

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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PHYSICIAN ALLEGING CVS REFUSED TO FILL PRESCRIPTIONS MUST SEEK RELIEF FROM PHARMACY BOARD

Kenneth S. Bradley, et al. v. CVS Pharmacy, Inc., et al., California Court of Appeals, Second District, Case No. B308040 (opinion filed May 28, 2021). A California intermediate appellate court ruled that a California physician alleging that CVS Pharmacy, Inc. (CVS) stopped filling controlled substance prescriptions for his patients must first seek relief with the California State Board of Pharmacy (Pharmacy Board). In June 2020, CVS stopped filling prescriptions for controlled substances written by Kenneth Bradley, a doctor specializing in pain management. CVS took this action because CVS's internal prescription monitoring program flagged Bradley several times in recent years, and he had been the subject of complaints by individual CVS pharmacists. Bradley filed suit in California state court against CVS, requesting a preliminary injunction requiring CVS to fill his prescriptions. The trial court denied the injunction, holding that Bradley must first seek relief from the Pharmacy Board. The appellate court affirmed the trial court's ruling, holding that the Pharmacy Board has primary jurisdiction to consider state rules governing pharmaceutical licensees, including CAL. BUS. & PROF. CODE § 733, covering a pharmacist's duty to dispense prescribed or ordered drugs and devices. Thus, an order requiring CVS to honor Bradley's prescriptions would involve judgments concerning statutory obligations of pharmacists that the Pharmacy Board is expected and equipped to resolve. The appellate court stayed the action to allow Bradley to pursue a complaint with the Pharmacy Board. Following the Pharmacy Board's final decision on such a complaint, the action will proceed on any remaining issues. Should Bradley elect not to file such a complaint with the Pharmacy Board, the action will be dismissed.

PHYSICIAN LOSES DEFAMATION SUIT OVER MEDICAL BOARD REPORTS

Mark H. Andrew v. Hamilton County Public Hospital, Supreme Court of Iowa, Case No. 20-0023 (opinion filed June 4, 2021). An Iowa physician lost a defamation suit against his former employer over statements the employer made about his allegedly suspicious prescription practices. Mark Andrew worked as a general surgeon for Hamilton County Public Hospital. In November 2016, a pharmacy contacted the hospital's quality assurance officer to express concerns about the quantity and frequency of hydrocodone prescriptions filled by one of Andrew's patients. Upon review of the patient's medical file, the hospital found that Andrew

prescribed almost 12,000 hydrocodone pills to the patient over a four-year period. During the hospital's investigation, the chief nursing officer, the medical director, and an outside consultant met with Andrew for an interview in which Andrew admitted that he did not use any type of pain management plan with the patient, nor did he refer the patient to a pain management specialist. After completing the investigation, the hospital made the decision to terminate Andrew. Subsequently, the hospital's outside consultant filed a report on Andrew with the Iowa Board of Medicine. The consultant's report included a recitation of facts surrounding the investigation and responses to a number of predefined questions including, "what would you like the Iowa Board of Medicine to do about your complaint?" and "could this be an impaired physician who needs intervention and help?" Additionally, the hospital's chief nursing officer filed a report with the National Practitioner Data Bank, a national repository for certain information about health care practitioners. This report included a factual recitation of Andrew's treatment of the patient in question. In response to the two reports, Andrew sued the hospital for defamation. The hospital moved for summary judgment seeking dismissal of the defamation claim. In general, a statement cannot be defamatory if it is true or constitutes opinion, rather than claimed fact. Moreover, Iowa law provides civil immunity to a person filing a report or complaint with a licensing board, so long as the defamatory statement is not done with malice. (IOWA CODE § 272C.8(1)(b)). At trial, the state court denied the hospital's motion, finding that issues of good faith and malice with respect to the statutory immunity are questions for the jury. On appeal, however, the Iowa Supreme Court reversed the decision, ruling that neither report was defamatory. The court concluded that the answers to the questions in the report to the Iowa Board of Medicine were opinions, and not defamatory statements, because the consultant did not accuse Andrew of improper conduct but rather expressed concern over things needing to be investigated. Likewise, the court found the statements made in the report informing the National Practitioner Data Bank of Andrew's termination to be true, and thus not defamatory. In light of these findings, the state's supreme court did not address whether statutory immunity applied. The court reversed the judgment of the trial court and remanded the case with instructions to enter summary judgment in favor of the hospital.

MARIJUANA DISPENSARY REFILES REQUEST FOR U.S. SUPREME COURT REVIEW OF TAX CASE

Standing Akimbo, LLC, et al. v. United States, U.S. Supreme Court, Case No. 20-645 (petition for certiorari denied June 28, 2021; petition refiled July 21, 2021). The Colorado marijuana dispensary, Standing Akimbo, LLC., renewed its request for the U.S. Supreme Court to review its tax dispute three weeks after the court denied the first petition. The issue in this case stems from 26 U.S.C. § 280E, a section of the tax code that bars businesses trafficking Schedule I or II controlled substances from deducting the cost of ordinary and necessary business expenses from income. In the case, Standing Akimbo is fighting an Internal Revenue Service (IRS) summons investigating whether the company deducted business expenses. The dispensary argues that it filed the information sought by the IRS with Colorado's Marijuana Enforcement Division pursuant to a state law that criminalizes the information's disclosure and, therefore, the Fourth Amendment to the U.S. Constitution protects its reasonable expectation of privacy in the records. In 2020, the U.S. Court of Appeals for the Tenth Circuit rejected Standing Akimbo's argument, holding that the Colorado law does not apply to official investigations of unlawful activity by marijuana businesses, which would include alleged improper tax filing. In its refiled petition for certiorari, Standing Akimbo cites to a written statement Justice Clarence Thomas made accompanying the court's denial for certiorari that suggests he would not have denied the petition. In the statement, Justice Thomas noted that "[i]f the [federal] Government is now content to allow States to act 'as laboratories' 'and try novel social and economic experiments,' then it might no longer have authority to intrude on the States' core police powers . . . to define criminal law and to protect the health, safety and welfare of their citizens. A prohibition on intrastate use or cultivation of marijuana may no longer be necessary or proper to support the Federal Government's piecemeal approach." Additionally, in the statement, Justice Thomas references Gonzales v. Raich (545 U.S. 1), a 2005 U.S. Supreme Court case in which the court ruled 6-3 that federal law overrules state-sanctioned use of cannabis even if the activity does

