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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USAO No. 2023V00171 (letter issued December 17, 2024). The U.S. Attorney's Office for the Middle District of Tennessee has issued a letter of findings against the Tennessee Board of Law Examiners (TBLE) and the Tennessee Lawyers Assistance Program (TLAP) concluding that the entities violated Title II of the Americans with Disabilities Act (42 U.S.C. § 12132 *et seq.*) by discriminating against bar applicants based on their diagnosis of or treatment for a substance use or mental health disorder. The U.S. Attorney's Office investigated complaints by two applicants, referred to as D.S. and C.B., to the Tennessee bar who alleged that they were subjected to discrimination because of their disabilities. The letter stated that the TBLE and the TLAP discriminated against D.S. because of his SUD and required him to undergo an evaluation by a psychiatrist and drug testing based on his use of prescribed medication for addiction treatment (MAT). He contended that the entities "forced him to choose" between his law license or his MAT after a medical report submitted to the TBLE stated that he was "not fit for the practice of law" and recommended that he "[explore] the possibility of abstinence-based recovery." Additionally, the letter noted that C.B. was similarly subjected to restrictions and conditions on his ability to obtain a law license, due to his history of alcohol use disorders, even though there was no evidence that he was unable to meet the bar admission standards. The U.S. Attorney's office determined that the restrictions and conditions that TBLE and TLAP imposed on D.S. and C.B. were based on speculation and stigma about their disabilities and were contrary to demonstrated conduct. To remedy these violations, the letter states that TBLE and TLAP should promptly implement corrective measures, including: (1) refraining from prohibiting, limiting, or restricting applicants or attorneys from taking MAT; (2) refraining from inquiring into an applicant's diagnosis of or treatment with medication for a substance use or mental health disorder unless the applicant voluntarily discloses this information to explain conduct or behavior that may otherwise warrant denial of admission; and (3) not recommending or imposing conditional admission, or conditions or restrictions on admission, solely on the basis of a diagnosis of or treatment for a substance use disorder or mental health disorder. If the TBLE or TLAP declines to enter into voluntary compliance negotiations or if negotiations are unsuccessful, the United States will likely take further action. *(Return to In This Issue)*

U.S. ATTORNEY'S OFFICE FILES SUIT AGAINST NURSE PRACTITIONER TO STOP ILLEGAL OPIOID SALES

***United States v. Joan Rubinger*, U.S. District Court for the Eastern District of California, Case No. 2:25-cv-00091-DAD-JDP (suit filed January 8, 2025).** The U.S. Attorney's Office for the Eastern District of California has filed a civil complaint against Joan Rubinger, a California nurse practitioner, over allegations that she operated a nationwide scheme to sell illegal opioid prescriptions for cash. According to court documents, between November 1, 2019 and June 17, 2024, Rubinger traveled around the country providing prescriptions for controlled substances. A licensed physician did not supervise Rubinger or her practice, and she would typically meet customers in non-medical environments without access to necessary diagnostic tools, proper medical records, or any other infrastructure required to treat patients. Per the complaint, Rubinger sold prescriptions to her customers for cash and would provide her customers with a price list that allowed them to select their own prescriptions from a menu of controlled substances. Rubinger would issue the prescriptions without conducting a medical examination or creating any medical records and would write the prescriptions under false names to conceal the excessive quantities of drugs she was prescribing. The government asserts that Rubinger knew that her conduct was illegal and that she would give her customers specific instructions so that they would appear as legitimate patients and minimize attention from the U.S. Drug Enforcement Administration. These included requiring them to pick up their prescriptions from the pharmacy regardless of the cost or if the pharmacist only gave the patient a partial prescription. The lawsuit brings forth one count of issuance of prescriptions without a legitimate medical purpose in violation of the Controlled Substances Act (21 U.S.C. §§ 842(a)(1) and 829). The government is asking the court to prohibit Rubinger from prescribing controlled substances and to impose civil penalties against her. *(Return to In This Issue)*

TWO INDIAN CHEMICAL COMPANIES AND SENIOR EXECUTIVE INDICTED FOR DISTRIBUTING FENTANYL PRECURSOR CHEMICALS

***United States v. Athos Chemicals PVT. LTD.*, U.S. District Court for the Eastern District of New York, Case No. 1:24-cr-00526-RPK and *United States v. Bhavesh Lathiya and Raxuter Chemicals*, U.S. District Court for the Eastern District of New York, Case No. 1:24-cr-00525-PKC (suits filed December 20, 2024).** The U.S. Department of Justice has filed indictments against two India-based companies, Raxuter Chemicals and Athos Chemicals PVT. LTD., and Bhavesh Lathiya, the founder and senior executive of Raxuter Chemicals, charging them with criminal conspiracy to distribute and import fentanyl precursor chemicals into the United States. As alleged in the indictments, the defendants supplied precursor chemicals to the United States and Mexico knowing that they would be used to manufacture fentanyl. The chemicals were sent via international mail and package carriers, and to prevent detection and interception of the packages, the defendants employed deceptive and fraudulent practices including mislabeling packages, falsifying customs forms, and making false declarations at border crossings. In one example, a package had a false manifest that listed its contents as Vitamin C, but it actually contained 1-boc-4-piperidone, a List I chemical[1] that is used to manufacture fentanyl. Police arrested Lathiya on January 4, 2025 in New York City, and the court detained him pending trial. If convicted, Lathiya faces a maximum penalty of 53 years in prison.
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[1] "List I Chemical" means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance. 21 U.S.C. § 802(34).

CHINESE CHEMICAL COMPANY EXECUTIVES ACQUITTED OF FENTANYL CHARGE BUT CONVICTED ON OTHER COUNTS

***United States v. Hubei Amarvel Biotech Co., LTD., et al.*, U.S. District Court for the Southern District of New York, Case No. 1:23-cr-00302-PGG (jury verdict reached January 29, 2025).** For previous updates on this case, please refer to the August 2023 issue of the LAPPA *Case Law Monitor*, available here. A Manhattan jury issued a verdict in a federal case involving two executives of a Chinese chemical company. The jury found Hubei Amarvel Biotech's principal executive Qingzhao Wang and marketing manager Yiyi Chen not guilty of conspiracy to distribute fentanyl or a fentanyl-related substance. However, the jury determined that Wang and Chen were guilty of importing the fentanyl precursor 1-boc-4-AP and importing the methamphetamine precursor methylamine into the United States. Additionally, the jury found both defendants guilty of conspiracy to commit money laundering. Wang and Chen are scheduled to be sentenced on May 29 and June 5, 2025, respectively. *(Return to In This Issue)*

FEDERAL COURT RULES OHIO CORRECTIONAL FACILITY STAFF WERE NOT DELIBERATELY INDIFFERENT TO DETAINEE'S MEDICAL NEEDS

***Stacey Berrier v. Lake County, Ohio and Lake County Board of Commissioners, et al.*, U.S. District Court for the Northern District of Ohio, Case No. 1:22-cv-00813-DCN (opinion filed October 28, 2024).** For previous updates on this case, please refer to the August 2022 issue of the LAPPA *Case Law Monitor*, available here. A federal district court has granted the defendants' motions for summary judgment in a wrongful death suit filed by the mother of a woman who died while in custody of the Lake County Adult Detention Facility (LCADF). Ryan Trowbridge took buprenorphine to manage her opioid use disorder. On June 2, 2020, police arrested Trowbridge and took her into custody at LCADF. Upon arriving at the facility, Trowbridge completed a medical screening indicating that she did not appear to be under the influence of any substances and that she did not have visible signs of withdrawal or suicidal behavior. Additionally, the form listed her medications as buprenorphine, sertraline (Zoloft), and hydroxyzine (Atarax). A physician reviewed Trowbridge's medications on June 4, 2020, and approved everything but her buprenorphine because LCADF policy prohibited the use of narcotics in the facility. That same day, Trowbridge submitted a request to "please see a doctor about medications." According to the record, Trowbridge's request was not reviewed by the nursing staff until June 7, 2020. On June 6, 2020, Trowbridge attempted to commit suicide in her cell. After being discovered, LCADF staff transported her to the hospital where she died from complications arising from her suicide attempt on June 21, 2020. The plaintiff brought forth three causes of action against the defendants: (1) deliberate indifference under the Eighth Amendment of the U.S. Constitution; (2) failure to properly train staff on how to care for individuals suffering from substance use disorder; and (3) wrongful death under Ohio Law (OHIO REV. CODE ANN. § 2125.01 (West 2024)).

