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EDITORIAL

Damaging State Legislation Regarding Opioids: The Need To Scrutinize Sources Of Inaccurate Information Provided To Lawmakers

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On January 22, 2019, a Massachusetts State Representative introduced House Bill 3656, "An Act requiring practitioners to be held responsible for patient opioid addiction".[1] Section 50 of this proposed legislation reads, "A practitioner, who issues a prescription for a controlled substance placed in Schedule II, which contains an opiate, shall be liable to the patient for whom the written prescription was written, for the payment of the first 90 days of in-patient hospitalization costs if the patient becomes addicted and is subsequently hospitalized". The bill was assigned to a joint House/Senate committee, and the Representative testified in a hearing of the Joint Commission of the Judiciary on September 17, 2019. According to the Representative, the Joint Commission "didn't vote on it, and I don't suspect it will ever get a vote". After speaking to him, he acknowledged that the bill would not be resurrected. When asked of the source of medical information on which he based his bill, the Representative mentioned the name of a nationally known addiction psychiatrist. Unfortunately, this psychiatrist, to the best of our knowledge, had no training or clinical experience in treating chronic pain, nor has he published research on the topic area.

Irrespective of the ultimate status of the legislation, its introduction and consideration by the state's Joint Committee on the Judiciary has caused unnecessary anxiety among patients with pain and the physicians who treat them, not only in Massachusetts, but throughout the United States. Although some have denied that legislation curtailing opioid prescription has a significant "chilling effect" on prescribers,[2,3] Ballantyne and Fleisher were not in agreement with this denial.[4] They noted that going back to the early twentieth century, legislation limiting opioid prescription resulted in "an immediate switch of the moral imperative from patient to physician, and in fact a chilling effect on the provision of opioids for pain", and that the "stigmatization and criminalization of opioids produced by regulations continues to interfere with the rational use of opioids for pain to this day (p. 365)". Ballantyne and Fleisher were not the first to write of this potential for ill-conceived legislation to result in physician fear of prescribing,[5–7] although many more have addressed this concern subsequent to the publication of their article.[8–17]

Some pain management professionals have blamed the current suffering and potential suffering of chronic pain patients and those who prescribe opioids to them on the 2016 Centers for Disease Control and Prevention (CDC) Guideline for

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Prescribing Opioids for Chronic Pain.[18,19] One of the most common criticisms of the Guideline pertains to its chilling effect on prescribers and appropriate use of opioid analgesia.[20,21] However, others have unabashedly defended the Guideline,[22] although often these opinions have been written by CDC itself, its representatives, and/or those who were involved in the Guideline writing process.[23,24] This group of supporters has not been uncomfortable in noting that many of those in opposition to the Guideline have ties to the pharmaceutical industry, thereby only thinly veiling accusations of ethical impropriety.[25–27] Perhaps the most thoughtful analysts of the document have taken a more nuanced view, citing both its strengths and weakness.[28–30] Accordingly, it has been suggested that the Guideline per se has not caused the deterioration of the quality of pain medicine in the United States, but rather its misapplication or "weaponization" has been responsible for such.[31–35] The CDC has recently published its "mea culpa" regarding policies and practices supposedly derived from the Guideline that have been misapplied.[36] The authors of this recent admission claimed that CDC made an effort to educate various stakeholders regarding appropriate implementation of its Guideline. Although they acknowledged that the document was associated with a number of unintended deleterious consequences, the authors failed to mention the potentially most damaging consequence, i.e. draconian state laws written "in the spirit" of the Guideline without adequate evidence-bases.[37]

Contrary to popular belief, ill-informed state legislation may be more responsible for the current plight of patients with pain than is the oft-blamed CDC Guideline, the United States Drug Enforcement Administration, or regulations imposed on physicians by state medical boards. Gilson and Rich have recently noted that state laws regarding opioid prescribing, unlike federal laws, generally fail to recognize the importance of opioid analgesia to public health.[16] Consequently, a great deal of individual state legislation pertaining to opioid prescribing that "misses the forest for the trees" has been passed and enacted. For example, the state of Rhode Island instituted a law in 2017, limiting daily prescription of opioids for acute pain to 30 milligrams morphine equivalents (MME).[38] Besides being arbitrary and without evidence-basis, this law fails to take into account that "a regulatory approach that takes into account prescriber intent and patient-specific factors that influence prescribing is likely more effective than a strict limitation on the amount or duration of opioid prescribing".[39]

