

## Medicolegal rounds: Medicolegal issues and alleged breaches of standards of medical care in a patient motor vehicle accident allegedly related to chronic opioid analgesic therapy

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### ABSTRACT

*The objective of this medicolegal case report is to present the details of the case of a chronic pain patient (CPP) who was placed on chronic opioid analgesic therapy (COAT) and was involved in a motor vehicle accident, alleged in litigation to be related to COAT. COAT standards are in a process of evolution, and this process is influenced by recent literature developments. We aim to present both the plaintiff's and defendant's expert witnesses' opinions on whether the defendant physician fell below the "standard" in allowing the CPP to drive. Both the methadone and the driving literature are utilized to explain the defendant's and plaintiff's experts' opinions and the differences between them. Based on these opinions, we have attempted to develop some recommendations on how pain physicians should approach the problem of deciding whether patients should be allowed to drive when on COAT.*

*Key words: chronic pain, intractable pain, opioids, chronic opioid analgesic therapy, driving, motor vehicle accidents, standards of medical care, informed consent, breaches of standards, methadone*

### INTRODUCTION

Chronic opioid analgesic therapy (COAT) for chronic, benign, nonmalignant pain, although still controversial,<sup>1</sup> has become part of the pain physician's armamentarium and has recently been adopted as a treatment by other specialties, such as family medicine. The acceptance of COAT as a potential treatment option for chronic, benign, nonmalignant pain is the result of a number of pain medicine developments that began to surface in the early 1980s. The first and most important of these was the

appearance of published studies claiming success in treating intractable chronic pain patients (CPPs) with COAT without the development of significant addiction.<sup>2,3</sup> Second, COAT treatment for pain was demonstrated to be efficacious. Recently, this literature has been compiled and analyzed in two meta-analyses and in one evidence-based, structured review.<sup>4-6</sup> Both meta-analyses (of over 40 double-blind, placebo-controlled studies) showed opioids to be more effective than placebo, and one demonstrated improvement in functional outcomes.<sup>5</sup> A significant body of literature developed which spoke to the chronic undertreatment of pain by healthcare professionals, and research studies reported that some physicians were prejudiced against the use of opioids ("opiophobia") because of fears of iatrogenic addiction.<sup>7,8</sup> In the late 1990s, the chronic undertreatment of pain led state licensing boards to begin to develop policies that supported appropriate opioid prescribing, rather than policies that hindered opioid prescribing. Early in this century, the Joint Commission on Accreditation of Healthcare Organizations incorporated the adequate treatment of pain as a patient right. Finally, in the 1980s drug technology developed a number of controlled-release opioids, which were believed to control pain in a more effective manner than the immediate-acting opioids.

In response to the widening use of COAT and publicity over the abuse of medically prescribed opioids, state medical boards developed state-specific physician practice guidelines for the appropriate utilization of COAT; these plans were based on some of the model guidelines developed by the American Academy of Pain Medicine and the American Pain Society.<sup>1,9</sup> The widening literature on how to "do COAT" and the development of the aforementioned guidelines then led to their application as "standards" in malpractice cases related to COAT.<sup>1</sup> Some

of these cases have been reported and explored in reference to pseudoaddiction, suicide related to unmanaged chronic pain, and methadone use.<sup>10,11</sup> An issue that has not yet been explored in the COAT/medicolegal/opioid-prescribing literature is that of the medicolegal standard for COAT in relation to driving rights. The medicolegal case discussed in this article addresses this issue.

## CASE REPORT

Mr. X was a 45-year-old white male who presented to a pain physician's office with a chief complaint of chronic low back pain. His pain had started after a lifting injury at work when he was 40 years old. Subsequent surgery for an L5-S1 disc rupture had not relieved his pain. As a result, he was not working, had settled his workers' compensation case, and was on Social Security. Since the surgery, Mr. X's pain had worsened. He was prescribed hydrocodone (four 5 mg tablets per day), but the medication was yielding unsatisfactory pain control (pain levels over a 24-hour period ranged from 7 to 9 out of 10). No further surgery was indicated, and the current working diagnosis was degenerative disc disease and myofascial pain syndrome. Mr. X had also failed physical therapy but had not undergone any interventional procedures. He was referred by his family doctor for evaluation for the possibility of an epidural.

