LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

Case Law Monitor

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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.

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***United States v. Grei Mendez, et al.*, U.S. District Court for the Southern District of New York, Case No. 1:23-cr-00504-JSR (guilty pleas entered May 23, 2024, June 10, 2024, and July 11, 2024).** For previous updates in this case, please refer to the October 2023 issue of the LAPPA *Case Law Monitor*, available here. Three men connected to a toddler's fatal fentanyl overdose at a New York City daycare center have pleaded guilty to drug charges and causing bodily harm. The men admitted to storing fentanyl in the floorboards of the facility. On May 23, 2024, Renny Antonio Parra Paredes pleaded guilty to one count of conspiracy to distribute narcotics resulting in death and serious bodily injury. Police found drug processing and packaging equipment in Parra Paredes' apartment and a stamp bearing the words "Red Dawn." The "Red Dawn" branding was on glassine bags found in Parra Paredes' apartment and at the daycare center. Parra Paredes is scheduled to be sentenced on October 24, 2024. On June 10, 2024, Felix Herrera Garcia, the husband of the operator of the daycare facility, pleaded guilty to drug conspiracy resulting in death and serious bodily injury, along with two counts related to possession with intent to distribute. Herrera Garcia is scheduled to be sentenced on September 16, 2024. On July 11, 2024, a final defendant, Jean Carlo Amparo Herrera, pleaded guilty to one count of conspiracy to distribute narcotics and is scheduled to be sentenced on October 22, 2024. The case remains ongoing against Grei Mendez, the operator of the daycare, and Carlisto Acevedo Brito, who lived inside a bedroom located in the daycare facility. A two-week jury trial is scheduled for Grei Mendez starting November 4, 2024.

MOTHER CHARGED WITH MURDER IN SUSPECTED FENTANYL POISONING OF TWINS

***The People of the State of California v. Jestice James*, Los Angeles County Superior Court, Case No. 24VWCF01433-01 (suit filed July 15, 2024).** The Los Angeles County District Attorney's Office has charged Jestice James, the mother of twin three-year-old boys, with two counts of murder and two counts of child abuse after the boys died from a suspected fentanyl poisoning. On July 11, 2024, James found the two toddlers unresponsive in their home and called for emergency services. The children were rushed to the

hospital, where one twin was pronounced dead, and the other twin died two days later. A preliminary investigation revealed that the children had ingested, or had been exposed to, an unknown substance, and evidence indicates that fentanyl may have been involved. The medical examiner's investigation into the boys' official cause of death is ongoing. James is being held in jail in lieu of $4 million bail. If convicted, James faces life in prison.

WRONGFUL DEATH CASE FILED INVOLVING TIANEPTINE PRODUCT

***Karen Haggarty v. Neptune Resources LLC, et al.*, Ohio Court of Common Pleas (Lorain County), Case No. 24CV212590 (suit filed June 4, 2024).** The mother of a man who died after consuming the tianeptine containing product "Neptune's Fix Elixir" has filed a wrongful death lawsuit against the manufacturer, Neptune Resources, LLC (Neptune Resources). Tianeptine is prescribed as an antidepressant in some countries, but it is not approved for any medical use by the U.S. Food and Drug Administration (FDA). Despite not being an FDA-approved drug, tianeptine is available for purchase in the U.S. as a dietary supplement and can be purchased in gas stations, head shops, and on the internet. Because of tianeptine's ability to bind to mu-opioid receptors[1] in the brain, the media has given the substance the nickname "gas station heroin."[2] Neptune Resources manufactures dietary supplements, including those containing tianeptine. The company markets its tianeptine supplement, Neptune's Fix Elixir, as "happiness in a bottle." In addition to containing tianeptine, Neptune's Fix Elixer contained two synthetic cannabinoids, namely ADB-4en-PINACA and MDMB-4en-PINACA, which mimic the biological effects of THC and have not been approved for any use in the U.S. On December 22, 2022, Ohio made the sale of tianeptine illegal by classifying the substance as a Schedule I controlled substance.[3] Immediately upon having classified tianeptine as a Schedule I controlled substance, the Ohio Board of Pharmacy issued a notice to Ohio retailers informing them that products containing tianeptine were now illegal and could no longer be sold in the state. On November 5, 2023, Christopher Haggarty purchased a single dose bottle of Neptune's Fix Elixer from K&B Sunoco in Ohio. Haggarty consumed the product as directed and died later that day. The coroner reported that his death was due to the toxic effects of tianeptine, ADB-4en-PINACA, and MDMB-4en-PINACA. Haggarty's mother, on behalf of his estate, filed suit against both Neptune Resources and K&B Sunoco, arguing that the product posed a substantial and unreasonable risk of serious injury to users of the product and that the manufacturer and the retailer had a conscious disregard for the safety of consumers. The estate brings forth claims of product liability, wrongful death, and negligence. The estate is asking the court for compensatory and punitive damages.

NEW JERSEY EXPANDS ACCESS TO TREATMENT COURTS FOR THOSE CHARGED WITH PETTY OFFENSES

***State of New Jersey v. Jessica Matrongolo,* Superior Court of New Jersey, Appellate Division, Case No. A-1098-23 (opinion filed July 3, 2024).** An appellate court in New Jersey has sided with a woman convicted of a disorderly conduct offense in her bid to receive treatment court benefits. Pursuant to a plea agreement, Jessica Matrongolo pleaded guilty to a "petty disorderly persons (PDP)" offense for possession of a device to defraud the administration of a drug test. (N.J. STAT. ANN. § 2C:33-2 (West 2024)). As part of her plea agreement, Matrongolo was ordered to attend recovery court. However, Matrongolo's application to join the program was denied, with the judge determining that she was ineligible due to the nature of her offense.

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[1] Mu-opioid receptors are a type of receptor in the brain that is responsible for pain control, drug reward, and addictive behaviors. Mu-opioid receptor agonists, such as morphine and heroin, effectively bind to mu-opioid receptors and produce a physiological response in the body. Gavril W. Pasternak and Ying-Xian Pan, "Mu-opioids and Their Receptors: Evolution of a Concept," *Pharmacological Reviews* 64, no. 4 (October 2013): 1257-1317, https://doi.org/10.1124/pr.112.007138.

[2] For more information on tianeptine, please refer to LAPPA's *Novel Psychoactive Substances: Tianeptine* factsheet, available at https://legislativeanalysis.org/novel-psychoactive-substances-tianeptine/.

[3] OHIO ADMIN. CODE 4729:9-1-01.3 (West 2022). Tianeptine scheduled effective December 22, 2022.

