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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NEW YORK JAIL MUST PROVIDE MAT TO INMATES WHILE CLASS ACTION PENDING

***M.C. and T.G. v. Jefferson County, New York, et al.*, U.S. District Court for the Northern District of New York, Case No. 6:22-cv-00190-DNH-ATB (preliminary injunction granted May 16, 2022).** For information on the facts and previous updates in this case, please refer to the April 2022 issue of the LAPPA *Case Law Monitor*, available here. Plaintiffs M.C. and T.G. filed a civil rights class action against Jefferson County (NY) over the Jefferson County Jail's (Jail) policy of banning medication for addiction treatment (MAT) for non-pregnant inmates. On March 29, 2022, the federal district court granted M.C.'s motion for a preliminary injunction requiring the Jail to provide him with his prescribed methadone treatment. On April 6, 2022, the plaintiffs moved for a preliminary injunction permitting members of the proposed class to access MAT until the court evaluates the lawfulness of the Jail's practice. The court held oral arguments on the class certification motion and the preliminary injunction motion on May 10, 2022. In an order issued May 16, 2022, the court certified the class and granted the plaintiffs' motion for a preliminary injunction. The Jail must now provide plaintiffs and class members with MAT during their detention. A case conference is scheduled for June 7, 2022.

SUIT OVER NEW YORK DEPARTMENT OF CORRECTIONS' MEDICATION POLICY SURVIVES CHALLENGE

***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 (motion to dismiss denied May 19, 2022).** For information on the facts and previous updates in this case, please refer to Volume 1, Issue 1 of the LAPPA *Case Law Monitor*, available here. This case, filed in September 2019, involves a

proposed class of inmates in the custody of the New York State Department of Corrections and Community Supervision (DOCCS) who require pain management and/or neuromodulating medications to treat chronic health conditions. In 2017, DOCCS initiated its "Medications with Abuse Potential" Policy (MWAP Policy), which states 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. Plaintiffs assert that the MWAP Policy violates the Eighth Amendment and strips medical providers of the ability to properly address the medical needs of their patients. Defendants moved to dismiss the case for failure to state a claim. For the plaintiffs to prevail, they must prove: (1) that the alleged deprivation of adequate medical care is sufficiently serious; and (2) that defendants acted or failed to act while aware of the substantial risk of harm that could result to the inmates. In a motion to dismiss, the defendants argued that the plaintiffs cannot assert a deliberate indifference claim because "plaintiffs were frequently seen and treated, prescribed pain medication, sent to pain clinics, and referred to outside specialists." The federal district court disagreed with the defendants, denying the motion and finding that the plaintiffs adequately pled the deprivation of adequate medical care. Additionally, using an example where DOCCS stopped an inmate's multiple sclerosis medication and replaced it with a less effective alternative after denial of his provider's MWAP request, the court held that it could infer that the defendants' dismissal of the doctors' recommendations without explanation resulted from the MWAP Policy and not from the defendants' independent medical judgment. Additionally, the defendants argued that, because they provided alternative treatments to the plaintiffs following the implementation of the MWAP Policy, the plaintiffs did not adequately plead the required mental culpability. The court disagreed with this argument, finding that the plaintiffs properly alleged that the defendants knew of the plaintiffs' chronic pain and neurological issues after discontinuing medications subject to the MWAP Policy.

RHODE ISLAND DETENTION CENTER AGREES TO PROVIDE MAT TO INMATES

DOJ No. 204-66-75 (agreement reached May 19, 2022). The U.S. Attorney's Office for the District of Rhode Island reached an agreement with the Donald W. Wyatt Detention Facility (Wyatt) to ensure that detainees treated for opioid use disorder (OUD) prior to entering the facility will continue to receive medication for addiction treatment (MAT) while in custody, as required by the Americans with Disabilities Act (ADA). Based on an investigation, the U.S. Attorney's Office determined that Wyatt did not comply with the ADA due to its failure to provide MAT. Additionally, the investigation found that Wyatt performed no individualized medical determinations to assess whether a detainee should be maintained on, or withdrawn from, his or her MAT. As a result, Wyatt detainees who previously received MAT under the supervision of a licensed health care professional faced forced withdrawal while incarcerated. Under the terms of the agreement, Wyatt will adopt non-discriminatory medication management policies at the facility. It will provide MAT to individuals with OUD who were taking medication under the supervision of a licensed health care professional prior to their incarceration. Wyatt must implement the new policies by June 30, 2022.

INMATE'S SUIT AGAINST PENNSYLVANIA DEPARTMENT OF CORRECTIONS FOR DENIAL OF MAT SURVIVES

***Mark Rokita Jr. v. Pennsylvania Department of Corrections*, Commonwealth Court of Pennsylvania, Case No. 340 MD 2020 (preliminary objection denied April 12, 2022).** Mark Rokita, Jr., an inmate at the Houtzdale, Pennsylvania, State Correctional Institution, has a substance use disorder (SUD). During his incarceration, the department of corrections (Department) refused his requests for medication for addiction treatment (MAT) because Department policy prohibits it, except for prisoners whose release on parole is imminent. For individuals like Rokita, the Department offers only group counseling sessions for SUD. After unsuccessfully filing and appealing his grievance with the Department, Rokita filed suit in state court,

asserting that the Department's refusal to allow him MAT violates his Eighth Amendment rights and the Americans with Disabilities Act. The Department filed a demurrer—a preliminary objection akin to a motion to dismiss for failure to state a claim. On April 12, 2022, a state trial court denied the objection. A demurrer can be upheld under Pennsylvania law only when "on the facts averred, the law says with certainty that no recovery is possible." The court found it conceivable that Rokita could establish either that the Department acted with deliberate indifference to his medical needs or that it discriminated against Rokita's disability. Thus, the case can proceed. The Department's answer to the complaint is due on or before June 13, 2022.

