LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

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Each issue of *Case Law Monitor* highlights unique cases from around the United States in the areas of public health and safety, substance use disorders, and the criminal justice system. Every other month, LAPPA will update you on cases that you may have missed but are important to the field. We hope you find the *Case Law Monitor* helpful, and please feel free to provide feedback at info@thelappa.org.

IN THIS ISSUE...

WRONGFUL DEATH SUIT FILED IN FLORIDA AGAINST STORE THAT SOLD KRATOM PRODUCTS

***Mary Dobson v. Glass Chamber West Palm Beach, Inc., et al.*, Florida Circuit Court for the 15th Judicial Circuit, Case No. 50-2023-CA-014707-XXXA-MB (suit filed October 12, 2023).** The sister of a man who died from an alleged kratom overdose filed suit for wrongful death against the business that sold the kratom products he ingested. Patrick George regularly purchased kratom products from Glass Chamber West Palm Beach, Inc. (Glass Chamber). On December 13, 2022, George died in his home. An autopsy revealed the cause of death as mixed drug toxicity including mitragynine, which is the psychoactive compound in kratom. Mary Dobson filed a suit on behalf of George's estate, asserting that Glass Chamber misrepresented and misled consumers about the risks of kratom. Dobson alleges that Glass Chamber had a duty to warn consumers about the risks associated with the use of kratom products, including the risk of dependance, addiction, overdose, and death. The complaint brings forth claims of strict liability for failure to warn and negligence. Dobson asks the court for loss of wages, loss of consortium, and funeral expenses and seeks a jury trial. Florida has a kratom-specific law, the Florida Kratom Consumer Protection Act (FLA. STAT. ANN. § 500.92 (West 2023)), that makes it unlawful to "sell, deliver, barter, furnish, or give, directly or indirectly, any kratom product to a person who is under 21 years of age," but it does not require any specific product label requirements.[1]

NEW MEXICO DETENTION FACILITY SUED FOR WRONGFUL DEATH OF INMATE

***Vanessa Griego v. Board of County Commissioners of the County of Rio Arriba, et al.*, New Mexico First Judicial District Court, Case No. D-117-CV-202300400 (suit filed November 3, 2023).** The estate of Manuel Gutierrez, who died while in custody at the Rio Arriba County Adult Detention Facility (RACADF) in New Mexico, filed a wrongful death suit against the county and Roadrunner Health Services, LLC (RHS), the

[1] For more information about kratom laws, please refer to LAPPA's "Kratom: Summary of State Laws," available here.

contracted health care services provider at RACADF (collectively, the "defendants"). On March 23, 2022, police arrested Gutierrez and transported him to the hospital for a medical clearance examination prior to taking him to RACADF. During the medical clearance examination, Gutierrez informed hospital staff that he drinks "five fifths a day" and uses cocaine and methamphetamine. According to RHS's intake and screening records, Gutierrez had elevated blood pressure, which required daily monitoring. The complaint asserts that RHS failed to take Guiterrez's vitals daily or monitor him for symptoms of withdrawal while he was at RACADF. On March 27, 2022, RACADF staff found Gutierrez unresponsive in his cell. Emergency medical services pronounced him dead at the scene and noted pill bottles in his cell. According to the defendants' records, no one prescribed Gutierrez any medications while at RACADF, nor did he have a cellmate for 24 hours prior to his death. Postmortem toxicology results found methamphetamine and fentanyl in Gutierrez's system, and the medical examiner determined his cause of death to be fentanyl and methamphetamine toxicity with hypertensive cardiovascular disease being a contributing factor. The estate brings forth claims of negligence against the defendants, arguing that Gutierrez got fentanyl and methamphetamine during his detainment because of the acts and/or omissions of the defendants. The estate asserts that the defendants breached their duty of care owed to Gutierrez by failing to detect and intercept contraband coming into RACADF. The estate requests compensatory and punitive damages.

FAMILY SUES AFTER MAN'S OVERDOSE DEATH IN MICHIGAN JAIL

***Dana Hale et al., v. Clinton County et al.*, U.S. District Court for the Western District of Michigan, Case No. 1:23-cv-01063-JMB-PJG (suit filed October 6, 2023).** The family of a Christopher Fisher, a man who died while in custody in a Michigan jail, filed a lawsuit against the county for wrongful death. In December 2022, Michigan state troopers pulled over Fisher for a missing license plate. Discovering an outstanding arrest warrant, the troopers arrested Fisher and took him to the Clinton County Jail. In the complaint, Fisher's family alleges that as staff processed Fisher into the jail, on his person they discovered a plastic tube from a pen containing a white powdery residue, suggesting that he recently used drugs. According to the complaint, Fisher allegedly showed clear signs of acute opioid intoxication during the jail's intake screening, but his intake form indicated he did not appear to be under the influence of drugs. The family asserts that within a few hours of entering jail, Fisher became unconscious and remained motionless for over 12 hours. Jail staff failed to provide Fisher with any medical attention during that time. The next morning, jail staff discovered Fisher dead in his cell. An autopsy revealed that Fisher had methamphetamine and fentanyl in his system and concluded that he had died of a drug overdose. On October 6, 2023, Fisher's family filed a lawsuit in federal district court for violation of Fisher's Eighth and Fourteenth Amendment rights under the U.S. Constitution. The family seeks compensatory and punitive damages for the jail's alleged failure to: (1) properly train its staff; (2) identify Fisher's serious medical risk; and (3) promptly provide medical attention. The defendants filed their answer on December 4, 2023, arguing that the plaintiffs failed to state a claim.

INDIANA APPELLATE COURT FINDS COSTCO NOT LIABLE FOR EMPLOYEE'S FENTANYL-RELATED DEATH

***Bobby L. Timbrook v. Kurt Russell and Costco Wholesale Corp.*, Indiana Court of Appeals, Case No. 23A-CT-00379 (opinion filed October 12, 2023).** An Indiana intermediate appellate court ruled that Costco Wholesale Corp. (Costco) cannot be held liable for the fentanyl overdose death of one of its employees. In January 2020, Maxwell Timbrook purchased heroin from Kurt Russell, his fellow employee at an Indianapolis, Indiana, Costco. The heroin contained fentanyl, and Timbrook suffered a fatal overdose. Russell was tried and convicted for dealing in a controlled substance. (For information about Russell's conviction and subsequent appeal, please refer to the October 2023 issue of the LAPPA *Case Law Monitor*, available here.) Timbrook's father, Bobby Timbrook, as administrator of his son's estate, filed a lawsuit against Costco, arguing that the company proximately caused his son's death by negligently retaining Russell as an employee

despite knowing his history of drug use and dealing. After the estate conceded that Russell's illegal drug sales did not arise out of his employment with Costco and did not occur on Costco's premises, the trial court granted Costco's motion for summary judgment. The estate appealed, asserting that it was foreseeable to Costco that Russell would sell Timbrook controlled substances that could cause death. While the appellate court agreed with the estate's assessment of foreseeability, it ruled that foreseeability alone is insufficient to demonstrate Costco's liability. Rather, the estate needed to demonstrate that Costco had some ability to control Russell at the time in question. Accordingly, the court affirmed the lower court's entry for summary judgment, holding that the estate needed to prove that, if Russell's actions occurred outside the scope of his employment, they at least occurred on Costco's premises or using Costco property. The estate filed a petition for rehearing on November 14, 2023, for which the court has yet to issue a decision on.

