NAMSDL Case Law Update

October 5, 2017

In This Issue

This issue of *NAMSDL Case Law Update* focuses on several recent court decisions involving the marketing, distributing, and prescribing of controlled substances, primarily opioids. The topics addressed include a recently filed request to transfer ongoing federal litigation concerning the marketing and distribution of opioids to one federal district judge for coordinated pre-trial proceedings and a bipartisan coalition of state attorneys general who are investigating the same issue. In addition, in the cases analyzed below, the respective courts: (1) uphold the decertification of a pharmaceutical company by the DEA for failing to report suspicious orders of controlled substances; (2) question whether an employer's requirement that an employee disclose prescription medication violates the ADA; (3) deal with the intersection of workers compensation claims and (potential) opioid abuse; and (4) consider a pharmacist's duty to a customer when faced with repeated requests to dispense high dosages of opioids. The court decisions originate from the District of Columbia, Idaho, New Mexico, Tennessee, Utah, and Washington. Within this *Update*, cases are divided by the type of court (federal or state) and then listed in approximate descending order of appellate level.

CASES IN THIS ISSUE

Federal Cases

In re National Prescription Opiate Litigation, U.S. Judicial Panel on Multidistrict Litigation, MDL No. 2804. On September 25, 2017, Plaintiffs in 66 ongoing federal court cases filed by counties, cities, or other governmental entities against opioid manufacturers and distributors, moved the Judicial Panel on Multidistrict Litigation ("MDL Panel") to transfer each case to one federal district court judge for pre-trial coordination or consolidation. Created by Congressional legislation in 1968, the MDL Panel is a group of seven sitting federal district court judges who determine whether civil cases pending in different judicial districts involve sufficient common questions of fact to warrant conducting centralized pretrial proceedings in the interest of judicial efficiency. Plaintiffs' motion to transfer indicates that each of the cases involves "substantially similar claims" seeking "substantially similar relief." In particular, Plaintiffs state, defendant "opioid manufacturers and distributors conducted and continued to conduct an association-in-fact enterprise and legal entity enterprise to illegally profit by the unlawful sale of dangerously addictive and foreseeably abused prescription opioid drugs." In these cases, Plaintiffs seek injunctive relief, "costs to abate the public nuisance created by Defendants," compensatory damages, and attorneys' fees. According to Plaintiffs, the 66 ongoing cases are spread throughout the following 11 federal districts, with the number of individual actions in parenthesis: Eastern District of Kentucky (19), Southern District of West Virginia (17), Southern District of Ohio (14), Western District of Kentucky (5), Southern District of Illinois (3), Northern District of Ohio (2), Western District of Washington (2), Northern District of Alabama (1), Eastern District of California (1), District of New Hampshire (1), and the Eastern District of Tennessee (1). Plaintiffs ask that the MDL Panel transfer the actions to a specific judge in the Southern District of Ohio, or alternatively, to a specific judge in the Southern District of Illinois.

Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, U.S. Court of Appeals for the District of Columbia Circuit, Case No. 15-1335, 861 F.3d 206, June 30, 2017. In September 2015, the U.S. Drug Enforcement Administration ("DEA") revoked the certificate of registration of a pharmaceutical distributor, Petitioner, preventing it from selling controlled substances. DEA issued the revocation after concluding that Petitioner repeatedly failed to report suspicious orders of oxycodone products. Several years earlier, after being investigated by DEA for the failure to report suspicious orders, Petitioner developed a computer system that places a "hold" on potentially suspicious orders and designed a protocol to follow to investigate (and potentially dispel) the suspicion surrounding held orders. According to the DEA's 2015 decision, Petitioner repeatedly failed to report to DEA orders held by the computer system or implement the designed protocol. Petitioner sought review and reversal of the DEA's decision with the U.S. Court of Appeals for the D.C. Circuit.

In a decision issued in June 2017, the D.C. Circuit denied review. Reviewing the DEA's fact finding "deferentially," the D.C. Circuit first concluded that DEA "reasonably determined that all held orders [by the computer program] were 'suspicious' within the meaning of the regulation [21 C.F.R. § 1301.74(b)]." Accordingly, such orders should have been reported to DEA absent a documented investigation quelling the suspicion. Next, the court found DEA's decision backed up by files "replete with evidence that [Petitioner] routinely failed to investigate held orders." In the court's opinion, "faced with orders that were suspicious for the core reasons in the regulation—unusual size, pattern, or frequency—[Petitioner's] employees frequently simply brushed suspicion under the rug by deleting orders or paring them down and shipping them without reporting them to DEA" or "simultaneously acknowledged their own concerns while behaving in ways that ensured those concerns would not be addressed." Third, the court rejected Petitioner's assertion that DEA's adjudication "effectively amended existing DEA rules" in violation of notice-and-