not cross state lines. In his *Raich* dissent, Justice Thomas stated that the federal government should only have few and defined powers over intrastate activity. In its refiled petition, Standing Akimbo asserts that, "[i]f there was any question of the national importance of the federalism dispute regarding cannabis, it was answered when Justice Thomas' statement became front page headlines in the national press and network news."

U.S. SUPREME COURT DECLINES TO HEAR CASE ON FDA'S REGULATION OF E-CIGARETTES AND VAPES

Big Time Vapes, Inc., et al. v. FDA, et al., U.S. Supreme Court, Case No. 20-850 (petition for certiorari denied June 7, 2021). The U.S. Supreme Court declined to hear a challenge to the Food and Drug Administration's (FDA) regulation of electronic cigarettes and vape pens. The case involves the Family Smoking Prevention and Tobacco Control Act (TCA) (21 U.S.C. § 387, et seq.) which establishes a framework for the FDA to regulate tobacco products. Under § 387a, cigarettes, cigarette tobacco, "roll-your-own" tobacco, and smokeless tobacco are automatically subject to the TCA. However, § 387a also authorizes the Secretary of Health and Human Services (Secretary) to determine what other products should be governed by the TCA's regulatory scheme. In May 2016, the FDA promulgated a rule that deemed all products meeting the statutory definition of "tobacco product" subject to the FDA's tobacco product authorities under the TCA.



As a result of the FDA's rule, electronic nicotine delivery systems, like electronic cigarettes and vape pens, are subject to all of the statutory and regulatory requirements applicable to tobacco manufacturers. In 2019, Big Time Vapes, a manufacturer and retailer of e-liquids, and the United States Vaping Association, filed suit against the FDA in Mississippi federal court on the grounds that the TCA unconstitutionally delegates to the Secretary the power to deem tobacco products subject to the TCA's

mandates. In their suit, plaintiffs sought: (1) a declaration that § 387a violates the nondelegation doctrine; and (2) an injunction preventing the FDA from enforcing the TCA. The nondelegation doctrine is a doctrine rooted in the principle of separation of powers that holds that the lawmaking function belongs to Congress and that Congress may not delegate that power to another branch of government. Congress can, however, delegate some power to a federal agency if it clearly delineates the general policy, the public agency which is to apply it, and the boundaries of the delegated authority. The U.S. District Court for the Southern District of Mississippi found no nondelegation violation and dismissed the suit, holding that Congress restricts the FDA's discretion with a controlling definition of "tobacco product." The court also found Congress designated certain tobacco products as governed by the TCA and presented detailed policies behind its enactment of the TCA. The U.S. Court of Appeals for the Fifth Circuit affirmed the decision. According to researchers, the U.S. Supreme Court has not invalidated a law as an unconstitutional delegation since 1935 and, with the denial to hear this case, this precedent continues.

SUPREME COURT RULES CRACK COCAINE OFFENDER DOES NOT QUALIFY FOR SENTENCE REDUCTION

Tarahrick Terry v. United States, U.S. Supreme Court, Case No. 20-5904 (opinion filed June 14, 2021). The U.S. Supreme Court unanimously ruled that crack cocaine offenders are eligible for a sentence reduction under the First Step Act (Pub. L. 115-391) only if they were convicted of an offense that triggered a mandatory minimum sentence. In the 1980s, Congress created a law for crack and powder cocaine offenses. The law contains three penalties, two of which are quantity-dependent and subject to mandatory minimum sentences and one that is not quantity-dependent and contains no mandatory minimum. In 2008, Tarahrick Terry pled guilty to possession with intent to distribute an unspecified amount of crack cocaine and the court sentenced him without a mandatory minimum. In 2010, Congress passed the Fair Sentencing Act of 2010, which increased the crack cocaine quantity thresholds necessary to reach the five-year and 10-year mandatory

minimum sentence offenses. In 2018, Congress enacted the First Step Act which, among other things, enabled the Fair Sentencing Act to apply retroactively. After the Fair Sentencing Act became retroactive, Terry filed suit in Florida federal court seeking resentencing on the ground that the Fair Sentencing Act modifies his conviction. The U.S. District Court for the Southern District of Florida denied his motion, and the U.S. Court of Appeals for the Eleventh Circuit affirmed. The First Step Act makes an offender eligible for a sentence reduction only if the offender previously received a sentence for a covered offense. The Act defines a "covered offense" as a violation of a federal criminal statute, the statutory penalties for which were modified by certain provisions in the Fair Sentencing Act. The Fair Sentencing Act modified the statutory penalties for offenses that triggered mandatory minimum penalties because a person charged with the same conduct today would no longer face the same statutory penalties that he or she would have faced before 2010. Because Terry's conviction did not involve a mandatory minimum sentence, the Supreme Court ruled that his offense is not a covered offense and, thus, he is not eligible for a sentence reduction under the Fair Sentencing Act.