The plaintiff's deliberate indifference claim rests on the premise that Trowbridge had a serious medical need that was treatable with buprenorphine, and LCADF deliberately denied access to that medication. The denial or delay of medication can constitute a constitutional violation of deliberate indifference. However, in this case, LCADF's treatment plan for withdrawal was to provide non-narcotic care through the use of comfort medication and other medically accepted medications to treat individual symptoms. As a practice, when a correctional facility's doctors pursue a different method of treatment than prescribed or recommended by an outside physician, a plaintiff cannot recover damages unless he or she can provide medical proof that the alternative treatment was so inadequate that it constituted a conscious disregard of the risk that a plaintiff faced. The plaintiff did not present such medical proof, nor had she cited any cases establishing that providing alternative treatments would be a constitutional violation. Furthermore, there is no evidence that LCADF staff

perceived that Trowbridge was at substantial risk of suffering serious withdrawal symptoms from having her buprenorphine withheld. Though Trowbridge submitted a request to see a doctor about medication, the court noted that she did not specifically ask about buprenorphine, complain of any serious health issue, or require any medical attention for withdrawal as part of the request. Thus, the court determined that there was not any medical evidence to support a finding that the defendants were deliberately indifferent to Trowbridge's needs or that her treatment was inadequate based on her symptoms and granted the defendants' motion for summary judgment with respect to this claim. The court also granted the defendants' motion for summary judgment with respect to the failure to train claim, finding that the failure to train theory was undermined by the fact that the plaintiff admitted that LCADF had an official policy prohibiting the distribution of narcotics in the facility. Finally, with the federal claims dismissed, the court determined that it did not retain supplemental jurisdiction over the state wrongful death claim. The plaintiff filed a motion for appeal on November 26, 2024, which the Sixth Circuit accepted on December 2, 2024. *(Return to In This Issue)*

PILOT SUES JETBLUE FOR DISCRIMINATION AND HARASSMENT AFTER REQUIRED ALCOHOLICS ANONYMOUS PARTICIPATION

***Chadwick Troeger v. JetBlue Airways Corp.*, U.S. District Court for the Southern District of New York, Case No. 1:23-cv-10859 (opinion filed December 17, 2024).** A former JetBlue pilot's lawsuit for religious and sexual orientation discrimination has survived a motion to dismiss in federal district court. In February 2020, JetBlue pilot Chadwick Troeger's supervisors confronted him about data found on his company-issued tablet which indicated that he had searched for gay pornography and information about the half-lives of illicit drugs. Troeger denied that he had viewed this content on his tablet. Troeger's supervisor allegedly threatened to terminate his employment unless he agreed to undergo a medical evaluation at Cornerstone of Recovery (Cornerstone), a substance use disorder treatment center. Claiming he was under "extreme emotional distress," Troeger agreed to the evaluation. The evaluation involved questions about Troeger's personal life, substance use, and sexual history, and Cornerstone tested his blood alcohol level and performed a hair follicle drug test. The evaluators informed Troeger that his hair test was positive for amphetamines despite his claim that he had not taken any amphetamines. Based on the results of the evaluation, Troeger's supervisors required him to attend treatment at Cornerstone which required him to participate in Alcoholics Anonymous (AA), which includes, according to the record, "steps that are religious or spiritual in nature and mimic Christian beliefs." As a gay man and an atheist, Troeger felt uncomfortable participating in AA, but Cornerstone did not provide an alternative treatment plan. After Cornerstone discharged Troeger, JetBlue placed him into a random drug and alcohol testing program pursuant to Federal Aviation Administration (FAA) regulations. The FAA requires individuals placed into drug testing programs to receive 14 drug screens in 12 months, but Troger claimed that, unlike heterosexual, religious employees, he was subjected to more than the required drug screens.

Troeger also claimed that he was required to attend monthly JetBlue Human Intervention Motivation Study (HIMS) meetings and was "forced to speak about his recovery from a substance use issue he did not have and his submission to a higher power he did not believe in." When Troeger requested a non-religious alternative to AA meetings, the HIMS program administrators denied the request. In June 2022, he filed a discrimination and harassment complaint with JetBlue, but he did not receive a response. On March 13, 2023, JetBlue terminated Troeger, citing violations of JetBlue's Crewmember handbook and Drug and Alcohol Policy.

In December 2023, in federal district court, Troger brought an employment discrimination action under Title VII of the 1964 Civil Rights Act (42 U.S.C. § 2000e), the New York State Human Rights Law (N.Y. EXEC. LAW § 296, *et seq*. (West 2024)), and the New York City Human Rights Law (N.Y.C. ADMIN. CODE § 8-502(a), *et seq*. (West 2024)) against JetBlue and his supervisors. The defendants moved to dismiss the case. The court determined that Troeger plausibly alleged a hostile work environment under Title VII, noting that being repeatedly forced to lie about holding certain religious beliefs and "falsely aver" to having a substance use disorder describes a continuous and concerted form of harassment. Additionally, the court ruled that

Troeger adequately pleaded the adverse employment action needed to advance his disparate treatment discrimination claims, finding that the circumstances alleged in the complaint depicted an "anti-atheistic and anti-gay" bias. Troeger's hostile work environment allegations under New York State and New York City laws also survived the motion to dismiss. The court, however, dismissed Troeger's retaliation claim, finding that too much time had passed between his initial bias complaint and termination to infer a causal link. *(Return to In This Issue)*

FOURTH CIRCUIT ALLOWS FALSE CLAIMS ACT SUIT AGAINST AN OPIOID TREATMENT PROGRAM TO PROCEED

***United States ex rel. Lisa Wheeler v. Acadia Healthcare Company, Inc., et al.*, U.S. Court of Appeals for the Fourth Circuit, Case No. 23-2101 (opinion filed 2/3/2025).** The Fourth Circuit has allowed a False Claims Act (FCA; 31 U.S.C. § 3729) suit to continue against substance use disorder treatment and behavioral health service provider Acadia Healthcare Company (Acadia). Acadia is certified as an opioid treatment program (OTP) by the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services (HHS).[2] Lisa Wheeler worked as a physician assistant at Acadia's Asheville, North Carolina clinic from January 2014 through December 2021. Beginning in September 2020, she noticed that the Ashville clinic was documenting that its patients were receiving group therapy, but she was unaware that such therapy had occurred. Wheeler began asking her patients about their group therapy, and they told her that Acadia had not provided such therapy for them. After reviewing patients' counseling notes, Wheeler realized that Acadia's therapist and counselors were signing off on false treatment notes. Wheeler attempted to raise her concerns with her supervisors on multiple occasions, but Acadia did not investigate her reports. Acadia had previously reached settlements involving FCA claims with the U.S. Department of Justice in 2014 and 2019. As a condition of the 2019 settlement, Acadia entered into a corporate integrity agreement (CIA) with HHS. The CIA required Acadia to provide training to certain staff and to develop a disclosure program that would enable individuals to internally report any potential concerns about Acadia's policies or procedures with respect to a federal healthcare program believed by the individual to be a potential legal violation. Wheeler claimed that Acadia never provided her or other staff with the annual training required by the CIA and never made her aware of the disclosure program. On September 10, 2021, Wheeler filed an FCA whistleblower suit against Acadia. Acadia filed a motion to dismiss, which the district court granted in full. Wheeler appealed the ruling to the Fourth Circuit.