FORMER INMATE SUES NORTH CAROLINA PRISON OVER MAT POLICY

***Tracey Edwards v. Erik Hooks, et al.*, U.S. District Court for the Eastern District of North Carolina, Case No. 5:21-ct-03270-D (suit filed September 2, 2021).** A woman in custody at the North Carolina Correctional Institution for Women (NCCIW) from May 2019 to June 2021 for a nonviolent drug charge filed a lawsuit against the prison system over the denial of medication for addiction treatment (MAT). Tracey Edwards was diagnosed with opioid use disorder and prescribed MAT prior to her incarceration. NCCIW has a policy to provide MAT only to pregnant inmates. At first, doctors at NCCIW prescribed MAT to Edwards because she was pregnant. However, on December 23, 2019, three days after Edwards gave birth, the defendants ordered termination of her MAT prescription. According to the plaintiff's complaint, the defendants did not provide medical justification for refusing to provide Edwards with her MAT nor did they allow a doctor to see her to help manage her withdrawal symptoms. Edwards claims that NCCIW's policy of denying MAT to non-pregnant people violates the Eighth Amendment, Title II of the Americans with Disabilities Act, and the Rehabilitation Act. Edwards requests the court to issue a declaratory judgment and enjoin the defendants from denying MAT to inmates. Additionally, Edwards asks the court to provide her with compensatory and punitive damages. Case discovery must be completed no later than September 13, 2022.

NINTH CIRCUIT HOLDS THAT DELTA-8 THC PRODUCTS ARE LEGAL UNDER FEDERAL LAW

***AK Futures LLC v. Boyd Street Distro LLC*, U.S. Court of Appeals for the Ninth Circuit, Case No. 21-56133 (opinion filed May 19, 2022).** The U.S. Court of Appeals for the Ninth Circuit ruled that the delta-8 THC found in e-cigarettes and vape products is legal under the Agriculture Improvement Act of 2018 (Pub. L. No. 115-334; informally, "the 2018 Farm Bill") and that companies selling delta-8 THC products can receive trademark protections. This suit involves AK Futures, LLC's (AK Futures) "Cake" branded delta-8 THC products. Delta-8 THC is a chemical compound that occurs naturally in the cannabis plant, which can be grown into either hemp or marijuana. According to the U.S. Food and Drug Administration, delta-8 THC has psychoactive and intoxicating effects similar to delta-9 THC, the main psychoactive component of marijuana. Delta-8 THC is not found in significant amounts in the cannabis plant, meaning that concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol. The 2018 Farm Bill legalized the possession and cultivation of hemp and defined hemp as "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 [THC] concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 1639o). In 2021, AK Futures learned that Boyd Street Distro LLC (Boyd Street) sold counterfeit branded versions of its Cake e-cigarette.

AK Futures sued Boyd Street in California federal court for copyright infringement as well as federal unfair competition and false designation under the Lanham Act. AK Futures moved for a preliminary injunction. The district court granted the preliminary injunction, finding that: (1) AK Futures' products are lawful under the 2018 Farm Bill; and (2) AK Futures would likely succeed in showing both copyright and trademark infringement. On appeal to the Ninth Circuit, Boyd Street contended only that AK Futures is not legally

allowed to own a valid trademark of its Cake products because federal law forbids the possession and sale of delta-8 THC. AK Futures argued that the 2018 Farm Bill's definition of hemp encompasses delta-8 THC products so long as those products contain no more than 0.3 percent delta-9 THC. In ruling for AK Futures, the Ninth Circuit supported AK Futures' interpretation of the 2018 Farm Bill finding that a straightforward reading of § 1639o yields a definition of hemp applicable to all products, including the AK Futures products at issue, that are sourced from the cannabis plant, contain no more than 0.3 percent delta-9 THC, and can be called a derivative, extract, cannabinoid, or one of the other enumerated terms. In reaching this conclusion, the Ninth Circuit rejected two other counterarguments from Boyd Street: (1) the Drug Enforcement Administration interprets the 2018 Farm bill as not to apply to delta-8 THC because of the compound's method of manufacture; and (2) Congress never intended for the 2018 Farm Bill to legalize any psychoactive substances. First, the court held that the 2018 Farm Bill's clear statutory text overrides a contrary agency interpretation. Second, the court concluded that "regardless of the wisdom of legalizing delta-8 THC products, [it] will not substitute its own policy judgment for that of Congress. If Boyd Street is correct, and Congress inadvertently created a loophole legalizing vaping products containing delta-8 THC, then it is for Congress to fix its mistake." In sum, because delta-8 THC is legal under the 2018 Farm Bill, products containing delta-8 THC are protectable by trademarks. Therefore, the court affirmed the grant of the preliminary injunction in AK Futures' favor and remanded the case to federal district court for further proceedings.

AMAZON CAN TEST NEW YORK CITY WAREHOUSE WORKERS FOR MARIJUANA

***Michael Thomas, et al. v. Amazon.com Inc.*, U.S. District Court for the Eastern District of New York, Case No. 21-cv-1325 (motion to dismiss granted April 12, 2022).** Three individuals who lost Amazon job offers after testing positive for marijuana during a pre-employment drug screening brought forth a single claim, proposed class action in federal district court against the company, asserting that Amazon violated § 8-107(31) of the New York City Administrative Code, which prohibits employers from testing potential employees for marijuana use as a condition of employment, subject to certain exceptions. In moving to dismiss the complaint, Amazon asserted that it took lawful actions, because the testing policy falls within the exceptions to § 8-107(31) that allow an employer to require potential employees to pass a pre-employment screening for marijuana if: (1) the position requires that an employee regularly operate heavy machinery (47 R.C.N.Y. § 2-07(a)(2)); or (2) if an impairment caused by marijuana would interfere with the employee's ability to take adequate care in carrying out his or her job duties and would pose an immediate risk of death or serious physical harm to the employee or to other people (27 R.C.N.Y. § 2-07(a)(6)). The district court ruled that the position for which the plaintiffs applied—"sortation associate"—falls under the exception for jobs involving the operation of heavy machinery due to the required regular use of conveyor belts as part of the job. Although the plaintiffs claimed that conveyor belts are not heavy machinery, the court disagreed, finding that the types of conveyor belts used in Amazon warehouses are similar to industrial conveyors used in the construction industry and present hazards that could cause serious injury. The court also noted that it is foreseeable that an employee impaired by marijuana could cause serious physical harm to him or herself or another employee as sortation associates must move quickly and attentively through an active warehouse. Thus, because Amazon's policy falls into an exception to § 8-107(31), the court granted Amazon's motion to dismiss the complaint.