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comment requirements. Instead, the court held that DEA "neither created nor imposed any new duties" and instead relied on the existing reporting requirements. Fourth, the court rejected Petitioner's contention that it detrimentally relied on DEA's prior commitment to undertake a "Compliance Review" of the newly designed computer hold system and investigation protocol, which generated no notice of deficiencies. According to the court, this argument might hold water if Petitioner "rigorously implemented" its protocol after the DEA review. Instead, the court continued, "following the Compliance Review . . . [Petitioner's] employees consistently failed to implement" the protocol. The court also discredited other arguments put forth by Petitioner, including that DEA decertified it for requesting an evidentiary hearing and relied on arguments/evidence not presented at the administrative trial.

Steven Williams v. FedEx Corporate Services, et al., U.S. Court of Appeals for the Tenth Circuit, Case No. 16-4032, 849 F.3d 889, February 24, 2017. In 2011, Plaintiff, a Utah man, initiated a claim with his employer's short-term disability insurer for benefits due to work-related stress and anxiety. During the intake process, however, Plaintiff also told the insurer that his withdrawal from Suboxone—taken for a year in an effort to address opioid dependency—prevented him from working. The insurer concluded that Plaintiff suffered from a self-reported "Chemical Dependency" rather than an "Occupational Disability" and authorized (reduced) benefits accordingly. While on leave, Plaintiff obtained a substance abuse assessment that resulted in no abuse/dependence diagnosis. Nevertheless, when Plaintiff returned to work, the employer required Plaintiff to subject to "return-to-duty testing," five years of follow-up testing, and disclose his use of prescription medications, as is required for employees "who seek assistance for drug/alcohol abuse." Plaintiff left the employer in 2014. Shortly thereafter, Plaintiff sued the employer and the insurer, asserting that the employer violated the Americans with Disabilities Act ("ADA") by discriminating against him based on his disability, and that the insurer violated the Employee Retirement Income Security Act ("ERISA") by breaching its fiduciary duty to him. A federal district court dismissed all of Plaintiff's claims in January 2016 on summary judgment and Plaintiff appealed. On appeal, the U.S. Court of Appeals for the Tenth Circuit affirmed the district court in all respects except one. Before the Tenth Circuit, Plaintiff asserted that the district court did not address his claim that the employer violated the ADA (specifically 42 U.S.C. § 12112) when it "unlawfully required medical examinations and made disability-related inquiries," such as requiring monthly drug tests and requiring the disclosure of legally prescribed medications. The Tenth Circuit noted that several appellate courts—including itself—had held that "requiring disclosure of prescription drugs may violate § 12112(d)(4)(A)." In this case, the court agreed with Plaintiff that the district court did not address this issue in the first instance, and thus the court lacked "an adequate record from which we can decide this issue on appeal." Accordingly, the Tenth Circuit remanded the question of the disclosure of prescription drugs to the district court for consideration. The Tenth Circuit affirmed the grant of summary judgment on all other counts.

City of Everett, Washington v. Purdue Pharma, L.P., et al., U.S. District Court for the Western District of Washington, Case No. 17-cv-00209, 2017 WL 4236062, September 25, 2017. Earlier issues of the *NAMSDL Case Law Update* contain a more comprehensive summary of this case. The City of Everett, Washington ("Plaintiff") sued a pharmaceutical manufacturer and several of its executives (collectively, "Defendants"), alleging that from at least 2008 to 2010, Defendants "knowingly, recklessly, and/or negligently" marketed and supplied OxyContin "to obviously suspicious physicians and pharmacies in Everett (and other areas within the State of Washington)" without reporting such suspicious orders. This supply of drugs allegedly enabled "the illegal diversion of OxyContin into the black market, including to drug rings, pill mills and other dealers for dispersal of the highly addictive pills in Everett,"

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which led directly to the city's prescription drug, and now heroin, abuse problems. Plaintiff's causes of action include: (1) gross negligence; (2) negligence: (3) public nuisance; (4) violation of the Washington Consumer Protection Act; (5) unjust enrichment; and (6) punitive damages under the laws of Connecticut and/or California. At the time Plaintiff filed the case, news reports indicated that this is the first lawsuit that focuses on what Defendants knew about the illegal distribution of their products at the time the company filled orders. Defendants removed the case to federal court in February 2017.