According to the lower court's interpretation of New Jersey regulations, these programs are only available to people who have committed a crime, not for "offenses," such as disorderly conduct, which are not included in the criminal code of New Jersey. Furthermore, the lower court pointed to the language of the New Jersey Statewide Recovery Court Manual in deciding that the program was intended to be available only for those facing significant periods of incarceration. The appellate court disagreed, stating that the damage done by substance use disorder to the people and communities in New Jersey, combined with the lack of resources available statewide, are pressing issues that the recovery court system was designed to handle. Recovery courts such as the one in New Jersey aim to divert those with substance use disorder out of the criminal justice system, instead offering them treatment. The decision pointed to the Recovery Court Manual as well as the enabling statute, N.J. STAT. ANN. § 2C:35-14 (West 2024), both of which read that a party qualifies to participate in recovery court if he or she faces a sentence of probation as a result of the offense. The decision elaborated that the governing law and regulations do not state that the offense must be labeled a "crime." In addition, the court pointed to the history and intent of the recovery court program through the years, which has repeatedly aimed to increase eligibility for more New Jersey citizens. Unfortunately, Matrongolo passed away as a result of a suspected drug overdose while the court was deciding the case. The judge pointed to this fact as yet another reason to expand access to critical services such as recovery court.

ESTATE FILES SUIT AGAINST JAIL THAT FAILED TO PROVIDE DECEDENT WITH MAT

***Nicole Bissonette v. Cumberland County Sheriff Kevin Joyce, et al.*, U.S. District Court for the District of Maine, Case No. 2:24-cv-00251-JCN (suit filed July 12, 2024).** The estate of a man who died of an overdose while in custody at the Cumberland County Jail (CCJ), in the care of Armor Correctional Health Care Services, Inc. (Armor Health), has filed a wrongful death suit against the entities. Armor Health is the sole health care provider at CCJ and is responsible for the implementation, oversight, and supervision of medical policies and practices at CCJ. James Mannion arrived at CCJ on December 3, 2021. During his medical intake evaluation, a nurse employed by Armor Health noted in Mannion's medical record that he was currently enrolled in a medication for addiction treatment (MAT) program and was "currently withdrawing." Despite knowing that Mannion was suffering from substance use disorder (SUD) and had been taking MAT, none of the defendants or their agents enrolled him in CCJ's MAT program. Between his arrival at CCJ in December 2021 and his death in August 2022, Mannion filed several sick-call requests. In these requests, Mannion stated that he was suffering from daily opioid cravings and that he was dreaming of using heroin. Mannion mentioned that he had an active Suboxone prescription when he entered custody and that he "wanted help." The complaint alleges that the defendants failed to provide him with essential medical care, telling him in July 2022, that "when we expand the [MAT] program [at CCJ] we will let you know." On August 11, 2022, defendant Edie Woodward, a physician assistant employed by Armor Health, conducted a medical evaluation of Mannion's SUD needs and whether he would benefit from MAT. Woodward recognized that Mannion was suffering from "moderate/severe opioid use disorder" and previously had success taking Suboxone to control his SUD. However, Woodward did not enroll Mannion in CCJ's MAT program, nor did she select any specific start date for him to begin MAT. Instead, Woodward, placed Mannion on a list for a chronic care clinic and noted in his medical record that she would "discuss [MAT] with the group and try to determine a start date." On August 14, 2022, Mannion overdosed and died from fentanyl supplied to him by another detainee at CCJ. Mannion's estate argues that the defendants failed to provide him with proper medical care or access to medical care in violation of the Fourteenth Amendment of the U.S. Constitution. The estate also brings forth claims under the Americans with Disabilities Act (42 U.S.C. § 12132) and the Rehabilitation Act (29 U.S.C. § 794) for failing to reasonably accommodate Mannion's SUD. The estate is asking the court for declaratory relief, compensatory and punitive damages, attorneys' fees and costs, and any other relief the court deems just and appropriate.

ESTATE CLAIMS TEXAS JAIL FAILED TO PROVIDE PROPER MEDICAL CARE TO DETAINEES

***Cassandra Johnson, et al. v. Tarrant County, Texas*, U.S. District Court for the Northern District of Texas, Case No. 4:24-cv-00682-P (suit filed July 19, 2024).** The estate of a man who overdosed and died while in custody of the Tarrant County, Texas Jail has filed a wrongful death suit against the county claiming that it has a pattern and practice of disregarding the medical, mental health, and substance use issues faced by those it is tasked with protecting. On July 20, 2022, Trelynn D'Maun Wormley was being held in the Tarrant County Jail while awaiting trial. Later that day, jail staff found Wormley unresponsive in his cell; the staff sent Wormley to the emergency room where he was pronounced dead. The medical examiner declared that Wormley's cause of death was the toxic effects of fentanyl. Wormley's estate claims that Tarrant County failed to: (1) implement systems and procedures to effectively prevent drugs from entering the jail; and (2) adequately treat and protect those with mental health disorders who are prone to substance use. The complaint asserts that these failures are widespread and notes that from 2017 to date, there have been 145 in-custody deaths in Tarrant County. It further states that several of the deceased exhibited behavioral health issues prior to their deaths and, in some cases, their deaths were from drug overdoses. Additionally, the complaint mentions several instances of jail staff who brought prohibited items, including drugs, into the jail. The suit asserts that Tarrant County violated the Fourteenth Amendment of the U.S. Constitution by failing to provide Wormley with adequate medical care while in custody and failing to protect him from harm. The suit also claims that Tarrant County violated the Texas Tort Claims Act (TEX. CIV. PRAC. & REM. CODE § 101.021 (West 2024), under which government units, such as Tarrant County, are liable for "personal injury and death so caused by a condition or use of tangible personal or real property if the governmental unit would, were it a private person, be liable to the claimant according to Texas Law." The estate is asking the court for actual and punitive damages, as well as funeral and burial expenses, pain and suffering, lost earning capacity, and loss of consortium.

NEW YORK HOSPITAL FACES ADA SUIT RELATED TO PATIENT WHO REPORTED TAKING MEDICATION FOR OPIOID USE DISORDER

***Nicole Costin, individually and on behalf of her minor son, Baby A. v. Glens Falls Hospital, et al.*, U.S. Court of Appeals for the Second Circuit, Case No. 23-379 (opinion filed June 12, 2024).** The U.S. Court of Appeals for the Second Circuit has ruled that a New York hospital must face claims that it discriminated against a woman and her son when it subjected her to drug testing and reported her results to the state's child welfare agency as part of her care during childbirth. The court remanded part of a previously dismissed case against the hospital, reviving the discrimination claim at the heart of the dispute. Nicole Costin, a woman recovering from opioid use disorder and currently taking medication for addiction treatment (MAT) as part of her treatment protocol, claimed that she reported her use of Subutex (buprenorphine) immediately upon admission to Glens Falls Hospital. Following her disclosure, the hospital staff performed multiple drug screens on her and her newborn child. The hospital staff claimed that the drug testing was routine for any patient who reported use of MAT and that it was done in order to measure the levels of the drug in the patient's system with the prescribed level of medication to determine if the patient was diverting or selling the medication. Costin's first drug screen came back positive for cocaine and PCP, but her subsequent tests came back negative for all substances. Further, Costin claimed that she was denied routine pain relief during her labor, including an epidural, and was prohibited from holding her newborn child immediately after birth. A day after Costin's delivery, the hospital contacted the New York State Child Abuse and Maltreatment Register to report Costin for suspicions of child abuse. The hospital then refused to discharge the child until child protective

services (CPS) could conduct a home visit. When Costin asked why CPS was involved, a physician informed her that the hospital reports "possible child abuse by every patient that comes in on [MAT]." The next day, the hospital informed Costin that her initial drug screen was a false positive and that CPS had closed its investigation. She was then allowed to leave the hospital with the baby. Costin later received a letter from CPS stating that the hospital's suspicions of child abuse were unfounded.