PENNSYLVANIA HOTEL REACHES SETTLEMENT IN METHADONE DISCRIMINATION CASE

***Jeanna Godwin v. The George Washington, LP.*, U.S. District Court for the Western District of Pennsylvania, Case No. 2:22-cv-01066 (settlement reached October 27, 2023).** For previous updates on this case, please refer to the October 2023 issue of the LAPPA *Case Law Monitor*, available here. On October 27, 2023, the federal district court announced that the parties reached a settlement in the disability discrimination suit. In the case, Jeanna Godwin claimed that the George Washington Hotel (hotel) rescinded her job offer after the owners learned of her prescription methadone use. The district court previously rejected the hotel's motion for summary judgment in August 2023, holding that genuine issues of material fact exist about whether the hotel discriminated against Godwin in violation of the Americans with Disabilities Act. The details of the settlement are not publicly available.

FEDERAL COURT ORDERS NEW YORK STATE DEPARTMENT OF CORRECTIONS TO PROVIDE INMATES WITH PAIN MEDICATION

***Allen, et al. v. New York State Department of Corrections and Community Supervision, et al.*, U.S. District Court for the Southern District of New York, Case No. 19-CV-8173 (permanent injunction ordered November 22, 2023).** For previous updates on this case, please refer to the June 2022 issue of the LAPPA *Case Law Monitor*, available here. A federal district court judge issued a permanent injunction requiring the New York State Department of Corrections and Community Supervision (DOCCS) to provide inmates suffering from chronic health conditions with pain management and/or neuromodulating medications. In September 2019, a group of inmates filed a suit against the DOCCS alleging violations of their Eighth Amendment rights. Specifically, the plaintiffs claimed that the DOCCS medical staff denied and/or discontinued medications with abuse potential pursuant to its new "Medications with Abuse Potential" (MWAP) Policy, which stated that a medical provider cannot give an inmate certain medication until he or she submits a "MWAP request form" to the regional medical director and that request is approved by the regional director or the chief medical officer. On June 12, 2023, the court issued a preliminary injunction specifically finding that the defendants continued to deny or discontinue chronic pain and neuropathy medications to the plaintiffs without medical justification. In September 2023, after a four-day bench trial to determine the necessity of a permanent injunction, the court found that the plaintiffs succeeded on the merits of their claims. The court determined that: (1) the plaintiffs successfully established an Eighth Amendment deliberate indifference claim and established that they suffered irreparable harm as a result of such deliberate indifference; (2) policies and customs still existed causing DOCCS providers to fail to provide inmates with reasonable pain medications without individualized assessments; and (3) a permanent injunction is in the public interest. On November 22, 2023, the court vacated the June 2023 preliminary injunction and issued the permanent injunction order. The order states that a DOCCS medical provider may prescribe any medication deemed appropriate for the treatment of the patient's chronic pain and that there is no requirement for an

approval process except when a non-formulary medication is requested. Additionally, the order states that pain management medication shall only be discontinued after a provider meets with the patient, discusses the issues regarding the use of the medication, analyzes the patient's health status, and subsequently determines that it is in the best interest of the patient for the medication to be discontinued. The order also requires patients with chronic pain to be seen by a medical professional at least once every 90 days. Two years after the implementation of the order, the parties must inform the court of their respective positions on whether the terms of the permanent injunction should be continued or terminated.

ALLEGHANY COUNTY, PENNSYLVANIA AGREES TO OFFER MEDICATION FOR ADDICTION TREATMENT IN COUNTY JAIL

(Agreement reached November 30, 2023). Allegheny County, Pennsylvania has reached an agreement with the U.S. Attorney's Office for the Western District of Pennsylvania to offer any U.S. Food and Drug Administration approved medication for addiction treatment (MAT) to all individuals booked into the county jail for whom such treatment is medically appropriate. Under the three-year agreement, Allegheny County will implement new policies and personnel training programs to ensure that inmates with opioid use disorder (OUD) receive MAT. Allegheny County will medically evaluate all individuals for OUD at the start of their incarceration and will ensure that individuals who were receiving MAT prior to their incarceration are allowed to continue that medication. Additionally, Alleghany County has agreed not to change or discontinue an individual's use of MAT unless doing so is based on an individualized determination by a qualified medical provider. Furthermore, Alleghany County will pay $10,000 to an individual allegedly denied access to methadone while incarcerated at the county jail.

WASHINGTON NURSING CARE CENTERS SETTLE ALLEGED ADA VIOLATIONS

(Agreement announced October 26, 2023). The U.S. Attorney's Office for the Western District of Washington recently investigated two companies, Avalon Health Care Management (Avalon) and Arcadia Medical Resorts (Arcadia), both of which operate nursing home facilities in Washington. The investigation determined that both companies denied admission to potential patients with substance use disorder, including those prescribed medication for addiction treatment, which violates the Americans with Disabilities Act (42 U.S.C. § 12101 *et seq*.). On October 26, 2023, the U.S. Attorney's Office announced a settlement agreement resolving the allegations. Both Avalon and Arcadia must adopt new non-discrimination policies, institute new employee training, and pay a $12,000 fine.

BOSTON NURSING FACILITY SETTLES ALLEGED ADA DISCRIMINATION VIOLATION

(Agreement announced November 13, 2023). The North End Rehabilitation and Healthcare Center (North End) is a skilled nursing facility in Boston, Massachusetts. In 2022, in response to complaints of discriminatory activity, the U.S. Attorney's Office for the District of Massachusetts conducted a compliance review of North End's operations. Allegedly, North End expressly declined admission to potential patients who were taking Suboxone or methadone to treat opioid use disorder (OUD). Because OUD is a recognized disability under the Americans with Disabilities Act (42 U.S.C. § 12101 *et seq.*), such refusal constitutes unlawful discrimination against people with disabilities. On November 13, 2023, the U.S. Attorney's Office and North End entered into an agreement to resolve these allegations. Going forward, North End must adopt new non-discrimination and admissions policies, provide additional training to staff, and pay a $111,614 civil penalty (of which all but $10,000 will be forgiven if North End complies with the terms of the agreement).

