Opioid Prescribing Practices in Chronic Pain Management: Guidelines Do Not Sufficiently Influence Clinical Practice

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Abstract: To examine the use of extended-release (ER) opioids relative to immediate-release (IR) opioids in chronic opioid prescription episodes, pharmacy claim data from a national health plan database were analyzed. Enrollees having at least 1 pharmacy claim for an opioid formulation between June 2003 and May 2006, and at least 1 year of continuous enrollment after their first observed pharmacy claim were included. Opioid prescription episodes were created by combining contiguous days of therapy, allowing for a maximum of 7 days between refills ($\leq 8 \text{ d} = \text{new episode}$). Outcomes are reported in the form of probabilities and odds ratios (ORs). A total of 3,993,011 opioid prescription episodes were derived from 1,967,898 enrollees. Overall, prescription episodes involving IR preparations (97.7%) were more prevalent than episodes using ER preparations (2.3%). The odds of an ER preparation being prescribed chronically ($\geq 60 \text{ d}$) were approximately 11 times that of an IR preparation (OR = 10.7); however, the majority of chronic prescription episodes used IR formulations (84.8%). When stratified by prescriber type (specialist vs nonspecialists), the probability of a specialist prescribing ER opioids in these chronic prescription episodes was 19.1% versus 13.7% for nonspecialists. Specialists were about 50% more likely to prescribe ER opioids relative to nonspecialists (OR = 1.49).

Perspective: This analysis suggests that the availability of pain-treatment guidelines, recommendations, and education alone may not be enough to influence opioid-prescribing practices in the treatment of chronic pain.

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Key words: Pain-management specialists, nonspecialists, treatment guidelines, opioids.

Chronic pain affects approximately 48 million Americans (24% of the population). Chronic pain remains poorly managed in the entire population and in subpopulations, including patients with lower back pain, osteoarthritis, cancer, and pain at the end of life. A 2005 insurance-claims analysis found that patients with painful conditions had 3-fold higher total healthcare costs compared with other patients, although medication costs accounted for <20% of total costs.

Effective pain management remains challenging because pain pathophysiology is complex and because pain may continue, owing to multiple underlying mechanisms, beyond the expected time of healing. Furthering the complexity, there is also an affective component of pain because patients with chronic pain may become depressed, anxious, or need to deal with alterations in daily life or with the approach of death. Multifaceted pain management incorporates nonpharmacologic approaches (ie, physical or cognitive-behavioral therapy) and pharmacotherapy for both the pain and psychological sequelae. Opioids have become a cornerstone of pharmacotherapy for chronic cancer pain and are increasingly accepted for use in chronic noncancer pain because of data demonstrating their efficacy, general tolerability, and low cost vs other interventions.

Incorporation of evidence-based medicine into pain-management guidelines aids the decision-making process in patient care. The available guidelines focus on patient-specific factors and generally recommend the least-intensive therapy, which provides effective analgesia with acceptable tolerability. Nonopiod medications (eg, nonsteroidal anti-inflammatory drugs [NSAIDs]) are often considered first for patients with mild to moderate pain without significant risk for cardiovascular, gastric, or hepatic adverse events. For many patients with chronic pain, an opioid trial, dosed to achieve a balance between adequate analgesia and acceptable tolerability, is recommended as either an add-on to current nonopioid medication when additional analgesia is required or alone when use of an NSAID is contraindicated. In
patients treated chronically, extended-release (ER) opioids that allow for twice-daily, or even once-daily, dosing are proposed to present advantages over immediate-release (IR) opioids that must be administered 4 or more times daily. Over the past decade, guidelines have indicated that fewer daily doses likely promote improved patient adherence and may produce more consistent plasma concentrations and better tolerability.\textsuperscript{3,6,9,18,22} Moreover, ER opioids can provide consistent around-the-clock analgesia with fewer interruptions of sleep compared with IR formulations that may require nighttime administration to maintain adequate pain relief.\textsuperscript{22} The most recent guidelines (2009) of the American Pain Society and American Academy of Pain Medicine state that there is insufficient evidence to recommend a preference of ER over IR opioids for chronic noncancer pain.\textsuperscript{8} One distinction of these new guidelines is that they are limited to chronic noncancer pain, and cite a lack of evidence concerning the use of IR vs ER opioids for the management of noncancer pain. However, there has been little documentation of the extent to which clinicians adhered to the earlier guidelines in the pain-specialty literature which recommend ER opioids for the treatment of chronic pain.