Costin's initial complaint included multiple claims of discrimination based on her disability under the Americans with Disabilities Act (42 U.S.C. §§ 12181-12189) and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794), as well as state law claims. The district court dismissed the original complaint for failure to allege a plausible claim of discrimination based on her disability for any of the claims. On appeal, the Second Circuit agreed with the district court's ruling in part. The Second Circuit ruled that a hospital is protected from a discrimination claim when it makes a medical decision, such as the actions the hospital took in withholding pain medication and removing the baby when it was born before allowing skin-to-skin contact. The court held that decisions regarding the medical care of the patient are not subject to a discrimination claim if they are informed by the doctor's training and knowledge. However, the court explained, a medical facility is subject to a discrimination claim if it has blanket policies, such as drug testing and reporting to child services every patient who discloses the use of MAT, since those decisions are not related to medical care and instead, are meant to track and punish those patients. The court stated that the plaintiffs made a plausible claim that the motive of the hospital was discriminatory and not informed by any medical knowledge or training. The court vacated and remanded the parts of the claim related to discrimination based on disability for the hospital's blanket policy to drug test and report patients for the use of MAT.

ADDICTION SPECIALIST IN MAINE CONVICTED OF 15 COUNTS OF DISTRIBUTING CONTROLLED SUBSTANCES

***United States v. Merideth Norris,* United States District Court for the District of Maine, Case No. 2:22-cr-00132-NT (jury verdict returned June 21, 2024).** Merideth Norris, DO, an addiction medicine doctor in Maine, has been convicted in a federal jury trial of distributing controlled substances without legitimate medical purpose. Norris was originally indicted in 2022 on 10 counts of distributing drugs such as oxycodone and fentanyl to her patients, most of whom were being seen for substance use disorder. Federal prosecutors alleged that Norris' prescribing was outside the usual course of her professional practice and that it put her patients at risk. Moreover, they noted that many of the patients to whom Norris issued prescriptions either diverted the medication or provided urine samples that screened positive for substances that were not prescribed to them. The prosecution provided assertions that Norris continued her illegal prescribing practices despite insurance companies refusing to reimburse her claims. In fact, the prosecution noted that the retail pharmacy, Walmart, issued a nationwide ban on filling any prescriptions written by Norris due to suspicious prescribing practices. The final indictment, updated shortly before trial, included 16 counts of illegal prescribing, most involving methadone and anti-anxiety medications such as diazepam but also included fentanyl and oxycodone. The jury found Norris guilty of 15 of the 16 counts, with each count carrying a possible sentence of up to 20 years. On August 3, 2024, Norris filed a motion for acquittal, arguing that the outcome of the case violated the U.S. Supreme Court's 2022 decision in *Ruan v. United States* (597 U.S. 450) because the jury was not presented with any evidence to suggest that she was subjectively aware that her prescriptions were "unauthorized."

SIXTH CIRCUIT DEFENDANT NOT ENTITLED TO WITHDRAW GUILTY PLEA IN LIGHT OF RUAN

***United States v. Martin Escobar*, U.S. Court of Appeals for the Sixth Circuit, Case No. 22-3685 (opinion filed July 2, 2024).** For previous updates about this case, please refer to the October 2022 issue of the LAPPA

Case Law Monitor, available here. The Sixth Circuit has ruled that Martin Escobar, a former Ohio physician, is not entitled to withdraw his guilty plea in light of the 2022 U.S. Supreme Court decision in *Ruan v. United States* (597 U.S. 450). Escobar ran a pain management clinic that created fake medical records to justify prescriptions, dispensed large amounts of controlled substances, and ignored medical tests indicating that patients were not using the substances as prescribed. A grand jury charged Escobar with 55 counts of violating the Controlled Substances Act (CSA; 21 U.S.C. §§ 841, 856, and 859) and 30 counts of healthcare fraud (18 U.S.C. § 1347). Escobar pleaded guilty to all but one of the charges. As to the CSA charges, Escobar admitted as part of his plea that he "knowingly or intentionally" dispensed controlled substances and that his acts were "not for a legitimate medical purpose and were outside the usual course of professional practice." Five months after Escobar entered his plea agreement, the U.S. Supreme Court decided the *Ruan* case which held that when a defendant produces evidence that he or she dispensed controlled substances in connection with a prescription, the government must show that he or she knew the prescriptions were unauthorized. After the *Ruan* decision, Escobar moved to withdraw his guilty plea, arguing that, based on precedent established by *Ruan*, he was not informed of the charges against him, and he did not knowingly or intentionally write illegal prescriptions under the CSA. The district court rejected Escobar's motion because he could not show "a fair and just reason" for withdrawal, noting that the factual admissions Escobar made in his guilty plea made clear that there was no basis to vacate the plea. Escobar appealed, arguing that the district court should have permitted him to withdraw his guilty plea after *Ruan*. The Sixth Circuit ruled that the district court did not abuse its discretion by denying Escobar's motion because in his plea agreement, he admitted to the subjective knowledge that his actions were against the law. The court noted that the factual allegations and admissions show that Escobar did not plead guilty to mere negligence or recklessness. The court determined that Escobar's admissions undercut any claim that *Ruan* "turned the tables" on his guilty plea. On July 17, 2024, Escobar filed a petition for a rehearing *en banc*, which the court denied on August 12, 2024.

HARM REDUCTION ORGANIZATIONS SUE THE CITY OF PUEBLO OVER NEW BAN ON SYRINGE SERVICES

***Colorado Health Network Inc. and Southern Colorado Harm Reduction Association v. City of Pueblo,* Colorado District Court (Pueblo County), Case No. 2024-CV-30274 (suit filed June 4, 2024).** Two nonprofit organizations offering syringe exchange and harm reduction services in the City of Pueblo, Colorado have filed a lawsuit to stop a recent citywide ban on free syringe exchange programs (SEPs). In May 2024, in an attempt to combat used needle litter, the Pueblo City Council enacted Ordinance No. 10698 prohibiting the operation of SEPs. The American Civil Liberties Union (ACLU) of Colorado, on behalf of the Colorado Health Network and the Southern Colorado Harm Reduction Association, filed suit June 4, 2024, seeking an injunction and temporary restraining order to allow the various SEPs to continue. The complaint alleges that the ban on SEPs is in violation of superseding state law as well as established public health norms. Colorado state law expressly allows these types of harm reduction services which include offering clean drug injection equipment, medical supplies, and disposal services as well as referrals to social services and health providers. (COLO. REV. STAT. ANN. § 25-1-520 (West 2024)). The ACLU argues in its complaint that Pueblo's ordinance is in direct contradiction to state law and impedes state regulation of public health. In addition, the complaint points to evidence showing that SEPs reduce the spread of communicable disease, overdose rates, and reliance on public health facilities such as emergency rooms and hospitals. The plaintiffs claim that these benefits support the public good accomplished by SEPs and that halting their operations will cause harm to people who use drugs and to the community. The complaint further states that eliminating SEPs does not address the used needle litter which was the goal of the ordinance. On June 6, 2024, the district court granted the temporary restraining order, enjoining enforcement of the ordinance. A preliminary injunction hearing occurred on August 13, 2024.