ILLINOIS FEDERAL COURT RULES MEDICAL CANNABIS USE NOT COVERED BY ADA

***Gary Hill v. Dayton Freight Lines, Inc.*, U.S. District Court for the Northern District of Illinois, Case No. 1:23-cv-03370 (opinion filed November 21, 2023).** An Illinois federal district court ruled that medical cannabis use is not covered by the Americans with Disabilities Act (ADA; 42 U.S.C. § 12101 *et seq*.) because cannabis is illegal under federal law. Gary Hill worked for Dayton Freight Lines, Inc. (Dayton Freight) as a tractor mechanic. In September 2018, Hill was diagnosed with lung cancer and in December 2018, his doctor prescribed him medical cannabis to help alleviate symptoms caused by his cancer and cancer treatment. In February 2021, Dayton Freight subjected Hill to a random drug test which screened positive for cannabis. Hill asked Dayton Freight to exempt him from its drug free workplace policy due to his medical cannabis prescription. Dayton Freight refused to make an exception and terminated Hill's employment. Hill filed suit against Dayton Freight asserting that the company violated the ADA by discriminating against him on the basis of his disability and denying him disability accommodations. Dayton Freight filed a motion to dismiss arguing that Hill's use of cannabis, even if under the supervision of a doctor, precludes him from pursuing an ADA claim because it is an illegal drug. Hill responded by arguing that 42 U.S.C. § 12111(6)(A) provides an exception for the "illegal use of drugs" if the individual takes the drug under the supervision of a licensed health care professional. In reaching its conclusion, the district court relied on a 2012 decision by the U.S. Court of Appeals for the Ninth Circuit, *James v. City of Costa Mesa* (700 F.3d 394), which considered the identical language, albeit in a different part of the ADA (42 U.S.C. 12210(d)(1)). In *James*, the Ninth Circuit determined, after reviewing the ADA, the federal Controlled Substances Act (CSA; 21 U.S.C. § 801 *et seq.*), and their legislative histories, that "federally prohibited marijuana use does not fall within § 12210(d)(1)'s supervised use exception." The Ninth Circuit ruled that "to conclude that use of marijuana for medical purposes is not an illegal use of drugs under the ADA would undermine the CSA's clear statement that marijuana is an unlawful controlled substance that has no currently accepted medical use in treatment in the United States." The Ninth Circuit further stated that "Congress could not have intended to create . . . a capricious loophole that would allow a doctor to recommend the use of any controlled substance—including cocaine or heroin—and thereby enable the drug user to avoid the ADA's illegal drug exclusion." The Illinois trial court agreed with the Ninth Circuit's analysis in *James*, stating that, although some states, including Illinois, allow cannabis for medical use, cannabis is still classified federally as a Schedule I drug. Therefore, the court ruled that Hill cannot claim ADA protections for his use of medical cannabis. The court granted Dayton Freight's motion to dismiss and dismissed Hill's complaint without prejudice. As of this writing, Hill has not filed an appeal.

WEST VIRGINIA REMOVES RELIGIOUS-BASED TREATMENT PROGRAM FROM PAROLE REQUIREMENTS

***Andrew T. Miller v. William K. Marshall, et al.*, U.S. District Court for the Southern District of West Virginia, Case No. 2:23-cv-304 (out of court settlement announced November 15, 2023).** The West Virginia Division of Corrections and Rehabilitation (WVDCR) agreed to change its parole requirements following a lawsuit by an atheist inmate who claimed that the state denied him parole because of his refusal to participate in a religious based substance use disorder treatment program. Andrew Miller, incarcerated at the time at Saint Mary's Correctional Center, filed a lawsuit against WVDCR in April 2023 claiming that the state would not accommodate his request for a non-religious substance use disorder treatment program. The suit asserted that the state denied Miller parole multiple times because of his refusal. In a November 15, 2023 press release, American Atheists, which represented Miller in the case, stated that WVDCR removed both its requirement that participants attend religious 12-step meetings and the religious components from its federally funded residential substance abuse treatment (RSAT) program handbook. The release also noted that WVDCR agreed to pay $80,000 in legal fees. This out-of-court settlement follows a July 2023 ruling in which a federal district court judge denied the state's motion to dismiss. In that ruling, the judge found Miller's claims to be

"likely–if not inevitable" to succeed. The opinion noted the "undeniably religious nature of the program," which included mandatory recitation of Christian prayers during meetings and overtly religious content in the course material. The judge ruled that the plaintiff sufficiently alleged a violation of the Establishment Clause and Free Exercise Clause of the First Amendment of the U.S. Constitution. In addition to denying the state's motion to dismiss, the judge issued a preliminary injunction requiring WVDCR to remove completion of the state's RSAT program from Miller's parole eligibility requirements. WVDCR officially released Miller from its non-violent offender parole program in October 2023. The court issued a formal dismissal order on November 21, 2023.

OHIO LAWSUIT ALLEGES SEVERE TOOTH DECAY IS A SIDE EFFECT OF SUBOXONE

***David Sorensen v. Indivior, Inc., et al.*, U.S. District Court for the Northern District of Ohio, Case No. 1:23-cv-01855-PAB (suit filed September 25, 2023).** On September 25, 2023, David Sorensen of Ohio filed a lawsuit in federal district court against several companies that manufacture, promote, or sell Suboxone (the defendants). In the lawsuit, Sorensen alleged that using Suboxone resulted in permanent damage to his teeth and that the defendants' "fraudulent and illegal conduct" had caused hundreds or thousands of Suboxone users to develop severe tooth damage. Suboxone contains buprenorphine, which is acidic, and when it is ingested in a dissolvable form it can cause dental erosion and decay. Indeed, in early 2022, the U.S. Food and Drug Administration (FDA) issued a drug safety communication that some patients reported dental problems caused by ingesting medicines containing buprenorphine that are dissolved in the mouth. At that time, the FDA required a new warning about the risk of dental problems to be added to the prescribing information and patient medication guides for all buprenorphine medications dissolved in the mouth. In June 2022, Indivior, Inc. changed Suboxone's prescribing information to warn of the risk of dental problems, but the medication guide for Suboxone did not warn of these risks as possible side effects. In his lawsuit, Sorensen argues that the defendants knowingly withheld and/or misrepresented information concerning the safety and efficacy of Suboxone. Sorensen brings forth claims of strict products liability, negligent failure to provide adequate warnings and instructions, defective design, and negligent design defect. Sorensen seeks damages for medical expenses and pain and suffering as well as punitive damages. The defendants have not yet responded to the complaint.

WEST VIRGINIA NURSING COMPANY MUST FACE SUIT OVER NEGLIGENT URINE TEST COLLECTION

***James Atkinson v. NCI Nursing Corps and MedTox Laboratories, Inc.*, West Virginia Intermediate Court of Appeals, Case No. 22-ICA-233 (opinion filed November 15, 2023).** A West Virginia miner who lost his job after testing positive for cannabis can proceed with a negligence suit against the nursing company that collected his urine sample. On July 14, 2020, James Atkinson, a coal mine belt supervisor at Harrison Coal Company (HCC), took a random drug and alcohol screen. Atkinson provided a urine sample to a nurse from NCI Nursing Corps (NCI) who then split the sample into two containers and mailed them to MedTox Laboratories, Inc. (MedTox) for urinalysis. The screen came back positive for cannabis. Upon receipt of the test results, HCC suspended Atkinson without pay and shortly thereafter terminated his employment. The West Virginia Office of Miners' Health, Safety, and Training also suspended Atkinson's mining certifications. Atkinson alleged that he "did not ingest any illegal drugs or anything else" and requested that the other sample be tested. The second sample also tested positive for cannabis. In an attempt to show that the urine drug screens were incorrect, Atkinson, on his own initiative, took a hair follicle drug test, which came back negative for cannabis. In a separate proceeding, Atkinson protested the suspension of his mining certifications. During that proceeding, the NCI nurse who conducted the urine drug screen collection testified that he did not conduct the drug screen in accordance with 49 C.F.R. § 40.33(a) and (e), which requires that parties collecting

urine samples for miners subscribe to a U.S. Department of Transportation list-serv about workplace drug testing. The nurse also testified that he did not have any documentation showing that he met the requirements set forth in 49 C.F.R. § 40.33(g), which is required for an individual to be permitted to act as a collector in the drug testing program. Atkinson alleged that these failures automatically rendered the urine drug screen results null and void, but neither NCI nor MedTox voided the results of the drug screen.