On appeal, Wheeler argued that Acadia knowingly submitted a false claim to the federal government for counseling services that did not take place. The court noted that Wheeler pleaded detailed allegations that Acadia created notes for therapy sessions that did not occur, falsifying specific case notes that were reused on different dates for different patients. Additionally, the court noted that OTPs are required to provide adequate substance use disorder counseling in order to obtain authorization to participate in government healthcare programs. Acadia argued that Wheeler failed to allege that the fraudulent therapy notes were submitted in actual claims for payment, but the court noted that precedent only requires a plaintiff to "connect the dots, even if unsupported by precise documentation, between the alleged false claim and government payment." Thus, "if an FCA whistleblower cannot allege the details of an actually submitted false claim, the complaint may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that leads to a strong inference that claims were actually submitted." The court concluded that Wheeler plausibly alleged that Acadia submitted claims that falsely certified compliance with federal regulations.

As part of her FCA claim, Wheeler also alleged a reverse false claim which is the improper withholding of money or property to which the United States is legally entitled.[3] Wheeler asserted that Acadia violated the

[2] To obtain certification, OTPs must meet certain opioid treatment standards under federal law, including providing "adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary." (42 C.F.R. § 8.12).

[3] A company may be held liable for a reverse false claim if it: "(1) knowingly makes, uses, or causes to be made or used, a false

CIA by failing to provide staff with the required training and by failing to investigate, take remedial action, or report any of the information she provided about the false therapy reports to the Office of the Inspector General at HHS. The CIA contained a provision for a stipulated monetary penalty in the event of a breach but argued that it is not "obligated" to pay those penalties because they are contingent on the government choosing to take action to enforce them. The court rejected Acadia's argument, holding that a contracting party's discretion to enforce a penalty does not eliminate the existence of the obligation. The court concluded that Wheeler adequately pled her reverse false claim because the stipulated penalties in the CIA, if accrued, would constitute an obligation under the FCA. The court ruled that Wheeler adequately pleaded her FCA claims, reversed the district court's dismissal, and remanded the case for further proceedings.
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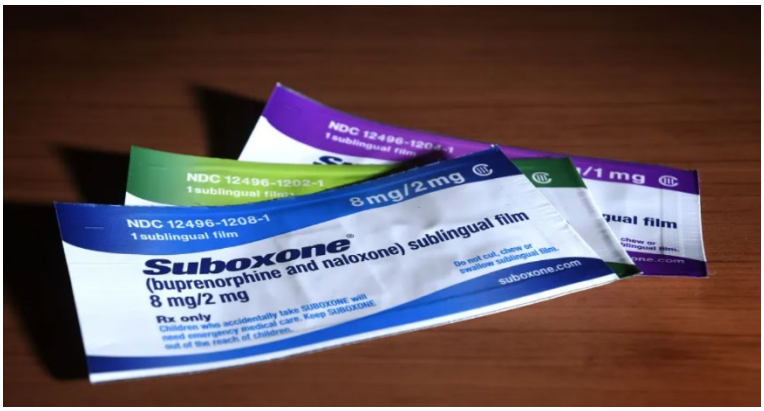
DRUG TEST COMPANY SETTLES WITH DOJ OVER UNNECESSARY TESTING CLAIMS FOR $4.425 MILLION

Drug Test Company Settles with DOJ Over Unnecessary Testing Claims for $4.425 Million (settlement reached January 3, 2025). A toxicology laboratory has reached a settlement with the U.S. Attorney's Office for the Western District of Michigan for $4.425 million over allegedly ordering medically unnecessary drug tests. Physicians Toxicology Laboratory (PTL) provided urine drug testing for Medicare patients at several medical practices in Michigan. According to an investigation by the U.S. Attorney's Office, PTL urged medical practices to issue "blanket" orders for all patients, despite Medicare rules requiring an individualized determination for every patient before a urine drug test can be ordered. Between 2017 and 2019, PTL allegedly knowingly submitted false and unnecessary billing claims to Medicare in violation of the federal False Claims Act (31 U.S.C. § 3729). In January 2025, PTL entered into an agreement with the U.S. Attorney's Office to resolve these allegations. Under the terms of the settlement, PTL did not admit liability but agreed to pay $4.425 million, establish a compliance program, hire a clinical director to review policies and practices related to clinical decision-making, and engage an independent party to review claims for medical necessity and appropriate documentation. *(Return to In This Issue)*

FEDERAL DISTRICT JUDGE DISMISSES PART OF SUBOXONE TOOTH DECAY LITIGATION



***In re Suboxone (Buprenorphine/Naloxone) Film Products Liability Litigation*, U.S. District Court for the Northern District of Ohio, Case No. 1:24-md-3092 (opinion filed December 31, 2024).** For previous updates on this case, please refer to the February 2024 issue of the LAPPA *Case Law Monitor*, available here. A federal district court has ruled that some aspects of a plaintiff's lawsuit involving Suboxone tooth decay allegations are preempted by federal law. In 2010, the U.S. Food and Drug Administration (FDA) approved Suboxone (Buprenorphine/Naloxone) film as a safe and effective treatment of opioid use disorder (OUD). Defendant Indivior Inc. distributes and holds the new drug application for Suboxone film, while defendant Aquestive Therapeutics is the exclusive global manufacturer of Suboxone film. In January 2022, the FDA issued a drug safety communication warning that dental problems have been reported with

record or statement material to an obligation to pay or transmit money or property to the government; or (2) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government." (31 U.S.C. § 3729(a)(1)(G)).

medicines containing buprenorphine that are dissolved in the mouth. On June 17, 2022, the FDA required the defendants to change the label for Suboxone film to add information about adverse dental events. On November 2, 2023, Ryan Bennett, who used Suboxone to treat his OUD, filed a products liability suit against the defendants asserting claims under Ohio law of failure to warn of design defects. Bennett claimed that the defendants knew or should have known that "when used as prescribed and intended," Suboxone film causes "harmful damage to teeth due to the drug's acidity." Defendants filed a motion to dismiss arguing that federal law preempts the plaintiff's failure to warn and design defect claims.