DOJ INDICTMENTS TARGET MEXICAN CARTELS AND CHINESE MONEY LAUNDERING OPERATION

***United States v. Edgar Joel Martinez-Reyes, et al.*, U.S. District Court for the Central District of California, Case No. 2:23-cr-524(A)-DMG (indictment unsealed June 17, 2024).** A multi-year investigation by the U.S. Department of Justice (DOJ), in cooperation with Chinese and Mexican authorities, discovered evidence that from 2019 to 2023, Los Angeles-based agents of the Sinaloa Cartel sold large quantities of drugs in the United States and laundered their drug trafficking proceeds with the assistance of money-laundering groups linked to Chinese underground banks. Many Chinese nationals wish to transfer assets to the U.S. for various reasons but are barred by the Chinese government from transferring the equivalent of more than $50,000 USD per year out of China. In order to transfer larger sums of money, individuals will seek out informal alternatives to the conventional banking system. Representatives of the cartel allegedly reached a deal with an illicit currency exchange network in China whereby Chinese nationals would obtain U.S. dollars and avoid Chinese currency restrictions, and the Sinaloa Cartel would launder its drug proceeds. During the conspiracy, more than $50 million in drug proceeds flowed between the Sinaloa Cartel and the Chinese underground money exchanges. Following the arrest of 24 suspects, which included both Sinaloa Cartel members and members of the illicit currency exchange network, by Chinese and Mexican authorities, DOJ issued an indictment in April 2024 charging each of them with one count of conspiracy to aid and abet the distribution of cocaine and methamphetamine, one count of conspiracy to launder monetary instruments, and one count of conspiracy to operate an unlicensed money transmitting business. Additional charges filed against some defendants include possession of cocaine and methamphetamine, structuring funds to avoid federal reporting requirements, and assault with a deadly weapon on a federal officer. The charges were unsealed on June 17, 2024. If convicted of all charges, each defendant faces a mandatory minimum of 10 years in prison and a maximum penalty of life in prison.

DOJ UNSEALS DRUG TRAFFICKING CHARGES AGAINST 47 ALLEGED CARTEL MEMBERS

***United States v. Mario Alberto Urena, et al.*, U.S. District Court for the Southern District of California, Case No. 24cr00094-RSH (indictments unsealed June 5, 2024).** On June 5, 2024, over 400 federal, state, and local law enforcement officers in California, Arizona, and Oregon arrested 36 individuals allegedly part of the Sinaloa Cartel and seized significant quantities of cocaine, heroin, methamphetamine, and fentanyl and 52 firearms. The U.S. Department of Justice unsealed 14 indictments against 47 defendants the same day. The defendants, allegedly part of a drug trafficking ring that supplied many drug dealers in the regions, were charged with conspiracy to distribute controlled substances, possession with intent to distribute, money laundering, and firearm offenses. On February 10, 2022, the petitioner, on behalf of itself and its members, initiated the suit by filing a petition for review, seeking declaratory and injunctive relief from DOH's "terpene recall mandate." The petitioner argued that the terpene recall mandate is an unlawful *de facto* regulation and that its promulgation outside of the formal rulemaking process renders it void, and the petitioners argued that the terpene recall mandate was an interpretive rule regarding patient safety and the approval of medical cannabis products in the state. While regulations are subject to the formal rulemaking process, interpretive rules are not, as they merely provide guidance. If an interpretative rule "functions as a regulation, then it will be nullified due to the agency's failure to obey the processes applicable to the promulgation of a regulation." In determining whether an agency action is a regulation or a statement of policy, the court looks at the "extent to which the challenged pronouncement leaves the agency free to exercise discretion to follow or not follow the announced policy in an individual case." The court determined that the terpene recall mandate went beyond "a mere statement of policy and instead create[d] a binding norm." Thus, because the respondents failed to obey the processes applicable to the promulgation of a regulation, the petitioner was entitled to summary relief. Additionally, having entered judgment in favor of the petitioner, the court concluded that the petitioner was entitled to permanent injunctive relief but only as to the DOH's current terpene recall mandate.

PENNSYLVANIA COURT STRIKES DOWN MEDICAL CANNABIS VAPE ADDITIVE RECALL FOR IMPROPER RULEMAKING PROCESS

***Medical Marijuana Access & Patient Safety, Inc. v. Denise A. Johnson, et al.*, Pennsylvania Commonwealth Court, Case No. 58 MD 2022 (opinion filed May 30, 2024).** Pennsylvania's Commonwealth Court has ruled that the Pennsylvania Department of Health (DOH) cannot enforce an interpretive rule that prohibits medical cannabis growers from selling flavored vape cartridges. The DOH is the agency responsible for administering and enforcing the Pennsylvania Medical Marijuana Act (PMMA; 35 PA. STAT. AND CONS. STAT. ANN. § 10231.101, *et seq.* (West 2024)), section 303 of which specifically authorizes the dispensation and patient use of certain forms of medical cannabis, including "a form medically appropriate for administration by vaporization" (35 PA. STAT. AND CONS. STAT. ANN. § 10231.303(b)(2)(iv) (West 2024)). The cannabis in vaporization products contain substances known as terpenes which are naturally occurring chemical compounds found in cannabis and other plants that give the plants their flavor, aroma, and color. Medical cannabis growers and processors, also known as medical marijuana organizations (MMOs), add terpenes extracted from cannabis or other sources to add flavor to the vapor and to improve the aromatic component of a substance. In 2021, the Pennsylvania General Assembly amended the PMMA to require the DOH to consider whether a cannabis additive is permitted by the U.S. Food and Drug Administration (FDA) for use in food or is generally recognized as safe under federal guidelines when determining whether to approve an additive. On November 16, 2021, the respondents sent an email to a group of MMOs advising them that the DOH was "conducting a review of all vaporized medical marijuana products containing additional ingredients," including terpenes, and was requiring every grower/processor to submit each additional agreement for approval, even if the product was previously approved. In response, the MMOs submitted approval requests and provided the DOH with declarations from medical and scientific professionals affirming that there are not any safety concerns associated with the inhalation of fruit or botanically derived terpenes. On February 4, 2022, the DOH denied the approval requests, rescinded prior approval of vaporized products containing substances that had not been approved for inhalation by the FDA, and instituted a recall of those products.