On July 18, 2022, Atkinson filed suit against NCI and MedTox for professional malpractice, negligence, and violation of statutes. On August 29, 2022, NCI filed a motion to dismiss arguing that Atkinson's claim of professional malpractice was a Medical Professionals Liability Act claim under West Virginia law (MPLA; W. VA. CODE ANN. § 55-7B-6 (West 2023)) and subject to a pre-suit notice requirement.[2] On October 31, 2022, a West Virginia trial court entered an order granting NCI's motion to dismiss, finding that Atkinson failed to comply with the requirements of the MPLA given the determination that NCI is a health care provider pursuant to the MPLA and the services rendered to Atkinson qualified as health care. Atkinson appealed the ruling, arguing that the actions and services performed by NCI were not "health care" as defined by W. VA. CODE ANN. § 55-7B-2(e) (West 2023) and thus, his claim did not fall under the MPLA. Under § 55-7B-2(e)(1), health care means either: (1) any act, service, or treatment provided under, pursuant to, or in the furtherance of a physician's plan of care; or (2) any act, service, or treatment provided under, pursuant to, or in the furtherance of a health care facility's plan of care, medical diagnosis, or treatment. The intermediate appellate court concluded that NCI's actions did not constitute health care under subsection (e)(1) because, first, neither a physician nor health care facility took part in the collection of Atkinson's urine, and second, there was no plan of care, treatment, or diagnosis provided to Atkinson. The definition of health care provided in § 55-7B-2(e)(2) states: "an act, service, or treatment provided by a health care provider to a patient during the patient's medical care, treatment, or confinement." The court determined that while there was an act or service (the collection of a urine sample for the purpose of detecting drugs or alcohol), NCI did not provide Atkinson with any medical care. Instead, the court found that NCI simply acted as an agent assisting in the collection, preservation, and transport of the urine sample. Thus, the court ruled that because NCI's acts do not meet the MPLA's definition of health care, the MPLA is not applicable to Atkinson's claims. The appellate court reversed the trial court's order and remanded the case to the West Virginia trial court for further proceedings.

FORMER MASSACHUSETTS NURSE SENTENCED FOR DIVERTING DRUGS FROM HOSPITAL

***United States v. Andrea Falzano*, U.S. District Court for the District of Massachusetts, Case No. 1:23-cr-10042-NMG (sentenced November 15, 2023).** In August of 2023, a federal district court sentenced a former nurse, Andrea Falzano, to three months in prison followed by three years of supervised release after she pleaded guilty to three counts of unlawfully obtaining controlled substances by fraud, deception, and subterfuge. Starting in May 2019, Falzano used her position as a nurse in the emergency department at a Massachusetts based hospital to withdraw controlled substances from a locked drug cabinet. The substances Falzano took included morphine, fentanyl, and hydromorphone. In total, Falzano withdrew these substances 412 times for 299 already discharged patients over a five-month period. Negative drug tests performed during the investigation indicated that Falzano did not self-administer the drugs that she stole, despite stating otherwise to her employer and the Board of Registration in Nursing.

[2] "At least 30 days prior to the filing of a medical professional liability action against a health care provider, the claimant shall serve by certified mail, return receipt requested, a notice of claim on each health care provider the claimant will join in litigation." W. VA. CODE ANN. § 55-7B-6 (West 2023).

NEW JERSEY'S HIGHEST COURT IMPOSES LIMITS ON DRUG-IMPAIRED DRIVING PROTOCOLS

***State of New Jersey v. Michael Olenowski*, Supreme Court of New Jersey, Case No. 082253 (Opinion filed November 15, 2023).** In a 5-2 decision, the New Jersey Supreme Court ruled that New Jersey police can continue using its drug recognition expert (DRE) protocol to identify drug-impaired driving but with new limits on how it can be used. On two occasions in 2015, New Jersey police pulled over Michael Olenowski. On both occasions, Olenowski failed a field sobriety test and was arrested. The failed field sobriety tests triggered a full DRE examination at police headquarters by a certified DRE. The DRE protocol consists of a 12-step process entailing interviewing and observing the driver, checking vital signs, administering standardized field sobriety tests, and other information gathering measures. At the end of the DRE protocol, the DRE concludes whether the driver is under the influence of drugs from one or more type of substance and is thereby unable to operate a motor vehicle safely. In both criminal trials, the state offered DRE testimony to prove that Olenowski was under the influence of stimulants and depressants. Both trial courts convicted him. Olenowski appealed to the intermediate level, which affirmed his convictions, and then to the New Jersey Supreme Court. Olenowski died before his appeal finished, but the public defender's office continued the case and challenged the admissibility of DRE evidence. The public defender's office argued that the DRE protocol is not a scientifically valid method for determining if a suspect is under the influence of drugs and can lead to unjust arrests. The five-judge majority upheld the use of DRE testimony in New Jersey, generally, but subjected it to new limitations and posthumously vacated the judgments against Olenowski on the grounds the DRE testimony used against him did not adhere to those guidelines. The majority noted that the DRE protocol is widely used across the country and has been studied multiple times. Under the majority's new guidelines, DREs may testify that their observations are consistent with drug usage but not that those drugs conclusively caused impairment. Moreover, DRE testimony will be excluded in cases where the state does not make reasonable efforts to obtain a toxicology report. The dissent would have rejected DRE testimony completely, asserting that the majority discounted the legitimate concerns about the reliability and accuracy of the DRE protocol, including the high false positive error rate.

UNITED STATES ANNOUNCES ADDITIONAL CHARGES AGAINST CHINA-BASED CHEMICAL MANUFACTURING COMPANIES

On October 3, 2023, the U.S. Department of Justice announced the unsealing of eight indictments in two Florida federal court districts charging China-based companies and their employees with crimes related to fentanyl and methamphetamine production, distribution of synthetic opioids, and sales of precursor chemicals. These indictments mark the second set of prosecutions to charge China-based chemical manufacturing companies and Chinese nationals with trafficking fentanyl precursor chemicals into the United States. The U.S. announced the first set of indictments in June 2023. (For more information on the first set of indictments, please refer to the August 2023 issue of the LAPPA *Case Law Monitor*, available here).

The five indictments unsealed in the Middle District of Florida charge five Chinese corporations and eight Chinese nationals with the illegal importation of fentanyl and fentanyl-related chemicals into the U.S. According to the indictments, the defendants openly flaunted their ability to avoid detection by U.S. customs through the use of fake shipping labels and special delivery procedures. The indictments also assert that the companies demonstrated past success in delivering a stable supply of product to clients in Mexico.

- ***United States v. Hebei Shenghao Import and Export Co., LTD, et al.*, U.S. District Court for the Middle District of Florida, Case No. 8:23-cr-00335 (suit filed September 27, 2023).** The U.S. charged Hebei Shenghao Import and Export Company with fentanyl trafficking conspiracy, along with four Chinese nationals: Qingshun Li, who allegedly negotiated the sale of precursor chemicals and maintained a bank account for the

receipt of payments; Qingsong Li and Chunhui Chen, both of whom allegedly maintained cryptocurrency wallets for the remittance of payments of precursor chemicals; and Chunzhou Chen, who allegedly received Western Union payments on behalf of the company.

