IADC COMMITTEE NEWSLETTER

MEDICAL DEFENSE AND HEALTH LAW

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IN THIS ISSUE

This article is intended to serve as a primer for the defense attorney's use in defending pain management physicians against allegations of over-prescribing opioid pain medications to patients and also to provide the tools necessary for effective cross examination of the pain management physician's opinions regarding future medical care involving opioid therapy.

The Risks of Long Term Use of Narcotics for Pain Management:
Preparing an Effective Cross Examination of the Over Prescriber

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"Why then, can one desire too much of a good thing?"
WILLIAM SHAKESPEARE, AS YOU LIKE IT, act IV, sc. I (1623)

The above quote was risqué at the time of its publication, but in the centuries that have followed the truth that something good becomes just the opposite when pursued to excess has become a mainstream observation. In the context of opioid pain relievers, recent studies demonstrate too much of these drugs can indeed be lethal. Thus, the objective of this report is to provide health care attorneys with tools to both defend pain management physicians against allegations of over-prescribing opioid pain medications and to effectively rein in the opinions of the prescribing physician in cross examination.

The Epidemic of Accidental Death by Overdose

The instances of opioid-related overdoses is on the rise and defense attorneys need to be cognizant of this not only for purposes of shielding health care providers against charges of prescription abuse, but also to ensure that treating physicians do not overly prescribe expensive pain medications to personal injury plaintiffs. In 2010, a groundbreaking medical article was published and quickly gained acceptance, explaining that Oxycodone has a Morphine equivalent and that potential overdose events occur at or above 100 mg Morphine equivalents, with an eleven-fold increase in the risk of a life threatening overdose at that level. This article was the first notice to many that Oxycodone was potentially more lethal than morphine and that chronic pain patients were experiencing fatal overdoses at an alarming rate.[1]

Dr. Mark D. Sullivan commented in 2011 that despite the absolute risk of mortality associated with high-dose opioids seemingly low at 1%, "death due to therapy for a nonprogressive, nonfatal condition must be taken very seriously."[2] He noted that because other harms such as opioid misuse, alcohol, drug-related medical encounters and interestingly, fractures have also been demonstrated to have a relationship to the prescribed daily dose of opioid therapy, other aspects of opioid exposure such as the number of days the medication is prescribed to be taken and long versus short-acting formulations also seem to be related to risk of adverse outcomes of opioid therapy; however, dosage is the most well studied risk factor.

Notably, all the higher-risk aspects of opioid exposure are more common in higher-risk patients with histories of substance abuse and mental health disorders. In his article, Dr. Sullivan calls this "pairing of high-risk patients with high-risk regimens adverse selection" and believes this constitutes an important link between increases in opioid use and corresponding increases in opioid abuse and overdose.

The Center for Disease Control and Prevention published a report on November 1, 2011, announcing that overdose deaths involving

[1] K. M. Dunn, K. W. Saunders, et al, *Opioid Prescriptions for Chronic Pain and Overdose. A Cohort Study*. ANN INTERN MED., vol. 152, pp. 85-92 (2010).

[2] Mark D. Sullivan, MD, PhD, *Limiting the Potential Harms of High-Dose Opioid Therapy*, ARCH INTERNAL MEDICINE, vol. 171, no. 7, p. 692 (April 11, 2011).

opioid pain relievers had increased to the point that they outnumbered the number of accidental deaths by overdose of both cocaine and heroin combined and constituted an epidemic in the United States, the severity of which was only worsening with implications being that health care providers were advised to only use opioid pain relievers in carefully screened and monitored patients when non-opioid treatments are demonstrated to be insufficient to manage pain.[3]

Leonard J. Paulozzi, M.D., MPH, followed these works with a 2012 study in which he examined the likelihood of death from chronic ingestion of opioids and noted an odd ratio for risk of overdose at four times the risk when taking 40 mg of daily morphine equivalent.[4] He noted that health care providers were in the best position to identify patients with overdose risk factors including multiple prescriptions, providers and pharmacies and high daily doses of opioid analgesics, and to then make informed prescribing decisions with a better appreciation of the patient's risk for serious adverse events.

By 2014, concerns of mortality associated with the chronic use of opioids was well documented in medical literature, some of which has been cited above. A study reported in the Annals of Internal Medicine warned that deaths resulting from prescription opioid overdoses had increased dramatically necessitating guidelines for prescribers.[5] The number of annual fatalities associated with prescription opioids had risen from 4,000 in 1999 to nearly 14,000 by 2006. The increased mortality tracked the increased number of patients being prescribed the medications along with acceptance of chronic pain patients in treatment plans and allowing patients to self-report adequate pain control following upward titration of dosage amounts.

