NJ Practitioner Liability for Patient Opioid Abuse

A look at new issues that are developing

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Over the last two decades, our country has witnessed a staggering rise in prescription opioid abuse resulting in addiction, overdose and death. According to the American Society of Addiction Medicine, both sales of prescription opioids and the overdose death rate roughly quadrupled from 1999 to 2008. The Centers for Disease Control and Prevention reports that, in 2014 alone, over 28,000 people suffered opioid-related deaths, of which at least half involved prescription opioids. The CDC estimates that those addicted to prescription pain killers are 40 times more likely to become addicted to heroin. The opioid crisis has reached a point where first-responders and even some schools now carry the opioid antidote Narcan in order to provide emergency treatment to victims of overdose.

As this public health epidemic gains more public awareness, we are seeing a shift in public perception of addiction as more of a mental health issue. Aggressive steps are being taken by federal, state and local governments to curtail the epidemic. In turn, increased pressure is placed on health-care practitioners to use sound clinical judgment when determining whether to prescribe opioids, such that new sources of liability have arisen. This article provides an overview of prescriber liability claims based upon opioids and discusses recent efforts to halt the opioid crisis, including prescription monitoring programs and the promotion of abuse-deterrent opioids, and their impact on assessing liability.

Overview of the Claims

A practitioner may be liable for negligently prescribing opioids to a patient who abuses or misuses the drug and then suffers injury or death as a result. While prescription opioids provide relief for acute and chronic pain, given the risks of addiction and overdose, prescribers must be vigilant in properly selecting the type, formulation, dosage, quantity and duration of use while also screening and monitoring patient usage. The prescriber must be especially careful with patients who have a history of prior abuse, as they are vulnerable to future abuse and a risk of relapse into addiction.

For instance, in *Taglieri v. Moss*, 367 N.J. Super. 184 (App. Div. 2004), a doctor was sued after knowingly prescribing excessive amounts of Schedule II drugs to two patients. One patient died from a fall while under the influence. The other patient

allegedly became addicted after being given post-dated and undated prescriptions (including 3,760 units over a seven-month period). The court granted partial summary judgment in favor of the plaintiff on liability, but left causation and damages for the jury to determine. The Appellate Division affirmed, noting that the evidence was "so one-sided."

Causation and damages issues present even more complex problems, as illustrated in *Komlodi v. Picciano*, 217 N.J. 387 (2014). In *Komlodi,* a doctor prescribed a fentanyl patch to a patient with a history of drug abuse. The patient ingested the patch and suffered a brain injury. The trial court charged on pre-existing condition (*Scafidi*), avoidable consequences and superseding/intervening cause. The jury found a deviation from the standard of care and that the deviation increased the risk of harm, but that the increased risk was not a substantial factor in causing the injury. The Appellate Division held that the *Scafidi* charge was not warranted because the patient ingested the patch and suffered an acute injury after it was negligently prescribed. The N.J. Supreme Court agreed, noting that the case did not involve a claim that negligent treatment caused the prolonging or aggravation of a pre-existing illness.

Komlodi does not substantially alter the applicability of the *Scafidi* charge to cases involving the negligent prescription of opioids to patients with a history of substance abuse. Whether the charge applies still depends upon the nature of the injury claimed. If, as in *Komlodi*, a patient abuses or misuses a negligently prescribed drug and suffers an acute injury as a result, then the charge is not warranted. If, however, the patient is negligently prescribed the drug and alleges to have suffered a prolonging or worsening of a pre-existing addiction, such as a relapse, then the *Scafidi* charge would be indicated. Given the fact-sensitive nature of causation in these types of cases, an expert in addiction psychiatry is important to explain to the jury the nature and extent of the injury claimed, the type of therapy required, and whether there is an increased risk of future harm, such as the risk of relapse.

Non-Use of PMP Is Not a Potential Source of Civil Liability

New Jersey's development of a Prescription Monitoring Program (PMP) has significantly enhanced prescribers' ability to adequately screen and monitor prescription opioids given to patients. Despite practitioners' now being required to access the PMP database for purposes of prescribing opioids and monitoring usage, the statute still provides immunity from civil liability for noncompliance.