Mr. X denied any previous psychiatric treatment or any current psychiatric symptoms such as depression or anxiety. In addition, Mr. X denied ever having been a smoker, having a previous history of alcohol abuse/addiction, and any illicit drug use or treatment. There were no other medical problems, and he was not taking any medications other than the hydrocodone. Mr. X had a standard physical examination, and his recent imaging studies were reviewed. It was concluded that Mr. X was unlikely to benefit from epidurals and was offered COAT as an alternative. Mr. X consented and signed the standard COAT agreement. He was then placed on methadone 2.5 mg BID and was advised to discontinue hydrocodone use. In addition, he was started on tizanidine 4 mg HS for spasms. A follow-up appointment was scheduled for two weeks in the future, and Mr. X was provided with a call number. On the second day after the initiation of methadone treatment, Mr. X advised the prescribing office that he had been involved in a motor vehicle accident (MVA) (he had hit a tree) and that he thought this had happened because of the medication. He claimed that his low back pain was now worse. Two years later, the office received a letter from Mr. X's lawyers initiating a malpractice suit.

In the litigation discovery process for medical malpractice cases, the plaintiff's lawyer is allowed to name an expert who can determine whether the defendant (in this case the pain physician) fell below the standard of

care in the plaintiff's treatment (that which a reasonably prudent and competent physician with the same or similar training would do in the same or similar circumstances).<sup>10</sup> If that expert finds that the plaintiff's care was below the standard, then in all likelihood the malpractice case will proceed. Similarly, upon receipt of the complaint the defendant's lawyer is able to name an expert who will then respond to all the allegations of falling below the standard as opined by the plaintiff's expert. Table 1 presents the opinions of the plaintiff's and the defendant's medical experts on the alleged breaches of the standard of medical care in Mr. X's case. As can be seen, the plaintiff's expert found eight alleged breaches of standards. The defendant's medical expert disagreed and absolutely refuted allegations 1, 3, 4, 7, and 8. He also partially refuted allegation 2. According to the record provided, he could not refute allegations 5 and 6. The eventual legal outcome of this case was that it was settled for much less than the requested amount.

## DISCUSSION

The defendant's expert's responses to the allegations of the plaintiff's expert (Table 1) will be discussed below.

### Allegation 1

In administering COAT and selecting CPPs for COAT, it is important to remember that most state practice guidelines indicate that CPPs selected for COAT should have intractable chronic pain and should have failed to find relief through other methods of pain treatment. This information should be documented to allow prescribers to avoid or refute this allegation.

### Allegation 2

In a recent evidence-based, structured review, Fishbain et al.<sup>12</sup> examined the epidemiological evidence regarding whether opioids are associated with intoxicated driving, MVAs, or MVA fatalities. The evidence they found indicates that opioids are probably not associated with intoxicated driving, are not associated with MVAs, and are probably not associated with MVA fatalities. In another evidence-based review, Fishbain et al.<sup>13</sup> examined the evidence for opioid-related driving-skill impairment in opioid-dependent/tolerant patients. They found moderate, generally consistent evidence that there is no impairment of psychomotor abilities in patients on chronic opioid therapy. Their study reports strong, consistent evidence that there is no greater incidence in motor vehicle violations/MVAs in such patients versus comparable controls, and they present consistent evidence that no impairment has been measured in driving simulators for off- or on-road driving. It is to be noted that Mr. X had

**Table 1. Allegations made by the plaintiff's expert witness as to breach of standards in Mr. X's medical care and the responses to those allegations made by the defendant's expert witness**

Allegation	Response
1. There was no indication or reason to place Mr. X on COAT. Thus, this action is below the standard.	1. Mr. X's history indicated that he suffered from chronic pain that was not responsive to other forms of treatment, making him an "intractable" CPP. According to the state practice guidelines for COAT, this made Mr. X a candidate for COAT. Thus, no standard was breached here.
2. Mr. X's accident was related to his taking methadone.	2. Based on the literature, there is a reasonable degree of medical certainty that Mr. X's accident may not have been related to the opioid (methadone). <sup>12</sup> In contrast, the accident could have been related to other issues, e.g., patient characteristics, inattention, etc.
3. The defendant negligently prescribed methadone.	3. The defendant prescribed a very low starting dose of methadone that, according to equivalency tables, was approximately equivalent to or less than the dose of hydrocodone that the patient had been taking. Thus, no standard was breached here.
4. The defendant was negligent in that he failed to advise the plaintiff not to drive while on opioids.	4. There is a reasonable degree of medical certainty, as demonstrated in the literature, that patients taking opioids on a routine basis can drive safely. <sup>12,13</sup>
5. The defendant was negligent in that he failed to obtain informed consent from the plaintiff regarding the possibility that methadone could, under certain circumstances, be sedating, and could thus interfere with the plaintiff's ability to drive.	5. There is no evidence of this type of informed consent being obtained or requested in the defendant's notes or in the COAT agreement.
6. The defendant was negligent in that he failed to advise the plaintiff or seek informed consent regarding the possibility that methadone could, under certain circumstances, interact with other drugs (such as tizanidine) and thereby cause increased sedation.	6. There is no evidence of this type of informed consent being obtained or requested in the defendant's notes or in the COAT agreement.
7. The defendant was negligent in that he did not monitor the plaintiff closely enough after methadone treatment was initiated.	7. The defendant placed the plaintiff on methadone and tizanidine and scheduled a two-week follow-up appointment. The defendant was also available to the plaintiff by phone for advice regarding changes in medication dosages. If the plaintiff was feeling sedated on the new medication, a call should have been placed to the defendant.
8. The defendant was negligent in that he chose to place the plaintiff on methadone rather than another long-acting opioid with fewer side effects.	8. There is currently no absolute contraindication noted in the literature to utilizing methadone in COAT as a first-line drug. Although this literature may be developing, the defendant did not fall below the standard here.