Under Ohio law, a product is defectively designed if, "at the time it left the manufacturer's control, the foreseeable risks associated with the product's design or formulation outweighed the design's benefits." (Ohio Rev. Code § 2307.75(A) (West 2024)). Bennett claimed that the risk of adverse effects from Suboxone film in the form of serious dental injuries outweigh the product's benefits. Bennett presented defective design claims related to two different time periods: before the FDA's approval of Suboxone film and after it was on the market. For the pre-market approval claim, Bennett argued that the defendants failed to exercise due care in the development of Suboxone film before its approval and designed a defective product. The defendants counterargued that they could not have complied with state law without obtaining FDA approval for a differently designed product. The court determined that federal law does not preempt the plaintiff's pre-approval design defect claim for two reasons. First, the U.S. Congress has not preempted such claims, and if it wished to, it would have included a preemption provision like it has done for medical devices. Second, the U.S. Supreme Court has not addressed preemption of a design defect claim involving a brand-name drug. The court also cited Sixth Circuit precedent stating that "there is no physical impossibility between complying with a state law duty to exercise reasonable care in the process leading up to placing a drug on the market and complying with federal government's process for approving drugs." Furthermore, a design defect claim based on pre-approval conduct would require the defendants to design a differently formulated product.[4] Because a drug manufacturer cannot change a drug' formulation after it is FDA approved , the Sixth Circuit recognizes that federal law preempts state law design defect claims following the approval of a new drug application except in certain narrow circumstances.[5] Because none of those circumstances apply in this case, the plaintiff is effectively asking the defendant to stop selling Suboxone film, which is something that the preemption doctrine does not allow. Therefore, the court determined that federal law preempts the plaintiff's design defect claim to the extent that the claim relates to the period after the FDA's approval of Suboxone film.

Ohio law imposes liability on a product's manufacturer or supplier which, at the time of marketing, knows of a risk associated with the product that caused the plaintiff's harm and failed to provide an adequate warning of that risk. (OHIO REV. CODE § 2307.76(A)(1) (West 2024)). The defendants argued that the FDA's approval of the product label along with Suboxone film in 2010 forecloses Barrett's pre-approval failure to warn claim and any claim following the June 2022 label change which the agency approved. Note that the defendants do not make a preemption argument for the period between approval of Suboxone film in 2010 and the June 2022 label change. Under Ohio law, a product is not defective if it contains an adequate warning at the time of marketing. (§ 2307.76(A)(1)). Because the plaintiff did not use Suboxone film before its approval, the court determined that it did not need to address whether FDA approval of the label forecloses any failure to warn claim arising before then. The defendants argued that the label change that the FDA approved in June 2022 preempts the plaintiff's claim that the label was not adequate after that date. Barrett's complaint cited a research study published in December 2022 that found an increased risk of dental side effects associated with Suboxone film. The court noted that the study could constitute "newly acquired information" that would have allowed the defendants to make additional warnings on the label without FDA approval but determined that at this stage of the proceedings, it is not clear if the study satisfies the definition of newly acquired information;

[4] The court noted that the plaintiff identified a specific alternative design to deliver buprenorphine and points to the FDA's approval of Sublocade (injectable buprenorphine) in 2017 which does not result in dental injuries.

[5] Once approved, the FDA's regulations require a drug's sponsor to obtain the agency's approval before making "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients in the specifications provided in the approved new drug application." (21 C.F.R. § 314.70).

the court ruled that the question requires further factual development.[6] Thus, the court granted in part and denied in part the defendants' motion to dismiss. The plaintiff will be able to proceed with his claims for pre-approval design defect and for failure to warn. *(Return to In This Issue)*

CLASS ACTION TARGETS AMERICAN ADDICTION CENTERS FOR DATA BREACH

***Ethan Parker v. American Addiction Centers, Inc.*, U.S. District Court for the Middle District of Tennessee, Case No. 3:24-cv-01505 (complaint filed December 27, 2024).** After a data breach at a recovery center exposed confidential patient information, patients have filed a class-action lawsuit seeking damages and enhanced security against American Addiction Centers (AAC) which operates a network of substance use disorder treatment and recovery centers in several states. In September 2024, AAC detected suspicious activity on its computer network which, after investigation, was revealed to be a cyberattack that potentially exposed the confidential personal and health information of over 400,000 people. In December 2024, affected patients filed a class action lawsuit against AAC in federal court in the Middle District of Tennessee claiming negligence, unjust enrichment, and breach of implied contract by AAC. The class members seek monetary damages for their increased risk of identity theft, as well as injunctive relief requiring AAC to improve its network security. AAC has until February 28, 2025 to file its answer with the court. *(Return to In This Issue)*

FTC SUES FLORIDA COMPANY FOR DECEPTIVE ADS FOR TREATMENT CLINICS

***Federal Trade Commission v. Evoke Wellness, LLC*, U.S. District Court for the Southern District of Florida, Case No. 0:25-cv-60073-MD (complaint filed January 13, 2025).** The Federal Trade Commission (FTC) has sued a wellness company for using deceptive advertisements to direct potential patients to their clinics. Evoke Wellness (Evoke) is a Florida-based company that operates substance use disorder (SUD) treatment clinics. Evoke paid for online advertising through Google, which placed ads for Evoke alongside search results for certain consumer search queries. Tying advertisements to search keywords is a common practice, but from 2021 to 2023, Evoke bought ads tied to the names of other, unrelated SUD clinics. When consumers searched for a non-Evoke clinic, the sponsored ad displayed that clinic's name, but the phone number listed belonged to Evoke. When Evoke staff answered these calls, they would not identify themselves as working for Evoke. On January 13, 2025, the FTC sued Evoke in federal district court for violations of the FTC Act (15 U.S.C. §§ 45(a) and 52) and the Opioid Addiction Recovery Fraud Prevention Act (15 U.S.C § 45d) which prohibits unfair or deceptive acts or practices with respect to any SUD treatment service. The FTC is seeking civil penalties and injunctive relief to halt alleged deceptive practices by Evoke. Evoke has not yet filed its answer. *(Return to In This Issue)*

HEALTH INSURERS SUE HHS OVER MENTAL HEALTH INSURANCE PARITY RULE

***ERISA Industry Committee v. Department of Health and Human Services, et al*, U.S. District Court for the District of Columbia, Case No. 1:25-cv-00136 (complaint filed January 17, 2025).** A group of health insurance companies has sued the U.S. Department of Health and Human Services (HHS) over a September 2024 administrative rule implementing mental health insurance parity legislation. The federal Mental Health

[6] The FDA has a regulation known as the "changes being effective regime," which permits certain changes to a label before receiving the agency's approval. Through this process, a drug's sponsor may "add or strengthen a contraindication, warning, precaution, or adverse reaction," as long as the newly acquired information prompting the change satisfies the standard of a causal association for inclusion on the label. It then can seek FDA approval. (21 C.F.R. § 314.70).