Previous analyses conducted with patient data, primarily derived from the late 1990s, suggested that clinicians were routinely prescribing IR opioids for extended periods for patients with chronic pain.\textsuperscript{15,21,25} For example, for more than 10,000 nursing home residents with persistent noncancer pain who were receiving analgesics, IR opioids were prescribed to 18.9% and ER opioids to 3.3% of the residents, despite the observation that patients treated with ER opioids reported improved functional and psychosocial status vs patients receiving IR formulations.\textsuperscript{25}

As noted, available studies of prescribing practices were largely based on decade-old data. Historically, a variety of factors have limited ER opioid use, such as few available ER opioids and the absence of guidelines recommending their use beyond cancer pain. Currently, it is not clear whether prescribing practices have been influenced by the introduction of additional ER formulations or by guidelines and increased education on opioid use for chronic pain. The current analysis examines recent prescribing of ER and IR opioids to patients for either <60 days or ≥60 days (ie, those without or with chronic pain) and compares the prescribing practices of specialists vs nonspecialists. Portions of this work were presented at the 2008 Annual Meeting of the American Pain Society.\textsuperscript{4}

**Methods**

Data for this analysis were derived from a national health plan database comprising data on more than 39 million insured lives. The study population included health plan enrollees with at least 1 pharmacy prescription for an IR opioid, ER opioid, or combination opioid analgesic between June 2003 and May 2006. To be eligible for the analysis, enrollees had to have at least 1 year of continuous enrollment since their initial opioid pharmacy claim.

Patients who received an opioid prescription during the analysis period were included, and an opioid-prescription episode was calculated for each patient. The length of each opioid prescription was defined as beginning on the prescription date and extending to the imputed end of the prescription based on the number of tablets dispensed and the dosing instructions. Opioid-prescription episodes were created by combining consecutive prescriptions for the same opioid formulation (ER or IR) with ≤7 days between prescriptions. If another prescription for the same opioid formulation was filled for a patient ≤7 days after the imputed end of the preceding prescription, the 2 prescriptions were combined as 1 opioid-prescription episode. If ≥8 days passed from the imputed end of the prescription and the date of the next prescription, a new prescription episode was defined. If a patient switched between an IR and an ER drug, a new prescription episode was defined. If a patient switched between 2 ER opioid drugs (eg, Kadian to OPANA\textsuperscript{6} ER) within the 7-day window, the data were analyzed as a single prescription episode (in this case, as an ER episode).

Patient prescription episodes were defined only by the physician specialty (specialist or nonspecialist) of the physician who prescribed the opioid without regard to any specialized training or certificates (eg, a primary-care doctor who acted as a pain specialist was categorized as a nonspecialist). If a patient consulted with a physician but was not prescribed an opioid, no data would be present to determine an opioid-prescription episode.

Chronic-prescription episodes were defined as any opioid-prescription episode lasting ≥60 days. During the development of our analytical methodology, we compared data with the definition of chronic at ≥60 vs ≥90 days and found no difference except for the last decade. Because there was no difference in the overall inference, ≥60 days was chosen to increase the sample size and thus, the precision of the analysis. Only the results derived from defining chronic as ≥60 days are presented. We acknowledge that ≥90 days may be a more frequently cited definition of chronic pain.\textsuperscript{2}

Opioids were classified as ER or IR, with combination therapies that contain both an opioid and nonopioid included in the IR category. Methadone was also included in the IR category based on formulation and not based on duration of action, which is acknowledged as being of greater duration. Prescribing patterns for ER and IR opioids for all prescription episodes and for the subset of episodes lasting ≥60 days were quantified.