After removal, Defendants filed a motion seeking dismissal of all claims "for lack of a cognizable legal duty, for failing to adequately plead proximate cause, for lack of a cognizable injury, and for violating applicable statutes of limitation." Defendants also asserted that the public nuisance, undue enrichment, and punitive damages claims failed under Washington law. In a decision issued in September 2017, the federal district court denied Defendant's motion except as to the public nuisance and punitive damage claims. First, in the court's opinion, Plaintiff sufficiently pled a basis for legal duty, observing that Plaintiff adequately alleged that Defendants "engaged in an affirmative act which created or exposed [Plaintiff] to a high degree of risk of harm," that, if proven, "trigger a legal duty under Section 302B [of the Restatement of Torts] and Washington law." Second, with respect to proximate cause, the court determined that the causal chain, while "not as direct as a car accident or slip-and-fall case," is still "a 'direct sequence,' and it is facially plausible that the involvement of third parties, even criminals, was reasonably foreseeable" given Defendants' alleged extensive knowledge. Third, the court summarily rejected Defendants' request to dismiss Plaintiff's claims for lack of a cognizable injury. Fourth, the court held that Plaintiff adequately pled that it discovered the acts giving rise to its causes of action within the applicable statute of limitations, but noted that Plaintiff's diligence in discovery, which could be the basis of affirmative defenses, remained a "factually intensive inquiry" for the case. As for the dismissed claims of public nuisance and punitive damages, the court granted Plaintiff leave for a short period to amend its complaint. In terms of public nuisance, the court held that the complaint failed to allege an interference with property or a property interest. Regarding punitive damages, the court required Plaintiff in any amended complaint to show that California or Connecticut "has a more significant relationship to these claims than Washington State," and to seek the damages as a remedy rather than a stand-alone cause of action. This case is one of the 66 pending matters in which plaintiffs seek transfer by the MDL Panel to the Southern District of Ohio for pre-trial proceedings.

State Cases

Bipartisan Coalition of State Attorneys General. In June 2017, numerous state attorneys general ("AGs") issued press releases announcing that a bipartisan coalition of AGs started an "ongoing investigation to evaluate whether manufacturers have engaged in unlawful practices in the marketing and sale of opioids." As of mid-September 2017, the coalition includes 39 AGs and is investigating five pharmaceutical manufacturers and three pharmaceutical distributors. According to the press releases, the coalition is "using its investigative tools, including subpoenas for documents, to determine what role the opioid manufacturers and distributors may have played in creating or prolonging this epidemic."

Judy Kilburn v. Granite State Insurance Company, et al., Supreme Court of Tennessee, Case No. M2015-01782-SC-R3-WC, 522 S.W.3d 384, April 10, 2017. The widow of a Tennessee carpenter, Claimant, sought workers compensation death benefits after her husband died because of an overdose of oxycodone combined with alcohol.

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Claimant's husband began taking oxycodone after suffering severe neck and back injuries in a car accident that occurred while he was working. Evidence presented during the matter indicated that at times Claimant's husband "took more of his opioid medication than prescribed and consumed alcohol while taking the pain medication." A state trial court concluded that the death was "a direct and natural consequence" of the injury and awarded benefits to the Claimant. The employer appealed to the Supreme Court of Tennessee. On appeal, the Supreme Court reversed the decision, holding that the husband's "failure to consume his medication in accordance with his doctor's instructions was an independent intervening cause," and thus his death was no longer causally related to his injury. In reaching this conclusion, the court rejected Claimant's argument that the death was still a direct and natural result of the work-related injury—even given the over-medication and alcohol use—because her husband "suffered from severe pain and anxiety that diminished his faculties to the extent that he was at risk to inadvertently overdose on his pain medication." In a footnote to the opinion, however, the court emphasized "the narrowness" of the fact-specific holding, adding that the court did not rule "that an individual can never prove that an overdose is the direct and natural result of the original compensable injury when a dependency or addiction to narcotics develops."