Accepted guidelines for prescribers of opioids in the treatment of chronic pain have now established a generally accepted standard of care to include mandatory drug testing of patients and calling patients back into the office in between prescription refills for pill counts.[6]

Careful Treatment of Chronic Pain Patients: Developing a Treatment Plan

Whether representing a prescriber of opioids or preparing for cross examination of such a witness in deposition, one of the first questions one might ask in evaluating prescription drug usage and attendant costs is

[3] Centers for Disease Control and Prevention, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008*, MORBIDITY AND MORTALITY WEEKLY REPORT, v. 60, Nov. 1, 2011; See also Len Paulozzi, MP, MPH, Centers for Disease Control and Prevention, *Populations at Risk for Opioid Overdose* (April 12, 2012), http://www.fda.gov/downloads/Drugs/NewsEvents/UCM300859.pdf

[4] L. J. Paulozzi, E. M. Kilbourne, N. G. Shah, et al., *A History of Being Prescribed Controlled Substances and Risk of Drug Overdose Death*, PAIN MEDICINE, vol. 13, pp. 87-95 (2012).

[5] Teryl K. Nuckols, MD, MSHS, Laura Anderson, MPH; et al., *Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain*, ANN INTERN MED., vol. 160, pp. 38-47 (2014).

[6] A. M. Trescot, M. V. Boswell, et al., *Opioid Guidelines in the Management of Chronic Non-Cancer Pain*, PAIN PHYS., vol. 9(1), p. 1 (2006), http://www.health.utah.gov/prescription/pdf/guidelines/Opioid%20Guidelines%20in%20the%20management%20of%20chronic%20non-cancer%20pain.pdf.

whether objective criteria were met before the patient is determined to be an acceptable candidate to be prescribed opioid therapy. An established treatment plan implementing objective criteria is essential and the practitioner's failure to have one in place will be grounds for fertile cross examination.

Questions that must be asked by the provider prior to initiating therapy include whether reasonable alternatives to treatment exist and whether they have been tried without success. Another essential question is whether the patient is likely to improve with opioid treatment. In answering this question, the prescriber should consider whether the patient showed improvement on opioid treatment in the acute and subacute phases, and whether other treatments were attempted, including non-opioid medications. Another element of a valid treatment plan includes an assessment of the patient's risk of addiction via screening implementing specific questions regarding current use of intoxicants including alcohol, illegal drugs, other prescription drugs and even over the counter medications.[7]

Red flags indicating opioids may not be helpful in the chronic phase must not be ignored. If the patient reports little to no relief with opioid therapy in the acute and sub-acute phases, opioid therapy is a questionable choice. If the patient has been given a diagnosis in one of the particular diagnostic categories wherein opioid therapy has not been shown to demonstrate good success, the appropriateness of the prescriber's decision may be called into question. Examples include conversion disorders, somatization disorders, and pain disorders associated with psychological factors such as anxiety, depression or a previous history of substance abuse.[8]

The careful prescriber will have taken the following steps prior to instituting a therapeutic trial of opioids: (1) attempted to determine whether the pain is nociceptive or neuropathic (opioids are not generally recommended as a first-line therapy for some neuropathic pain); (2) required goal-setting by the patient, with continued use of opioids contingent upon meeting these goals; (3) attempted a trial of non-opioid analgesics; (4) performed assessments of baseline pain and function including social, physical, psychological, daily and work activities, conducted using a validated instrument or numerical rating scale; (5) ensured that the pain related assessment included a history of pain treatment and its effect on pain and function; and (6) assessed the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function. If the pain management prescriber has not utilized some or all of these precautions, valid criticisms may be leveled against the prescriber for failure to observe recognized conservative alternatives to opioid prescriptions.

It has been noted that the patient should have at least one physical and psychosocial assessment by the prescribing physician (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate

[7] See Mark D. Sullivan, M.D., PhD, *Limiting the Potential Harms of High-Dose Opioid Therapy*, JAMA INTERNAL MEDICINE, vol. 171, no.7 (April 11, 2011).