PENNSYLVANIA MARIJUANA LAW CREATES NO AFFIRMATIVE DEFENSE TO DUI FOR REGISTERED CARDHOLDER

***Commonwealth of Pennsylvania v. Traa Alan Wagner*, Pennsylvania Superior Court, Case No. 491 WDA 2021 (opinion filed April 4, 2022).** In November 2020, a Pennsylvania State Police trooper pulled over Traa Wagner's vehicle because of a broken headlight. The trooper immediately noticed the smell of marijuana and

learned that Wagner, a holder of a Pennsylvania medical marijuana card, recently used marijuana. Moreover, two small children were in the back of Wagner's car. A drug recognition expert brought to the scene concluded Wagner showed cannabis impairment, and a blood draw confirmed the presence of THC in Wagner's system. The Commonwealth charged Wagner with three counts of DUI, two counts of endangering the welfare of a child, and one count each of possession of marijuana and drug paraphernalia. In December 2020, Wagner filed a pretrial motion, seeking suppression of all evidence from the traffic stop arguing, among other things, that as a registered marijuana patient, Pennsylvania law shielded him from violating the prohibition on driving with a Schedule I controlled substance in his system. Although a state trial court denied the motion, it found that Pennsylvania's marijuana law creates an affirmative defense for Wagner's claims. As a result, the Commonwealth would need to prove that the THC in Wagner's blood came from a source other than his lawful medical marijuana. The Commonwealth appealed to an intermediate appellate court. On appeal, the court held that the existence of a Pennsylvania law authorizing medical marijuana has no effect on the general prohibition against driving with THC in one's system and the law's silence on driving cannot be interpreted as creating an affirmative defense. The court reversed the order and remanded the case to the trial court. On May 5, 2022, Wagner filed a petition of appeal to the Pennsylvania Supreme Court.

PENNSYLVANIA'S DUI LAWS DO NOT DISTINGUISH BETWEEN MARIJUANA FOR MEDICAL AND NON-MEDICAL PURPOSES

***Commonwealth of Pennsylvania v. River Garrett Stone*, Pennsylvania Superior Court, Case No. 828 WDA 2020 (opinion filed April 12, 2022).** In March 2019, police pulled over River Stone for speeding. The officer smelled burnt marijuana and observed Stone's bloodshot eyes. Stone informed the officer he possessed a medical marijuana card and handed him a small amount of marijuana in his possession. The officer arrested Stone, and the commonwealth charged him with driving under the influence of a controlled substance. At trial, Stone filed a motion to dismiss the charge on the grounds that marijuana used for medical purposes is not a Schedule I controlled substance. The trial court denied the motion but approved a jury instruction that stated that marijuana used for medical purposes is not a Schedule I substance and that the commonwealth must prove that the THC in Stone's system came from marijuana used for recreational purposes. The commonwealth appealed the decision to an intermediate appellate court. The appellate court reversed the decision, finding that Pennsylvania's DUI statute prohibits driving with a Schedule I controlled substance in the driver's blood, "regardless of the driver's status as an authorized user." Although legislative action could alter the relationship between marijuana used for medical purposes and DUI laws in the future, the court observed that "we are charged to interpret the law as it is now, not what we want it to be, or what it might be in the future." The appellate court remanded the case to the trial court for further proceedings. On May 12, 2022, Garrett filed a petition for appeal to the Pennsylvania Supreme Court.

OHIO DOCTOR ACQUITTED OF KILLING PATIENTS WITH FENTANYL

***State of Ohio v. William Husel*, Franklin County Common Pleas Court, Ohio, Case No. 19 CR 002735 (jury verdict returned April 20, 2022).** On April 20, 2022, a jury acquitted Ohio doctor William Husel on 14 counts of homicide. The state charged Husel with causing or hastening the deaths of 14 patients through the use of fentanyl between 2015 and 2018. Prosecutors asserted that Husel intended to kill the patients, noting that he gave many of them 10 times the amount of fentanyl that would be the norm in a non-surgical hospital setting. Husel, in contrast, argued that he offered comfort care to dying patients and did not intend to kill them. As to the amount of fentanyl he gave the patients, Husel noted Ohio law provides no maximum dose of

fentanyl and that it is up to the physician to determine the appropriate dose of medication in each case. Although all 14 patients allegedly died within 30 minutes of Husel administering the fentanyl, the defense argued that each faced imminent death and that each died from underlying, terminal conditions, not the fentanyl. After an almost two-month trial and over seven days of deliberation, the jury concluded that prosecutors did not prove beyond a reasonable doubt that Husel intended to hasten his patients' deaths when he ordered the fentanyl. Although acquitted of the 14 homicide charges, Husel faces more than 10 civil lawsuits brought by the families of the decedents. Husel surrendered his medical license shortly after his acquittal.