Parity and Addiction Equity Act (MHPAEA; Pub. L. No. 110-343) regulates health insurance plans by requiring parity between any costs or limitations for mental health and substance use disorder (SUD) treatment benefits and those for medical and surgical benefits. HHS, the Department of the Treasury, and the Department of Labor (collectively, the "Departments") issued a final rule implementing the MHPAEA (89 Fed. Reg. 77,586). On January 17, 2025, the ERISA Industry Committee, an association of health insurance companies, sued the Departments in federal district court for exceeding their authority under the Administrative Procedures Act (5 U.S.C. § 553). In the insurers' view, the new rule is arbitrary and capricious, and its establishment of novel tests for parity between mental health/SUD benefits and medical/surgical benefits amounts to a policy reversal that requires greater justification than was provided in the final rule. Further, the insurers allege that the Departments unlawfully delegate regulatory authority by requiring insurers to meet generally recognized medical standards in third-party clinical literature. The suit requests that the court vacates the parity rule or at least the challenged provisions. In the wake of the U.S. Supreme Court's 2024 decision in *Loper Bright v. Raimondo* (603 U.S. 369), the courts are less likely to defer to the Departments' own interpretation of the MHPAEA. The Departments, under a new presidential administration, have not yet filed their answer to the complaint. *(Return to In This Issue)*

FOURTH CIRCUIT RULES VIRGINIA'S HEMP LAW IS NOT PREEMPTED BY FEDERAL LAW

***Northern Virginia Hemp and Agriculture, LLC, et al. v. Commonwealth of Virginia, et al.*, U.S. Court of Appeals for the Fourth Circuit, Case No. 23-2192 (opinion filed January 7, 2025).** The Fourth Circuit has upheld a decision denying a preliminary injunction that would have prevented Virginia from regulating the sale of certain hemp-derived products. In 2023, the Virginia governor signed S.B. 903 into law. The bill requires hemp products offered for retail sale in the commonwealth to have a *total* THC concentration of less than 0.3 percent, regardless of whether the THC is delta-9 or another natural or synthetic form. (VA. CODE ANN. § 3.2-4112 (West 2024)). Additionally, S.B. 903 prohibits Virginia hemp processors from selling hemp products to individuals or entities that the processor knows, or has reason to know, will use the hemp or extract in a substance that contains a total THC concentration of more than 0.3 percent. (VA. CODE ANN. § 3.2-4116 (West 2024)). Three plaintiffs[7] filed a lawsuit against the commonwealth, the governor, and state officials and agencies challenging the legality of S.B. 903. The plaintiffs argued that S.B. 903's total THC standard and restrictions on hemp processors are preempted by the Agriculture Improvement Act of 2018 (2018 Farm Bill; Pub. L. No. 115-334) and violate the Dormant Commerce Clause of the U.S. Constitution. The plaintiffs filed a motion for a preliminary injunction, and the district court denied the motion, holding that they were unlikely to prevail on their preemption arguments and that they lacked standing to challenge S.B. 903's restrictions on Virginia hemp processors. An appeal to the Fourth Circuit followed. On appeal, the court affirmed the district court's ruling that the plaintiffs did not have standing to challenge § 3.2-4116's hemp processor restrictions because they are not licensed hemp processors and, therefore, have not been directly injured by the law. The court ruled, however, that the plaintiffs did have standing to challenge S.B. 903's total THC standard.

The plaintiffs argued that the district court erred in rejecting their claim that the 2018 Farm Bill preempts S.B. 903's total THC standard because Virginia's standard for hemp is more stringent than it is under federal law. Under the 2018 Farm Bill, hemp is defined by the delta-9 THC concentration of the product, as opposed to the total THC concentration as established by S.B. 903. (7 U.S.C. § 1639o). This difference in definition means that hemp products that are legal under federal law might be considered illegal under Virginia's total THC standard. The court noted that the 2018 Farm bill explicitly prohibits states from interfering with the interstate transportation or shipment of hemp or hemp products that are legal under federal law, but it does not preclude states from creating laws that regulate the sale of hemp more stringently. Furthermore, the court noted that

[7] The three plaintiffs included a Virginia citizen who used now-outlawed hemp products to relieve arthritis pain, a Virginia entity that made and sold hemp products to the public, and an out-of-state entity that produced and sold hemp products.

under the principles of federalism, states retain the power to regulate matters of health and safety. Thus, the court ruled that S.B. 903's total THC standard is not preempted by the 2018 Farm Bill. Finally, the plaintiffs asserted that S.B. 903 violates the Dormant Commerce Clause by impeding the interstate commerce of industrial hemp. The court found that the plaintiffs failed to present any evidence that S.B. 903 seeks to be advantageous to in-state entities by disadvantaging out-of-state entities or applies to in-state and out-of-state purchasers differently. Thus, the court ruled that S.B. 903 does not violate the Dormant Commerce Clause. Accordingly, the court affirmed the order of the district court denying the plaintiffs' motion for a preliminary injunction as to S.B. 903's total THC standard. *(Return to In This Issue)*

MICHIGAN CANNABIS DISPENSARY CANNOT USE MEDICAL LICENSE TO CLAIM TAX CREDIT

***Lake Effect Group LLC v. Michigan Department of Treasury*, Michigan Tax Tribunal, Case No. 24-000162 (order issued December 6, 2024).** A Michigan tax court has ruled that a cannabis dispensary owes over $500,000 in back taxes after claiming a tax deduction for which it did not qualify. Lake Effect Group, LLC (Lake Effect), is a recreational and medical cannabis dispensary based in Michigan. Under state law, the Michigan Regulation and Taxation of Marihuana Act (MRTMA; MICH. COMP. LAWS § 333.27962) regulates adult use cannabis and provides tax deductions to recreational cannabis vendors, while the Medical Marihuana Facilities Licensing Act (MMFLA; MICH. COMP. LAWS § 333.27101, *et seq.* (West 2024)) governs medical cannabis businesses and does not provide for tax deductions. A Michigan Department of the Treasury (Treasury) audit of Lake Effect's corporate income taxes from 2017 to 2020 revealed that Lake Effect had relied upon the tax deductions in the MRTMA to reduce its total taxable income, despite being licensed only as a medical cannabis facility under the MMFLA; Lake Effect did not receive its recreational cannabis license under the MRTMA until 2020. The Treasury adjusted its assessment, increasing Lake Effect's taxes owed by $520,000, and Lake Effect disputed the assessment with the Michigan Tax Tribunal. On December 6, 2024, the Tax Tribunal entered summary judgment in favor of the Treasury, ruling that Lake Effect could not claim a tax deduction under the MRTMA because it was a medical cannabis facility at the time and that the company could not apply the MRTMA tax deductions retroactively after it received its recreational cannabis license. Thus, the Tax Tribunal determined that Lake Effect is liable for the larger, revised tax assessment. *(Return to In This Issue)*

THIRD CIRCUIT RULES JOBSEEKERS DENIED FOR USING CANNABIS CANNOT SUE EMPLOYERS

***Erick Zanetich v. Walmart Stores East, Inc.*, U.S. Court of Appeals for the Third Circuit, Case No. 23-1996 (opinion filed December 9, 2024).** For previous updates on this case, please refer to the June 2023 issue of the LAPPA *Case Law Monitor*, available here. In a 2-1 decision, the Third Circuit has ruled that, although New Jersey's recreational cannabis law prohibits employment discrimination based on cannabis use, the law does not provide individuals with a private cause of action to sue employers. Erick Zanetich applied for a job at one of Walmart Stores East, Inc.'s (Walmart) facilities. Walmart offered Zanetich the job subject to him submitting to and passing a drug test. Zanetich took the drug test and tested positive for cannabis. As a result, Walmart rescinded Zanetich's job offer. Zanetich filed a lawsuit against Walmart alleging that the company violated the New Jersey Cannabis Regulatory, Enforcement Assistance, and Marketplace Modernization Act (CREAMMA; N.J. STAT. ANN. § 24:6I-52 (West 2024)), which explicitly prohibits employers from taking certain adverse actions due to an individual's use of cannabis. Walmart filed a motion to dismiss arguing that CREAMMA does not contain a private cause of action. The district court granted the motion, and Zanetich appealed to the Third Circuit. The Third Circuit majority affirmed the ruling of the district court, holding that

while CREAMMA prohibits employment discrimination against cannabis users, it does not explicitly permit or expressly dictate a legal remedy. The majority determined that the "legislative silence," in light of other types of discrimination having codified legal remedies, means that lawsuits challenging employment actions based on cannabis use cannot stand. The dissenting judge argued that the question of whether CREAMMA has an implied cause of action is one that should be answered by the New Jersey Supreme Court. On December 23, 2024, Zanetich filed a petition for a rehearing *en banc*, but the court denied his petition on January 10, 2025. *(Return to In This Issue)*

