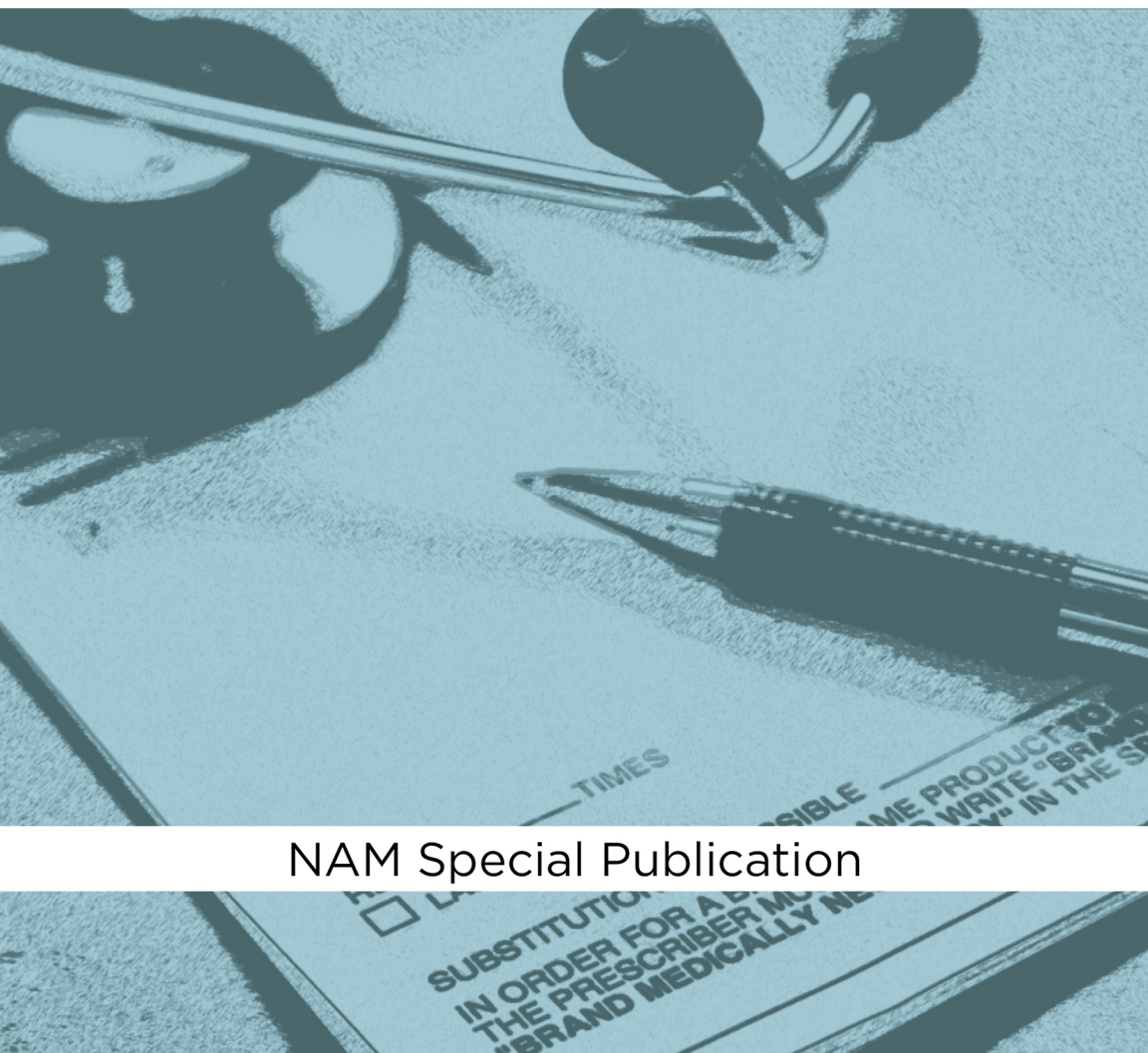




NATIONAL ACADEMY OF MEDICINE

First, Do No Harm

Marshaling Clinician Leadership to
Counter the Opioid Epidemic



NAM Special Publication

First, Do No Harm

Marshaling Clinician Leadership to
Counter the Opioid Epidemic



NATIONAL ACADEMY OF MEDICINE

WASHINGTON, DC

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*“Knowing is not enough; we must apply.
Willing is not enough; we must do.”*

—GOETHE

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NATIONAL ACADEMY OF MEDICINE

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FOREWORD

The nation is in the midst of a growing opioid-generated public health and medical crisis. The opioid epidemic now afflicts 2.5 million Americans, kills more than 90 every day, disrupts the lives of tens of millions more in the circles of victims' concerned families and loved ones, and imposes overwhelming treatment, financial, and organizational burdens on our states, communities, health care organizations, and clinicians. The President's Commission on Combating Drug Addiction and the Opioid Crisis has called for a national state of emergency, pointing out the scale of the epidemic as equivalent to a September 11 attack every 3 weeks, with a similarly tragic impact on the familial, social, and economic connections we all share.

