Discussion Topics

- Legislative Actions and Trends
- Regulatory Actions
- Investigations and Enforcement
- Q&A

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Legislative Actions and Trends

- Fentanyl, Marijuana, Treatment and Telehealth
- Recent Examples
  - Pardoning of Marijuana Offense for Simple Possession, 21 USC 844
  - S. 3984, Stop Illegal Online Sales of Controlled Substances Act
  - HR. 7259, Medical Controlled Substances Transportation Act of 2022
  - S. 3457, Protecting Americans from Fentanyl Trafficking Act of 2022
  - HR. 7653, Modern Authentication of Pharmaceuticals Act of 2022
  - HR. 8988, EPCS 2.0 Act
  - S. 2796, Rural Opioid Abuse Prevention Act
  - S. 4575, Right To Try Clarification Act

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Regulatory Actions – Pending Final Rule

- EPCS
- EMS
- Partial Filling of Prescriptions
- Suspicious Orders for Controlled Substances
- Implementation of the Agriculture Improvement Act of 2018
- Implementation of the SUPPORT Act: Dispensing and Administering Controlled Substances for MAT
- Management of Quotas for Controlled Substances and List I Chemicals

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Regulatory Actions – New Proposed for 2022

- Proposed Rule: Exempted Prescription Products (Apr. 2022)
- Proposed Rule: Providing Controlled substances to Ocean Vessels, Aircraft, and Other Entities (Jul. 18, 2022)
- Proposed Rule: Regulation of Telepharmacy Practice (Nov. 17, 2021)
- Proposed Rule: Transfer of Electronic Prescriptions for Schedule II-V Controlled Substances between Pharmacies for Initial Filling (Nov. 19, 2021)
- Proposed Aggregate Production Quotas . . . for 2023 (Oct 18, 2022)

Proposed Aggregate Production Quotas . . . for 2023
87 FR 63091, (Oct. 18, 2022)

- DEA indicated that FDA predicts a 5.3 percent decrease in the medical need for CII opioids
- FDA also indicated less than a .1 percent decline in medical use of stimulants amphetamine, methylphenidate and lsidexamfetamine. FDA expressed concern about shortages but DEA expressed concern over "forces that may be impacting the misuse. DEA continues to consult with federal partners.
- DEA did not propose any increase in stimulants, such as amphetamine, methylphenidate, etc.
- DEA did increase amounts for LSD, psilocyn and other substances related to the ongoing research for use of these substances, especially PTSD.

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Regulatory Actions - Still to Come

- Special Registration to Engage in Practice of Telemedicine
- Termination of Registration Upon Discontinuance of Business or Change of Ownership
- Campus Registration
- Changes to Prescriptions
- Employment Bar and New Employment Waivers
- Operation of ADS at LTCF by Hospital/Clinic Pharmacies
- Federal Regulations of Telepharmacy
- Audio-Only Telemedicine for Buprenorphine Initiation Treatment for Opioid Use Disorder
- Medical Missions

Guidance Documents and Policy Initiatives

- On June 23, 2022, DEA issued a "Guidance Summary" that was stated as having been emailed to all DEA registrants.
- "Some guidance documents issued prior to November 2019, were removed from DEA's Diversion Control Division website and are not in the guidance portal, pursuant to E.O. 13891. These guidance documents will not be restored and should be considered rescinded or not valid."
- With respect to the guidance documents that are currently listed on the Guidance Document Portal, these documents do not have the force and effect of law, and are not binding on the public in any way.
- DEA will continue to post new guidance on its Guidance Document Portal when the need arises.
- About 63 "Guidance Documents"
  - Many COVID related
  - 12 involving civil unrest
  - Some Q&A and information, e.g., detecting health care worker abuse
- No discussion of grandfathering