COLORADO SUBSTANCE USE DISORDER TREATMENT FACILITY SETTLES FALSE CLAIMS ACT ALLEGATIONS

***United States ex rel. Melissa Chaudhry v. Springbok Health Inc.*, U.S. District Court for the District of Colorado, Case No. 18-cv-00999 (settlement reached April 18, 2022).** Springbok Health Inc. (Springbok), a substance use disorder treatment facility in Colorado, and Mark Jankelow, Springbok's owner and chief executive officer, agreed to pay at least $125,000, and up to as much as $335,494, to resolve alleged False Claims Act violations. Between 2017 and 2019, Springbok and Jankelow allegedly billed Medicare and Medicaid for expensive medical evaluation and management services without actually providing those services to patients. The settlement includes the resolution of the *qui tam*, or whistleblower, case brought forth by a private party on behalf of the United States. The whistleblower, Melissa Chaudhry, will receive at least $22,500, and up to as much as $60,389, as her share of the settlement.

DOCTOR WHO PATICIPATED IN INSYS' SPEAKER PROGRAM FACES FALSE CLAIM LAWSUIT

***United States v. Edward Lubin*, U.S. District Court for the Middle District of Florida, Case No. 8:21-cv-02231-TPB-JSS (motion to dismiss denied April 25, 2022).** A federal district court ruled that a False Claims Act suit can proceed against a Florida doctor who allegedly issued medically unnecessary prescriptions for Subsys, a fentanyl-based spray manufactured by Insys Therapeutics Inc. (Insys). In a complaint filed in September 2021, the United States alleged that Dr. Edward Lubin knowingly participated in an illegal kickback scheme orchestrated by Insys. According to the complaint, Lubin participated in Insys's "Speaker Program," a sham program designed to disguise illegal kickbacks or bribes that Insys paid to physicians in return for prescribing high quantities of Subsys. Lubin allegedly received $160,000 from Insys between 2013 to 2016. Additionally, as a result of Lubin's Subsys prescriptions, Medicare and TRICARE, a uniformed services health care program, paid millions of dollars for false claims. The complaint brings causes of action against Lubin for violations of the False Claims Act and for common law fraud. In November 2021, Lubin filed a motion to dismiss, arguing that the complaint does not establish his knowing participation in the scheme. The district court disagreed with Lubin, finding that the complaint pleads facts constituting circumstantial evidence from which his state of mind can be inferred. According to the court, these facts "include the timing of Lubin's receipt of compensation in relation to Subsys prescriptions, the volume of his Subsys prescriptions compared to prescriptions of other drugs, the fact that most of his Subsys prescriptions were for non-cancer patients, statements by Insys insiders that Lubin could be relied on to increase Subsys prescriptions if his compensation went up, and the fact that some events for which Lubin received substantial compensation involved very brief visits to pharmacists at their pharmacy or never occurred at all." Lubin also contended that the complaint's allegations are insufficient to objectively show false claims made to the

insurance companies. The court disagreed with this argument as well, finding that the complaint offers alleged facts from which a trier of fact could infer that most, if not all, of Lubin's Subsys prescriptions were not medically necessary. Thus, the court denied Lubin's motion to dismiss. Lubin answered the complaint on May 9, 2022.

OREGON PATIENT'S SUIT FOR DEFAMATION OVER DOCTORS' MEDICAL RECORD NOTES DISMISSED

***Linda Sue Hofer v. Oregon Health and Science University,* Court of Appeals of Oregon, Case No. A172328 (opinion filed May 18, 2022).** The Oregon Health and Science University (OHSU), a government entity that provides health care and education, won a defamation suit arising out of doctors' medical notes questioning a patient's request for methadone. Linda Hofer suffers from restless leg syndrome that a Washington physician treated with methadone. After Hofer moved to Oregon, she visited the OHSU neurology clinic to establish care with a new doctor. A resident physician at OHSU provided Hofer with a short-term prescription for methadone. Hofer subsequently met with a different OHSU physician, who agreed to continue the methadone treatment if she provided a urine sample and signed a medication contract. Hofer refused to provide the urine sample and left. Nine months later, Hofer returned to the OHSU clinic and saw the same resident physician. This time, the resident refused to prescribe Hofer additional methadone. In the post-visit medical record notes within Hofer's chart, the resident wrote that Hofer seemed anxious, would not make eye contact, and demonstrated "numerous red flags." An attending physician who reviewed the resident's actions also wrote in the medical notes that the patient had "broken trust" with another clinic regarding her methadone prescriptions. In April 2018, Hofer sued OHSU in state court for defamation and negligence, asserting that the doctors' notes amounted to false reports of prescription fraud. OHSU moved for summary judgment of both claims, which the trial court granted. The trial court granted summary judgment to OHSU as to both causes of action, holding that Hofer's defamation claim failed because OHSU's absolute privilege as a governmental entity applied, and Hofer's medical negligence claim failed because she alleged insufficient facts to prove a basis for that claim. On appeal, an Oregon intermediate appellate court affirmed both bases for summary judgment. Noting that OHSU is a governmental entity, and its physicians are government officials, the appellate court found that the physicians may assert absolute privilege with respect to statements made in the course of their public duties that acts as a complete bar to liability for defamation. The court found evidence that the physicians' official duties included summarizing the care they provided to Hofer and entering it into her medical record. The appellate court also affirmed summary judgment for OHSU as to medical negligence because Hofer failed to show how her right to privacy gives rise to liability in negligence for emotional damages absent physical harm caused by a doctor's failure to maintain accurate records.