In 2007, New Jersey enacted N.J.S.A. 45:1-45 et seq. (P.L. 2007, c. 244, s. 25), which established an electronic PMP within the Division of Consumer Affairs. The law was implemented in 2011. It requires pharmacists to submit patient and prescriber information to a PMP database relative to drugs patients obtain. It also allows prescribers access to the database in order to check what drugs patients obtained in the past and to track usage of prescriptions given. In its original iteration, the PMP law did not require prescribers to register and access the PMP database.

On July 18, 2015, the statute was amended by way of P.L. 2015, c. 074, to include additional requirements to strengthen efforts to curb prescription opioid abuse. Under the amended statute, practitioners who are issued or renew their CDS registration shall also now be registered to access PMP information. Most significantly, the amended statute has a new provision (C. 45:1-46.1) that requires prescribers to access the database the first time they prescribe a Schedule II drug to a new patient for acute or chronic pain. For prescriptions of Schedule II drugs written on or after the effective date of the statute, the prescriber must access the database on a quarterly basis during the period in which the patient continues to receive the prescription. There are, however, 11 exceptions to the access requirement, the application of which is based upon the clinical setting in which drugs are prescribed and the practicality of accessing the database at the time of care.

If the practitioner is required to be registered with and access the program, and the database may reveal critical information about the patient's prior and concurrent usage of opioids, then it stands to reason that the failure to utilize the PMP database could serve as evidence of negligence. Pursuant to N.J.S.A. 45:1-48, however, a prescriber is immune from civil liability for noncompliance with the statute. The statute is also replete with confidentiality provisions that make no mention of allowing disclosure for use in civil litigation. Reconciling the immunity provision with the new access requirement is an issue that has not yet been litigated. From the defense perspective, if the plaintiff seeks to state a claim for noncompliance with the statute, there is a viable claim of immunity that should be entertained.

Will Non-Use of Abuse-Deterrent Opioids Become a Potential Source of Civil Liability?

The development of abuse-deterrent opioids (ADOs) as an alternative to traditional prescription opioids may eventually have an impact on prescriber liability in the near future. At this time, ADOs are viewed as a viable, albeit more costly, alternative to nondeterrent opioids that reduce the risk of abuse and misuse either by way of pill formulation or chemical composition.

Recent efforts to promote the creation of new ADOs include the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research's (CDER) April 2015 Guidance for abuse-deterrent opioid evaluation and labeling, and its March 2016 Draft Guidance for generic ADOs. As stated in the CDER's April 2015 Guidance, the development of ADOs to curtail prescription opioid abuse is viewed as a "high public health priority" for the FDA. Further, the FDA intends to take a "flexible, adaptive approach" to evaluating and labeling ADOs.

On Jan. 11, the New Jersey Legislature passed Bill A4271, which would have required health insurers to provide coverage for ADOs. Shortly thereafter, on Jan. 19, A4271 was pocket-vetoed because the estimated cost to the state (over $11 million per year) outweighed what is currently known about ADO effectiveness. Since that time, on March 10, the U.S. Senate cleared the Comprehensive

Addiction and Recovery Act of 2016 (S.524). The act is under consideration by the House at this time. If enacted, the act would authorize the U.S. Attorney General to award grants to states to support comprehensive opioid abuse response initiatives. If enacted, the act could provide more resources to New Jersey such that A4271, if reintroduced, may become more financially feasible.

If and when ADOs become more mainstream, their use may become the new standard such that practitioners may be held liable for not prescribing them. The decision whether to prescribe ADOs rests upon the prescriber's judgment based on the particular patient. As considerations of cost and efficacy of ADOs raise questions about their benefit, it remains to be seen whether ADOs will be a new standard.

Conclusion

New Jersey and the nation are taking significant steps to address the prescription opioid crisis, including improvements to prescription monitoring programs and efforts to promote the creation and use of new drugs with abuse-deterrent qualities. Ongoing efforts to stop the opioid crisis, and increased public awareness, serve as a reminder that practitioners must remain vigilant when prescribing opioids.

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