WHISTLEBLOWER FAILED TO MAKE A CLAIM AGAINST WALMART UNDER THE FALSE CLAIMS ACT

United States, ex rel. Ashwani Sheoran v. Walmart Stores East, LP, et al., U.S. Court of Appeals for the Sixth Circuit, Case No. 20-2128 (opinion filed June 4, 2021). The U.S. Court of Appeals for the Sixth Circuit ruled that a pharmacist failed to adequately allege that Walmart violated the False Claims Act (FCA) by billing Medicare and Medicaid for opioid prescriptions he believed would have harmed patients. Ashwani Sheoran worked as a pharmacist for Walmart in Michigan and noticed that several patients, all of whom had the same physician, would come to the pharmacy with prescriptions for very high doses of opioids. While working, Sheoran obtained one patient's medical expenses summary, which listed the patient's prescriptions and costs over a five-year period. Sheoran concluded that the patient's prescriptions were submitted to Medicare or Medicaid for payment, because the cost to the patient was \$1-2 for many of the prescriptions. Sheoran brought his concerns to his supervisor. Walmart conducted an investigation based on Sheoran's concerns, but the company did not conclude that any laws or regulations were violated. Subsequently, Walmart fired Sheoran for stealing the medical expenses summary. About a month after termination, Sheoran filed a complaint in Michigan alleging FCA violations against Walmart. The defendants moved to dismiss, and the district court granted their motions. On appeal, the Sixth Circuit agreed with the district court's dismissal of the case, holding that Sheoran failed to state a proper claim under the FCA. While Sheoran argued that because some payments on a medical expenses' summary were so low that the patients must have received government reimbursement through Medicare or Medicaid, the court found this assertion insufficient to show that a claim for payment was presented to a government entity. Additionally, the court found Sheoran's reliance on the expenses summary insufficient to show that Walmart submitted payment claims for unsafe opioid doses because it is impossible to evaluate the strength of the doses without more information regarding the patient's medical history. The court also ruled that Sheoran's retaliation claim against Walmart failed because he did not allege Walmart knew about the contemplated FCA action before it fired him. Sheoran filed a petition for an *en banc* rehearing on June 21, 2021. The court has yet to rule on the petition.

INDEPENDANT LABS IN PENNSYLVANIA DO NOT HAVE A DUTY TO REPORT AN EMPLOYEE'S MEDICAL MARIJUANA STATUS TO AN EMPLOYER

Nathan Miller v. Amazon.com Services, Inc., et al., U.S. District Court for the Eastern District of Pennsylvania, Case No. 2:21-cv-00944-ER (opinion filed June 11, 2021). For previous updates and facts about this case, please refer to the April 2021 issue of the LAPPA Case Law Monitor, available here. The Eastern District of Pennsylvania ruled that a man allegedly fired from his job at an Amazon warehouse for

testing positive for marijuana despite having a valid medical marijuana license is unable to sue the company that performed the drug test. As a requirement for applying for a permanent position at the warehouse, Nathan Miller took a drug test administered by Quest Diagnostics (Quest). According to Miller, at the time of the test, he informed a Quest employee and an Amazon Human Resources employee that he possessed a medical marijuana license. After Miller's drug test came back positive for marijuana, Amazon fired him from his current seasonal position and did not consider him for the permanent position. Miller sued both Amazon and Quest. With respect to Quest, Miller alleged negligence and civil conspiracy, claiming that Quest should have reported to Amazon that he held a medical marijuana license. Quest filed a motion to dismiss both counts for failure to state a claim. In ruling on the motion, the federal court noted that the Pennsylvania Supreme Court has not addressed the question of whether a testing company has a duty to inform an employer about an employee's medical marijuana status. The federal court predicted that it would not extend current precedent to impose a duty to do so, ruling that it would be unreasonable to impose a duty on an independent drug testing company to report that an employee holds a valid medical marijuana license in a particular state. According to the court, the employee, as holder of the license, is in the best position to advise the employer, rather than relying on an intermediary to do so. Thus, because Quest did not owe a duty to report the existence of Miller's medical marijuana license to Amazon, the court dismissed both the negligence claim and civil conspiracy claim against it. With both claims dismissed, Quest was dropped from the lawsuit. Miller's claims against Amazon for violating the Pennsylvania Medical Marijuana Act, breach of contract and the implied covenant of good faith and fair dealing, and violation of public policy remain pending.

EEOC ENTERS CONSENT DECREE WITH COMPANY OVER EMPLOYEE'S PRESCRIPTION SUBOXONE USE

Equal Employment Opportunity Commission v. Lonza America, Inc., U.S. District Court for the Eastern District of Tennessee, Case No. 1:20-cv-00311-TRM-SKL (consent decree entered July 22, 2021). For previous updates and facts about this case, please refer to the December 2020 issue of the LAPPA Case Law Monitor, available here. The Equal Employment Opportunity Commission (EEOC) and Lonza America LLC (Lonza) agreed to enter into a consent decree to resolve this case. The consent decree resolves all issues and claims arising out of the EEOC's complaint alleging unlawful employment practices in violation of Title I of the Americans with Disabilities Act (ADA) by Lonza against former employee, Michael Ingram. As part of the decree, Lonza agreed to pay Ingram a total of \$150,000, with \$50,000 going toward back wages and \$100,000 for compensatory damages. Additionally, Lonza must provide a one-hour mandatory training program regarding the ADA to all human resources personnel.