- ***United States v. Lihe Pharmaceutical Technology Co. LTD, et al.*, U.S. District Court for the Middle District of Florida, Case No. 8:23-cr-00336 (suit filed September 27, 2023).** The U.S. charged Lihe Pharmaceutical Technology Company with fentanyl trafficking conspiracy and international money laundering, along with two Chinese nationals: Mingming Wang, who is the alleged holder of three bitcoin accounts shared by sales agents for the company; and Xinqiang Lu, the alleged recipient of funds via Western Union on the company's behalf.
- ***United States v. Henan Ruijiu Biotechnology Co. LTD, et al.*, U.S. District Court for the Middle District of Florida, Case No. 8:23-cr-00334 (suit filed September 27, 2023).** The U.S. charged Henan Ruijiu Biotechnology Company with attempted importation of fentanyl precursor chemicals and attempted international money laundering, along with Chinese national Yongle Gao, who is the alleged registered owner of the bitcoin wallet associated with the company.
- ***United States v. Xiamen Wonderful Biotechnology Co. LTD, et al.*, U.S. District Court for the Middle District of Florida, Case No. 8:23-cr-00333 (suit filed September 27, 2023).** The U.S. charged Xiamen Wonderful Biotechnology Company with attempted importation of fentanyl precursor chemicals and attempted international money laundering, along with Chinese national Guo Liang, the alleged registered owner of the bitcoin wallet associated with the company.
- ***United States v. Anhui Ruihan Technology Co. LTD, et al.*, U.S. District Court for the Middle District of Florida, Case No. 8:23-cr-00338 (suit filed September 27, 2023).** The U.S. charged the Anhui Ruihan Technology Company with attempted importation of fentanyl precursor chemicals and attempted international money laundering.

The three indictments unsealed in the Southern District of Florida charged three Chinese companies and four Chinese nationals with multiple drug trafficking charges.

- ***United States v. Hanhong Medicine Technology Co. LTD, et al.*, U.S. District Court for the Southern District of Florida, Case No. 1:23-cr-20394 (suit filed September 27, 2023).** According to the indictment, Hanhong Medicine Technology Company exported large quantities of fentanyl precursor chemicals and non-opioid additives, like xylazine, to the U.S. and Mexico. The indictment also names Changgen Du, who is allegedly the director of the company and negotiated sales with customers, and Xuebi Gan, who is an alleged sales representative. Du and Gan also each allegedly operated a cryptocurrency wallet that accepted payment for the company. The four-count indictment charges the company, Du, and Gan with conspiracy to manufacture and distribute fentanyl; conspiracy to manufacture and distribute a fentanyl precursor with intent to unlawfully import it into the U.S.; manufacturing and distributing a fentanyl precursor with intent to unlawfully import it into the U.S.; and conspiracy to commit money laundering.
- ***United States v. Hubei Guanlang Biotechnology Co. LTD., et al.*, U.S. District Court for the Southern District of Florida, Case No. 0:23-cr-60176 (suit filed September 27, 2023).** According to the indictment, Hubei Guanlang Biotechnology Company openly advertised online and sold an array of chemicals including methamphetamine precursors like methylamine hydrochloride. The indictment also names Wei Zhang, who allegedly ran the daily operations of the company and operated a cryptocurrency wallet that accepted payment for the company. The company and Zhang face charges of conspiracy to manufacture and distribute a methamphetamine precursor and unlawfully import into the U.S.; conspiracy to unlawfully import a methamphetamine precursor into the U.S. with the intent to manufacture methamphetamine; and the manufacture and distribution of a methamphetamine precursor that was unlawfully imported into the U.S.
- ***United States v. Jiangsu Bangdeya New Material Technology Co. LTD., et al.*, U.S. District Court for the Southern District of Florida, Case No. 1:23-cr-20393 (suit filed September 27, 2023).** The indictment alleged that Jiangsu Bangdeya New Material Technology Company (Bangdeya) openly advertised itself online as an export company for chemicals, including the synthetic opioids, protonitazene and metonitazene. The indictment also named Jiantong Wang who is the alleged owner and operator of the company. Bangdeya and Wang face charges of conspiracy to import protonitazene and metonitazene; conspiracy to distribute

protonitazene and metonitazene; multiple counts of distribution of protonitazene; conspiracy to defraud the United States and make and use forged and counterfeited postage; and making and printing unauthorized postage meter stamps.

SEVERAL INDIVIDUALS INDICTED IN INTERNATIONAL SYNTHETIC DRUG TRAFFICKING CONSPIRACY

***United States v. Brian Lumbus, Jr., et al.*, U.S. District Court for the Northern District of Ohio, Case No. 1:23-cr-00585 (suit filed November 1, 2023).** The U.S. Attorney's Office for the Northern District of Ohio filed an indictment against 11 individuals for their alleged roles in an international drug trafficking conspiracy involving the importation and distribution of synthetic opioids and synthetic cannabinoids, including fentanyl, isotonitazene, metonitazene, alpha-PiHP, and ADB-BUTINACA. According to the indictment, Brian Lumbus, Jr., while incarcerated in an Ohio state prison, orchestrated the drug trafficking operation. Lumbus allegedly ordered significant quantities of controlled substances from Giancarlo Miserotti, an Italian citizen and resident. Miserotti arranged for the exportation of kilogram quantities of controlled substances from several foreign countries, first into Italy and then to the U.S. The U.S.-based conspirators received the shipments, cut and mixed the drugs, and redistributed them. The U.S. charged all of the defendants with conspiracy to distribute and possess with intent to distribute controlled substances. Additionally: (1) six defendants face charges of substantive possession with intent to distribute controlled substances; (2) nine defendants face charges of interstate travel in aid of racketeering; (3) eight defendants face charges in an international money laundering conspiracy; and (4) nine defendants face charges of using a communications facility to facilitate a felony drug offense.[3]

PRESS RELEASE ABOUT POTENTIAL OVERDOSE REVERSAL DRUG IS NOT SPEECH PROTECTED BY CALIFORNIA "ANTI-SLAPP" LAWS

***BioCorRx, Inc., et al. v. VDM Biochemicals, Inc., et al.*, California Court of Appeals, Fourth District, Case No. G061535 (opinion filed October 23, 2023).** A California intermediate appellate court ruled that a company's press release about a potential new overdose reversal drug containing alleged confidential information about a second company is not protected speech under California law. VDM Biochemicals, Inc. (VDM) specializes in the synthesis and distribution of chemicals, reagents, and other specialty products for life science research. VDM owns a patent for "VDM-001," a compound with potential use as an overdose reversal drug. BioCorRx is a publicly traded corporation that provides substance use disorder treatment services and medication for addiction treatment. In September 2018, VDM and BioCorRx entered into a mutual nondisclosure and confidentiality agreement (NDA), which restricted each party's disclosure of confidential information as they discussed forming a business relationship. A month later, VDM and BioCorRx signed a letter of intent to enter into a definitive agreement to acquire a stake in intellectual property. The letter memorialized the parties' desire to partner together to develop and commercialize VDM-001 as a treatment for opioid overdose. BioCorRx issued press releases concerning VDM and VDM-001 multiple times between 2018 and 2020. The relationship between the two companies eventually soured and, in March 2022, BioCorRx sued VDM. In its complaint, BioCorRx alleged that although the parties did not have a formal contract, they reached an agreement via email concerning VDM-001's development. Under the alleged agreement, BioCorRx owned a portion of VDM-001 based on the amount of research and development funding it provided and retained a right to purchase an additional interest in VDM-001 of up to 49 percent. VDM filed a cross-complaint alleging that BioCorRx induced VDM to disclose confidential information under the NDA and to enter the letter of intent. VDM claimed that BioCorRx never intended to