The prescribing behavior of specialists vs nonspecialists was compared with respect to all prescription episodes and the subset of episodes lasting ≥60 days. Specialists were defined as physicians specializing in areas that frequently involve pain management, including neurologists, anesthesiologists, rheumatologists, nurse anesthetists, orthopedists, and other specialists in physical medicine and rehabilitation. The data did not indicate whether the prescribers defined as specialists by our criteria were in fact practicing as pain specialists or had fellowship training in pain management. Odds ratios (OR) for prescribing an ER opioid rather than an IR opioid were calculated using logistic regression models.
Prescription Episodes

A total of 3,993,011 distinct opioid-prescription episodes were identified, of which 3,810,894 (95.4%) lasted <60 days (nonchronic). The remaining 182,117 (4.6%) episodes were identified, of which 3,810,894 (95.4%) lasted >60 days. Thus, a typical prescription episode using ER opioids was nearly 11-fold more likely to be chronic ($P = .001$) (Fig 1). However, most chronic-prescription episodes used IR opioids (84.8%; $n = 154,369$), with ER opioids being prescribed for only 15.2% of chronic-prescription episodes ($P = .001$) (Fig 2). The most frequently used ER opioids were oxycodone controlled release (OxyContin, 59.6% of ER opioid-prescription episodes), fentanyl transdermal system (Duragesic, 30.3%), morphine controlled release or sustained release (Kadian, MS Contin, Oramorph SR, 5.4%), and 24-hour morphine (Avinza, 4.5%), which together accounted for 99.8% of ER opioid prescription episodes (Table 2). Six therapies accounted for 95.4% of IR opioid-prescription episodes. These included hydrocodone/acetaminophen (50.4% of IR opioid-prescription episodes), propoxyphene/acetaminophen (14%), oxycodone/acetaminophen (12.6%), codeine/acetaminophen (10.1%), tramadol (5.3%), and tramadol/acetaminophen (3%).

Study Population

A total of 1,967,898 enrollees with an opioid prescription and at least 1 year of continuous eligibility since their initial opioid claim were identified. Of these, 56.9% were women and 43.1% were men. The mean age ±SD in the entire cohort was 41.6 ± 16.6 years (range, <1 – 88 y).

Most enrollees (94.1%) were insured through their employers. The remaining enrollees were insured through Medicare (3.1%) or Medicaid (2.8%). The most common plan types were point-of-service plans (POS; 47.6%), health maintenance organizations (HMO; 23.9%), preferred provider organizations (PPO; 14.4%), and exclusive provider organizations (EPO; 12.1%) (Table 1). Patients enrolled in independent plans (financed solely by the insured, 1.8%) or other plan types (2%) were on average older (72.9 ± 9.6 and 68.4 ± 17 y, respectively) than patients insured through EPO (38.9 ± 14.7 y), HMO (43.5 ± 18.2 y), POS (39.9 ± 14.8 y), or PPO (42.1 ± 16.8 y) plans.

The majority of patients (84%) received opioid prescriptions from a nonspecialist rather than from a specialist (8.1%); 7.9% received prescriptions from both a specialist and a nonspecialist. More patients enrolled in an independent plan (21.4%) or other plan of type (19.1%) received opioid prescriptions from a specialist (either alone or with a nonspecialist) than did patients enrolled in an EPO, HMO, POS, or PPO plan (14.9%–16.3%). Thus, patients enrolled in independent plans were 24% to 30% more likely to receive a prescription from a specialist, and enrollees in other plan types were 15% to 22% more likely to receive a prescription from a specialist relative to patients enrolled in EPO, HMO, POS, or PPO plans.

Prescription Episodes

A total of 3,993,011 distinct opioid-prescription episodes were identified, of which 3,810,894 (95.4%) lasted <60 days (nonchronic). The remaining 182,117 (4.6%) prescription episodes lasted ≥60 days (chronic). Overall, most episodes used IR opioids (97.7%; $n = 3,902,486$) rather than ER formulations (2.3%; $n = 90,525$).

Of prescription episodes using IR opioids, 4% lasted ≥60 days. By comparison, 30.7% of prescription episodes using ER opioids lasted ≥60 days. Thus, a typical prescription episode using ER opioids was nearly 11-fold more likely to be chronic (≥60 d long) than a typical prescription episode using an IR opioid (OR = 10.7, $P = .001$) (Fig 1). However, most chronic-prescription episodes used IR opioids (84.8%; $n = 154,369$), with ER opioids being prescribed for only 15.2% of chronic-prescription episodes ($n = 27,748$) (Fig 2). The most frequently used ER opioids were oxycodone controlled release (OxyContin, 59.6% of ER opioid-prescription episodes), fentanyl transdermal system (Duragesic, 30.3%), morphine controlled release or sustained release (Kadian, MS Contin, Oramorph SR, 5.4%), and 24-hour morphine (Avinza, 4.5%), which together accounted for 99.8% of ER opioid