previously been exposed to hydrocodone and was presumably tolerant to that opioid. Thus, he should have been partially tolerant to the effects of methadone. Based on the information in the two above-mentioned reviews, the defendant's expert concluded that Mr. X's accident may not have been related to methadone.

**Allegation 3**

When changing from one opioid to another, equivalency tables should be utilized, and the calculated dose of the new opioid should be documented in the patient's

chart. This was done by the defendant, and the very low dose of methadone utilized in a non-opioid-naïve subject essentially negates the possibility that this standard was breached in this case.

**Allegation 4**

It is clinical lore that patients on psychotropic medications should be advised not to drive or should be warned about driving. However, according to the studies described above regarding allegation 2, this clinical lore may be incorrect in reference to opioids.<sup>12,13</sup> The

reviewed literature indicates that patients on opioids can drive safely, especially when they have developed a tolerance to the sedating effects of the medication.<sup>12,13</sup> Thus, the defendant's expert concluded that there was no breach here.

### **Allegation 5**

Although the evidence in the two cited evidence-based reviews indicates that patients stabilized on COAT and tolerant to opioids can be advised that they can drive,<sup>12,13</sup> Fishbain et al.<sup>13</sup> present some caveats to this possibility.

First, patients placed on long-term opioid treatment should be advised of the current status of this driving research. They should then be advised that whether they do or do not drive should be based on this information, but that it is their own personal decision. Third, they should be advised that if they choose to drive, they should obey the following rules:

- After beginning opioid treatment or after a dose increase, the patient should not drive for four to five days.
- Patients should not drive if they feel sedated.
- Patients should report sedation/unsteadiness/cognitive decline immediately to their physicians so that a reduction in dosage can be initiated.
- Under no circumstances should patients use alcohol or other illicit drugs such as cannabinoids and then drive.
- Patients on opioids should avoid taking any over-the-counter antihistamines.
- Patients should not make any changes in their medication regimens without consulting with their physician.

A final issue pointed out by Fishbain et al.<sup>13</sup> relates to what the physician should do if he or she is requested to complete paperwork where questions are asked about a patient's driving ability. For this problem, the same type of approach was recommended. The physician should explain the current status of the relevant research in the paperwork. In addition, the physician should also report whether he or she has noted any opioid side effects that might interfere with driving (or the absence of such effects). However, if a specific question relating to whether the patient can or can not drive is encountered, that status should be marked as unknown. More specifically, the physician should state that he or she does not

have knowledge of the patient's ability to drive, as that can only be determined via a driving simulator and/or on-road/off-road driving tests.

According to the above recommendation, some form of informed consent in reference to the risks of driving concurrent with opioid use should have been obtained from Mr. X. Ideally, COAT agreements could be utilized for this issue.

### **Allegation 6**

Unfortunately, there are large variations in the pharmacokinetics of methadone from one individual patient to the next, and this makes it a difficult drug to use.<sup>11</sup> Methadone is characterized by a slow elimination phase, which can vary from 4.2 to 130 hours.<sup>11</sup> Thus, variations in the elimination phase could lead to accumulation toxicity in some patients. In addition, methadone may interact with other drugs, as it particularly inhibits the CYP2D6 isoenzyme systems. This inhibition can affect the levels of drugs metabolized by CYP2D6.<sup>14</sup> Tizanidine is 95 percent metabolized in the liver, and therefore any inhibition of liver metabolism could cause decreased tizanidine metabolism, resulting in increased sedation. Thus, there is a possibility that methadone, in spite of the low dose used, accumulated in the plaintiff and/or interacted with tizanidine, causing sedation. As noted in the allegations, no informed consent for these possibilities was furnished. It has been recommended that when mixing drugs, the patient should be educated about all potential problems.<sup>15</sup>

### **Allegations 7 and 8**

It is recommended that the physician remain available for patient monitoring when a patient is placed on a new medication.<sup>15</sup> The defendant, by the nature of his situation, did not fall below the standard here. In reference to allegation 8, physicians can utilize whichever drug they wish over any other drug. This applies as long as the side-effect profile of the chosen drug is not so burdensome that there is a specific contraindication for use in the patient in question.