NORTH CAROLINA REACHES \$40 MILLION SETTLEMENT WITH JUUL

State of North Carolina, ex rel. Joshua H. Stein v. JUUL Labs, Inc., North Carolina Superior Court, Case No. 19-CVS-2885 (settlement reached June 28, 2021). JUUL Labs, Inc. (JUUL) agreed to pay \$40 million to North Carolina to settle a lawsuit brought by North Carolina Attorney General Josh Stein accusing the company of employing unfair and deceptive practices targeting young people to use its vaping products. Per the settlement, JUUL will pay \$40 million to the state over six years. The money from the settlement will fund research of e-cigarettes as well as programs to help people quit e-cigarettes and prevent e-cigarette addiction. In addition to the \$40 million, JUUL also made the following commitments about its advertising and business practices in North Carolina: (1) no marketing that appeals to people under the age of 21; (2) no use of most social media advertising, influencer advertising, outdoor advertising near schools, or sponsorship of sporting events and concerts; (3) no claims in advertising that compare the health effects of using JUUL with the health

effects of using combustible cigarettes; (4) no online sales by JUUL or any third-party sales partners to anyone not age-verified by an independent verification system; (5) no retail sales to anyone not age-verified using a barcode scanner; (6) placement of retail products behind counters so that shoppers cannot access them without an employee's assistance; (7) maintain a retailer compliance secret shopper program to ensure these measures are followed and hold accountable retailers that fail; and (8) no new flavors or nicotine content levels without authorization from the U.S. Food and Drug Administration.

NEW WEST VIRGINIA SYRINGE SERVICE PROGRAM LAW GENERATES LITIGATION

Milan Puskar Health Right, et al. v. Bill J. Crouch, et al., U.S. District Court for the Southern District of West Virginia, Case No. 3:21-cv-00370 (suit filed June 25, 2021). On April 10, 2021, West Virginia Governor Jim Justice signed Senate Bill (SB) 334 into law. The new law requires licenses for communitybased prevention programs known as syringe services programs (SSPs). Additionally, the law requires: (1) SSP operators to offer an array of health outreach services, including overdose prevention education and substance use disorder treatment program referrals; (2) participants to show an identification card to obtain a syringe; and (3) SSPs to receive majority support from local commissions and municipal councils. On June 25, 2021, the American Civil Liberties Union (ACLU), on behalf of several SSP providers, filed a complaint for declaratory and emergency injunctive relief in federal court alleging constitutional violations. The ACLU asserts that SB 334 violates: (1) the void for vagueness doctrine; (2) procedural due process rights under the Fourteenth Amendment of the U.S. Constitution; (3) the equal protection clause under the Fourteenth Amendment; and (4) the West Virginia Constitution. On June 28, 2021, the district court granted the plaintiffs' motion for a temporary restraining order, thereby blocking SB 334 from taking effect on July 9, 2021. After a preliminary injunction hearing on July 8, 2021, the court extended the emergency injunctive relief pending further action. However, on July 15, 2021, the court dissolved the June 28, 2021 temporary restraining order and denied the plaintiffs' request for a preliminary injunction. The court ruled that while the plaintiffs will likely succeed on their claim that the law violates their equal protection rights by discriminating between new and existing SSP providers, the plaintiffs did not show that they are likely to prove that the law violates their due process rights. Given those findings, the court did not think plaintiffs would be irreparably harmed without injunctive relief. With the temporary restraining order removed, West Virginia can enforce the new law.

SAFETY-BASED DRUG TESTING LIMITED IN IOWA

Tyler Dix, et al. v. Casey's General Stores, Inc, et al., Supreme Court of Iowa, Case No. 18-1464 (opinion filed June 25, 2021). In a 4-3 ruling, the Iowa Supreme Court held that companies must consider the specific duties of each worker when designing safety-based drug testing programs. Plaintiffs Julie Eller, Jimmy McCann, Jason Cattell, and Tyler Dix were all employed by Casey's Marketing Company and Casey's General Stores (collectively "Casey's"). Eller and McCann performed light work, sorting cigarette returns, while Dix and Cattell performed heavy work, operating forklifts and lifting heavy objects. In early 2016,



Casey's amended its drug and alcohol testing policy to add unannounced random testing of employees working in a pool of safety-sensitive positions. Casey treated all four employees as being in safety-sensitive positions on the basis that all worked in a in a warehouse. Dix tested positive for marijuana, while McCann and Cattell tested positive for marijuana and amphetamines. Casey's subsequently fired all three employees. Eller attempted to provide a urine sample, but she did not produce a large enough

sample; her failure to produce a valid sample constituted a refusal to take the test, and she was deemed to have