FEDERAL DISTRICT COURT DISMISSES CHALLENGE TO FEDERAL CANNABIS REGULATIONS

***Canna Provisions, Inc., et al. v. Merrick Garland,* U.S. District Court for the District of Massachusetts, Case No. 23-30113-MGM (motion to dismiss granted July 1, 2024).** A federal district court dismissed a challenge to overturn the federal prohibition on cannabis. The 2005 U.S. Supreme Court decision *Gonzalez v. Raich* (545 U.S. 1) upheld the federal government's authority to criminalize personal use of cannabis, even where it is legal under state law and the cannabis does not enter interstate commerce. Seeking to overturn this decision, four Massachusetts cannabis dispensary companies filed suit in federal district court against U.S. Attorney General Merrick Garland, alleging that they had suffered economic injury as a result of federal cannabis regulations. The cannabis companies further argued that there was no rational basis for the federal government to conclude that the plaintiffs' activities substantially affect interstate commerce. Garland moved to dismiss, and on July 1, 2024, the court granted the motion. While the court conceded that the cannabis companies may have made a persuasive argument for reevaluating cannabis regulations, it ultimately ruled that the complaint was in direct opposition to U.S. Supreme Court precedent and had to be dismissed. The cannabis companies filed an appeal to the First Circuit on July 3, 2024.

FEDERAL COURT DISMISSES COMPLAINT AGAINST HUD OVER MEDICAL CANNABIS POLICY

***Sara Bloch, et al. v. U.S. Department of Housing and Urban Development and Marcia Fudge*, U.S. District Court for the Western District of Pennsylvania, Case No. 2:23-cv-01660-NR (opinion filed June 17, 2024).** For previous updates about this case, please refer to the February 2024 issue of the LAPPA *Case Law Monitor*, available here. A federal district court has dismissed a suit that two Section 8 housing applicants filed against the U.S. Department of Housing and Urban Development (HUD) regarding its stance on medical cannabis use in government housing. Plaintiffs Sara Bloch and Mary Cease were denied Section 8 housing benefits due to their medical cannabis use. Noting that medical cannabis was legal in Pennsylvania, they sued the Housing Authority of Indiana County, Pennsylvania (HAIC) in state court. The state court ordered HAIC to provide the plaintiffs with Section 8 benefits. (*Cease v. Housing Authority of Indiana County*, 247 A.3d 57). HAIC refused to comply with the order, claiming that HUD would pull its funding if it complied with the *Cease* decision. The plaintiffs then sued HUD, seeking a declaration that federal law does not require denial of Section 8 housing benefits based on the use of medical cannabis and that such a policy violates equal protection rights. HUD filed a motion to dismiss.

The plaintiffs' first cause of action against HUD is that the agency's policy requiring denial of admission for applicants who use medical cannabis in accordance with state law violates the equal protection guarantees of the Fifth Amendment of the U.S. Constitution's due process clause because it discriminates against low income and disabled individuals. An equal protection claim under the Fifth Amendment must prove the existence of purposeful discrimination. A plaintiff "must show intentional discrimination against him because of his membership in a particular class, not merely that he was treated unfairly as an individual." The plaintiffs claimed that HUD unlawfully penalizes low income individuals for using medical cannabis, while "more affluent" individuals are not penalized for using medical cannabis. The court ruled that the plaintiffs' income discrimination claim failed to assert disparate treatment because "more affluent" individuals cannot even qualify for Section 8 housing based on their higher incomes. Thus, because HUD does not provide Section 8 assistance to "more affluent" individuals, then by definition, HUD cannot treat those individuals more favorably than low-income individuals. The plaintiffs also argued that HUD treats individuals with serious medical conditions that use medical cannabis differently from individuals not using medical cannabis. The court rejected that argument, however, finding that it does not establish discrimination based on disability but instead a preference for a certain type of treatment. The court held that the plaintiffs failed to allege disparate treatment to state a plausible equal protection claim and dismissed the claim with prejudice. The court also determined that the plaintiffs' remaining claims were premature because HUD's "threat" to withhold federal funding from HAIC if it complied with *Cease* is not sufficient to obtain judicial review. The court noted that the threat is not a final agency action because it does not represent the definitive position of HUD, and it does not have the status of law. Additionally, the court notes that it is not certain at this point that HAIC will face any negative enforcement action should it decide to comply with *Cease*. Thus, the court ruled that it cannot resolve the issues presented in this case until HAIC follows the order in *Cease*, and HUD institutes formal action to withhold funding in response to HAIC compliance with *Cease*. Accordingly, the court dismissed the remaining counts without prejudice, subject to the plaintiffs filing a motion to re-open the case upon a showing of a final agency action by HUD.

SUIT AGAINST AUSTIN, TEXAS' CANNABIS DECRIMINALIZATION ORDINANCE DISMISSED

***State of Texas v. City of Austin, et al., Texas District Court* (Travis County), Case No. D-1-GN-24-000586 (motion to dismiss granted June 12, 2024).** For previous updates about this case, please refer to the February 2024 issue of the LAPPA Case Law Monitor, available here. A Travis County, Texas district court judge has dismissed Texas Attorney General Ken Paxton's lawsuit against the City of Austin regarding its 2022 voter-approved ordinance that decriminalized low-level cannabis possession. Paxton filed the suit in January 2024,

claiming that the Austin ordinance violated state law and promoted the use of illicit drugs. Similar suits were filed against the Texas cities of San Marcos, Killeen, Denton, and Elgin, which also decriminalized cannabis. The judge denied Paxton's request for a temporary injunction to block enforcement of the ordinance and granted the defendants' motion to dismiss the case. On June 14, 2024, Paxton filed a request for appeal with the Texas Third Court of Appeals. On July 22, 2024, a Hays County, Texas district court judge dismissed the sister suit filed against San Marcos.