DEA Guidance Documents

- Clarification that DEA employee screening guidelines apply only to screening for prospective employees at a non-practitioners DEA registered location and does not apply to prospective employees who will be employed at non-registered locations such as corporate HQ or sales offices.
- A pharmacy may deliver a prescribed buprenorphine product to a practitioners for direct administration to a patient and must be administered by injection or implantation to the patient within 14 days after the date of the receipt of the controlled substance.
- DEA registrants participating in double-blind studies should indicate the total quantity on of each test material on requested n the DEA From 222. Upon completion of the study the supplier will notify the researcher of the actual name and quantity of the controlled substances provided
- Witnessed breakage or spillage of a controlled substance does not constitute a loss of controlled substance because it can be accounted for. No notification required.
- Black Bag Exception – DEA will permit a DEA registered physician to dispense controlled substances to travel to other unregistered locations in the same state on an “as-needed and random basis.

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Federal Enforcement Actions

Ruan v. United States, No. 20-1410 and Kahn v. United States, No. 21-5261, 597 U.S. _____ (2022),

- *Ruan* is a consolidation of two cases involving two doctors (Ruan and Kahn) that were found guilty of issuing prescriptions that violated 21 U.S.C. § 841 because they were not "authorized:" That is, the prescriptions were not issued for a legitimate medical purpose.

- The relevant CSA provision provides:

(a) Unlawful acts - Except as authorized by this subchapter, it shall be unlawful for any person **knowingly or intentionally**

- (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

- (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

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Ruan – What did the SCt find

- Supreme Court held that the statutory language "knowing or intentionally" (*mens rea)* applies to the "except as authorized" clause under section 841, meaning that if the prescriber was otherwise authorized to issue the prescription (e.g., appropriately licensed, etc.) the government must prove beyond a reasonable doubt that the prescriber knowingly or intentionally acted illegally in issuing the prescription.
- In other words, the government must prove the prescriber issued a prescription that he or she knew or intended was not for a legitimate medical purpose. Applying this "knowledge" requirement "helps separate wrongful from innocent acts," diminishes the risk of "overdeterrence" or, more specifically, punishing "close calls" in prescribing.
- The Court's comment is particularly relevant given the years-long debate related to setting and considering (and potentially criminalizing) the standards or limits for appropriate prescribing of opioid substances (i.e., MMEs) for pain treatment.
- The Court also rejected the government's argument that it could criminally convict a prescriber by merely showing that the prescriber did not make an "objectively reasonable" effort to meet the appropriate medical standard. In doing so, the Court stated that to apply a "good faith" or "reasonable" standard would base the extent of criminal liability on a "reasonable doctor" standard, rather than on the "mental state of the doctor himself or herself."

Ruan Decision not extended to Civil Penalty cases

- *US v. Howen, US Dist. Ct, ED CA, 1:21-cv-00106-DAD-SAB.*
  - Found that "knowing" requirement of the CSA criminal statute 21 USC 841 applies to a finding of criminal intent and civil penalty under 21 USC 842 does not impose the same knowing requirement to prove a violation.
- *US v. Spivak, US Dist. Ct, ED Pa, CA 22-343.*
  - Also found the "knowing or intentionally" language of 841 is not contained in sec 842.
  - Government also sought civil penalties against pharmacy techs and court held that pharmacy techs can be charged with civil penalties because the CSA applies to anyone involved in the dispensing of controlled substances and a pharmacy tech's personal involvement in dispensing in violation of the CSA was sufficient.

Published DEA Administrative Actions

- 49 DEA Administrative actions as of September 30, 2022; 43 revocation decisions related to prescribers
- Many cases based on lack of state authority or federal exclusion
- Of the 6 pharmacy cases: Issues Raised….
  - 3 Immediate Suspension Orders
  - Red flags ignored
  - No state authority
  - Filling fraudulent prescriptions
  - Manufacturing compounded controlled substances without DEA manufacturer registration
  - Recordkeeping violations
  - Owner surrendered after testing positive for controlled substances
- Adjudicated cause to finality notwithstanding fact pharmacy registration had lapsed/expired pending completion of hearing process

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Gulf Med Pharmacy
86 Fed. Reg. 72,694 (Dec. 22, 2021)

- DEA refining requirements and impose bright line standards related to "red flags" and the ***need for documentation***, which are not currently defined in the statute or regulations.