[3] The term "communication facility" means "any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication." 21 U.S.C. § 843(b).

abide by the NDA or to enter into a formal agreement concerning VDM-001 and instead entered into these agreements to attract investors and boost its stock price. VDM asserted that BioCorRx perpetrated this scheme by issuing various press releases, which contained confidential information and misrepresentations about BioCorRx's relationship with VDM and VDM-001's development. In response, BioCorRx filed an anti-strategic lawsuit against public participation ("anti-SLAPP") motion seeking to strike all the allegations from the cross-complaint concerning the press releases.

The purpose of anti-SLAPP laws is to prevent people from using courts, and potential threats of a lawsuit, to intimidate those exercising their First Amendment rights. California's anti-SLAPP statute (CAL. CIV. PROC. § 425.16 (West 2023)) provides for a special motion to strike a complaint where the complaint arises from activity exercising the rights of petition and free speech. California law, however, prohibits anti-SLAPP motions in response to certain actions against a business that arise from commercial statements or conduct of the business (CAL. CIV. PROC. § 425.17 (West 2023)). VDM filed an opposition to BioCorRx's anti-SLAPP motion, arguing that BioCorRx's press release statements are exempt from the anti-SLAPP statute under the commercial speech exemption. It also asserted that these statements are not protected activity under § 425.16 because they did not concern a matter of public interest. The trial court granted BioCorRx's anti-SLAPP motion, finding that VDM failed to establish all the elements of the commercial speech exemption. The court also held that the press release statements are protected speech under § 425.16, based on authority finding medical care and treatment to be topics of public interest. VDM appealed, arguing that the commercial speech exemption does apply to the press releases.

On appeal, the intermediate appellate court worked through the four elements necessary to determine if California's commercial speech exemption to its anti-SLAPP law applies. First, the court noted that it must determine whether BioCorRx "is a person primarily engaged in the business of selling or leasing goods or services." VDM argued that BioCorRx is primarily engaged in the business of providing substance use disorder treatment services and selling related medications. BioCorRx, however, argued that it is primarily engaged in research and development given the amount of funds it expends on and receives from such activities. The court rejected BioCorRx's argument, holding that it cannot solely look at the amount of money the company spends on research and development and instead must look at the entire context of its research and development efforts. The record showed that BioCorRx conducts research and development to create commercial products either for sale or for use in its treatment services. The court concluded that BioCorRx is not a research and development company but rather a health services company primarily engaged in the business of selling treatment programs and medications. Second, the court noted that it must determine whether the statements at issue are representations of fact about BioCorRx's business operations. The court concluded affirmatively because the statements pertain to a business opportunity consistent with BioCorRx's core business purposes: developing medications to treat opioid use disorder. The third and fourth elements of the commercial speech exemption are whether the statements were made with the purpose of promoting or securing sales and whether the "intended audience is an actual or potential buyer or customer, or a person likely to repeat the statement to, or otherwise influence, an actual or potential buyer or customer." The appellate court found both elements satisfied because the statements at issue were made to promote the sale of BioCorRx's securities to investors. Furthermore, BioCorRx intended for the press releases to attract investors that could otherwise influence a potential buyer by investing in BioCorRx to help it continue to develop VDM-001 for commercialization. Although BioCorRx argued that it made the statements to the public at large and not directly to investors, the court rejected that argument, holding that the record supports the conclusion that investors were the intended audience (*e.g.*, inclusion of the company's stock market ticker symbol, safe harbor statements informing investors of certain investing risks, and investor specific contact information within the press releases). Because all the elements of the commercial speech exemption were met, the appellate court reversed the trial court's order granting BioCorRx's anti-SLAPP motion and remanded the case for further proceedings.

FEDERAL WHISTLEBLOWER CLAIM CAN ADVANCE AGAINST INDIVIOR

***United States ex rel. Rebecca Miller v. Reckitt Benckiser Group PLC, et al.*, U.S. District Court for the Western District of Virginia, Case No. 1:15-cv-00017 (opinion filed October 2023).** A Virginia federal district court ruled that a whistleblower, Rebecca Miller, can advance her claim that Reckitt Benckiser Pharmaceuticals Inc. n/k/a Indivior, Inc. (Indivior) conspired with a pharmacy benefit manager, Express Scripts, to defraud the government by engaging in a kickback scheme involving its opioid use disorder treatment medication, Suboxone. Pharmacy benefit managers (PBMs) are the intermediaries between drug manufacturers and insurance companies. This position effectively gives PBMs the ability to shut drug manufacturers out of certain health plans. Thus, a PBM can demand favorable pricing from a drug manufacturer in exchange for the PBM's inclusion or favorable treatment of the manufacture's drug on the PBM's formularies.[4] In February 2013, Suboxone lost its patent exclusivity in the market when other manufacturers received approval to sell a generic buprenorphine/naloxone combination tablet. By the end of 2013, Express Scripts announced that it planned to remove Suboxone from its formularies and replace it with the generic tablets. According to Miller's assertion, to avoid this outcome, Indivior agreed to provide rebates for Suboxone in exchange for Express Scripts' preferential treatment of Suboxone on certain commercial drug formularies.

Pharmaceutical manufacturers must report to the government the lowest price, also known as the "best price," for which they sell Medicaid covered prescription drugs to ensure that state Medicaid agencies receive the same benefits that other purchasers receive. The rebates that Indivior provided to Express Scripts would have set a new, reportable best price. To avoid triggering this, however, Indivior allegedly structured its contracts with Express Scripts to make it appear that it negotiated a portion of the rebates under Medicare because Medicare prices are excluded from best price reporting requirements. In her whistleblower lawsuit, Miller asserts that the rebates led to Indivior submitting false best price data which, in turn, prevented state Medicaid agencies from obtaining a lower price. Miller brings forth claims that Indivior violated and conspired to violate the False Claims Act (31 U.S.C. § 3729) and violated the Anti-kickback Statute (42 U.S.C § 1320a-7b). In response, Indivior filed a motion to dismiss the suit, arguing that the complaint fails to allege underlying False Claims Act and Anti-kickback Statute violations and fails to sufficiently allege each defendant's participation in the alleged acts. The district court judge ruled that Miller's conspiracy claim can advance because she adequately alleged that Indivior and Express Scripts executed the contracts with the intent to submit underreported best price data to the government. However, the judge dismissed other aspects of Miller's complaint but granted her leave to amend her complaint. Miller had until December 7, 2023 to file her amended complaint. A settlement conference is scheduled for February 15, 2024.

