

## The Opioid Crisis in the United States: Chronic Pain Physicians Are the Answer, Not the Cause

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pioids for the treatment of acute pain and the pain of malignancy have been strongly encouraged for more than 25 years.1 In the past 2 decades, the treatment of chronic noncancer pain using long-term opioid therapy has become more common. However, recent studies have revealed the astonishing rapidity with which the therapeutic use of prescription opioids can become challenging.<sup>2</sup> In light of this public health problem, chronic pain physicians have often been maligned as the root cause of addiction and death because of good faith efforts to treat selected patients suffering long-standing pain with opioids. But, anesthesiologists practicing chronic pain medicine do not prescribe the most opioids, and the multidimensional management most often practiced by these clinicians appears to be a paradigm for responsible opioid treatment of patients with all types of pain. Chronic pain physicians must take the lead as educators of the entire field of medicine on the appropriate and comprehensive management of acute and chronic pain.

Though prescription writing for opioids has slowed modestly, the death and disability curves from opioid abuse continue to climb.<sup>3</sup> This increase in mortality and addiction is occurring, in part, because there are 2 superimposed societal problems, not 1. First, despite robust action by the US Department of Justice and dramatic attempts at the control of our borders enforced through the Department of Homeland Security, substantial quantities of illicit heroin, fentanyl, and other opioids continue to pour into the country. Second, opioids continue to be used liberally by world standards and are likely a gateway into the drug culture for some.<sup>4</sup> Complicating this picture, mental illness, despair borne of economic uncertainty, and societal pressure, especially in adolescents, also play a role in the abuse of opioids. Heroin addiction as a final

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Accepted for publication July 19, 2017.

Funding: None.

The authors declare no conflicts of interest.

This article does not represent the policies of the US Food and Drug Administration (FDA), the Department of Health and Human Services, or the University of Kentucky.

Reprints will not be available from the authors.

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Copyright © 2017 International Anesthesia Research Society DOI: 10.1213/ANE.000000000002417

common pathway for patients originally prescribed legal opioids continues to be a recurrent theme in a small, but not insignificant, population.<sup>5</sup>

State and federal governments track groups of clinicians most involved in the prescribing of opioids. As one would expect, there is remarkable variation in prescribing practices between specialties and the individuals within each specialty.6 From these data, one can begin to comprehend some of the reasons for the excess of opioids prescribed. For a substantial number of physicians in the United States, the treatment of pain and the prescribing of opioids represent a major portion of their practice. Opioid prescribing as a method to quickly bring pain under control is fast and easy. Government and insurers also reimburse prescription writing. Responding to a patient's concerns with a prescription, even in the face of clinical signals suggestive of a high abuse potential, is a default behavior driven by economics and time considerations. Most important, perhaps, the time required to write a prescription is minimal.

The United States consumes 80% or more of all the opioids manufactured in the world each year. This statistic intimates either that US physicians, other prescribing clinicians, and their patients, view acute and chronic pain differently than almost every other country in the world, or that our knowledge of the risks of using opioids as a primary treatment for chronic pain is insufficient. Either of these assumptions would suggest that observing the practice of our colleagues outside the United States could provide solutions to some of our problems. Physicians in Israel, France, the United Kingdom, and other advanced countries treat patients effectively for chronic nonmalignant pain, yet the volume of opioids prescribed in these countries are minuscule relative to the US experience.<sup>7</sup> It has become apparent that the prescribing of opioids for chronic pain has, and will always have, associated risks as well as benefits.8 The cost in dollars, death, and disability of not understanding the inherent risks are impossible to know, but it has been suggested that considering only the financial cost of treating all current American addicts would amount to nearly 80 billion dollars a year, while the true societal cost may approach 7-10 times that.9

The response by government to the increase in opioid addiction and death has been dramatic and expensive, but one must question effectiveness when thousands continue to die. The US Department of Health and Human Services and the Institute of Medicine produced a comprehensive plan more than 3 years ago that was meant to provide a road map to stem the tide of opioids. To date, most of the elements of the scheme have either not been implemented

or have not been shown to be effective. We will review and comment on some of these key elements of the federal plan.

Risk evaluation and mitigation strategies (REMS) were first proposed in 2012 as a method to educate physicians about the dangers and adverse events associated with longterm prescribing of opioids. After 5 years of this program, recent data, presented at a Food and Drug Administration (FDA) Advisory Committee Meeting (May 2016), demonstrated that fewer than one-third of clinicians avail themselves of this educational approach, and those who do have not substantially changed their clinical practice.<sup>11</sup> Four Advisory Committees (Advisory Committees on Analgesic and Anesthetic Drug Products and the Drug Safety and Risk Management Advisory Committees on 2 separate occasions), composed of experts in addiction, medical education, pharmacology, drug safety, and epidemiology, have stated unequivocally that for this educational plan to change physician behavior, it must be compulsory. To date, REMS training is still voluntary, controlled by the funding of pharmaceutical companies, and, in a recent article from the journal Pain, is ineffective in changing the prescribing behavior of clinicians. 12 This should not be a revelation, as multiple attempts to define and implement risk reduction plans associated with opioids in the past 20 years have been relatively ineffective.

