

Commentary: The Potential for Unintended Consequences from Public Policy Shifts in the Treatment of Pain

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Recently, due to a number of converging factors, there have been significant shifts in public policy regarding the legitimacy of treating chronic pain with opioids. Traditional tenets handed down in medical, dental, nursing, and pharmacy education created a distinct reluctance on the part of practitioners to prescribe opioids on a continual basis. Much has been written about the reasons for these attitudes.¹ One of the barriers that is very consistently reported by prescribers is the fear of regulatory and legal repercussions to ongoing prescription of this class of medications.² It is in this arena that sentinel changes have occurred, the most recent of which is the promulgation of a document prepared by the Federation of State Medical Boards (FSMB), which suggests a set of guidelines meant to be endorsed or adopted by individual medical licensing boards on how to approach this particular aspect of practice.³ These guidelines, representing a broad consensus from a wide constituency, were developed in a relatively open forum and detail a balanced approach to the prescription of opioids for chronic pain. Similar actions have occurred at the state level, such as intractable pain treatment acts (IPTAs) in multiple states⁴ and the recent California law, known as the Pain Patient's Bill of Rights.⁵ Even though these products, borne of rethinking the place of opioids and the treatment of chronic pain, are encouraging, there is with any law, rule, or policy the potential for unintended consequences. Here, we discuss some potential negative sequelae of these generally positive actions from the perspective of two pain physicians who were involved in the development of FSMB's guidelines.

Probably the most bothersome of these unintended consequences is the notion that some patients, with access

to the Internet or other sources, will read about these documents without having the benefit of the medical or regulatory context under which they are meant to be interpreted. Therefore, patients could easily assume that they have a legal right to demand any type of treatment they see fit. This can be problematic, in a number of ways. Although patients should certainly be active participants in their care, including selecting options presented to them, they should not be in the position of demanding a specific treatment, because they do not have the medical education necessary to make those decisions without being informed of reasonable options. In many instances of chronic pain, a contributing problem is not undermedication, but overmedication or inappropriate medication, with adverse drug-drug or drug-disease interactions. Some patients may actually benefit from the careful tapering of medications. This might be done in the context of an intensive, and sometimes, expensive comprehensive pain rehabilitation program. It is, of course, much easier to take a few pain pills than to arrive promptly each day, participate in physical conditioning, physical therapy, psychological therapies, and be a part of a therapeutic milieu. Additionally, insurers, looking only at the bottom line, may opt for ongoing medication therapy in lieu of more definitive nonmedication therapies.

One can foresee the case of an individual wishing to have opioids for a nontherapeutic purpose who might, under the guise of being a legitimate patient, demand that opioids be prescribed and, armed with one of these documents, might persuade a physician to prescribe analgesia out of fear of regulatory repercussions. The California law mentioned above, as originally written, provided patients with the legal right to demand opioids. It further intended to state that if physicians were not willing to prescribe opioids for patients, they were obligated to refer patients to professionals who would. Had it passed in its original form,

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the law would have set two very dangerous precedents: (1) it would have legalized specific treatment on demand, regardless of medical appropriateness; and (2) it would have allowed micromanagement of everyday medical practice on the part of the legislature. It is our belief that medical practice should be governed by broad parameters set forth in state medical practice acts and by the rules, policies, and guidelines put forth by medical licensing boards, which are in a much better position to react to changes in science and to operate in a somewhat less politically charged environment than do the legislatures that empowered them.

Another concern for unintended consequences of these positive efforts to remove various impediments involves the unintended message to the public, regulators, and prescribers that all pain is responsive to or requires opioid medications. In actual practice, this is not the case. For mild or moderate pain, over-the-counter medications such as aspirin, acetaminophen, or ibuprofen are often quite adequate. Likewise, for more vexing neuropathic pain problems, such as painful diabetic neuropathy, an opioid may not be the drug of choice in a given person. Rather, a prescription nonopioid, such as an anticonvulsant or antidepressant medicine, may be preferable in terms of efficacy and tolerability. One can often avoid unacceptable side-effects seen with the opioids, such as constipation, by choosing a different medication.

A correlate to this is the implied message that all pain can be treated satisfactorily. Although practitioners of the field of pain medicine are generally expert at treating difficult pain problems, all of us have patients in whom the outcomes are less than perfect. We assume that this must also be the case in all other medical specialties. It is true that we have the means, knowledge, and medications to manage all pain more effectively than it is presently being managed, on average. However, this does not equate to the concept that all pain can be relieved. This notion of total analgesia could, therefore, be a basis for patient or family dissatisfaction and could potentially serve as the basis for a lawsuit. One can even imagine a patient who is unsatisfied with a physician for a different reason, but claims to have unrelieved pain as the basis for a complaint to a medical board.