PART OF GOVERNMENT'S LAWSUIT AGAINST AMERISOURCEBERGEN DISMISSED

***United States v. AmerisourceBergen Corporation, et al.*, U.S. District Court for the Eastern District of Pennsylvania, Case No. 2:22-cv-05209-GJP (motion to dismiss denied in part and granted in part on November 6, 2023).** For previous updates on this case, please refer to the February 2023 issue of the LAPPA *Case Law Monitor*, available here. A federal district court judge issued a 54-page ruling limiting the scope of the federal government's lawsuit against drug distributor Amerisource Bergen, now named Cencora. The court ruled that the government could only seek penalties for the alleged failure to report suspicious orders that occurred after October 2018, which is when Congress amended the federal Controlled Substances Act to explicitly require such reports. The lawsuit, which the government filed in December 2022, claimed that the

[4] A "formulary" is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. "Formulary," HealthCare.gov, last accessed November 8, 2023, https://www.healthcare.gov/glossary/formulary/.

company failed to report suspicious orders going back to 2014. As part of the ruling, the court dismissed with prejudice all claims for civil penalties alleging violations of the suspicious order report requirement prior to October 24, 2018. The court denied Cencora's motion to dismiss the remaining claims, however. Cencora has until December 11, 2023 to file an answer to the complaint.

SETTLEMENT REACHED IN OHIO OPEN MEETINGS LAWSUIT REGARDING OPIOID LITIGATION PROCEEDS

***Harm Reduction Ohio v. One Ohio Recovery Foundation*, Franklin County, Ohio Court of Common Pleas, Case No. 22 CV 005401 (settlement reached September 8, 2023).** For previous updates about this case, please refer to the April 2023 issue of the LAPPA *Case Law Monitor*, available here. Harm Reduction Ohio (HRO) and the One Ohio Recovery Foundation (One Ohio) reached a settlement in an open meetings case. In August 2022, HRO sued One Ohio, a nonprofit corporation established in December 2021 to oversee the distribution of funds received by the state through opioid related lawsuits, for holding meetings in violation of Ohio's Open Meetings Act (OHIO REV. CODE ANN. § 121.22 (West 2023)). In a March 2023 decision, an Ohio trial court dismissed One Ohio's motion for judgment on the pleadings, holding that the organization is subject to the open meeting law. The terms of the settlement are not publicly available. The court formally dismissed the case with prejudice on September 25, 2023.

INDIVIOR REACHES SETTLEMENT WITH DRUG WHOLESALERS IN SUBOXONE ANTITRUST CASE

***In re Suboxone Antitrust*, U.S. District Court for the Eastern District of Pennsylvania, Case No. 2:13-md-02445-MSG (settlement reached October 23, 2023).**For previous updates on this case, please refer to the October 2023 issue of the LAPPA *Case Law Monitor*, available here. Indivior, Inc. (Indivior) agreed to pay $385 million to settle lawsuits brought by drug wholesalers over claims that the company illegally suppressed generic competition for its opioid use disorder treatment medication, Suboxone. The wholesalers represented a class of about 70 direct purchasers of Suboxone. Indivior did not admit to any liability as part of the settlement. The settlement avoided a trial on the wholesalers' claims which was scheduled for October 30, 2023. In June 2023, Indivior reached a $102.5 million settlement with 41 states and the District of Columbia over the alleged Suboxone monopoly. Additionally, in August 2023, Indivior agreed to pay $30 million to settle a similar class action lawsuit by health plans.

PUERTO RICO PHARMACEUTICAL DISTRIBUTOR ORDERED TO PAY $12 MILLION FOR FAILING TO REPORT SUSPICIOUS ORDERS

***United States v. Droguería Betances, LLC*, U.S. District Court for the District of Puerto Rico, Case No. 3:23-cv-01538 (consent decree entered November 3, 2023).**
A federal court in Puerto Rico entered a consent decree requiring Droguería Betances, LLC (Betances), one of the largest drug distributors in Puerto Rico, to pay $12 million and make extensive improvements to its compliance program. The consent decree resolves a complaint filed by the U.S. Attorney's Office in Puerto Rico on October 25, 2023 alleging that from 2016 through at least June 2019, Betances failed to report to the Drug Enforcement Administration (DEA) hundreds of suspicious orders for opioids and other controlled substances distributed to Betances' pharmacy customers. The complaint also asserted that from May 2017 to July 2018, Betances failed to make required reports of its distribution transactions to the DEA via an automated reporting system. Furthermore, the complaint asserted that Betances committed hundreds of recordkeeping violations, such as filling orders for controlled substances with defective order forms and submitting inaccurate shipping or delivery information to DEA. Based in part on its ability to pay, the consent

decree requires Betances to pay $12 million over five years in annual payments, with $10.2 million in the form of civil penalties and $1.8 million in civil forfeiture. The consent decree also requires Betances to make extensive improvements to its compliance program, including implementing improved controlled substance monitoring program procedures and systems to review, detect, and report suspicious orders to the DEA. Additionally, Betances must submit annual reports about its compliance program and customers to the DEA.

SETTLEMENT REACHED BETWEEN U.S. AND DOCTOR WHO PARTICIPATED IN INSYS' SPEAKER PROGRAM

***United States v. Edward Lubin*, U.S. District Court for the Middle District of Florida, Case No. 8:21-cv-02231-TPB-JSS (settlement reached October 12, 2023).** For previous updates on this case, please refer to the June 2022 issue of the LAPPA *Case Law Monitor*, available here. Federal prosecutors reached an agreement with Edward Lubin, MD, to end a False Claims Act (31 U.S.C. § 3729) suit alleging that he issued medically unnecessary prescriptions for Subsys, a fentanyl-based spray manufactured by Insys Therapeutics Inc. (Insys). The federal government filed suit against Lubin in September 2021 and claimed that he participated in Insys' "sham" speaker program, under which he received kickbacks in return for prescribing high quantities of Subsys. Lubin filed a motion to dismiss the case, but the court denied the motion in April 2022, ruling that circumstantial evidence could be used to infer that Lubin knowingly participated in Insys' scheme. The details of the settlement are not publicly available. The settlement avoided a trial set to begin on October 16, 2023.

TEXAS PHARMACY ORDERED TO PAY CIVIL PENALTY FOR UNLAWFUL OPIOID DISTRIBUTION

***United States v. Zarzamora Healthcare LLC, et al.*, U.S. District Court for the Western District of Texas, Case No. 5:22-cv-00047-JKP (consent judgment entered October 10, 2023).** For previous updates on this case, please refer to the February 2022 issue of the LAPPA *Case Law Monitor*, available here. A federal court ordered a San Antonio, Texas pharmacy and its owner to pay a $275,000 civil penalty and imposed restrictions related to the dispensing of opioids and other controlled substances. In a consent judgment and permanent injunction issued on October 10, 2023, the court enjoined Zarzamora Healthcare LLC, doing business as Rite-Away Pharmacy & Medical Supply #2, along with pharmacist-owner Jitendra Chaudhary, from dispensing certain opioid prescriptions, including combination opioid and benzodiazepine prescriptions. The order resolved a civil complaint filed in January 2022, which alleged that the defendants repeatedly dispensed opioids and other controlled substances in violation of the Controlled Substances Act (CSA) by filling prescriptions while ignoring "red flags." The complaint also claimed that the defendants altered prescriptions that lacked required information to make them appear compliant with U.S. Drug Enforcement Administration regulations. As part of the order, the defendants must undergo periodic comprehensive reviews of their dispensing practices to ensure continued compliance with the CSA. The $275,000 civil penalty will be paid out over a six-year period.