voluntarily resigned from her position. All four employees brought actions against Casey's alleging various violations of IOWA CODE § 730.5. IOWA CODE § 730.5(8) allows an employer to conduct unannounced, suspicionless drug testing of employees selected from a predefined pool, as long as the employer's pool is either: (1) the entire employee population at a particular work site; (2) the entire full-time employee population at a work site; or (3) all employees at a particular work site who work in a "safety-sensitive position." A "safety-sensitive position" is defined by the statute as a job where an accident could cause loss of human life, serious bodily injury, or significant property or environmental damage. At trial, the state court ruled for Eller and McCann and awarded damages. The court denied all of Cattell's and Dix's claims for relief, however, because it found that Casey's statutory violations did not cause their terminations. On appeal, an Iowa intermediate appellate court upheld the district court's ruling. Before the Iowa Supreme Court, Casey's argued that regardless of the definition, whether an employee is in a safety-sensitive position should be decided by the employer based on its business judgment. Casey's asserted it labeled Eller and McCann as having safety-sensitive positions despite performing light work because they worked within the warehouse environment where others operated heavy machinery. While not disagreeing that employers are likely to know best which of their positions are safety-sensitive, the Supreme Court majority found that Casey's improperly focused on the environment in which a job is performed rather than the job function in making the decision about whether a position is safety-sensitive. As a result, the majority held that Casey's misclassified Eller and McCann as safety-sensitive employees, and the lower courts properly concluded they should not have been included in the pool subjected to drug testing. Thus, Eller and McCann were wronged when they lost jobs due to drug testing that should not have occurred. The majority denied relief to the two employees who performed heavy duty work. The dissenting Justices argued that the majority ventured into the role of human resources and that no grounds to overturn the company's determination on who to test existed.

RAILWAY COMPANY HAS LEGITIMATE, NON-DISCRIMINATORY REASON FOR REMOVING EMPLOYEE

Gary Armitage v. BNSF Railway Co., U.S. District Court for the Northern District of Texas, Case No. 4:20-cy-00209-O (opinion filed July 6, 2021). The U.S. District Court for the Northern District of Texas ruled in favor of BNSF Railway Company (BNSF) in a disability discrimination lawsuit brought by a former company employee. In 1996, Gary Armitage started working for BNSF as a train dispatcher, a safety-sensitive position. In 2003, Armitage injured himself in a motorcycle accident and developed chronic pain. Armitage's physicians managed, and continue to manage, his chronic pain with fentanyl patches and hydrocodone. In 2018, BNSF's medical department instituted a new policy that BNSF employees who regularly used a "restricted medication" (including fentanyl, hydrocodone, and oxycodone) may not work in a safety-sensitive position. BNSF urged those affected by the policy, like Armitage, to either transition away from those medications where feasible, or seek medical leave while they wait to be placed in another role. Because Armitage needed to continue his opioid therapy, he opted to work with the company's vocational rehabilitation program to move to a non-safety-sensitive position, to which he ultimately transitioned. After exhausting his remedies before the Equal Employment Opportunity Commission, Armitage sued BNSF in March 2020, claiming disability discrimination under the Americans with Disabilities Act (ADA) based on his disqualification from his train dispatcher position. BNSF moved for summary judgment. To establish a prima facie case for disability discrimination under the ADA, a plaintiff must show that: (1) he is disabled; (2) he is qualified for the job; but (3) he was subject to an adverse employment decision on account of his disability. Both parties agreed that chronic pain qualifies as a disability under the ADA. In ruling on the motion, the district court first concluded that Armitage is a qualified individual under the ADA because he performed the essential functions of a train dispatcher for over a decade while using his prescription pain medications. The court ruled that BNSF's creation of the restricted medication list does not necessarily mean that Armitage is no longer qualified to be a train dispatcher. Despite finding that Armitage is disabled and qualified for the job under the ADA, the court held that he could not show that BNSF removed him from his job because of his disability. The court accepted BNSF's assertion that it acted only on the basis of safety concerns, which is a

legitimate, non-discriminatory reason for its action. Because Armitage could not rebut BNSF's assertion with evidence of discriminatory pretext, the court granted BNSF's motion for summary judgment. Armitage filed an appeal with the U.S. Court of Appeals for the Fifth Circuit on July 23, 2021.

ORAL ARGUMENTS SCHEDULED IN NARCAN PATENT CASE

Adapt Pharma Operations v. Teva Pharmaceuticals USA, Inc., U.S. Court of Appeals for the Federal Circuit, Case No. 20-2106 (original suit filed October 21, 2016). Oral arguments have been scheduled for August 2, 2021 in a case involving four of Adapt Pharma's (Adapt) patents covering Narcan spray. Adapt sued Teva Pharmaceuticals USA, Inc. (Teva) in 2016 in federal court for patent infringement after Teva developed a generic version of Narcan. On June 22, 2020, the U.S. District Court for the District of New Jersey invalidated the Adapt patents as obvious, meaning that prior to patent issuance, a person with ordinary skill in "the art" (here, manufacturing drugs) could combine aspects of existing treatments (that is, use "prior art") to reach the patented solution. If affirmed, the ruling from the district court will allow companies like Teva to make generic versions of Narcan. On appeal, Adapt argues that the district court misapplied rules that the federal circuit laid out to avoid the risk that "once the path to an invention has been illuminated, a court might conclude that anyone would have seen it." In other words, Adapt believes the district court's decision reflects hindsight bias. In contrast, Teva argues that the court property invalidated Adapt's four patents because the components were widely used for decades. If the federal circuit upholds Adapt's patents, the company will be able to fend off generic competition until the patents expire in 15 years.