Table 1. Insurance Plan Types

<table>
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<tr>
<th>PLAN TYPE</th>
<th>COMMERCIAL, n (%)</th>
<th>MEDICAID, n (%)</th>
<th>MEDICARE, n (%)</th>
<th>TOTAL, n (%)</th>
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<td>737 (0.)</td>
<td>(0)</td>
<td>4303 (2.)</td>
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<tr>
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<tr>
<td>PPO</td>
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<td>4075 (2.1)</td>
<td>284,117 (14.4)</td>
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<td>Total</td>
<td>1,852,745 (94.2)</td>
<td>54,531 (2.8)</td>
<td>60,622 (3.1)</td>
<td>1,967,898 (100)</td>
</tr>
</tbody>
</table>

Abbreviations: EPO, exclusive provider organization; HMO, health maintenance organization; IND, independent; OTH, other; POS, point of service; PPO, preferred provider organization.

Figure 1. Breakdown of IR vs ER treatment episodes. ER, extended release; IR, immediate release; OR, odds ratio.
(n = 38,020) of chronic-prescription episodes. Long-acting opioid formulations accounted for only 15.2% (n = 27,748) of all chronic-prescription episodes.

Nearly all patients (97.4%) received an IR opioid only rather than an ER opioid only (.2%) or both an IR and ER opioid (2.4%). Patients insured through an EPO, HMO, POS, or PPO plan were prescribed an IR opioid alone slightly more frequently (96.8%–97.9%) than patients enrolled in independent or other plans (92.6%–94.0%). Patients enrolled in independent or other plans were therefore approximately 3 times more likely to receive an ER opioid alone or both an ER and IR opioid (5.9%–7.5%) than enrollees in other types of plan (2.1%–3.2%). Patients treated with an IR opioid alone were younger (41.4 ± 16.6 y) than patients treated with an ER opioid alone (52.6 ± 15.8 y) or both an ER and IR opioid (49.7 ± 14.1 y).

Specialist vs Nonspecialist Prescribing Patterns

Chronic-Prescription Episodes

Most chronic-prescription episodes (≥60 d) were treated by nonspecialists (70.8%; n = 128,982) rather than specialists (29.2%; n = 53,135; Figure 3). Specialists prescribed an ER opioid for 19.1% (n = 10,134) of chronic-prescription episodes and an IR opioid for 80.9% (n = 43,001) of chronic-prescription episodes. Nonspecialists prescribed an ER opioid for 13.7% (n = 17,614) of chronic-prescription episodes and IR formulations for 86.3% (n = 111,368) of chronic-prescription episodes. Thus, specialists were nearly 50% more likely than nonspecialists to prescribe an ER opioid when the episode was ≥60 days (OR = 1.49). However, specialists and nonspecialists each prescribed IR opioids for the majority of chronic-prescription episodes (80.9% and 86.3%, respectively).

In the majority of chronic-prescription episodes, the IR drug prescribed was a combination product. Nonspecialists prescribed IR combination drugs for 85,112 (66%) of the 128,982 chronic-prescription episodes they treated, or nearly 5 times the number of chronic-prescription episodes for which they prescribed an ER drug. Specialists prescribed an IR combination drug for 31,237 of the 53,135 (58.8%) chronic-prescription episodes they treated, or 3 times the number of chronic-prescription episodes for which they prescribed an ER opioid (OR = 1.60; 95% CI, 1.55–1.64; P < .0001).

Extended-Release vs Immediate-Release Prescribing

Specialists and nonspecialists did not differ substantially with respect to the proportion of chronic- vs non-chronic-prescription episodes for which they prescribed ER opioids. When specialists prescribed an ER drug, 31.2% (n = 10,134) of the episodes were chronic and 68.8% (n = 22,398) of the episodes were nonchronic. When nonspecialists prescribed ER drugs, the distribution of chronic (30.4%; n = 17,614) vs nonchronic (69.6%; n = 40,379) episodes was similar to that observed with specialists.