FTC SUES DRUG TREATMENT REFERRAL SERVICE OVER ALLEGED MISREPRESENTATIONS

***Federal Trade Commission v. R360 LLC et al.*, U.S. District Court for the Southern District of Florida, 0:22-cv-60924-CMA (suit filed May 16, 2022).** The Federal Trade Commission (FTC) sued R360 LLC (R360), a company that provides marketing services to substance use disorder (SUD) treatment facilities, and its owner, Steven Doumar, for deceiving people about the evaluation and selection criteria used to select treatment centers for their network. According to the complaint, in 2017, R360 started promoting its treatment centers to consumers suffering from SUD using television ads for a "R360 Network," which it promoted as a nationwide network of SUD treatment and recovery specialists. Consumers calling the R360 Network were automatically transferred via phone to a network treatment center. The FTC alleges that R360 misrepresented to consumers that it would "connect them with treatment centers that met their individual needs and were selected through a rigorous evaluation process conducted by an expert in substance use disorders." Doumar

was responsible for assessing the quality of the treatment centers and determining which ones could join the network. However, the FTC asserts that Doumar did not have any educational nor professional experience qualifying him to make those decisions. According to the complaint, Doumar performed only a brief review of potential network members and did not conduct any independent research to verify the information that the treatment centers provided to him. The FTC brought the suit under the Opioid Addiction Recovery Fraud Prevention Act of 2018 (OARFPA), representing the FTC's first such suit under the Act. OARFPA authorizes the FTC to seek civil penalties for unfair or deceptive acts or practices with respect to any SUD treatment service or product. A stipulated order issued by the FTC would prohibit the defendants from continuing to make similar misrepresentations to consumers and impose a $3.8 million civil penalty. The defendants must answer the FTC's complaint by July 15, 2022.

NEVADA DOCTOR SUES PHARMACIES FOR REFUSING TO FILL HIS PRESCRIPTIONS

***Michael D. Reiner v. CVS Pharmacy, Inc., et al.*, U.S. District Court for the District of Nevada, Case No. 2:22-cv-00701 (suit filed April 29, 2022).** A Nevada doctor filed a lawsuit against CVS Pharmacy, Inc. (CVS), Walmart, and Smith's Food & Drug Centers (Smith's) over alleged blanket refusals to honor his prescriptions for narcotic pain medications. Dr. Michael Reiner operates a family medicine practice that primarily treats patients over the age of 65, many with a history of chronic pain. In December 2019 and June 2020, CVS sent letters to Reiner asserting problematic prescribing patterns with his controlled substance prescriptions. Reiner responded to the letters by informing CVS that he treats a high number of elderly patients with chronic pain who are on stable doses of maintenance pain medication and are drug tested regularly. In October 2020, CVS informed Reiner of persisting concerns and that, as of the end of the month, it would no longer fill his prescriptions for controlled substances. Reiner received similar correspondence from Walmart and Smith's, with those companies issuing blanket refusals to fill his prescriptions for controlled substances in Schedules II-V in July 2020 and June 2021, respectively. Reiner filed suit against the three companies in April 2022. In his complaint, Reiner asserts that the conduct of CVS, Walmart, and Smith's jeopardizes the safety and care of his patients and interferes in the "free and legitimate exercise of a patient's right to choose their physician." Reiner asks the federal district court for declaratory and injunctive relief prohibiting the defendants from issuing or enforcing blanket "do not fill" orders for prescriptions written by him. Reiner brings forth causes of action for negligent and/or intentional interference with business and contractual relations, tortious interference with prospective economic advantage, and negligence against all three defendants. The defendants must answer the complaint by June 30, 2022.

JURY FINDS MINNESOTA DOCTOR NOT RESPONSIBLE FOR PATIENT'S ALLEGED OPIOID USE DISORDER

***Michael Faulhaber and Yvonne Faulhaber v. Minnesota Pain Center and Samuel K. Yue*, Minnesota District Court, County of Ramsey, Case No. 62-CV-20-1160 (jury verdict reached May 25, 2022).** An eight-member jury found a Minnesota doctor and pain clinic not responsible for a patient's alleged opioid use disorder (OUD). Michael Faulhaber started receiving care from Dr. Samuel Yue, the chief executive officer of the Minnesota Pain Center, in 2003. Yue prescribed Faulhaber opioids for pain management. In February 2020, Faulhaber filed suit against Yue and the Minnesota Pain Center for negligence and sought upwards of $50,000 in damages. Faulhaber asserted that Yue continued to prescribe opioids to him without considering or informing him of any alternative pain management treatments or the potential risk of addiction associated with opioid use. Faulhaber further contended that, during treatment, he became dependent on and addicted to the opioids prescribed to him by Yue. At trial, medical expert witnesses for the defense testified that, based on their review of Faulhaber's medical records, the symptoms he experienced were the result of previous psychological issues and not the result of an OUD. According to news reports, the jury deliberated for less

than two hours before returning a verdict finding Yue and Minnesota Pain Center not liable for Faulhaber's alleged OUD.

INDIANA RECOVERY HOUSE LEGAL BATTLE

***Pinnacle Treatment Centers, Inc. v. City of Crown Point, Indiana*, U.S. District Court for the Northern District of Indiana, Case No. 2:20-cv-00336-PPS-JPK (motion to dismiss denied April 11, 2022).** For information on the facts and previous updates in this case, please refer to the February 2021 issue of the LAPPA *Case Law Monitor*, available here. Pinnacle Treatment Centers (Pinnacle) operates a group home in Crown Point, Indiana for individuals in recovery from substance use disorder. The city of Crown Point believes that the recovery home violates the city's municipal zoning code, which prohibits lodging for more than five unrelated individuals in a residential area unless the individuals are related by blood or marriage. As a result, the city levied fines against Pinnacle for violating the zoning code. Pinnacle asserts that the city's actions constitute a violation of the Fair Housing Act (FHA). Crown Point filed a motion to dismiss on the grounds that Pinnacle lacks standing to sue under the FHA. The FHA authorizes any person "aggrieved" by a discriminatory act to bring a suit to enforce the law. The FHA defines an "aggrieved person" as any person claiming to be injured by a discriminatory housing practice or believing that such person will be injured by a discriminatory housing practice that is about to occur (42 U.S.C. § 3602). In denying the motion to dismiss, the federal district court determined that Pinnacle suffered injury in fact because of the city's fines. Thus, because Pinnacle asserts a concrete and particularized injury caused by Crown Point, it has standing under the FHA. The parties' expert reports and disclosures are due October 3, 2022, and all discovery is to be completed by December 22, 2022.