COURT VACATES PRIOR RULING THAT EXCESS INSURERS MUST DEFEND GIANT EAGLE IN OPIOID CASES

Giant Eagle, Inc., et al. v. American Guarantee and Liability Ins. Co., et al., U.S. District Court for the Western District of Pennsylvania, Case No. 2:19-cv00904-RJC (order vacating November 2020 decision filed May 25, 2021). For previous updates and facts about this case, please refer to the December 2020 issue of the LAPPA Case Law Monitor, available here. On May 25, 2021, U.S. District Judge Robert J. Colville ruled that his prior refusal to consider a part of grocery retailer Giant Eagle's primary insurance policy resulted in a clear error of law. Accordingly, the judge vacated his November 2020 opinion that Giant Eagle's excess insurers, American Guarantee and Liability Insurance Company (AGLIC) and XL Specialty Insurance Company (XL), must defend it in the lawsuits that the company faces as part of the federal multidistrict opioid litigation. The judge stated that, after reconsidering a section of Giant Eagle's primary policy with Old Republic Insurance Company, he found that the primary insurance is not exhausted. Therefore, AGLIC and XL are not currently obligated to provide a defense. On July 23, 2021, Giant Eagle filed a motion for leave to file a second amended complaint.

JOHNSON & JOHNSON DEFENDANTS NOT ENTITLED TO CALIFORNIA PATIENT RECORDS

County of Los Angeles v. The Superior Court of Orange County, California Court of Appeals, Fourth District, Case No. D077794 (opinion filed June 15, 2021). A California intermediate appellate court ruled that three defendants (the Johnson & Johnson defendants) in the ongoing opioid marketing and distribution case, People of the State of California, et al. v. Purdue Pharma, et al., are not entitled to data from California substance use disorder patients. The Johnson & Johnson defendants served subpoenas on two non-parties, Los Angeles County and Alameda County, seeking records, including individual prescription information and patient treatment records, from patients in county substance use disorder programs. The defendants argued

that the requested information related to their contention that any alleged increase in opioid misuse or substance use disorder was the result of illegal prescribing and other illicit drug-related activities. Initially, both the California trial court and intermediate appellate court ordered the counties to provide the requested information to a vendor which would de-identify the records and add cross-references before handing them over to the defendants. The California Supreme Court, however, reversed the ruling and remanded the case to the intermediate appellate court, finding that the court failed to apply the proper two-part inquiry for determining the right to privacy under the state constitution. On remand, the intermediate appellate court concluded that the counties adequately demonstrated a legally protected privacy interest, a reasonable expectation of privacy, and that producing the information would constitute a serious invasion of that privacy. Additionally, the court determined that the California patients whose records would be produced have a reasonable expectation of privacy because they are not litigating nor did they perform any other act indicating a willingness to disclose records. Because the Johnson & Johnson defendants failed to show that their interest in the records outweighed any of the privacy concerns, the court denied the defendants' motion to compel.

NEW YORK SUIT AGAINST MCKINSEY ONE OF MANY TRANSFERRED TO MULTI-DISTRICT LITIGATION

The City of New York, et al. v. McKinsey & Company, Inc., et al., U.S. District Court for the Eastern District of New York, Case No. 3:21-cv-05183-CRB (suit filed May 31, 2021). New York City and 21 New York counties filed a lawsuit against the consulting firm McKinsey & Company (McKinsey), alleging that the company contributed to the opioid crisis by helping opioid manufacturers like Purdue Pharma create strategies to increase prescription drug sales. In their complaint, the plaintiffs assert claims of deceptive acts and practices, false advertising, negligence, negligent misrepresentation, creation of a public nuisance, fraud, and unjust enrichment. The plaintiffs ask the court for damages caused by the opioid epidemic, including, but not limited to, costs: (1) for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid use disorder; (2) for providing treatment, counseling, and rehabilitation services; (3) for providing treatment of infants born with opioid-related medical conditions; (4) for providing care for children whose parents suffer from an opioid-related disability or incapacitation; (5) associated with law enforcement and public safety relating to the opioid epidemic; and (6) associated with drug court and other resources expended through the judicial system. The plaintiffs initially filed the case in Suffolk County trial court. McKinsey removed the case to the U.S. District Court for the Eastern District of New York on June 10, 2021. Meanwhile, on June 7, under 28 U.S.C. § 1407, which provides that civil actions involving one or more common questions pending in different federal districts may be transferred to a singular district for coordinated or consolidated pretrial proceedings, the United States Judicial Panel on Multidistrict Litigation (MDL Panel), transferred roughly two-dozen pending federal suits against McKinsey to a multidistrict litigation in the U.S. District Court for the Northern District of California styled, In re McKinsey & Company, Inc., National Prescription Opiate Consultant Litigation, Case No. 3:21-md-2996 (MDL-2996). On June 25, the MDL Panel transferred the New York suit to MDL-2996. As of July 15, 2021, there are 47 actions pending against McKinsey in MDL-2996. On July 9, 2021, the New York plaintiffs filed a motion to remand the case to state court. A hearing on the remand motion is scheduled for August 19, 2021.

THE CHEROKEE NATION SUES MCKINSEY & COMPANY

The Cherokee Nation v. McKinsey & Company, Inc., U.S. District Court for the Eastern District of Oklahoma, Case No. 6:21-cv-00200-RAW (suit filed June 2, 2021). In a case that is not part of the McKinsey & Company (McKinsey) multi-district litigation as of July 27, 2021, the Cherokee Nation sued McKinsey in Oklahoma court asserting that the company's role in assisting companies profiting from opioids, such as Purdue Pharma, was far more extensive than just advising opioid manufacturers. In its complaint, the



Cherokee Nation claims that, in addition to advising manufacturers, McKinsey, on its own account and through affiliations to private equity funds, made major investments in all aspects of the opioid trade, from drug manufacturers to substance use disorder treatment facilities. The complaint also alleges that McKinsey helped opioid distributors and retailers find ways to sell more opioids. The Cherokee Nation brings forth causes of action related to creation of a public nuisance, negligence, civil conspiracy, and unjust enrichment, and asks the court to order McKinsey to pay compensatory and punitive damages. The

Cherokee Nation initially filed the case in Oklahoma state court. McKinsey removed the case to the U.S. District Court for the Eastern District of Oklahoma on July 6, 2021. The Cherokee Nation filed a motion to remand on July 12, 2021. On July 26, 2021, the district court granted McKinsey's motion for an extension of time to answer the complaint.