Discussion

These results suggest that clinical practice for the management of chronic pain was not fully influenced by the accepted pain-treatment guidelines of the time. Although an ER-prescription episode was nearly 11-fold more likely than an IR-prescription episode to be ≥60 days, more than 80% of episodes lasting ≥60 days used an IR opioid. Physician specialization in areas that frequently involve pain management was associated with increased use of ER opioids (ie, specialists were 50% more likely than nonspecialists to prescribe ER opioids for chronic-prescription episodes). However, specialists still prescribed IR formulations for more than 80% of prescription episodes lasting ≥60 days. The specialist-prescribing practices observed in this study suggest that experience with chronic-pain populations and/or the
dissemination of guidelines may have influenced their treatment practices.

A number of factors, other than poor adherence to prescribing guidelines, might also contribute to the observed outcomes, including concurrent use of IR medications for breakthrough pain in patients also receiving ER medication. However, the number of IR prescriptions for chronic episodes was multifold the number of chronic-prescription episodes with an ER medication; even if all ER-prescription episodes had received concurrent IR medication for breakthrough pain, the majority of chronic episodes were still treated solely with an IR medication. Cost is another consideration; ER opioids are generally more expensive than IR single or combination formulations.

Older patients were more likely than younger patients to receive an ER-opioid prescription; however, it is unclear whether this might reflect greater pain severity or duration in older patients, greater familiarity with ER opioids among caretakers of elderly patients, or reluctance to take opioids among younger patients who may require years of treatment. Patients enrolled in independent or other plans were also more likely to receive an opioid than those enrolled in HMOs, PPOs (all Medicare patients were enrolled in HMOs or PPOs), or POS plans. Because the majority of enrollees in independent or other plan types were old enough to receive Medicare, questions can be raised about whether they are receiving opioids through these plans because of limited access to a variety of analgesics through Medicare. In addition, it remains to be determined whether observed prescribing differences in the independent and other plans compared with the EPO, POS, HMO, and PPO plans indicate an effect of patient age, of plan type, or other plan characteristics.

Specific issues concerning combination opioids may have influenced the disproportionate use of IR combination opioids in many chronic-prescription episodes. For all prescription episodes, 5 of the 6 most frequently used IR medications were combination therapies for which no ER formulation is available. A similar pattern was seen with chronic-prescription episodes (57.7% of patients received prescriptions for IR combination opioids). Although we cannot determine the precise reasons for this pattern, some broad possibilities can be suggested.

First, because of the complex pathophysiology of pain, a patient may respond better to combination analgesia than to a single drug. A single formulation that combines analgesics with different mechanisms of action is more convenient for a patient than 2 separate medications and may promote better adherence to treatment. Another factor that may contribute to the disproportionate use of combination IR medications is poor tolerability or efficacy with the limited number of available ER medications. For most of the 2003 to 2006 time frame that was assessed in this study, there were only 3 different distinct opioids available in ER formulations, and only 2 of these (oxycodone and morphine) were available as oral medications. Methadone, an opioid with a long half-life that can be used as an ER opioid, was prescribed infrequently. If patients were unable to obtain satisfactory treatment outcomes with these medications, an alternate IR opioid may have been prescribed. In cases in which patients had poor tolerability, an IR combination drug might have been chosen to reduce the opioid requirement and thereby improve tolerability.

Physician training is another factor that could contribute to this prescribing pattern. Physicians prescribe as they were taught during medical school, residency, and during continuing medical education. Lack of pain-management training, or a paucity of available ER opioids to learn about during their medical training, is a possible contributor. The trend on the part of both specialists and non specialists to prescribe an IR combination opioid could reflect medicolegal concerns. Because of the nonopioid component, IR combination opioids have a ceiling dose that may discourage overuse and abuse and may reside in a lower controlled schedule versus a single-drug opioid. Convenience may factor into the disproportionate prescribing of IR combination products. The IR combination opioids require less stringent documentation by prescribers. Prescriptions for Schedule II opioids such as oxycodone, morphine, and fentanyl cannot be refilled. Combination products containing hydrocodone, codeine, or propoxyphene are assigned to Schedule III or IV, and as such, prescriptions for these drugs can be refilled. The possibility that physicians find it inconvenient to schedule multiple patient visits or write multiple prescriptions during long-term treatment cannot be dismissed.