VIRGINIA DOCTOR SUES FORMER EMPLOYER AFTER LOSING JOB DUE TO FAILURE TO FOLLOW OPIOID PRESCRIBING PRACTICES

***James Michael Isernia v. Danville Regional Medical Center, LLC, et al.*, U.S. District Court for the Western District of Virginia, Case No. 4:22CV00022 (complaint filed April 4, 2022).** In December 2020, Sovah Health (Sovah) opened an internal audit into the prescribing practices of its employee Dr. James Isernia. Finding that Isernia prescribed controlled substances 420 times in a single month and failed to comply with its prescribing guidelines, Sovah placed him on leave and subsequently terminated his employment in January 2022. Following Isernia's termination, the commonwealth's department of health professions conducted a review of Sovah's actions. In March 2022, the department informed Isernia that it ended its inquiry without disciplinary action against him. Isernia then filed suit against Sovah in Virginia federal court, seeking damages for defamation, tortious interference, and lost wages; an injunction against any further such "discriminatory" actions against him; and reinstatement to his former position. Isernia's complaint includes allegations that Sovah's actions constitute retaliation: (1) for his complaints about Sovah's insufficient staffing to provide proper safety against COVID-19; and (2) because some of his patients received higher dosages of opioids than prescribed while under his care. Isernia requested a jury trial. The defendants filed a motion to dismiss for failure to state a claim on May 3, 2022.

UTAH POLICE OFFICER ILLEGALLY PROLONGED TRAFFIC STOP TO ARRANGE FOR CANINE DRUG SNIFF

***United States v. Antoine Frazier*, U.S. Court of Appeals for the Tenth Circuit, Case No. 20-04131 (opinion filed April 13, 2022).** Utah police pulled over Antoine Frazier for speeding and changing lanes without proper signals. State trooper Adam Gibbs questioned Frazier for several minutes while arranging for a canine unit to perform a drug sniff on the vehicle. The dog alerted officers to the likely presence of contraband, and the ensuing search revealed a firearm, fentanyl pills, and cocaine. Prosecutors charged Frazier with possession of fentanyl and cocaine with intent to distribute and possession of a firearm in furtherance of drug trafficking. At trial, Frazier moved to suppress evidence obtained during the traffic stop, arguing that Gibbs improperly prolonged the stop to obtain the necessary probable cause to search the vehicle. The federal district court denied the motion, at which point Frazier entered a conditional guilty plea, leading to an instant appeal. The U.S. Court of Appeals for the Tenth Circuit reversed the decision predicated on the 2015 U.S. Supreme Court case, *Rodriguez v. United States* (575 U.S. 348), stating that police officers' authority to detain the occupants of a vehicle ends when "tasks tied to the traffic infraction are—or reasonably should have been—completed." The Tenth Circuit concluded that Gibbs' efforts to arrange a drug sniff was unrelated to the traffic-based purpose of the stop and "thereby extended its duration." It further found Gibbs' reasons for suspecting Frazier of involvement in drug trafficking insufficient to support the "reasonable suspicion" needed to justify the delay. The government did not appeal the decision.

RECENT EVENTS IN THE PURDUE PHARMA BANKRUPTCY, INCLUDING SETTLEMENT DISCUSSIONS

***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).**

- On April 29, 2022, the U.S. Court of Appeals for the Second Circuit held oral arguments for the appeal regarding the first Purdue Pharma (Purdue) bankruptcy settlement (valued at $4.5 billion), originally approved by the bankruptcy court in September 2021. The legal question facing the three-judge panel is whether a bankruptcy judge has the authority to grant members of the Sackler family protection from civil lawsuits over the opioid epidemic. Lawyers for Purdue and others who support the settlement plan assert that the protections for the Sackler family would be limited to cases involving opioids and are necessary to reach a fair outcome and avoid lengthy and expensive trials. However, the U.S. Bankruptcy Trustee's Office within the U.S. Department of Justice (DOJ) argues that it is improper to provide a legal shield to members of the Sackler family who have not themselves filed for bankruptcy protection. During oral arguments, a DOJ lawyer stated that the settlement is inconsistent with the U.S. Bankruptcy Code and that there is no clear directive from Congress that the kinds of protections given to the Sacklers can be granted by a bankruptcy judge. Besides the U.S. Trustee's Office, the only remaining official objectors to the first settlement are Canadian local governments and First Nations, and two mothers of sons who died of opioid overdoses. Prior to oral argument, more than 1,000 families who lost loved ones to opioid overdoses signed a letter asking the DOJ to drop its opposition to the settlement. The families worry that if the settlement is derailed, individual victims will not receive timely payments. The Second Circuit did not indicate how or when it would rule, but no matter the ruling, an appeal to the U.S. Supreme Court is likely.
- On May 11, 2022, attorneys general from 24 states and the District of Columbia filed an objection with the bankruptcy court over a proposed $3 million bonus for Purdue CEO Craig Landau and called for him to step down. The attorneys general argue that the bonus "sends the wrong message to victims." The bankruptcy court held a hearing on the issue on May 18, 2022. A ruling on the issue has not yet been made.