Channel Rish v. The Home Depot, Inc. and Insurance Company of the State of Pennsylvania, Supreme Court of Idaho, Case No. 43677, 390 P.3d 428, February 28, 2017. An Idaho woman, Claimant, suffered a knee injury while working that eventually required three knee surgeries. Several months after the third surgery, in August 2007, her doctor concluded that she had achieved "maximum medical improvement," but that she continued to need pain management treatment with another doctor. The pain management treatment lasted into 2009. In January 2009, Claimant's employer and workers compensation insurer (collectively, "Respondents") arranged for Claimant to undergo an independent medical examination that concluded that Claimant should stop taking pain medication. Respondents stopped paying for medical treatment in May 2009. Claimant filed a workers compensation claim seeking past and future benefits and medical care. The Idaho Industrial Commission ("Commission") denied the request for future benefits, concluding that all medical care Claimant received after she reached maximum medical improvement (in August 2007) was unreasonable. Claimant appealed to the Supreme Court of Idaho. On appeal, the court vacated the Commission's denial and remanded the matter for further proceedings. In the court's view, the Commission wrongly thought under Idaho law "that palliative care is compensable only if it actually improves the medical condition, thereby discrediting the important role of pain management." Instead, the court highlighted its previously held principle that "palliative, pain-killing treatments can be compensable even though they will not necessarily cure the employee's condition," while also adding that this principle holds "even if the pain management treatment consists of prescribed pain medication that results in addiction or dependency, which, in turn, requires additional treatment." Accordingly, the court remanded the matter back to the Commission to decide the reasonableness of pain management treatment given the particular facts of the case. One of the judges issued a "special concurrence" to emphasize that the court left it to the Commission "to make a determination as to whether or not the continued prescription of opioids was reasonable or unreasonable, or whether [Claimant] was suffering from opioid addiction." The judge noted several aspects of the case raising potential "red flags" about opioid addiction that should be considered by the Commission.

Kathleen Oakey v. May Maple Pharmacy, Inc., Court of Appeals of New Mexico, Case No. 34,914, 399 P.3d 939, April 13, 2017. Plaintiff is the personal representative of the estate of a 19 year-old woman who died from an overdose caused by doctor-prescribed medications, including oxycodone, oxymorphone, and alprazolam.

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Plaintiff filed suit against the doctor who prescribed the medication and the pharmacy who filled the prescriptions. With respect to the pharmacy, Plaintiff alleged causes of action based upon negligence and negligence *per se* for dispensing "excessive quantities of Schedule II or other dangerous drugs," that "departed from the standard of care, knowledge, and skill of a reasonably trained pharmacist" and breached regulatory duties to "properly and reasonably dispense controlled medications." Facts developed at trial showed that the pharmacy filled repeated "early" requests for medications including "at least one instance in which [the decedent] paid a substantial amount of cash to purchase OxyContin from the Pharmacy, although her prescriptions were paid with insurance on other occasions." The pharmacy moved to dismiss all claims against it on grounds that "[a] pharmacist who accurately fills prescription medication as prescribed by the doctor has no liability exposure to one who is injured by the drugs on claims the amounts were excessive, unless the pharmacist has some reason to know the specific customer will be harmed." A state trial court agreed with the pharmacy and dismissed the claims. Plaintiff appealed.

On appeal, the New Mexico intermediate appellate court noted that the case involves a matter of first impression in New Mexico, "the conduct required of retail pharmacists in filling prescriptions for controlled substances with a significant potential for abuse and addiction." That said, the court found the parties' case development and the trial judge's opinion lacking in that "the factual record and the law potentially relevant to this determination were not adequately developed below, nor did the district court actually rule on the issue." Accordingly, the court reversed the grant of summary judgment and remanded the case back to the trial court for further proceedings. Nevertheless, the appellate court weighed in on some aspects of the law applicable to the case. First, the court observed that the pharmacy appeared to advocate that a retail pharmacist owes only a "clerical-accuracy" standard to a customer, "requiring only that a retail pharmacist fill a prescription accurately, unless the prescription is facially invalid or the pharmacist has personal knowledge that filling the prescription would harm a specific customer." In the court's opinion, the pharmacy failed to establish this as the standard under New Mexico law, given federal and state laws and regulations governing pharmacy practice and the prescribing/dispensing of opioids as well as cases in other jurisdictions rejecting that standard for a higher one. Indeed, the court continued, a standard of care that requires nothing more than clerical accuracy where the facts involve "repeated requests for high dosages of Schedule II opioids taken with Schedule IV benzodiazepines. . . raises other policy concerns related to the potential harm to patients and the public at large." The court also concluded that the pharmacy failed to demonstrate to the trial court that it actually complied with its proffered standard, leaving genuine issues of material fact to be determined that preclude summary judgment. Finally, the appellate court held that the pharmacy did not address the Plaintiff's claim for negligence *per se*, nor did the trial court rule on that issue. In June 2017, the Supreme Court of New Mexico declined to review the intermediate appellate court's decision.

Research is current as of October 4, 2017. In order to ensure that the information contained herein is as current as possible, research is conducted using nationwide legal database software and individual state legislative websites. Please contact Jon Woodruff at 703.836.6100, ext. 100 or jwoodruff@namsdl.org with any additional updates or information that may be relevant to this document. This document is intended for educational purposes only and does not constitute legal advice or opinion. This project was supported by Grant No. G1799ONDCP03A, awarded by the Office of National Drug Control Policy. Points of view or opinions in this documents are those of the author and do not necessarily represent the official position or policies of the Office of National Drug Control Policy or the United States Government.

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