IPTAs themselves are potentially problematic in a number of ways. Our first objection to IPTAs, as presently worded, is that they institutionalize the mistrust that has developed in some states between medical licensing boards and their licensees. In essence, these laws allow physicians to make an “end run” around their medical licensing board, provided that they stay within the confines of their state’s IPTA. We believe that this is, again, setting a potentially bad precedent of having legislative micromanagement over the practice of medicine. Second, the definition used in most IPTAs is terribly flawed. If intractable pain “cannot be removed or otherwise treated and no relief of the pain is

possible,” then a patient is treated with opioids and experiences relief. If this is the case, then, by definition, the pain was not intractable in the first place and hence the practitioner is not within the protection articulated by the IPTA. Likewise, many of the definitions include the clause “in the generally accepted course of medical practice” as part of the definition.⁶ This would suggest that treating a chronic pain problem with opioids is outside the generally accepted course of medical practice. We believe that the treatment of pain should be an integral part of any medical practice. Many state IPTAs have clauses requiring evaluation by at least one physician other than the treating or attending physician.⁷ This, of course, would raise health care costs, in many cases, unnecessarily. Last, many IPTAs contain wording that they do not apply to persons being treated by a physician for chemical dependency because of the use of drugs or controlled substances.⁸ This has a number of areas of ambiguity that require clarification. First, this wording blurs the distinction between addiction and physical dependence. Second, the wording may well preclude coverage by IPTAs for treatment of pain in addicts. This would seem to legislate the concept that addicts who suffer from pain have abrogated all future rights to treatment of their pain because of their addiction.

With the increased amount of attention these policy changes have received in medical media, it is likely that many physicians who were, heretofore, reluctant to prescribe opioids, now may feel that it is incumbent to do so. Unfortunately, with the exception of FSMB’s document, not one state IPTA makes specific recommendations regarding education in the pharmacology of drugs, the appropriate indications, the contraindications, and the distinction between physical dependence and addiction that would allow these drugs to be prescribed appropriately. Therefore, practitioners who were unfamiliar with their use may begin using them more liberally and may contribute to increased diversion or create complications that could otherwise be foreseen and prevented.

Our experience suggests that many physicians will briefly scan guidelines and may come away with the wrong impression. Often, physician behavior is hard to modify. It is entirely possible that the promulgation of guidelines will make physicians perceive that prescribing opioids for chronic pain is under even greater scrutiny than they thought, causing them to be even less willing to prescribe opioids for any reason. This may have the unintended consequence of creating exactly the opposite effect intended by these documents. Likewise, physicians may see the documentation requirements as onerous, even though most of us would suggest that they can be met with minimal additional effort.

Last, the potential always exists for the dishonest physician to hide behind policies and regulations. It has been reported by law enforcement officers that some physicians

“doctor the chart” to make prosecution difficult, even though the officers are convinced that these physicians are engaging in illegal activities. One could argue the point in a specific case, however, there will certainly be instances of abuse of the rules, policies, and guidelines in this manner.

In summary, the public policy changes that have been occurring are not happening in a vacuum. There is valid reason that attitudes and behaviors of prescribing, administering, and dispensing health care providers should change to improve the quality of life of many patients. In general, as evidenced by our contributions to some of these documents, we support the efforts to reduce regulatory barriers to good care. We all must beware, however, that even the best laid plans may go awry. Care and thought must be directed to remediation of the unintended consequences of attempts to change providers’ attitudes toward prescribing by regulatory clarification or relief.

References

1. See, for example, R.K. Portenoy, “Opioid Therapy for Chronic Nonmalignant Pain: Clinicians’ Perspective,” *Journal of Law, Medicine & Ethics*, 24 (1996): 296–309; R.J. McQuillan, “Narratives on Pain and Suffering: Mary’s Story,” *Journal of Law, Medicine & Ethics*, 24 (1996): 288–89; and C.K. Cassel, “Narratives on Pain and Comfort: Dr. M’s Story,” *Journal of Law, Medicine & Ethics*, 24 (1996): 290–91.
2. See, for example, S.H. Johnson, “Disciplinary Actions and Pain Relief: An Analysis of the Pain Relief Act,” *Journal of Law, Medicine & Ethics*, 24 (1996): 319–27; and S.H. Johnson, “Removing Legal Constraints on Effective Pain Relief,” *ABA Bioethics Bulletin*, 5, no. 3 (1997): 9–10.
3. See Federation of State Medical Boards of the United States, Inc., *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (Eules: Federation of State Medical Boards, May 1998).
4. See, for example, Texas’s Intractable Pain Treatment Act of 1989, Tex. Rev. Civ. Stat. Ann. art. 4495c (West 1996).
5. See California’s Pain Patient’s Bill of Right, Cal. Health & Safety Code §§ 124960–124961 (West 1998).
6. See, for example, Tex. Rev. Civ. Stat. Ann. art. 4495c, § 2(3).
7. See, for example, California’s Intractable Pain Treatment Act, Cal. Bus. & Prof. Code § 2241.5 (West 1998).
8. See, for example, Tex. Rev. Civ. Stat. Ann. art. 4495c, § 6(a)–(b).