SETTLEMENTS INVOLVING JOHNSON & JOHNSON AND THE "BIG THREE" DRUG DISTRIBUTORS AMERISOURCEBERGEN, CARDINAL HEALTH, AND MCKESSON

- On April 18, 2022, Johnson & Johnson's subsidiary Janssen Pharmaceuticals Inc. agreed to pay $99 million to settle a lawsuit in West Virginia in *In re Opioid Litigation*, Circuit Court of Kanawha County, West Virginia, Case No. 21-C-9000 MFR, that alleges that the company helped fuel the state's opioid crisis. West Virginia did not participate in Johnson & Johnson's nationwide $5 billion opioid settlement to resolve state and local government lawsuits against the company. In a press release, West Virginia Attorney General Patrick Morrisey stated that the independent settlement with Johnson & Johnson allows the state to recover more than double the $48 million that the state would have received from the national settlement.
- On April 19, 2022, Alabama Attorney General Steve Marshall announced that the state reached settlements with Johnson & Johnson and McKesson over the companies' alleged role in creating the opioid epidemic in the state. The settlements arise out of the case *State of Alabama v. Endo Health Solutions, Inc., et al.*, Montgomery County Circuit Court, Alabama, Case No. CV-2019-901174. Under the agreement, Johnson & Johnson will pay $70.3 million to Alabama in 2022, while McKesson will pay out $141 million over nine years. Alabama opted out of the $26 billion nationwide settlement with Johnson & Johnson and the "Big Three" distributors, choosing to pursue lawsuits against the companies individually. Had Alabama joined the national settlement agreement, the state would have received $115.8 million from McKesson over 18 years instead of the $141 million over nine years and would have received the same payment amount from Johnson & Johnson but spread out over nine years as opposed to a lump-sum. The settlement funds are to remediate the harms caused by the opioid crisis in Alabama.
- On May 3, 2022, Washington Attorney General Bob Ferguson announced that the state reached a $518 million settlement with the Big Three distributors to resolve opioid-related claims in the state. Washington did not participate in the global settlement with the three distributors, opting instead to take the three companies to trial in the case, *State of Washington v. McKesson Corporation, et al.,* King County Superior Court, Washington State, Case No. 19-2-06975-9. Had Washington joined the global settlement, it would have received $418 million from the distributors. Under the terms of the settlement, the state must spend $476 million of the total settlement amount to address the opioid crisis, including substance use disorder (SUD) treatment, expanding access to overdose-reversal drugs, and providing housing, job placement, and other services for those struggling with SUD. The rest of the money goes toward litigation costs.

TEVA AND ALLERGAN SETTLE OPIOID LITIGATION WITH WEST VIRGINIA

***In re Opioid Litigation*, Circuit Court of Kanawha County, West Virginia, Case No. 21-C-9000 MFR (settlements reached April 18, 2022 and May 25, 2022).** On May 25, 2022, Teva Pharmaceutical Industries Ltd. (Teva) and AbbVie Inc.'s Allergan (Allergan) agreed to pay a combined $161.5 million to end the trial against the two drug makers that began in April 2022. Under the settlement, Teva will pay $75 million to the state over the next 15 years, plus $8 million in attorneys' fees. Additionally, Teva will also provide the state with $27 million worth of naloxone over the next decade. Allergan will pay as much as $51.2 million over five years, along with attorneys' fees and costs to resolve opioid-related claims statewide.

ENDO INTERNATIONAL LITIGATION AND SETTLEMENTS

- In an April 19, 2022, press release, Alabama Attorney General Steve Marshall announced that Endo International's (Endo) October 2021 settlement in *State of Alabama v. Endo Health Solutions, Inc., et al.*,

Montgomery County Circuit Court, Alabama, Case No. CV-2019-901174 would result in a $25 million lump-sum payment in 2022. Details of the settlement with Endo were not previously public information. The settlement funds are to be used to remediate the harms caused by the opioid crisis in Alabama.

- On April 20, 2022, San Francisco reached a $10 million settlement with Endo five days before the city's opioid trial, *City and County of San Francisco, et al. v. Purdue Pharma L.P., et al.*, U.S. District Court for the Northern District of California, Case No. 3:18-cv-07591-CRB, began. Endo will pay $5 million in 2022 and another $5 million over the next 10 years. The trial began against the remaining defendants, which are the drugmakers Allergan and Teva, distribution company Anda, and pharmacy chain Walgreens. For information on the facts and previous updates of this case, please refer to the April 2021 issue of the LAPPA *Case Law Monitor*, available here.
- On April 20, 2022, in the matter *of Clay County v. AmerisourceBergen Drug Corp., et al.*, Court of Appeals of Tennessee, Case No. E2022-00349-COA-T10B-CV, a Tennessee intermediate appellate court unanimously determined that Judge Jonathan Young of the Circuit Court for Cumberland County should have recused himself from the case due to bias against Endo. For information on the facts and previous updates in this case, please refer to the April 2022 issue of the LAPPA *Case Law Monitor*, available here. The court also vacated the default judgment issued by Judge Young against Endo in February 2022 after finding that the company intentionally withheld evidence from the plaintiffs. Endo moved to disqualify Judge Young because of social media posts in which he said he wanted to "ban" opioids and complained of the lack of local media coverage for the case. Endo also pointed to an interview he gave to a website in which he said Endo's conduct was "the worst case of document hiding that I've ever seen" and "like a plot out of a John Grisham movie." The appellate court ruled that Judge Young's activity "can reasonably be construed to suggest that [he] has a specific agenda that is antagonistic to the interests of those in the pharmaceutical industry." Additionally, the appeals court held that Judge Young's actions suggest that he is trying to position himself publicly "as an interested community advocate and a voice for change in the larger societal controversy over opioids," as opposed to an impartial adjudicator. Regardless of his specific motivation, the appeals court found that Judge Young's comments and social media activity indicate partiality against Endo. The court remanded the case to a different judge.