COURT DISMISSES GEORGIA'S REQUEST TO EXTEND ITS MEDICAID EXPANSION PLAN

***The State of Georgia, et al. v. Chiquita Brooks-LaSure, et al.*, U.S. District Court for the Southern District of Georgia, Case No. 2:24-cv-00016-LGW-BWC (motion for summary judgment granted July 15, 2024).** The Federal District Court for the Southern District of Georgia granted summary judgment to the Centers for Medicare & Medicaid Services (CMS), upholding the agency's denial of the state's request to prolong its "Georgia Pathways to Coverage" (Pathways program) special demonstration until 2028. Georgia created the Pathways program as a Section 1115 demonstration waiver project that expands Medicaid coverage to Georgians who do not qualify for traditional Medicaid.[4] Coverage under the Pathways program is conditional, meaning that applicants must satisfy certain eligibility requirements. The rules governing the Pathways program are set forth in an agreement between Georgia and CMS. A few months after the parties entered into the agreement and CMS approved the Pathways program, CMS announced that it was rescinding its approval of the eligibility conditions for the Pathways program. Georgia sued CMS, and in 2022, a federal court determined that CMS's rescission violated the Administrative Procedures Act (5 U.S.C. §§ 551–559) because "it was arbitrary and capricious on numerous, independent grounds." As a result, the court vacated CMS's rescission of the Pathways program, and the state renewed its implementation efforts. Due to the delays caused by the litigation, however, the Pathways program did not go into effect until the summer of 2023. On February 24, 2023, Georgia asked CMS to amend the effective dates of the Pathways program. Specifically, Georgia asked CMS to extend the program's end date to September 30, 2028. Pursuant to the original agreement, the implementation period for the Pathways program was October 15, 2020 to September 30, 2025. The state asserted that extending the end date to 2028 would "provide the state with a full five-year period in which to operate, monitor, evaluate, and assess the effectiveness of the Pathways to Coverage 1115 Demonstration." Georgia further stated that based on the limited time remaining in the demonstration, it would not have sufficient time to evaluate and assess the effectiveness of the demonstration waiver prior to its expiration. As such, Georgia informed CMS that submitting a formal extension request would be premature because the state "would have just collected its baseline data and would not have had an opportunity to conduct any comparisons or perform its evaluation activities." On October 5, 2023, CMS denied Georgia's request to amend the end date to 2028 because the state had failed to comply with the requirements necessary for CMS to grant an extension. On November 16, 2023, Georgia asked CMS to reconsider its denial, arguing that the state was not asking for an extension for the program to last longer than its initially authorized term but instead to be able to implement its program for the originally authorized five-year term notwithstanding the delay caused by litigation. On December 22, 2023, CMS affirmed its denial. Georgia then filed the current lawsuit alleging that CMS's denial was arbitrary and capricious and violated the program agreement and the Social Security Act (42 U.S.C. § 1396). CMS filed a motion for summary judgment, which the court granted. The court determined that CMS's denial was appropriate because Georgia failed to submit a formal extension request as required by federal regulations. While the court agreed with Georgia's reasoning for wanting to extend the agreement, it determined that CMS's prior bad act of delaying the implementation of the Pathways program does not allow the state to avoid the rules and regulations governing time extensions.

[4] A "Section 1115 demonstration waiver" is a waiver authorized under 42 U.S.C. § 1315 that allows the United States Secretary of Health and Human Services to approve experimental, pilot, or demonstration programs that promote the objectives of Medicaid and Children's Health Insurance Program. *Section 1115 Demonstrations*, MEDICAID.GOV (last visited July 24, 2024), https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html.

NEW YORK SUBSTANCE USE DISORDER TREATMENT PROGRAM PAYS PENALTY FOR CONTROLLED SUBSTANCE ACT VIOLATION

(Settlement announced July 16, 2024). Conifer Park, Inc. (Conifer Park), a substance use disorder treatment facility, has agreed to pay $300,000 to resolve allegations that it violated the Controlled Substances Act's (CSA) recordkeeping requirements (21 C.F.R. § 1304.04). Conifer Park dispenses medication for addiction treatment, and the CSA requires entities that dispense controlled substances to maintain specific records and to conduct periodic inventories. A 2018 Drug Enforcement Administration (DEA) inspection of Conifer Park revealed that the facility failed to maintain accurate records or perform required inventories. At the time, Conifer Park stated that it would comply with CSA recordkeeping requirements in the future, but similar DEA investigations in 2021 and 2023 determined that the facility's recordkeeping practices continued to violate the CSA. Along with the monetary penalty, Conifer Park has entered into a memorandum of agreement with the DEA, agreeing to implement an electronic recordkeeping system no later than November 1, 2024.

CROSSROADS CLINICS AGREE TO SETTLE FALSE CLAIMS ACT ALLEGATIONS

***United States ex rel. Diana France v. Crossroads Treatment Centers*, U.S. District Court for the District of South Carolina, 6:21-cv-1263 (settlement reached July 25, 2024).** The federal government and the Commonwealth of Virginia have reached an $863,934 civil settlement with a chain of substance use disorder treatment clinics serving patients in Virginia, resolving allegations that the clinics submitted false and fraudulent claims to Medicaid. The clinics – Crossroads Treatment Center of Petersburg P.C., ARS Treatment Centers of New Jersey P.C., Crossroads Treatment Center of Greensboro P.C., and Starting Point of Virginia P.C. – are part of a chain called Crossroads, which is headquartered in Greenville, South Carolina. The federal government and Virginia claimed that from 2016 through mid-2023, the clinics submitted claims to Virginia Medicaid containing code 99215, which signifies a meeting with a patient involving at least two of the following three components: a comprehensive medical history, a comprehensive medical examination, and medical decision making of high complexity. However, the clinics were only conducting regular patient check-ins that did not meet the criteria necessary to be billed under code 99215. The investigation into the clinics was prompted by a lawsuit filed under the whistleblower provisions of the False Claims Act (31 U.S.C. § 3729). Of the $863,934 civil settlement, the United States will receive $356,891 and Virginia will receive $507,043. The settlement agreement provides for whistleblower, Diana France, a former Director of Network Management and Contracting for Crossroads, to receive $60,671 as her share of the federal recovery. France will also receive a share of Virginia's recovery.

FEDERAL COURT AGAIN RULES INSURERS DO NOT HAVE A DUTY TO DEFEND MCKESSON

***AIU Insurance Company, et al. v. McKesson Corporation*, U.S. District Court for the Northern District of California, Case No. 20-cv-07469-JSC (opinion filed July 30, 2024).** A federal court has once again ruled that two American International Group, Inc. (AIG) insurance units (collectively "insurers") do not have a duty to defend McKesson Corporation (McKesson) against opioid related litigation. In January 2024, The Ninth Circuit affirmed a district court's order granting partial summary judgment in favor of the insurers on the grounds that they did not have a duty to defend McKesson against three opioid related lawsuits under two policies issued to McKesson spanning from 2008-2009 and 2015-2016. (For more information on this case refer to the February 2024 issue of the LAPPA *Case Law Monitor*, available here.) The Ninth Circuit explained that McKesson was entitled to coverage for any "occurrence," which is defined as "an accident." The policy at issue in that case read that "an accident does not occur when the insured performs a deliberate

act unless some additional, unexpected, independent, and unforeseen happening occurs that produces the damage." Because the opioid related suits described "exclusively deliberate conduct" by McKesson, the Ninth Circuit ruled that the insurers did not have a duty to defend the company under the 2008-2009 and 2015-2016 policies. Notwithstanding that ruling, McKesson filed a separate suit seeking a declaration that the opioid related suits alleged that a potentially covered occurrence took place within the meaning of that term as defined in the 1999-2004 AIG policies. Under those policies, "occurrence" means "an accident, including continuous or repeated exposure to conditions, which results in bodily injury or property damage neither expected nor intended from the standpoint of the insured." Under California common law, "an accident is an unexpected, unforeseen, or undesigned happening or consequence from either a known or an unknown cause;" an accident does not require an intent to injure. McKesson argued that the additional language in the 1999-2004 policies' definition of occurrence meant that "the insured's subjective intent is relevant" and "an occurrence exists so long as the insurer cannot conclusively prove that the insured intended or had actual knowledge that the injury would result from its actions." The court found McKesson's argument to be unpersuasive, determining that "the language does not change California's definition of 'accident' in general liability policies as not including deliberate, intended conduct even if the insured did not intend the injury resulting from the deliberate conduct." McKesson then argued that the opioid related suits alleged at least a potentially covered occurrence because diversion of the opioids McKesson distributed from 1999 to 2004 was "an unforeseen, intervening cause of the alleged injuries." The court rejected this argument, noting that in 1970, Congress determined that "opium and opiate[s]" had "a high potential for abuse." Thus, the court found that, from at least 1970 onward, it was objectively foreseeable that a failure to maintain effective controls over these substances would lead to diversion and that diversion of McKesson's opioid shipments would result in the suits' alleged injuries. Accordingly, the court ruled that the opioid related suits do not potentially allege an accident during the 1999 to 2004 policy periods and denied McKesson's motion for partial summary judgment. The court scheduled a case management conference for August 22, 2024.