- DEA emphasized that "[r]ed flags are circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm." *Gulf Med* at 72,703.

- Administrator Milgram found that the presence of a red flag does not prohibit a pharmacist from filling a prescription, but "means that there is a potential concern with the prescription, which the pharmacist must address and resolve, and … ***make a record*** of its resolution, assuming it is resolvable." *Id.*

Gulf Med. (Cont.)

- **Cocktail Medications** - the Administrator found that dispensing cocktail medications requires documentation of investigation and resolution, which Gulf Med pharmacists failed to do.
- **Improper Dosing for Pain Managem**ent - DEA's expert opined that proper pharmacologic dosing of pain management patients receiving both long-acting and short-acting opioids is to use larger, scheduled doses of long-acting opioids to control chronic pain with smaller, as-needed doses of short-acting opioids for breakthrough pain.
- **Long Distances Traveled** - The ALJ determined that the Government failed to prove the distances traveled to fill prescriptions, ranging between 30 to 50 miles round trip, and the Administrator found it unnecessary to weigh in on that allegation.
- **Payment in Cash** - DEA expert explained that insurance companies frequently reject suspicious controlled Rxs that may be related to drug abuse or diversion, for example Rxs for the same patient filled by multiple pharmacies. Some patients choose to pay cash to avoid insurance rejections that would alert pharmacists of potential abuse or diversion. Cash payments are especially suspicious when the patient bills insurance for other Rxs but pays cash for Rxs.
- **Price Gouging** - legitimate patients, who can fill their Rx anywhere, will switch pharmacies to pay the fair market price while a "highly suspect patient can only fill Rxs at a suspicious pharmacy and must pay whatever price that suspicious pharmacy sets." Filling cs at inflated cash prices also demonstrates that a pharmacy "has knowledge that it is filling Rxs that are not legitimate, as its inflated prices reflect a 'risk premium' that the pharmacy charges to account for the risk it is taking by filling illegitimate prescriptions."

Civil Penalty Cases and Settlements

- 48 reported civil settlements in 2021; 37 as of September 2022
- Range from less than $50,000 to $4.3 million (Sovah Health)
- Courts uphold civil penalties where a pharmacist filled prescriptions they know are not legitimate but have held that civil penalties are not authorized for a violation of the duty to fill a prescription only in the course of legitimate professional practice.
- Also, courts have indicated that the Supreme Court *Ruan* decision cannot be applied in civil penalty cases.

Sovah Health, WD Virginia (June 2022)

- Sovah Health (“Sovah”), entered into a non-prosecution agreement (“NPA”) and $4.36 million civil settlement due in large part to the ability of two employees to divert significant controlled substance quantities over extended periods.
- The non-prosecution agreement resulting from the criminal investigation illustrates the extent of liability for hospitals and other health care entities and the importance to maintain robust controls and oversight over employee activities related to dispensing and administering controlled substances. The facts also highlight the health care risks when bad employees change employment only to continue their bad acts.
- The two employees devised separate and independent schemes to divert controlled substances, the common element was a lack of an effective corporate security program and monitoring of existing policies and procedures to prevent and detect diversion.
- The government alleged that Sovah failed to conduct a full physical inventory during this period which would have identified the pharmacy tech’s diversion exploiting that a non-utilized location was still in the computer system.
- Sovah failed to enforce or audit procedures requiring that all transfers of controlled substances be witnessed by two employees.