WALGREENS SETTLES OPIOID LAWSUIT WITH FLORIDA

***State of Florida v. Purdue Pharma, L.P., et al.*, Pasco County Circuit Court, Florida, Case No. 2018-CA-001438 (settlement reached May 5, 2022).** On May 5, 2022, Walgreens reached a $683 million settlement with Florida in the state's opioid lawsuit. The settlement comes after the state spent four weeks in court presenting evidence asserting that Walgreens improperly dispensed opioids in the state. Walgreens did not admit to any wrongdoing as part of the settlement, but the company will pay $620 million to the state over the next 18 years and a one-time sum of $63 million for attorneys' fees. The state plans to use the settlement money to address opioid misuse and overdoses. Walgreens is the twelfth and final defendant to settle with Florida

RECENT EVENTS IN THE OPIOID MULTI-DISTRICT LITIGATION

***In re National Prescription Opiate Litigation*, U.S. District Court for the Northern District of Ohio, Case No. 17-MD-2804 (MDL commenced December 12, 2017).** For information on the facts and previous updates in this case, please refer to the December 2021 issue of the LAPPA *Case Law Monitor*, available here. Court hearings started on May 10, 2022 in Ohio federal court to determine how much CVS, Walgreens, and Walmart should pay two Ohio counties, Trumbull and Lake, to help them address the ongoing costs associated with the opioid crisis. In November 2021, a jury found the pharmacy chains responsible for recklessly distributing massive amounts of opioids in the counties. Before trial, the plaintiff's attorneys stated that each

county needs about $1 billion to deal with the crisis. The counties plan to present testimony from doctors to discuss the harm suffered by individuals in the community and the opioid crisis' impact on child welfare. The counties will also share an abatement plan with the court that focuses on prevention, treatment, recovery, and measures intended to specifically address the needs of special populations who have been uniquely affected by the opioid epidemic.

UPDATE 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 Oct. 12, 2020).** In March 2022, pharmaceutical company Sanofi-Aventis U.S. LLC (Sanofi), one of Mallinckrodt's creditors, and a group of insurance companies that includes Attestor Ltd. and Humana Inc. (collectively "insurance companies") appealed the approval of Mallinckrodt's bankruptcy plan. Sanofi argues that the plan unfairly discriminates against creditors with disputed claims, while the insurance companies assert that the plan unfairly discriminates against creditors harmed by Mallinckrodt's alleged false statements and anti-competitive practices. Sanofi and the insurance companies asked the bankruptcy court to place the plan on hold while they appealed. On April 1, 2022, Judge John T. Dorsey denied Sanofi's and the insurance companies' request to pause the administration of the plan. Judge Dorsey also declined to decide whether the appeal should go straight to the U.S. Court of Appeals for the Third Circuit, ruling that the U.S. District Court for the District of Delaware must answer that question.

MCKINSEY & COMPANY'S ALLEGED CONFLICT OF INTEREST VIOLATIONS

- On April 5, 2022, Senate Democrats sent a letter to the Department of Health and Human Services' Office of the Inspector General encouraging investigators to probe McKinsey & Company's (McKinsey) alleged failure to disclose potential conflicts of interest when it contracted with the U.S. Food and Drug Administration (FDA) on issues related to opioids, while simultaneously doing consulting work for numerous opioid manufacturers. In the letter, lawmakers also questioned the FDA's vetting process for consultants and implied that the FDA awarded McKinsey contracts even after news reports called attention to the company's work on behalf of Purdue and other opioid manufacturers.

McKinsey & Company

- On April 13, 2022, the U.S. House Committee on Oversight and Reform (House Committee) published an interim majority staff report on McKinsey's alleged conflicts of interest. According to the report, McKinsey consultants leveraged their work with the FDA to attract business from companies like Purdue. Additionally, McKinsey consultants apparently tried to influence government officials to benefit their opioid clients. In particular, the report alleges details about at least 22 McKinsey consultants who worked for both the FDA and opioid manufacturers on related topics, sometimes at the same time. The committee report also reviews McKinsey's alleged lack of potential conflicts of interest disclosures to the FDA and argues that the lack of disclosure potentially violated contract requirements and federal law. McKinsey responded to the report with a statement saying that it will continue to cooperate with the House Committee but will defend its work for the FDA and its opioid clients. However, an April 22nd press release from the House Committee stated that "to date, McKinsey has failed to fully cooperate with the Committee's investigation and has refused to provide basic information about certain clients."
- On April 26, 2022, the Director of the FDA Center for Drug Evaluation and Research, Patrizia Cavazzoni, stated during a hearing of the Senate Committee on Health, Education, Labor, and Pensions that the FDA will not contract with McKinsey while lawmakers investigate the company's work with opioid makers and alleged conflicts of interest. Director Cavazzoni also stated that the FDA does not have any current contracts with McKinsey.

- On April 27, 2022, the House Committee held a hearing to examine the role of McKinsey in the opioid epidemic. The Committee questioned Bob Sternfels, the global managing partner of McKinsey, for three hours about allegations that the company allowed consultants working for Purdue to simultaneously advise the FDA. As part of the hearing, lawmakers released a 2013 McKinsey strategy presentation, in which its consultants recommended cash prizes and "unrivaled recognition" for top Oxycontin sales reps to increase Purdue's revenue. Sternfels challenged some of the Committee's findings, testifying that the Committee's April 13th interim report "took large speculative leaps" by focusing on the "time frame and not the nature of the work." Sternfels claimed that McKinsey's work with the FDA focused on administrative and operational topics and did not involve opioid-related matters. However, Sternfels apologized for the company's work with Purdue and other opioid manufacturers. He also stated that the company recognizes that its work fell short of its standards when working with these companies, and as such, has implemented new protocols and policies to prevent a similar situation from happening again. Massachusetts Attorney General Maura Healey, who testified remotely, stated that Massachusetts' investigation into McKinsey uncovered emails recommending that Purdue "band together" with other drugmakers in 2009 to "defend against strict treatment by the FDA." Sternfels described these assertions as inaccurate, and that McKinsey did not share FDA documents or intelligence with Purdue. Additionally, Sternfels testified that McKinsey openly informed the FDA about its pharmaceutical consulting work.

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.

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