OHIO SUPREME COURT ADDRESSES SIXTH CIRCUIT'S CERTIFIED QUESTION; SIXTH CIRCUIT VACATES 2022 JUDGMENT

***In re National Prescription Opiate Litigation* (*Trumbull County, et al. v. Purdue Pharma, et al.*), Ohio Supreme Court, Case No. 2023-1155 (opinion filed December 10, 2024).** For previous updates on this case, please refer to the October 2023 issue of the LAPPA *Case Law Monitor*, available here. In a 5-2 decision, the Ohio Supreme Court issued a ruling answering the certified questions presented to it by the Sixth Circuit as part of the National Prescription Opiate Litigation appeal involving a $650 million judgment granted to Trumbull and Lake (Ohio) Counties. In the original suit, Plaintiffs Trumbull and Lake Counties (collectively, the "counties") alleged that national pharmaceutical chains, including defendants Walgreens, CVS, and Walmart (collectively, the "pharmacies") "created, perpetuated, and maintained" the opioid epidemic. The counties pleaded their allegations as a common law absolute public nuisance claim. The pharmacies invoked the Ohio Product Liability Act (OPLA; OHIO REV. CODE ANN. § 2307.71, *et seq.* (West 2024)) and filed a motion to dismiss, arguing that the OPLA abrogates public nuisance claims like those brought by the counties because certain public nuisance claims are included in the OPLA's definition of product liability claims. The federal district court denied the pharmacies' motion to dismiss based on a prior decision in a separate action within the same multidistrict litigation brought by Summit County, Ohio. In the Summit County Action, the federal district court concluded that the OPLA does not abrogate absolute public nuisance claims seeking relief for harm other than compensatory damages. In the counties' public nuisance claim, they sought equitable relief, not compensatory damages. After the case went to trial and a jury rendered a verdict in the counties' favor, the pharmacies reiterated their OPLA abrogation argument in a motion for judgment as a matter of law. The district court denied the motion and the pharmacies appealed to the Sixth Circuit. Recognizing that the Ohio Supreme Court had not yet spoken on the proper interpretation of the OPLA, the Sixth Circuit certified a question of state law. The certified question presented was whether the OPLA abrogates a common law claim of absolute public nuisance resulting from the sale of a product in which the plaintiffs seek equitable abatement. The counties argued that the OPLA abrogates only the public nuisance claims seeking compensatory damages. The pharmacies argued that all public nuisance claims based on the design, manufacture, supply, marketing, distribution, or sale of a product are abrogated by the OPLA because the statute's definition of "product liability claim" states that it "also includes any public nuisance claim." (OHIO REV. CODE ANN. § 2307.71(A)(13) (West 2024)). The Ohio Supreme Court agreed with the pharmacies, answering the certified question in the affirmative and holding that all common law public nuisance claims arising from the sale of a product have been abrogated by the OPLA. The counties argued that the legislative history of the OPLA changes the meaning of the text. The Ohio Supreme Court rejected this argument, holding that because there is no ambiguity in the statute, the legislative history is irrelevant. The dissenting justices argued that public nuisance claims seeking equitable relief should still be allowed under Ohio law.

On January 31, 2025, the Sixth Circuit, based on the Ohio Supreme Court's ruling, issued an order vacating the $650 million judgment and corresponding injunction against the pharmacies. The Sixth Circuit remanded the case to the U.S. District Court for the Northern District of Ohio for further proceedings.
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FEDERAL DISTRICT COURT DISMISSES RICO CLAIM AGAINST PBMS; ALLOWS OTHER CLAIMS TO PROCEED

***Ohio County Commission, et al., v. Express Scripts, Inc., et al.*, U.S. District Court for the Northern District of West Virginia, Case No. 5:24-cv-00142 (opinion filed December 23, 2024).** A federal district court has dismissed a Racketeer Influenced and Corrupt Organizations Act (RICO; 18 U.S.C. § 1961, *et seq*.) brought by cities and counties in West Virginia against pharmacy benefit managers (PBMs), Express Scripts Inc. and OptumRx, Inc. The plaintiffs, a collection of cities, towns, and counties in West Virginia, filed suit in July 2024 against the PBMs over their alleged role in the opioid epidemic and brought forth claims of public nuisance, a federal civil RICO violation, negligence, civil conspiracy, and unjust enrichment. The defendants filed a motion to dismiss for failure to state a claim on October 11, 2024. The first of the defendants' arguments was that the plaintiffs' claims were barred by the statute of limitations and that they should have filed their claims by 2019. The court rejected the defendants' argument that the plaintiffs' claims were barred on their fact but determined that it could not conclude that their claims were time-barred as a matter of law at this stage of the proceedings. Next, the defendants argued that the plaintiffs' RICO claim should be dismissed because they cannot seek injunctive relief under the RICO statute. The court agreed with the defendants, stating that Fourth Circuit precedent establishes that RICO does not authorize private plaintiffs to sue for injunctive relief but may sue for treble damages and cost. In adherence to the Fourth Circuit's precedent, the court granted the defendants' motion to dismiss as it pertained to the RICO claim for injunctive relief. The motion to dismiss also included arguments to dismiss the negligence, civil conspiracy, and unjust enrichment claims, but the court denied those motions. For the public nuisance claim, the court held that it would defer ruling on the claim until a decision is issued by the West Virginia Supreme Court in the *City of Huntington and Cabell County Commission v. AmerisourceBergen Drug Corp.,* case. (For more information about this case, please refer to the April 2024 issue of the LAPPA Case Law Monitor, available here.) The court directed the defendants to file a new motion to dismiss with respect to the public nuisance claim within 14 days following the West Virginia Supreme Court's decision in *City of Huntington*. Finally, the defendants argued that the Employee Retirement Income Security Act of 1974 (ERISA; 29 U.S.C. § 1001, *et seq.*) and Medicare Part D (42 U.S.C. § 1395, *et seq*.) preempt the plaintiffs' state law claims. The court ruled that neither ERISA nor Medicare Part D preempt the plaintiffs' claims because the plaintiffs do not dictate any particular coverage scheme under ERISA and there is no common law preemption under Medicare Part D.
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INSURANCE COMPANIES' DUTY TO DEFEND/INDEMNIFY IN OPIOID RELATED LITIGATION

Insurance Companies' Duty to Defend/Indemify in Opioid Related Litigation

- ***In re AmerisourceBergen Corp. (N/K/A Cencora) Delaware Insurance Litigation*, Superior Court of Delaware, Case No. N22C-01-182 (opinion filed December 23, 2024).** A Delaware Superior Court has ruled that Cencora's (formally AmerisourceBergen) commercial general liability insurers do not have a duty to defend or indemnify the company in opioid-related litigation. The court determined that the holding in the 2022 Delaware Supreme Court case *ACE American Insurance Co. v. Rite Aid Corp* is applicable to Cencora because the policy language and allegations are substantively identical between this case and *Rite Aid*. (270 A.3d 239; for more information on this case, please refer to the February 2022 issue of the LAPPA *Case Law Monitor*, available here.) Applying the *Rite Aid* holding, the court determined that the insurers do not have a duty to defend Cencora and therefore, are not required to indemnify Cencora. Thus, the court granted the insurers' motion for partial summary judgment and denied Cencora's motion for partial summary judgment.
- ***Ace Property & Casualty Insurance Co. v. McKinsey and Company, Inc.*, Delaware Superior Court, Case No. N25C-01-353 (suit filed January 21, 2025) and *National Union Fire Insurance Co. v. McKinsey and***