CALIFORNIA AND KAISER PERMANENTE SETTLE INVESTIGATION OF BEHAVIORAL CARE PLANS

(Agreement announced October 12, 2023). Starting in 2006, the California Department of Managed Health Care (DMHC) brought several enforcement actions against Kaiser Permanente (Kaiser), operator of the largest health insurance plan in the state, for failure to ensure quality assurance compliance when providing medical and behavioral health care. In May 2022, the DMHC announced that it would conduct a non-routine survey of the health care plan in response to a 20 percent increase in stakeholder complaints. During this survey, which

overlapped with a spike in post-pandemic demand for behavioral health care and a strike by 2,000 behavioral health clinician employees in Northern California, the DMHC discovered issues in the plan's quality assurance, provider oversight, timely access, network adequacy, grievance and appeals, mental health parity, and communications. On October 12, 2023, DMHC and Kaiser reached a settlement agreement under which Kaiser must implement corrective actions to address its plan deficiencies, invest $150 million over five years into behavioral health service delivery improvements, and pay a $50 million fine.

NINTH CIRCUIT RULES DEA'S RESPONSE TO PSILOCYBIN REQUEST IS INADEQUATE

***Sunil Aggarwal v. United States Drug Enforcement Administration*, U.S. Court of Appeals for the Ninth Circuit, Case No. 22-1718 (opinion filed October 27, 2023).** The U.S. Court of Appeals for the Ninth Circuit ruled against the Drug Enforcement Administration (DEA) in a lawsuit over a doctor's petition to reschedule psilocybin. Sunil Aggarwal, MD, PhD, has been trying since 2020 to find a way to legally obtain psilocybin for terminally ill cancer patients undergoing end-of-life care. Aggarwal initially tried to win permission from regulators under state and federal right-to-try laws, which allow patients with terminal diseases to try investigational medications that have not yet been approved by the U.S. Food and Drug Administration (FDA). The DEA rejected Aggarwal's right-to-try request, and, in response, Aggarwal sued the agency. In 2022, a federal court dismissed the suit, holding that the court lacked jurisdiction because the DEA's rejection of the request did not constitute a reviewable agency action. Aggarwal then filed a formal rescheduling petition to move psilocybin from Schedule I to Schedule II. The denial of a rescheduling petition is a reviewable action. In September 2022, the DEA denied Aggarwal's rescheduling petition. In the denial letter, the DEA stated that the prerequisite to transferring a substance from Schedule I to Schedule II is for the FDA to conclude that a substance has a currently accepted medical use in the United States, and the FDA has not done so for psilocybin. Aggarwal appealed the denial to the Ninth Circuit arguing that the DEA should have referred the petition to the U.S. Department of Health and Human Services (HHS) to evaluate psilocybin's medical use before reaching a final decision. On appeal, the Ninth Circuit ruled that DEA's denial of the rescheduling petition "failed to provide sufficient analysis" and "failed to clearly indicate that it has considered the potential problem identified in the petition." The court remanded the petition to the DEA to either clarify its reasoning for denying it or reevaluate it on an open record. Aggarwal wanted the court to send the rescheduling petition to the FDA, an HHS agency, instead of back to the DEA, because Aggarwal believes the FDA is in a better position to evaluate the accepted medical use of psilocybin. However, the court decided not to address Aggarwal's argument that 21 U.S.C. § 811(b) (authority and criteria for classification of substances) requires the DEA to refer the petition to HHS, given the inadequacy of the DEA's denial letter.

RITEAID FILES FOR BANKRUPTCY

***In re Rite Aid Corporation*, U.S. Bankruptcy Court for the District of New Jersey, Case No. 23-18993 (suit filed October 15, 2023).**

- According to press releases, Rite Aid Corporation (Rite Aid) filed for Chapter 11 bankruptcy protection to address lawsuits over its role in the opioid crisis and rework a debt load of around $4 billion. Rite Aid faces multiple opioid lawsuits claiming that the company knowingly filled thousands of unlawful prescriptions for controlled substances.

  To fund itself during the Chapter 11 process, Rite Aid reached a deal with lenders for $3.45 billion in financing and entered into an agreement to sell its pharmacy benefit manager business, Elixir, to MedImpact Healthcare Systems Inc. (MedImpact). MedImpact agreed to pay $575 million for Elixir and assume certain liabilities. MedImpact's bid serves as a floor for other offers to buy the business, and any deal is subject to court approval. Rite Aid's initial filings estimate that it has more than 100,000 creditors and that funds would be available for distribution to unsecured creditors.

- On November 16, 2023, Rite Aid filed a verified adversary complaint with the bankruptcy court to block the U.S. Department of Justice's (DOJ) lawsuit against the company. (For more information on *United States ex rel. Andrew White v. Rite Aid Corporation, et al.*, please refer to the April 2023 issue of the LAPPA *Case Law Monitor*, available here.) According to the adversary complaint, the DOJ only agreed to a brief pause of its lawsuit after Rite Aid declared bankruptcy. Rite Aid asks the bankruptcy court to rule that the DOJ lawsuit cannot proceed while Rite Aid is in bankruptcy. The DOJ, in turn, argues that bankruptcy law does not stop it from exercising its police powers through lawsuits. Rite Aid believes that the New Jersey bankruptcy court should rule on that dispute rather than the judge overseeing the DOJ's lawsuit in the U.S. District Court for the Northern District of Ohio.

RECENT EVENTS IN THE MALLINCKRODT BANKRUPTCY PROCEEDINGS

***In re Mallinckrodt PLC*, U.S. Bankruptcy Court for the District of Delaware, Case No. 20-12522-JTD (suit filed October 12, 2020).** On October 10, 2023, U.S. Bankruptcy Court approved Mallinckrodt PLC's (Mallinckrodt) new debt-reduction plan that cuts about $1 billion from the amount the company must pay into a trust for opioid victims. Judge Dorsey overruled objections from shareholders and a group of holdout bondholders who claimed that Mallinckrodt's management incentive plan is unfair to creditors and that the company should try harder to resolve its debt without filing a Chapter 11 case. Judge Dorsey ruled that Mallinckrodt's reorganization plan does not violate any bankruptcy rules and is fair to creditors. This new reorganization plan replaced one approved by Judge Dorsey last year which had Mallinckrodt owing $3.6 billion to its lenders and providing the opioid victims trust with $1.3 billion. Under the new plan, Mallinckrodt owes its lenders $1.75 billion and will pay $250 million into the trust.

ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to model laws and policies that can be used by national, state, and local criminal justice and substance use disorder practitioners who want the latest comprehensive information on law and policy. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, law enforcement/community engagement, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

For more information about LAPPA, please visit: https://legislativeanalysis.org/.