An even more disconcerting piece of legislation signed into effect is the Arizona Opioid Epidemic Act of 2018.[40] The lengthy document begins by stating that 75% of heroin users in treatment "started with painkillers, according to a 2014 study by the Journal of the American Medical Association". The JAMA study to which the authors allude[41] was actually published in JAMA Psychiatry, not JAMA. The data were collected "from third quarter 2010 to third quarter 2013", and included only a sample of patients admitted for substance dependence/abuse treatment during that timeframe. Consequently, the generalizability of this sample to all heroin users is questionable, to say the least. Most importantly, the data were collected during the midst of the prescription opioid epidemic in the United States, i.e. at a time during which there were many more opioids being prescribed[42] and risk mitigation (e.g. more states requiring mandatory Prescription Drug Monitoring Program use,[43] increased ease and sophistication of toxicology testing to assess potential aberrancy,[44] percentage of market share of abuse-deterrent formulation opioids[45]) was far less comprehensive than was the case when the law was written in 2018. Failure to recognize the dramatic change in the opioid prescribing zeitgeist between the study period and the time at which the state's law was written essentially invalidates the claim on which it was based. In fact, many have posited that the "prescription opioid crisis" has been over, or at least dissipating, for the past several years.[17,31,46–48] Further, the first author of the 2014 JAMA Psychiatry retrospective analysis has subsequently posited that the recent reduction of prescription opioid availability "has led many to turn to heroin".[49] The author opined that "there is growing evidence that new opioid users, who previously used opioid drugs as their entry into opioid use, are now increasingly being introduced to opioids by using the more easily accessible heroin as their first exposure to an opioid" (p. 1322). Numerous others have recently analyzed the data and reached the same conclusion,[30,50–54] and have posited that restrictive opioid prescribing laws are related to the unintended consequence of broader demand for and use of far deadlier illicit fentanyl and its analogues. The rationale used to justify the Arizona law is rife with even more outdated and accordingly invalid data, such as its assertion that opioid prescribing rates for adolescents doubled between 1994 and 2007. In addition to the highly inaccurate premise behind the Arizona opioid law, implementation of the premise also leaves something to be desired. For example, the law dictates a 5-day limit on initial fills of prescription opioids in cases in which the state is the payer, even though there is no empirical evidence suggesting

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that this approach results in greater individual or societal safety. Regarding the law's 90 MME prescribing limit, officials in Arizona, not surprisingly, evoked the 2016 CDC Guideline.

Perhaps the most ludicrous of the recent opioid laws is that recently enacted by the state of Nevada.[55] According to this law, any provider who prescribes a controlled substance must, "Conduct an investigation, including, without limitation, appropriate hematological and radiological studies, to determine an evidence-based diagnosis for the cause of the pain" (p. 46). Although radiological and hematological testing can be useful in identifying pathophysiology and underlying systemic disease states that can cause severe pain, we cannot lose sight of the reality that much of the chronic pain that we treat is maldynic in nature, i.e. "pain that persists in the absence of ongoing tissue damage or injury" and is refractory to standard treatments.[56] Our concern with the Nevada legislation, of course, is that patients plagued with severe, intractable maldynia should not be denied access to opioid analgesia simply because radiographs and hematological evaluations are unable to pinpoint the exact cause of their pain and suffering.

In summary, the Massachusetts Representative's proposed legislation was ill advised, and had it passed, perhaps all physicians in Massachusetts would have been compelled to discontinue prescribing opioids altogether, at great potential cost to those patients for whom there are no other viable treatment options. Irrespective, we commend him for speaking and meeting with us, and responding appropriately to accurate medical information – once he received it. The take-away message of this editorial is that legislators cannot afford to rely on self-proclaimed experts who have backgrounds in disciplines such as addiction psychiatry with no training, clinical experience, or even research experience in pain medicine, nor can their constituent patients. As an alternative, legislators need to more thoughtfully consider the credentials of their experts. Pain education organizations and advocacy groups are willing to respond to legislators' (as well as the media's) inquiries for direction from experts who are bona fide key opinion leaders in pain medicine. We strongly believe that having access to better medical information when developing legislation will help reduce the stigmatization, marginalization, and persecution of chronic pain sufferers – as well as those prescribers still willing to consider judicious use of opioids in well-selected patients when such treatment is necessary.

Disclosure

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