PROPOSED CLASS ACTION ON BEHALF OF WEST VIRGINIA CHILDREN FILED AGAINST MCKINSEY

Cynthia Woolwine, et al., v. McKinsey & Co., et al., Case No. 5:21-cv-00418, U.S. District Court for the Southern District of West Virginia (suit filed July 23, 2021). A West Virginia woman, on behalf of herself and a minor child, filed a proposed class action in federal court against McKinsey & Company (McKinsey) and several related entities. The proposed class of plaintiffs contains "all persons born in West Virginia under the age of eighteen, born after 2002, who were diagnosed with opioid withdrawal and whose birth mother (1) used opioids during gestation and (2) had a medical prescription for opioids before or during the gestation period." In the complaint, plaintiffs allege that McKinsey substantially contributed to the minor child's injuries caused by opioid-based neonatal abstinence syndrome (NAS) "by masterminding an industry-wide conspiracy aimed at increasing their clients' profits through an illegal scheme that fueled the genesis and continuation of [the mother's] fatal addiction." Through their actions, plaintiffs continue, McKinsey foreseeably caused damages to the child and other class members, that include the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring causes of action for civil conspiracy, nuisance, negligence, gross negligence, and an equitable claim for medical monitoring of class members. The complaint does not state an exact amount of damages. As of July 27, 2021, the case is not part of the McKinsey multi-district litigation.

KENTUCKY ATTORNEY GENERAL SUES CVS FOR ITS ALLEGED ROLE IN THE OPIOID EPIDEMIC

Commonwealth of Kentucky, ex rel. Daniel Cameron v. CVS Health Corporation, et al., Kentucky Circuit Court, Franklin County, Case No. 21-CI-00445 (suit filed June 2, 2021). Kentucky Attorney General Daniel Cameron filed a lawsuit against CVS Health Corporation (CVS) accusing the pharmacy chain of flooding Kentucky with prescription opioids and, thus, contributing to the commonwealth's opioid epidemic. The complaint asserts causes of action for deceptive acts and practices in violation of the Kentucky Consumer Protection Act (KCPA), continuing a public nuisance, unjust enrichment, negligence, and civil conspiracy. The commonwealth asks the court to award it civil penalties of \$2,000 for each willful violation of the KCPA and \$10,000 for each violation of the KCPA where the defendants' conduct was directed at a person aged 60 or older. The commonwealth also requests punitive damages.

ENDO ANNOUNCES SETTLEMENT IN TENNESSEE OPIOID CASE

Barry Staubus, et al. v. Purdue Pharma, LP, et al., Tennessee Circuit Court, Sullivan County, Case No. 82CC3-2017-CK-41916 (agreement reached July 22, 2021). For previous updates and facts about this case, please refer to the June 2021 issue of the LAPPA Case Law Monitor, available here. Endo International, PLC announced that its subsidiaries, Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. (collectively, "Endo"), reached an agreement in principle to settle an opioid-related case in Sullivan County, Tennessee, dubbed the "Sullivan Baby Doe lawsuit." In April 2021, the state trial court entered a default judgment against Endo as a sanction for willingly withholding records during legal discovery. A damages trial was scheduled to begin on July 26, 2021. The settlement will fully resolve the case in exchange for a payment by Endo of \$35 million to be apportioned among all 28 plaintiffs. On July 29, 2021, the lead lawyer for the Tennessee municipalities announced that all plaintiffs approved the settlement offer. The settlement will include no admission of wrongdoing, fault, or liability of any kind by Endo.

PROPOSED SETTLEMENT FOR FOUR DEFENDANTS IN NATIONAL OPIOID LITIGATION

In re National Prescription Opiate Litigation, U.S. District Court for the Northern District of Ohio, Case No. 17-MD-2804 (multi-district litigation commenced December 12, 2017). On July 21, 2021, a bipartisan coalition of state attorneys general announced a proposed \$26 billion settlement of the national opioid litigation with drug manufacturer Johnson & Johnson and three drug distributors, McKesson Corp., Cardinal Health, Inc., and AmerisourceBergen. According to the announcement, states have 30 days to decide whether to accept the settlement while local governments have 150 days to decide. If this deal is accepted by enough plaintiffs, the three drug distributors will spread their \$21 billion payments over 18 years, while Johnson & Johnson will contribute \$5 billion over a nine-year span, with up to \$3.7 billion paid during the first three years. The ultimate amount the companies will pay under the settlement depends on the number of states that sign on to it and confirm that their cities and counties are in agreement. The settlement also calls for the creation of an independent clearinghouse to provide all three distributors and state regulators aggregated data about where drugs are going and how often. Additionally, as part of this agreement, Johnson & Johnson will no longer manufacture opioid medications. This settlement does not cover the following groups of defendants: (1) Purdue Pharma and Mallinckrodt, both of whom are in bankruptcy proceedings; (2) Teva, whose 2019 offer to settle for a combination of cash and donated buprenorphine naloxone tablets remains outstanding; and (3) various national pharmacies. Shortly after the announcement, West Virginia signaled that it will not participate in the settlement, stating that the deal allocates too much of the \$26 billion based on population rather than severity of the opioid crisis. The Attorney General for Washington State also issued a news release summarily rejecting the settlement.