SHAREHOLDERS SUE INDIVIOR OVER CLAIMS THAT IT OVERSTATED SUBLOCADE AND OPVEE'S 2024 REVENUE PROJECTIONS

***Herbst Capital Management, LLC v. Indivior PLC, et al.*, U.S. District Court for the Eastern District of Virginia, Case No. 3:24-cv-00554 (suit filed August 2, 2024).** Herbst Capital Management, LLC, an Illinois-based hedge fund manager, on behalf of itself and others similarly situated (the "plaintiffs"), has filed suit against Indivior PLC (Indivior) over allegations that the Indivior overstated the financial prospects for some of its products. In July 2024, Indivior reduced its 2024 revenue forecast for Sublocade (buprenorphine) and Opvee, a nalmefene nasal spray for the reversal of opioid overdose. According to the complaint, the adjusted revenue forecast resulted in Indivior's stock price falling almost 34 percent. The complaint asserts that Indivior misled the plaintiffs by falsely stating that they were confident in Sublocade delivering strong net revenue growth. The plaintiffs argue that Indivior should have known that Medicaid disenrollment triggered by the end of the COVID-19 Public Health Emergency in early 2023 would have a negative impact on Sublocade sales. The suit also claims that Indivior knew that the early adoption of Opvee was not meeting expectations. Thus, the plaintiffs claim that it was false and misleading for Indivior to state that they remained confident in delivering on their net revenue ambitions for Opvee in 2024. The plaintiffs bring forth claims that the defendants violated Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)) by making various untrue statements of material facts and omitting material facts necessary to make the statements not misleading and Section 20(a) of the Exchange Act (15 U.S.C. § 78t) by failing to disseminate accurate and truthful information with respect to Indivior's financial condition.

NEW MEXICO HOSPITAL FILES CLASS ACTION RICO SUIT AGAINST MCKINSEY & COMPANY

***San Miguel Hospital Corporation d/b/a Alta Vista Regional Hospital v. McKinsey & Company, Inc. et al.*, U.S. District Court for the Northern District of California, Case No. 3:24-cv-04217-CRB (suit filed July 12, 2024).** A New Mexico hospital has filed a class action lawsuit against the global management consulting firm, McKinsey & Company (McKinsey), under the Racketeering Influenced and Corrupt Organizations Act (RICO; 18 U.S.C. §§ 1961–1968). San Miguel Hospital Corporation d/b/a Alta Vista Regional Hospital (Alta Vista) asserts that McKinsey devised strategies for opioid manufacturers, including Purdue Pharma, that resulted in the increased sale of prescription opioids. Alta Vista claims that McKinsey increased the demand for prescription opioids by using misleading marketing strategies that convinced doctors and patients that opioids could be safely prescribed for common ailments. The complaint states that Alta Vista was financially impacted by the opioid epidemic that McKinsey had a role in creating due to the increased demand in treating patients suffering from opioid use disorder (OUD). The complaint notes that treating patients with OUD is often more complex and that they consume more hospital resources than patients without OUD. Alta Vista also notes that private and government insurance does not fully cover the increased costs associated with treating patients with OUD. Alta Vista is asking the court for compensatory damages. Note that this case is filed in the District of Northern California for pretrial proceedings under *In re McKinsey & Co., Inc. National Prescription Opiate Litigation*.

ARKANSAS SUES PHARMACY BENEFIT MANAGERS OVER ROLE IN OPIOID EPIDEMIC

***State of Arkansas, ex rel. Tim Griffin v. Optum, Inc., et al.*, Arkansas Circuit Court (Pulaski County), Case No. 60CV-24-5073 (suit filed June 24, 2024).** Arkansas Attorney General Tim Griffin has filed a lawsuit against the pharmacy benefit managers (PBMs), Optum Rx, Inc. and Express Scripts, Inc. along with their subsidiaries (collectively "PBMs"), over allegations that the PBMs enabled the opioid epidemic in the state. PBMs are the companies that manage prescription drug benefits on behalf of health insurers. The suit claims that the PBMs fueled the opioid epidemic by increasing the sale of prescription opioids through the placement of the drugs on lower tiers of their formularies. The complaint also asserts that the PBMs operated online retail pharmacies that dispensed "billions of morphine milligram equivalents of opioids" while failing to follow state and federal laws on controlled substances. The complaint brings forth claims of public nuisance, negligence, and unjust enrichment. Arkansas is asking the court to declare the PBMs' acts as a violation of state statutory and common law and enjoin the PBMs from failing to comply with state law requiring the monitoring and reporting of suspicious opioid distributions.

BALTIMORE REACHES SETTLEMENT WITH ALLERGAN AND CVS

***Mayor & City Council of Baltimore v. Purdue Pharma L.P., et al.*, Circuit Court of Maryland (Baltimore City), Case No. 24-C-18-000515 (settlements announced June 10, 2024 and August 9, 2024).**

- The City of Baltimore, Maryland has reached a $45 million settlement with Allergan Finance, LLC (Allergan) to resolve claims that the company helped fuel the opioid epidemic in the city. Allergan will pay the entire $45 million settlement amount within 30 days of the agreement approval. Baltimore had opted out of Allergan's global settlement, and if the city had participated, it would have received approximately $7 million over the next seven years. As part of the agreement, Baltimore has agreed to use $5 million of the settlement for its peer navigator program and another $5 million for its Charm City Care Connection program. Baltimore Mayor Brandon Scott plans to create an advisory board to oversee how the rest of the settlement funds will be spent.
- On August 9, 2024, Mayor Scott announced that Baltimore reached a $45 million settlement with CVS to resolve allegations that the pharmacy chain helped fuel the opioid epidemic in the city. CVS will pay the entire

settlement amount by the end of 2024. Baltimore did not have the option to join CVS's global settlement because Maryland was not one of the states to sign onto the agreement. However, this independent settlement has likely secured more money for Baltimore than any expected under a global deal between Maryland and CVS. Of the funds secured from CVS, Baltimore has committed to using $5 million for the Law Enforcement Assisted Diversion program, $5 million for Healing City Baltimore, $1 million for Roberta's House, and $1 million for From Prison Cells to PhD.