### **CONCLUSIONS**

This case is interesting and instructive for a number of reasons. First, it outlines the process by which allegations are generated by the "experts." Second, it outlines how experts utilize the current literature in arriving at their opinions. Third, this presentation outlines the importance of the agreed-upon standards of care and how they are applied utilizing current literature. It is to be noted that there is an intimate relationship between the current literature and the development of the standards.

However, when a standard of care is in the process of being developed, such as with recent research reports, most jurisdictions recognize the “respectable minority” defense.<sup>16</sup> This defense applies when a standard of care is in a transitional phase, as are those being developed for COAT, and it may apply here to allegations 5 and 6. A “respectable minority” of physicians may not have provided informed consent for methadone in circumstances such as Mr. X’s because this information was not widely disseminated. In that case, this alleged breach would not necessarily be deemed negligence by the courts. Finally, this case brings to light a potential area of malpractice liability for physicians administering COAT: patient driving risk.

Physicians utilizing COAT should remain abreast of the developing COAT literature. This can be an effective method for improving COAT patient care and decreasing liability risk.

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## REFERENCES

1. Fishbain DA: Chronic pain and addiction. In Boswell MV, Cole BE (eds.): *Weiner's Pain Management: A Practical Guide for Clinicians*, 7th edition. Boca Raton, FL: American Academy of Pain Management, CRC Taylor & Francis Press, 2006, pp. 117-139.
2. Portenoy RK, Foley K: Chronic use of opioid analgesics in non-malignant pain: Report of 38 cases. *Pain*. 1986; 25(2): 171-186.
3. Portenoy R: Opioid therapy in the management of chronic back pain. In Tollison CD (ed.): *Interdisciplinary Rehabilitation of Low Back Pain*. Baltimore: Williams & Wilkins, 1989, pp. 137-157.
4. Eisenberg E, McNicol ED, Carr DB: Efficacy and safety of opioid agonists in treatment of neuropathic pain of nonmalignant origin: Systematic review and meta-analysis of randomized controlled trials. *JAMA*. 2005; 293(24): 3043-3052.
5. Furlan AD, Sandoval JA, Mailis-Gagnon A, et al.: Opioids for chronic noncancer pain: A meta-analysis of effectiveness and side effects. *CMAJ*. 2006; 174(11): 1589-1594.
6. Devulder J, Richarz U, Nataraja SH: Impact of long-term use of opioids on quality of life in patients with chronic, nonmalignant pain. *Curr Med Res Opin*. 2005; 21(10): 1555-1568.
7. Bendtsen P, Hensing G, Ebeling C, et al.: What are the qualities of dilemmas experienced when prescribing opioids in general practice? *Pain*. 1999; 82(1): 89-96.
8. Weinstein SM, Lang LF, Thornby JI, et al.: Physicians' attitudes toward pain and the use of opioid analgesics: Results of a survey from the Texas Cancer Pain Initiative. *Southern Med J*. 2000; 93(5): 479-487.
9. Federation of State Medical Boards of the United States, Inc.: Model guidelines for the use of controlled substances for the treatment of pain. *S D J Med*. 1999; 52(1): 25-27.
10. Fishbain DA: Medico-legal rounds: Medico-legal issues and breaches of “standards of medical care” in opioid tapering for alleged opioid addiction. *Pain Med*. 2002; 3(2): 135-142.
11. Fishbain DA, Cutler RB, Cole B, et al.: Medico-legal rounds: Medico-legal issues and alleged breaches of “standards of medical care” in opioid rotation to methadone: A case report. *Pain Med*. 2003; 4(2): 195-201.
12. Fishbain DA, Cutler RB, Rosomoff HL, et al.: Can patients taking opioids drive safely? A structured evidence-based review. *J Pain Palliat Care Pharmacother*. 2002; 16(1): 9-28.
13. Fishbain DA, Cutler RB, Rosomoff HL, et al.: Are opioid-dependent/tolerant patients impaired in driving-related skills? A structured evidence-based review. *J Pain Symptom Manage*. 2003; 25(6): 1-19.
14. Bruera E, Sweeney MC: Methadone use in cancer patients with pain: A review. *J Palliat Med*. 2002; 5(1): 127-138.
15. Grant JE: When mixing drugs makes malpractice. *Current Psychiatry*. 2006; 5(4): 52-54.
16. Rich BA: Medico-legal commentary. *Pain Med*. 2003; 4(2): 202-205.