Civil Penalties – Distributors/ Health Systems

- **Henry Schein: (S.D. W. Va., December 2021)–** Multi-year investigation involving illegal distribution of opioids and other controlled substances to medical and dental practitioners in five states in violation of the CSA. ($500,000 civil penalty).
- **Virtua Health System: (D. NJ, December 2021)** - Nonprofit healthcare system owns and operates a network of healthcare entities, including hospital failed to keep accurate inventory of controlled substances; keep controlled substances in a secure location; properly supervise its employees concerning controlled substances. Investigated after reported loss from hospital inpatient pharmacy. ($150,000 civil penalty).
- **University of Texas Southwest Medical Center: (ND TX. November 2021)** Multiple CSA violations over a 5-year period; significant employee diversion, recordkeeping violations. ($4,500,000 civil penalty)

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Civil Penalty Cases

- *Comanche County Hospital Authority; Troy L. Harden, D.O.; Moncy Varkey, D.O. (Oklahoma Feb 2022).* Payment of $550,000 civil penalty because from 2016 -2018 two prescribers issued prescriptions for various non-opioid schedule II controlled substances without establishing a doctor-patient relationship via a face-to-face encounter with the patient.

- *Sixth Street Drugs, Inc.,(Munson Healthcare subsidiary)(E.D. Michigan May 2022***).** Civil penalty of $1,500,000 and 3-year MOA. Government alleged Sixth Street filled hundreds of prescriptions that resulted in patients receiving dangerous drug cocktails, extraordinarily high opioid doses that far exceeded federal dosage guidance, prescriptions for hundreds of individuals who were traveling long distances, prescriptions from numerous prescribers and used multiple pharmacies (physician-shopper and pharmacy-shopper patients); early refills of opioid prescriptions on hundreds of occasions. Government recognized Munson Healthcare's efforts on remedial action.

- *Asheboro Drug Company (pharmacists, Isaac F. Brady III and Isaac F. Brady, IV (father and son), E.D North Carolina July 2022).* Civil penalty of $300,000 and injunction prohibits the defendants from filling certain "red flag" prescriptions and requires the defendants to fill other orders only after receiving documentation justifying the prescriptions.

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Civil Penalty Cases

- *Tara Pharmacy, SE, LLC (ND Alabama, July 2022).* Civil penalty of $622,000 against a specialty pharmacy supply LTCF and failing to get original physician signature and failed to get written prescriptions for Schedule II controlled substances within the required 7-day period after an emergency dispense. False Claims Act Varey allegations were originally brought by former employees under the whistleblower provisions of the Act, employees received $52,000.

- *Dunn Meadow LLC (dba Dunn Meadow Pharmacy); Allegheny Pharmacy, D. (New Jersey, August 2022).* Civil penalty of up to $50,000,000 over next 5 years to resolve civil liability if company generates future revenue. Pleaded guilty to an information charging with conspiring to illegally distribute fentanyl and giving kickbacks to healthcare providers. Also signed civil settlement with the United States for violations of the False Claims Act and the Controlled Substances Act.

- *Bradley Home Health Care Center, Inc., and Bradley Extended Care, Inc. (pharmacies), (MD Tennessee August 2022).* Civil penalty of $250,000 because Bradley Drug and Bradley Extended Care failed to maintain complete and accurate records of controlled substance movement and transferred more than 5% of its controlled substance stock to Bradley Drug without registering as a distributor.

MDL Opioid Update

- Nationwide settlements brought by states and local political subdivisions against the three largest pharmaceutical distributors: McKesson, Cardinal Health and AmerisourceBergen (“Distributors”), and manufacturer Janssen Pharmaceuticals, Inc. and its parent company Johnson & Johnson (collectively, “J&J”).
- Distributors will pay a maximum of $21 billion over 18 years, while J&J will pay a maximum of $5 billion over no more than nine years, with approximately $22.8 billion in settlement proceeds payable to state and local subdivisions.
- July 2022, Injunctive relief terms went into effect:
  - Requirements for establishing thresholds, onboarding and due diligence, and suspicious order reporting
  - Selection of a monitor to audit and review controlled substance monitoring programs
  - Establishment of a clearinghouse for dissemination of data related to ordering and shipping of controlled substances
- August 2022: Pharmacies CVS, Walmart and Walgreens ordered to pay a combined $650.6 million to two Ohio counties to address the damage done by the opioid epidemic.

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38 Annual Conference
October 24-27, 2022

QUESTIONS?

THANK YOU!

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