodic audits and investor due diligence. Tesch also represents providers in federal and state government investigations and litigation matters relating to criminal, civil, and administrative allegations, including violations of federal healthcare program fraud and abuse laws.

Join us next month!

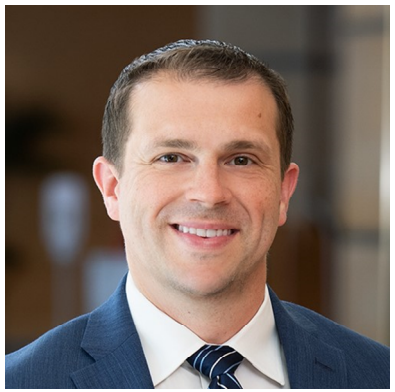
Please join us for the next edition of Fast Break:

Part II: DEA Regulation

Thursday, June 15 3:00 pm ET

Host
Tesch Leigh West

Presenter
Alexandre Gapihan



Presenter
Jacob J. Harper

Our Global Reach

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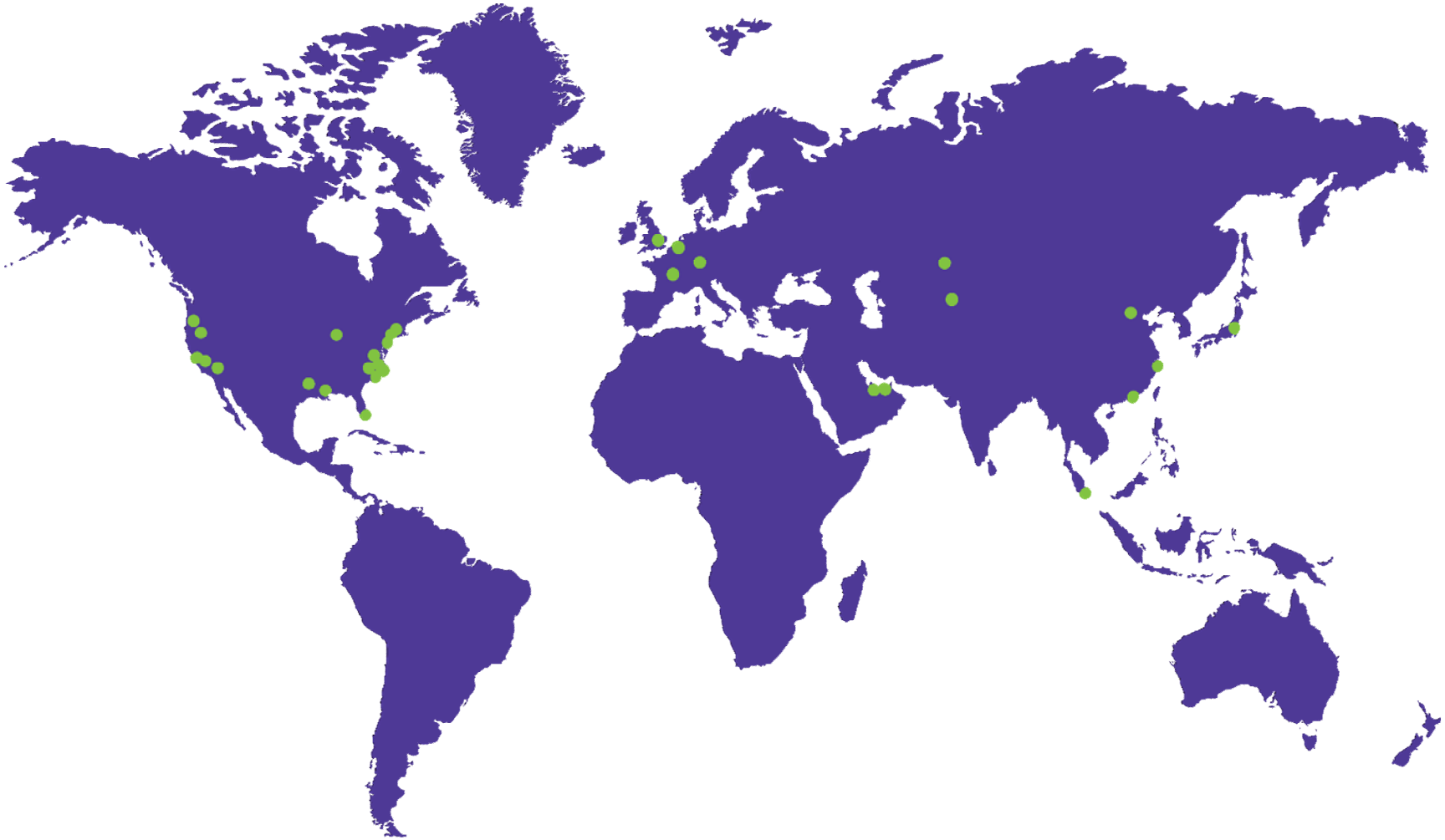

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