[8] See *id*.

with imaging studies and/or physical findings and/or when psychosocial concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained.[9]

Defense counsel should also be aware that due to the serious risks of long term usage of opioids, the FDA now requires special safety procedures called Risk Evaluation and Mitigation Strategies, or REMS, be put into place to protect patients who are prescribed opioids. The REMS require patients for whom opioids are prescribed to receive a Medication Guide, informing patients of the serious associated risks of the drug. Defense counsel can advise their client to make sure this is documented and placed in the patient record, and consideration should be given to having the patient sign and acknowledge that they have reviewed this documentation.

Initiating Therapy

Once it is properly determined that a patient is a suitable candidate for a trial of opioid therapy, there are three phases of opioid therapy: initiation, titration and maintenance. The selection of an appropriate opioid agent and dose for the individual patient following consideration obtained in the comprehensive assessment is done in the initiation phase. The titration phase involves modification of dosage to achieve the maximum pain relief with a minimum of intolerable or unmanageable adverse side effects. When the patient's required daily dose becomes and remains relatively stable, the maintenance phase has begun.10

On-Going Management

Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. These domains have been summarized as the "4 A's" and consist of analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs.[11]

According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.[12]

The careful prescriber will attempt to ensure that all prescriptions are written by a single practitioner and filled at a single pharmacy, and that the medications be taken as directed. In the titration phase, the lowest possible

[9] See Simon G. Tordoff, FRCA, FIPP et al, *Chronic Pain and Prescription Opioid Misuse*, CONTINUING EDUCATION IN ANAESTHESIA, CRITICAL CARE AND PAIN, vol. 20(5), pp. 158-161 (2010).

[10] The Management of Opioid Therapy for Chronic Pain Working Group, Dept. of Veterans Affairs, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, p. 25 (May 2010).

[11] Kenneth L Krish, PhD, Steven D. Passik, PhD, *Managing Drug Abuse, Addiction and Diversion in Chronic Pain: The 4 A's for Ongoing Monitoring*, PAIN, vol. 112, pp. 65-75 (2004).

[12] Medical Board of California, *Guidelines for Prescribing Controlled Substances for Pain* (Nov. 2014), http://www.mbc.ca.gov/Licensees/Prescribing/Pain_Guidelines.pdf.

dose should be prescribed to improve pain and function.

Office visits during the ongoing management phase should include review and documentation of pain relief, functional status, appropriate medication use, and unwanted side effects. It is believed to be generally advisable for the prescribing physician to call in the patient for random drug screens and pill counts in between office visits to ensure the medications, and no others, are being taken as prescribed.[13] Some practitioners will admit to these procedures being required by the standard of care of pain management physicians.

At home, in order to aid the physician in assessing pain and functioning, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.

When Opioids Should be Discontinued

The Official Disability Guidelines (ODG) published a pamphlet in 2013 for prudent prescription practice using evidence based medicine, in which suggestions are offered for circumstances in which opioids should be discontinued.[14] Such instances include situations where the patient continues to have pain with intolerable adverse effects; has a lack of significant benefit despite doses up to 120 mg per day of Morphine equivalent dosage; has resolution of pain; requests discontinuance; or where serious non-adherence occurs. That pamphlet also advises discontinuation where there is evidence of illegal activity such as diversion, stealing or forgery of prescriptions, motor vehicle accidents related to opioid use or aggressive/threatening behavior.

Conclusion

Few would dispute that opioid therapy is not going away. When used properly, it can be an effective pain management tool for patients, which is no doubt, a good thing. Nonetheless, like all good things, the key is making sure that protocols are put in place to ensure that patients do not indulge in too much of this good thing. Clearly, the literature advises to be wary of opioid therapy and that the risks of addiction and premature death are real. A goal of weaning the patient away from Morphine equivalency doses should be part of a treatment plan and precautions must be observed along the way to ensure the patient is not diverting or abusing the medications, all of which may be covered in deposition testimony with both the patient and the prescribing doctor. As the medical literature is evolving and standards are changing, defense counsel are advised to keep abreast of new developments in this area of medical treatment, because by being armed with such information, both defense counsel and physicians will be better prepared at all stages

[13] Paul J. Christo, MD, Laxmaiah Manchikanti, MD, et al., *Urine Drug Testing in Chronic Pain*, PAIN PHYSICIAN, vol.14, pp. 123-143 (2011).

[14] Work Loss Data Institute, Just *the facts on Opioid Management: Prudent Prescription Practice Using Evidence-Based Medicine (EBM)*, (Summary of Official Disability Guidelines), See http://www.worklossdata.com/new-odg-opioid-outreach-flyer-available.html (June 2013).

of litigation involving claims of prescription opioid abuse.

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