In summary, the use of combination IR opioids for chronic treatment may be motivated by many factors, including the need for multiple drugs with different mechanisms of action; the fact that an analgesic must be efficacious and tolerable; a lack of ER opioid formulations; inadequate physician training or deep-rooted behaviors developed early in the educational process; concerns about patient abuse and possible prosecution for improper prescribing of Schedule II opioids; and the convenience of writing a refillable prescription.

It is not clear how effective the prescribing of IR combination opioids for chronic pain is or whether extensive prescribing of these drugs leads to undertreatment of pain. Several clinical trials of opioids for chronic pain have documented that some opioid-experienced

**Figure 3.** Specialist vs nonspecialist opioid prescribing patterns for chronic prescription episodes (≥ 60 d). ER, extended release; IR, immediate release; OR, odds ratio.
patients have daily-dose requirements (in morphine equivalents) that are well in excess of those that could be safely obtained with IR combination drugs due to the dose limitations of the acetaminophen component of these products.\textsuperscript{12-14,20} Even if the combination product is administered as rescue medication, the dose cannot be indefinitely increased as the dose of the around-the-clock long-acting opioid increases; hence, the nonopioid component of the combination also limits its utility for breakthrough pain during long-term therapy.

Regardless of the reasons, there are potential risks associated with the overreliance on combination IR products for chronic pain. As noted above, the maximum dose that can be administered safely is limited by the nonopioid component of the combination (eg, acetaminophen is associated with abnormal liver enzyme elevations at a dose of 4 g per day\textsuperscript{23}). A recent survey suggests that acetaminophen overdose is the leading cause of acute liver failure cases presenting at tertiary care facilities in the United States; approximately one-half of acetaminophen overdoses were believed to be from unintentional overuse rather than attempted suicide, and the majority (63%) of unintentional overdose was in patients using opioid-containing combinatorial products rather than acetaminophen alone.\textsuperscript{16} Moreover, it appears that even when patients understand the dangers associated with overuse of IR combination products, many do not understand that use of additional acetaminophen from over-the-counter sources is also dangerous.\textsuperscript{7,16}

Another puzzling finding was that although ER opioid prescriptions accounted for <3% of all prescription episodes, approximately 70% of those prescription episodes lasted <60 days (suggesting treatment of nonchronic pain). The possibility exists that these prescription episodes were actually initiated because of recurrent chronic pain in patients who had been previously prescribed an ER opioid. For instance, if a patient with chronic pain was being managed by a physician but was dispensed less than a 60-day supply of medication and then did not pick up another prescription within ≤7 days of the imputed end of the previous prescription, the patient would have been categorized by our methodology to have 2 nonchronic-prescription episodes despite the fact that the patient was experiencing chronic pain. Although our data could determine serial-prescription episodes, no official pain diagnosis was available, and it was not possible to determine if the nonchronic ER opioid prescription episode was for a nonchronic pain attack or for a recurrence of a previously treated chronic pain condition. As such, this can be considered a limitation.

Other limitations of our analysis include inability to determine whether there might be a difference in the prescribing of ER vs IR opioids for opioid-experienced vs opioid-naïve patients. In addition, our analysis is unable to capture situations in which the patient actually did consult a specialist, but the specialist advised the primary care physician to write the prescription (our analysis would have credited the prescription only to the nonspecialist). Furthermore, limited information was gathered on switching from IR to ER formulations of the same opioid and from 1 brand of ER opioid to another.

Future research should be conducted to evaluate prescribing behaviors in the management of chronic pain and to assess why treatment guidelines alone or in combination with educational efforts may be insufficient for modifying prescribing practices. In particular, the influences of insurance plan type and availability of multiple (eg, both IR and ER) formulations of individual opioids as well as training and mentor influence on prescribing behavior will need to be addressed. For clinicians, the current study should present an opportunity to consider whether their treatment practices are influenced by pain management guidelines for patients with chronic pain.

Acknowledgments

All authors are employees of Endo Pharmaceuticals Inc, makers and marketers of pain medications. Meg Palmatier, PhD, of Complete Healthcare Communications, Inc, Chadds Ford, PA, provided editorial assistance for the development of the submitted manuscript, with support from Endo Pharmaceuticals Inc, Chadds Ford, PA.

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