Abuse deterrent formulations (ADFs) of opioids were developed with the hope that they would play a significant role in reducing deaths from opioids. By providing hydrocodone, oxycodone, morphine, and other opioids in forms that were difficult to inject or inhale, it was assumed that users would not take the time and effort to negate the ADF technology, thus extracting large quantities of opioid, and, therefore, fewer deaths would ensue. This predicted behavior has not reliably occurred for several reasons: First, users who do not have the technological skill to neutralize the ADF migrate to cheaper and more available illicit opioid products such as fentanyl and heroin. Second, despite the best effort of industrial chemists, many of the technologies created to produce the specific abuse deterrent technology are bypassed, some before the FDA has finished its evaluation.<sup>13</sup>

The Secretary of the US Department of Health and Human Services placed naloxone, a rescue agent for opioid intoxication, on the agenda for overdose prevention in 2015. Despite numerous public meetings and much public discussion, this life-saving drug, which has few contraindications, is still less available than it should be given the gravity of the present public health conundrum. This is in part due to increases in cost of the generic formulation likely driven by a desire for an increased profit margin. Therefore, despite an early flurry of activity, the federal action plan to reduce exposure and death due to opioids has been less than a success. What are we to make of this?

Our current situation demonstrates that despite dramatic resource utilization, more must be done to assure that every clinician prescribing opioids is aware of the risks to patients who are receiving these analgesics. Fortunately, there are specialist clinicians, those that practice comprehensive chronic pain medicine and addiction medicine, that have already provided a pathway for the consistent analysis and treatment of chronic pain, acute pain, and malignant pain, yet have been vilified to some extent because of the activities of a small number. Physicians who practice chronic pain

medicine are ideally placed to lead in the struggle against opioid misuse and abuse. The model of careful and continuing assessment of the need for opioids and the risks of long-term opioid treatment offer a pathway for the education of every clinician who prescribes the drugs. As we follow trends in opioid prescribing, we recognize that chronic pain physicians do not write most opioid prescriptions. Unfortunately, when the media and the public reflect on the possible causes of this crisis, clinicians dealing with chronic nonmalignant pain receive a disproportionate share of the blame. We believe that this assignation is misplaced, and that the public must be appropriately informed about the role that chronic pain physicians who use multimodal therapy, who educate their patients about the risks of opioids, and who closely monitor their patients on a continuing basis could play in the management of chronic pain and in reducing the risks of opioid therapy. We believe it is essential to utilize the tenets of chronic pain medicine as a requirement for the training of all clinicians who prescribe opioids.

Chronic pain physicians, in many respects, initiated the model of analyzing and treating chronic nonmalignant pain. In a seminal paper published in 1996, Portenoy<sup>14</sup> provided a treatise in 14 pages that only recently is being recreated in guidelines and statements from the Centers for Disease Control and Prevention and numerous professional organizations. Functional assessment rather than reliance on pain scores, the use of multimodal therapy with opioids as the last rather than the first treatment, the use of opioid treatment agreements with the patient, and early patient education concerning the risks of long-term opioid management have all come from the practice that we now term chronic pain medicine. The use of psychological resources to determine whether a patient is at risk for opioid abuse was an important addition to chronic pain treatment. Bringing psychologists, social workers, pharmacists, and nurses with specialized training to the table opened our eyes to the complexities of the medical disease and, further, the importance of mental health as an independent variable worthy of consideration. The early initiation of specialized physical therapy was an important precept that continues to play a significant role in advancing the patient's core and mental health. Yoga, stretching, and other physical remedies can assist patients in improving their functional condition. Each can play an important role in the overall treatment of pain. These and other modes of modifying a patient's requirement for long-term opioids reflect the framework that Portenov<sup>14</sup> predicted would be necessary for the successful management of pain. An increased use of these physical and psychological methods can incrementally reduce the necessity for the use of opioids while improving function and providing analgesia. If chronic pain can be treated without opioid medications, the worst of the risks are rarely experienced.

Certainly, the multimodal model of chronic pain treatment as demonstrated by pain specialists daily is a more complex therapy than that received by most patients who obtain opioids regularly from primary care physicians, nurse practitioners, and others. Thus, it is imperative to educate all health professional students and residents concerning the tenets of chronic and acute pain management and many active opioid-sparing treatments, as well as the fundamentals of addiction treatment. For the current generation of providers, opportunities to reduce opioid prescribing should be an integral part of all current REMS programs for all opioids. We ask that the FDA do what must be done: require mandatory training of all clinicians who will prescribe opioids and press the academic chronic pain medicine community to take the lead in this task. Also, given the association between addiction and mental illness, the negative stigma that patients feel when receiving treatment for mental health needs to be addressed. Many patients with major psychological risk factors receive opioids without due consideration to the increased risks. This represents a societal issue related to, among other things, the lack of expert psychiatrists, psychologists, and social workers, and is a national infamy. We implore Congress to greatly increase funding for the training and education of needed mental health specialists, chronic pain providers, and addiction specialists, and to provide predictable and ongoing support for the complex, multimodal pain therapy that is often needed but rarely reimbursed.

An action plan to train every physician, nurse, nurse practitioner, dentist, or any other health care provider on the principles of chronic pain medicine as part of a risk reduction program will be anathema to many. Some physicians will reject the idea out of hand, just as they have dismissed the current REMS programs that the FDA has championed. To these professionals, we would point out that we have turned a blind eye to addiction and death, not for 15 years, but for several generations. The "soldier's disease" has been with us since the Civil War, and now addiction and death affect children, adolescents, and moms and dads of every color and social station. We are paying a considerable price for our negligence.

The federal government has spent an inconceivable amount of money attempting to reduce prescription drug abuse and the use of illicit opioids. Though there have been incremental reductions in the number of prescriptions written, and these decrements should be recognized as the small but significant victories that they are, it will require a breathtaking change in the approach that individual clinicians take in the use of opioids to influence the addiction and mortality curves substantially. The model of medical care that chronic pain physicians have given us, careful assessment of risk in individual patients, continuing evaluation for the possibility of the development of complications

including diversion, and utilizing opioids as only one part of a multimodal approach to treatment, when used with care, is one answer to our national conundrum that, in our opinion, must be considered.

## **DISCLOSURES**

Name: Raeford E. Brown Jr, MD, FAAP.
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