***Company, Inc.*, Delaware Superior Court, Case No. N25C-01-384 (suit filed January 23, 2025).** Units of Chubb Ltd. and American International Group Inc. insurance companies have filed separate lawsuits against McKinsey & Company (McKinsey) in Delaware state court over coverage for opioid-related litigation. The insurance companies argue that they do not have a duty to pay McKinsey's legal defense or settlement costs for suits over its alleged contributions to the opioid. Both complaints cite the 2022 Delaware Supreme Court ruling in *Rite Aid* claiming that the McKinsey opioid lawsuits seek to recover economic losses, which the Delaware Supreme Court ruled are not damages "because of bodily injury." *(Return to In This Issue)*

FOOD CITY GROCERY CHAIN AGREES TO $8 MILLION SETTLEMENT TO RESOLVE FALSE CLAIMS ACT ALLEGATIONS

***United States ex rel. K-VA-T Litigation Partnership, LLP v. K-VA-T Food Stores, Inc. d/b/a Food City*, U.S. District Court for the Eastern District of Tennessee, Case No. 3:20-cv-436 (settlement announced December 23, 2024).** The regional grocery chain K-VA-T Food Stores Inc. d/b/a Food City (Food City) has agreed to settle False Claims Act (FCA; 31 U.S.C. § 3729) allegations related to the company's dispensing of controlled substances. Under the settlement, Food City will pay the federal government more than $8 million and $78,621 to Virginia and Kentucky for claims paid to Food City by state Medicaid programs. The federal government had alleged that, from January 2011 through December 2018, 24 Food City store pharmacies dispensed controlled substances that were medically unnecessary, lacked a legitimate medical purpose or medically accepted indication, and/or were not dispensed pursuant to valid prescriptions. As a result, the federal government claimed that Food City knowingly submitted, or caused to be submitted, false claims to federal healthcare programs. This civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the FCA by K-VA-T Litigation Partnership, LLP. The whistleblower will receive $1,527,908 of the proceeds from the settlement. *(Return to In This Issue)*

KENTUCKY REACHES SETTLEMENT WITH KROGER TO RESOLVE OPIOID LAWSUIT

***Commonwealth of Kentucky, ex rel. Russell Coleman v. The Kroger Co., et al.*, Kentucky Circuit Court (Bullitt), Case No. 24-CI-00154 (settlement announced January 9, 2024).** For previous updates on this case, please refer to the April 2024 issue of the LAPPA *Case Law Monitor*, available here. Kentucky has reached a settlement with The Kroger Co. (Kroger) to settle the lawsuit it filed against the company in February 2024 over allegations that the grocery chain's pharmacies helped fuel the opioid epidemic in the commonwealth. As part of the settlement, Kroger will pay Kentucky $110 million over the next 13 years. Half of the settlement dollars will go to the Kentucky Opioid Abatement Advisory Commission while the other half will be distributed among the commonwealth's cities and counties. About $18 million of the funds will go toward lawyers' fees and costs. Kentucky chose not to participate in the $1.2 billion global settlement that Kroger reached with 30 states in 2023. If Kentucky had participated in the global settlement, it would have only received $50 million. *(Return to In This Issue)*

MCKINSEY & COMPANY ENTERS $650 MILLION RESOLUTION WITH FEDERAL GOVERNMENT

***United States v. McKinsey & Company*, U.S. District Court for the Western District of Virginia, Case No. 1:24-cr-00046-RSB-PMS-1 (deferred prosecution agreement entered December 13, 2024).** The global management consulting firm, McKinsey & Company, Inc. (McKinsey), has agreed to pay $650 million to resolve a criminal and civil investigation into the firm's consulting work with Purdue Pharma (Purdue). As part of the federal government's resolution, McKinsey has entered into a five-year deferred prosecution

agreement (DPA) in connection with a criminal information filed in federal district court. The information charges McKinsey with one felony count of knowingly destroying records, documents, and tangible objects with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of the U.S. Department of Justice; and one misdemeanor count of knowingly and intentionally conspiring with Purdue and others to aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid prescriptions. The $650 million resolution includes a penalty of over $231 million, a $93 million forfeiture reflecting the money that Purdue paid to the company between 2004 and 2019, a $2 million payment to the Virginia Medicaid Fraud Control Unit, and a $323 million payment to resolve the company's civil liability under the False Claims Act (31 U.S.C. § 3729). In addition to the monetary penalties, McKinsey has agreed to implement a compliance program that will, among other things, establish new document retention procedures and training for all partners, officers, and employees who provide advice to clients. McKinsey also has agreed not to do any work related to the marketing, sale, promotion, or distribution of controlled substances during the five-year term of the DPA. The resolution requires McKinsey to certify, on an annual basis, the company's compliance with its obligations under the DPA and federal law. *(Return to In This Issue)*

FORMER SENIOR PARTNER AT MCKINSEY & COMPANY PLEADS GUILTY TO OBSTRUCTION OF JUSTICE

***United States v. Martin Eric Elling*, U.S. District Court for the Western District of Virginia, Case No. 1:24-cr-00045-RSB-PMS-1 (guilty plea entered January 10, 2025).** Martin Elling, a former senior partner at McKinsey & Company (McKinsey), has pleaded guilty to one count of knowingly destroying records with the intent to impede, obstruct, and influence the investigation and proper administration of a matter within the jurisdiction of the United States Department of Justice. The obstruction of justice charge related to Elling's consulting work with Purdue Pharma (Purdue). He served as the director of the client services team for approximately 30 of McKinsey's engagements with Purdue. According to court documents, forensic analysis of Elling's McKinsey-issued laptop found that he deleted materials related to McKinsey's work for Purdue from the laptop, as well as a Purdue-related folder from his email account. Elling is scheduled to be sentenced on April 4, 2025 and faces a maximum penalty of 20 years in prison. *(Return to In This Issue)*

U.S. DEPARTMENT OF JUSTICE UNSEALS CIVIL COMPLAINT AGAINST CVS

***United States ex rel. Hillary Estright v. CVS Health Corporation, et al.*, U.S. District Court for the District of Rhode Island, Case No. 1:22-cv-00222-WES-PAS (case unsealed December 18, 2024).** The U.S. Department of Justice has unsealed a civil complaint against CVS Pharmacy Inc. and various subsidiaries (collectively "CVS") which alleges that the company filled unlawful prescriptions in violation of the Controlled Substances Act (CSA; 21 U.S.C. §§ 842 & 829) and sought reimbursement from federal healthcare programs for unlawful prescriptions in violation of the False Claims Act (FCA; 31 U.S.C. § 3729). The complaint asserts that, from October 2013 to the present, CVS knowingly filled prescriptions for controlled substances that lacked a legitimate medical purpose, were not valid, and/or were not issued in the usual course of professional practice. According to the complaint, CVS ignored substantial evidence that its stores were dispensing unlawful prescriptions. The complaint also asserts that CVS' violations resulted from corporate mandated performance metrics, incentive compensation, and staffing policies that prioritized corporate profits over patient safety. If CVS is found liable, it could face civil penalties for each unlawful prescription filled in violation of the CSA and treble damages and applicable penalties for prescriptions reimbursed by federal healthcare programs in violation of the FCA. Whistleblower Hillary Estright, who previously worked for CVS, filed the original action in October 2019 under the *qui tam* provisions of the FCA. The federal government intervened in the suit in December 2024. *(Return to In This Issue)*