PHILADELPHIA DISTRICT ATTORNEY SUES ATTORNEY GENERAL OVER PROPOSED SETTLEMENT



Commonwealth of Pennsylvania v. Attorney General, Commonwealth Court of Pennsylvania, Case No. 233 MD 2021 (suit filed July 22, 2021). Philadelphia's District Attorney, Larry Krasner, sued the office of Pennsylvania Attorney General Josh Shapiro a day after Shapiro announced that Pennsylvania would accept the proposed settlement in the national opioid litigation, referenced above. The suit asks a state trial court to declare that the attorney general's office does not have the authority to relinquish Philadelphia's claims in the settlement. According to the complaint, Krasner estimates that Philadelphia will get less than \$10 million per year from the

proposed national opioid litigation settlement, but Krasner believes that the opioid suit he filed in 2018 against various drug companies could generate more money for Philadelphia. There is no trial date set in Philadelphia's lawsuit. According to reports, the proposed national settlement would deliver about \$1 billion to Pennsylvania, but that assumes full participation by local governments, which have 150 days to decide if they would like to join the settlement. To get the full settlement amount, a large number of counties and cities, like Philadelphia, would need to give up their individual opioid lawsuits.

RECENT EVENTS IN THE NEW YORK STATE OPIOID LITIGATION

In Re Opioid Litigation, New York Supreme Court, Suffolk County, Case No. 40000/2017 (suit filed March 28, 2019).

- Just days before the jury trial began on June 29, 2021, Johnson & Johnson settled with New York state, Nassau County, and Suffolk County for \$230 million. According to reports, the payments will be made over a nine-year period, and the payment plan depends on the status of legislation creating an opioid settlement fund. In addition to the cash settlement, Johnson & Johnson must no longer manufacture or sell opioids in New York. The settlement will cover attorney's fee and costs as well as funding for opioid related issues. Johnson & Johnson will not admit liability or wrongdoing as part of the settlement.
- Also, shortly before trial, pharmacy defendants, Walgreens, Boots Alliance Inc., CVS Health Corp., Rite Aid Corp., and Walmart, Inc., agreed to pay a combined \$26 million to settle claims in the case. The pharmacies do not admit to wrongdoing as part of the settlement.
- On July 21, 2021, three opioid distributors, McKesson Corp., AmerisourceBergen Corp., and Cardinal Health, Inc., agreed to pay \$1.1 billion to New York State to settle claims against them. The payments will be made over the course of 17 years. According to reports, the majority of the \$1.1 billion payment will be a guaranteed, while the remaining funds are earmarked as incentive payments payable if New York bars, resolves, or releases current and future subdivision litigation. Additionally, as part of the agreement, the companies will implement a new process for collecting and analyzing data about opioid orders received by the other companies through the creation of a clearinghouse, operating under the oversight of an independent third-party monitor.
- The ongoing trial continues in state court. Just three defendants remain, Endo Health Solutions, Teva Pharmaceuticals USA, and Allergan Finance.

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).

- On June 8, 2021, the U.S. House Committee on Oversight and Reform held a hearing to examine the Sackler family's role in the opioid epidemic. The hearing also evaluated the need for Congress to enact reforms like the SACKLER Act (H.R. 2096) which was introduced by Rep. Carolyn Maloney in March 2021 and would prevent individuals who have not filed for bankruptcy, like members of the Sackler family, from obtaining releases for individual liability through bankruptcy proceedings. Massachusetts Attorney General Maura Healey and Idaho Attorney General Lawrence Wasden testified at the hearing, and both endorsed the SACKLER Act.
- According to court documents filed on July 7, 2021 by a mediator, 15 states (Colorado, Hawaii, Idaho, Illinois, Iowa, Maine, Massachusetts, Minnesota, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Virginia, and Wisconsin) that previously opposed Purdue Pharma's (Purdue) bankruptcy plan agreed to sign on to it. According to the mediator's report, the Sackler family agreed to boost their settlement payment of \$4.28 billion by roughly \$50 million. Moreover, at least \$175 million from the family foundation will be contributed to fight the opioid epidemic, bringing the total settlement from the Sacklers

- to roughly \$4.5 billion. Additionally, under this modified deal, Purdue will agree to make public more than 30 million internal documents from the years when the company developed and promoted OxyContin.
- Nine states (California, Connecticut, Delaware, Maryland, New Hampshire, Oregon, Rhode Island, Vermont, and Washington) and the District of Columbia have yet to agree to the Purdue bankruptcy plan. Many of these states have criticized the plan for providing a "legal shield" to the Sackler family. West Virginia announced that it will not participate in the deal due to the state's attorney general believing that the state would get shorted in settlement money since the distribution of the funds is largely based on population. A confirmation hearing for the bankruptcy plan is scheduled for August 9.
- On July 19, 2021, the U.S. Department of Justice (DOJ) filed an objection to Purdue's proposed bankruptcy plan. The DOJ's U.S. Trustee Program asserts that the deal is unconstitutional and illegal. William Harrington, the U.S. Trustee overseeing New York State, described the proposed liability releases of the Sackler family as impermissible and accused the family and its associates of using the bankruptcy system to avoid liability. Additionally, the U.S. Attorney for the Southern District of New York, Audrey Strauss, asserts that the proposed plan violates the constitutional right to due process for those with potential opioid claims.

ABOUT LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

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