- Litigation will continue against defendants Johnson & Johnson, McKesson, Cardinal Health, AmerisourceBergen, Walgreens, Teva, and former Insys CEO John Kapoor. The case is set for trial on September 16, 2024.

OPTUMRX AGREES TO RESOLVE ALLEGATION THAT IT FILLED CERTAIN PRESCRIPTIONS IN VIOLATION OF THE CONTROLLED SUBSTANCES ACT

(Agreement announced June 27, 2024). OptumRx Inc. (Optum Rx), the prescription drug benefits provider for UnitedHealthcare, has agreed to pay $20 million to resolve allegations that it improperly filled certain opioid prescriptions in violation of the Controlled Substances Act (21 U.S.C. § 801, *et seq.*). The settlement resolves an investigation initiated by the Drug Enforcement Administration (DEA) into whether, between April 2013 and April 2015, OptumRx improperly filled certain opioid prescriptions in combination with other drugs such as benzodiazepines and muscle relaxants. The combination of an opioid, benzodiazepine, and a muscle relaxant is colloquially referred to as the "Holy Trinity" due to synergized euphoria and an increased risk of death. The DEA alleged that these combination prescriptions, which OptumRx filled primarily from a mail order pharmacy in Carlsbad, California, raised "red flags" that the prescriptions may not have been intended for a legitimate medical use and that these red flags were rarely investigated or resolved. During the course of the DEA's investigation, OptumRx closed its mail order pharmacy operations in Carlsbad. OptumRx did not admit to any liability as part of the settlement agreement.

RITE AID AGREES TO SETTLE WHISTLEBLOWER SUIT ALLEGING CONTROLLED SUBSTANCE ACT VIOLATIONS

***United States ex rel. Andrew White v. Rite Aid Corporation, et al.*, U.S. District Court for the Northern District of Ohio, Case No. 1:21-cv-01239-CEF (settlement announced July 10, 2024).** For previous updates on this case, please refer to the April 2023 issue of the LAPPA *Case Law Monitor*, available here. The U.S. Department of Justice has reached an agreement with Rite Aid Corporation (Rite Aid) and 10 of its subsidiaries and affiliates to resolve allegations under the False Claims Act (FCA; 31 U.S.C. § 3729) and the Controlled Substances Act (CSA; 21 U.S.C. § 829(a), (b), and (c); and 21 U.S.C. 842(a)(1)). The settlement includes a payment of $7.5 million to the federal government and an allowed, unsubordinated, general unsecured claim of $401.8 million in Rite Aid's ongoing bankruptcy case in New Jersey. This settlement resolves the claims that certain Rite Aid pharmacies in Washington State violated the CSA by filling prescriptions written by individuals who lacked proper controlled substance prescribing authority. The settlement also resolves claims brought in 2019 under the *qui tam*, or whistleblower, provisions of the FCA by Andrew White, Mark Rosenberg, and Ann Wegelin, who all previously worked for Rite Aid at various pharmacies. The whistleblowers will receive 17 percent of the government's FCA recovery in this matter. In addition to the settlement, Rite Aid agreed to enter into agreements with the Drug Enforcement Administration and the Office of Inspector General of the U.S. Department of Health and Human Services to address the company's obligations going forward.

INDIVIOR REACHES OPIOID SETTLEMENT WITH 16 STATES

(Settlement in principle announced July 26, 2024). The drug manufacturer, Indivior has agreed to an $86 million settlement with 16 states over the company's alleged role in the opioid crisis. The company had been accused of improperly targeting sales to doctors running pill mills and failing to monitor suspicious orders, leading to inappropriate prescriptions. The $86 million settlement will be paid out over the next five years and will be used for treatment, recovery, and prevention programs. The attorneys general of Illinois, Tennessee, Utah, and Virginia negotiated the settlement in principle in coordination with an executive committee consisting of the attorneys general of California, Colorado, Delaware, Georgia, Idaho, Iowa, Massachusetts, New York, North Carolina, Ohio, Oregon, and Vermont.

RECENT EVENTS IN THE PURDUE PHARMA BANKRUPTCY PROCEEDINGS

***In re Purdue Pharma L.P.*, U.S. Bankruptcy Court for the Southern District of New York, Case No. 19-23649 (suit filed Sept. 15, 2019).**

- For previous updates on this case, please refer to the June 2024 issue of the LAPPA *Case Law Monitor*, available here. On June 27, 2024, the U.S. Supreme Court issued a 5-4 ruling in *Harrington v. Purdue Pharma L.P.* (144 S.Ct. 2071) which struck down the liability shield previously granted to the Sackler family in the Purdue Pharma (Purdue) bankruptcy plan. As part of the original bankruptcy plan, the Sacklers had agreed to pay $6 billion to settle opioid-related claims but only in return for a complete release from any liability in future cases. The main issue in the case was whether the legal shield that bankruptcy provides can be extended to individuals, such as Sackler family members, who have not declared bankruptcy themselves. This practice is known as third-party release. The U.S. Bankruptcy Trustee argued that U.S. bankruptcy law did not permit protecting the Sackler family from being sued. The majority ruled that "the bankruptcy code does not authorize a release and injunction that, as part of a plan of reorganization under Chapter 11, effectively seek to discharge claims against a non-debtor without the consent of affected claimants." Thus, the majority determined that the liability releases granted to the Sacklers under Purdue's bankruptcy plan are impermissible because they were obtained without the consent of some individuals who sued over the company's opioid sales tactics. The majority also criticized the Sacklers for not placing "virtually all their assets on the table for distribution to creditors," and stated that the family sought to "pay less than the [bankruptcy] code ordinarily requires and receive more than it normally permits." The dissent argued that the majority's decision was wrong on the law and that the ruling would be devastating to opioid victims and their families who would now be deprived of a long awaited substantial monetary recovery.
- In a July 1, 2024 court filing, New York and 47 other states, territories, and districts (collectively "the states")[5] agreed to additional mediation following the U.S. Supreme Court decision that struck down the Sacklers' liability shield. However, the states were only willing to sign on to a 60-day mediation period. The states agreed not to object to Purdue's request for an extension of its preliminary injunction halting litigation against the Sacklers while mediation continues but urged the court not to continue to shield the Sacklers any further if the mediation ultimately fails to produce a new deal. On July 9, 2024, the bankruptcy judge extended Purdue's injunction for 60 days. Purdue has asked the judge to appoint a pair of mediators to oversee talks involving the creditors committee, victim groups, the Sacklers, and other parties.
- In a July 8, 2024 court filing, Purdue stated that, should the new round of mediation fail, it would back efforts by an official committee of creditors to recover more than $11.5 billion from the Sackler family that they

[5] Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Northern Mariana Islands, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virgin Islands, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

allegedly shifted offshore in the years preceding Purdue's 2019 bankruptcy. The creditors stated in a court filing that they are seeking to ensure that the Sacklers are "not allowed off the hook" for their role in the opioid crisis. The Sacklers released a statement disputing the allegations and said that roughly half the money transferred from Purdue was paid in taxes.

ABOUT 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/.