U.S. DEPARTMENT OF JUSTICE FILES NATIONWIDE LAWSUIT AGAINST WALGREENS

***United States ex rel. Novak v. Walgreens Boots Alliance, Inc., et al.*, U.S. District Court for the Northern District of Illinois, Case. 1:18-cv-05452 (suit filed January 16, 2025).** The U.S. Department of Justice has filed a civil complaint against Walgreens Boots Alliance, Walgreen Co., and various subsidiaries (collectively "Walgreens") claiming that the pharmacy chain dispensed millions of unlawful prescriptions in violation of the Controlled Substances Act (CSA; 21 U.S.C. §§ 842(a)(1) & 829) and then sought reimbursement for these unlawful prescriptions from the federal healthcare programs in violation of the False Claims Act (FCA; 31 U.S.C. § 3729). The complaint asserts that from August 2012 through the present, Walgreens knowingly filled prescriptions for controlled substances that lacked a legitimate medical purpose, were not valid, and/or were not issued in the usual course of professional practice. The federal government claims that Walgreens ignored substantial evidence from multiple sources that its stores were dispensing unlawful prescriptions, including from its own pharmacist and internal data. Moreover, the complaint asserts that the company systematically pressured its pharmacies to fill prescriptions quickly without taking the time to confirm each prescription's validity and deprived its pharmacists of crucial information, including preventing pharmacists from warning one another about certain prescribers. In addition to the claims that Walgreens violated the CSA and the FCA, the complaint also brings forth claims of payment by mistake of fact and unjust enrichment. If Walgreens is found liable, it could face civil penalties of up to $80,850 for each unlawful prescription filled in violation of the CSA and treble damages and applicable penalties for each prescription paid by federal programs in violation of the FCA. This case is a consolidation of four different whistleblower *qui tam* suits in which the United States has intervened. *(Return to In This Issue)*

WALGREENS SUES DEA AND DOJ CLAIMING THE "RESOLVE RED FLAGS RULE" IS INVALID

***Walgreen Co. v. U.S. Drug Enforcement Administration, et al.*, U.S. District Court for the Eastern District of Texas, Case No. 25-cv-19 (suit filed January 16, 2025).** Walgreen Co. (Walgreens) has filed a suit seeking equitable relief against the U.S. Drug Enforcement Administration (DEA) and the U.S. Department of Justice (DOJ) challenging the imposition of new rules governing how pharmacies dispense controlled substances. According to the complaint, through a patchwork of agency enforcement orders, the DEA has established a new "rule" requiring a pharmacist to resolve all "red flags" before dispensing the prescription. referred to as the "resolve red flags rule"). A "red flag" is a sign or indication that a prescription may be unsafe or medically inappropriate. The failure to follow this rule can result in the imposition of severe criminal and civil penalties on both a pharmacist and pharmacy, and the revocation of the pharmacy's DEA registration. Walgreens argues that to resolve red flag rules, effectively reverses the knowledge requirement in 21 C.F.R. § 1306.04(a) and imposes legal duties on pharmacies beyond those required by the Controlled Substances Act (CSA; 21 U.S.C. § 801, *et seq*.). In other words, the resolve red flags rule "revises the obligation of a pharmacist from a sanctionable duty not to dispense if the pharmacist knows a prescription is not valid to a duty not to dispense unless the pharmacist knows a prescription is valid." Walgreens claims that by requiring pharmacists to resolve red flags and document that resolution before dispensing controlled substances, DEA has altered the regulatory requirements and has imposed the duty on pharmacists to determine the legitimacy of a prescription. Walgreens argues that the resolve red flags rule is arbitrary and capricious and is invalid due to the DEA not following the required process for notice-and-comment rulemaking required under the Administrative Procedures Act (5 U.S.C. § 553). Walgreens has asked the court to issue a declaratory judgment finding that the "resolve red flags rule" is unlawful and cannot be enforced against the company. *(Return to In This Issue)*

WALGREENS STOCKHOLDERS FILE SUIT AGAINST COMPANY AND EXECUTIVES CLAIMING THEY DEFRAUDED INVESTORS

***Steve Klein v. Walgreens Boots Alliance, Inc.*, U.S. District Court for the Northern District of Illinois, Case No. 1:25-cv-01058 (suit filed January 30, 2025).** A class of individuals who acquired Walgreens stock have filed a suit against Walgreens Boots Alliance, Inc. (Walgreens) and several of its former and current executives over allegations that they defrauded investors by scheming to increase the company's profits through opioid sales. The plaintiffs claim that between April 2020 and January 16, 2025, the defendants made materially false and misleading statements regarding the company's business, operations, and prospects. Specifically, the complaint asserts that the defendants failed to disclose that, contrary to the Company's commitment to improve regulatory compliance, it continued to engage in widespread violations of federal law governing the dispensing of prescriptions and reimbursement. Additionally, the plaintiffs assert that the defendants failed to disclose that the company's revenue from the sale of prescriptions was unsustainable to the extent that they were the result of unlawful conduct. The lawsuit references the January 16, 2025 lawsuit that the U.S. Department of Justice (DOJ) filed against Walgreens and noted that following the DOJ's announcement of the suit, Walgreens' stock price feel 12.06 percent over the following two trading sessions. Because of the defendants' wrongful acts and omissions and the sharp decline in the market value of the Company's common stock, the plaintiffs claim to have suffered significant losses and damages. The plaintiffs assert claims under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission (17 C.F.R. § 240.10b-5). The plaintiffs are seeking damages, pre- and post-judgment interest, and reasonable attorneys' fees and related costs. *(Return to In This Issue)*

RECENT EVENTS IN THE PURDUE PHARMA BANKRUPTCY CASE

***In re Purdue Pharma L.P.*, U.S. Bankruptcy Court for the Southern District of New York, Case No. 19-23649 (settlement in principle reached January 23, 2025).** For previous updates on this case, please refer to the December 2024 issue of the LAPPA *Case Law Monitor*, available here. As part of a settlement in principle, Purdue Pharma (Pharma) and Purdue's owners, the Sackler family, have agreed to pay $7.4 billion to a group of states and other parties to settle litigation involving the company's role in the opioid epidemic. This deal comes after the U.S. Supreme Court rejected the previous $6 billion proposal that would have provided the Sackler family with protection from further litigation related to the opioid crisis. The new deal does not give the family automatic protection from future litigation. Under the deal, the Sackler family will pay a total of $6.5 billion while Purdue will pay $900 million. The settlement funds would be paid out over the next 15 years. Furthermore, Purdue will continue to be overseen by a monitor and will be barred from lobbying or marketing opioids. A board of trustees selected by participating states in consultation with the other creditors will determine the future of the company. The new settlement resolves claims brought by 15 states[8] as well as thousands of potential individual lawsuits that could have gone forward against the Sackler family. The agreement, however, allows parties that do not sign on to the settlement to bring forth claims against the Sacklers. The deal will need to be approved by a bankruptcy court judge before it can go into effect. *(Return to In This Issue)*

[8] California, Colorado, Connecticut, Delaware, Florida, Illinois, Massachusetts, New York, Oregon, Pennsylvania, Tennessee, Texas, Vermont, Virginia, and West Virginia.

ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

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

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

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