Last year, 46 Governors signed the 2016 *Governors Compact to Fight Opioid Addiction*, pledging to redouble efforts, including the reduction of inappropriate prescribing and the provision of needed treatment services. It marked the first time in over a decade that the Governors have used a compact to drive collective action. A blueprint has been developed, and each state has set in motion renewed efforts to improve the effectiveness of community-level prevention and treatment activities, including shoring up the state-wide policy and enforcement capacities needed. Although we are seeing improved awareness, commitment, and initiative for change, the opioid crisis—the rapid rise of opioid use disorder—cannot be controlled without the partnership of key stakeholders.

Given its leadership role in science, policy, and practice, the National Academy of Medicine (NAM) is a committed stakeholder in this work. The National Academies' 2017 report *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* called attention to the importance of achieving the right balance in medicine's twin obligations to treat pain effectively and to prevent and treat opioid use disorder. It proposed a comprehensive strategy for doing so, including the use of effective nonopioid analgesics for chronic pain management, improved monitoring and assessment of the prescribing and use of opioids, incorporation of a public health perspective

in the FDA's review of pharmaceuticals, and reduction of barriers to treatment of opioid use disorder.

To ensure the synergy and reach of our efforts to the front lines, the NAM, at the request of the National Governors Association, has brought together a group of experts representing the key leadership of the nation's scientific, professional, and policy organizations to explore clinicians' role to counter the opioid epidemic. We are pleased to present the result of that work in this NAM Special Publication, *First Do No Harm: Marshaling Clinician Leadership to Counter the Opioid Epidemic*.

This call to action for the nation's clinicians—physicians, physician assistants, nurses, nurse practitioners, dentists, social workers, behavioral health practitioners, pharmacists, and first responders—examines the potential that resides in their reach, expertise, and commitment, and highlights their roles in prevention, management, and leadership to address this crisis. Through this lens, it outlines action steps to quicken the pace of progress as we marshal their energies and effectiveness in implementing strategies that will benefit both the health and well-being of their patients and the health of their communities. Only through the sort of collaboration represented here can we anticipate countering the opioid crisis and its toll on our patients, communities, states, and the nation. We are pleased to join together in this work and grateful to the authors for their foundational contribution.

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INTRODUCTION

The medical dictum *primum non nocere* (first, do no harm) is usually attributed to Hippocrates, and a poignant modern example of the injunction's warning lies in the balance between the legitimate value and inappropriate use of the substances derived from the opium poppy plant. Provisional estimates suggest that nearly 65,000 Americans died from an overdose of drugs in 2016, a 21 percent increase from the previous year (CDC, 2017b) that represents a nearly eight-fold increase in the past 37 years (Katz, 2017). All of the data suggest that the escalation is due substantially to opioids, with nearly two-thirds of all recent drug deaths now attributable to opioid misuse (Rudd et al., 2016).

For the nation's clinicians, the burdens are heavy and multifaceted, as they contend with the immediate consequences of the crisis for their patients, their colleagues, and their own families, and with the reality that a share of the responsibility for the problem lies with them. Although the underground illegal market for opioids is active, about half of opioid overdose deaths are related to medications obtained legally by prescription. It is, in part, a problem driven by supply, as the rapid increase in deaths involving both prescription and illicit opioids has mirrored the increase in opioid marketing and availability (*Figure 1*). Matching a four-fold increase in opioid sales between 1999 and 2010, overdose death rates quadrupled, and treatment admissions increased six-fold in roughly the same period (Paulozzi et al., 2011). Opiates are prescribed in the United States at rates many times higher than those in other countries (INCB, 2016). In 2015, about a third of American adults used a prescribed opioid (Han et al., 2017), with the total number of prescriptions exceeding 225 million at a prescribing rate of about 71 prescriptions per 100 persons (CDC, 2017c). Halting this epidemic therefore requires aggressive action across multiple dimensions, including informed, active, and determined frontline leadership from clinicians working in every setting throughout the nation.

Because of the essential leadership and action needed from clinicians to help prevent harm and suffering from prescription opioids, the National Academy of

Medicine, at the request of the National Governors Association, has stewarded the development of this publication. Written from the perspectives of the authors (active researchers, leaders, and participants in organizations committed to mobilizing the actions necessary to address this important public health problem), this publication summarizes the state of the opioid crisis—its sources, its impact, its solutions—and speaks in particular to the roles of clinicians, both as primary gatekeepers on the appropriate use of these drugs and as first responders to the consequences of their misuse.

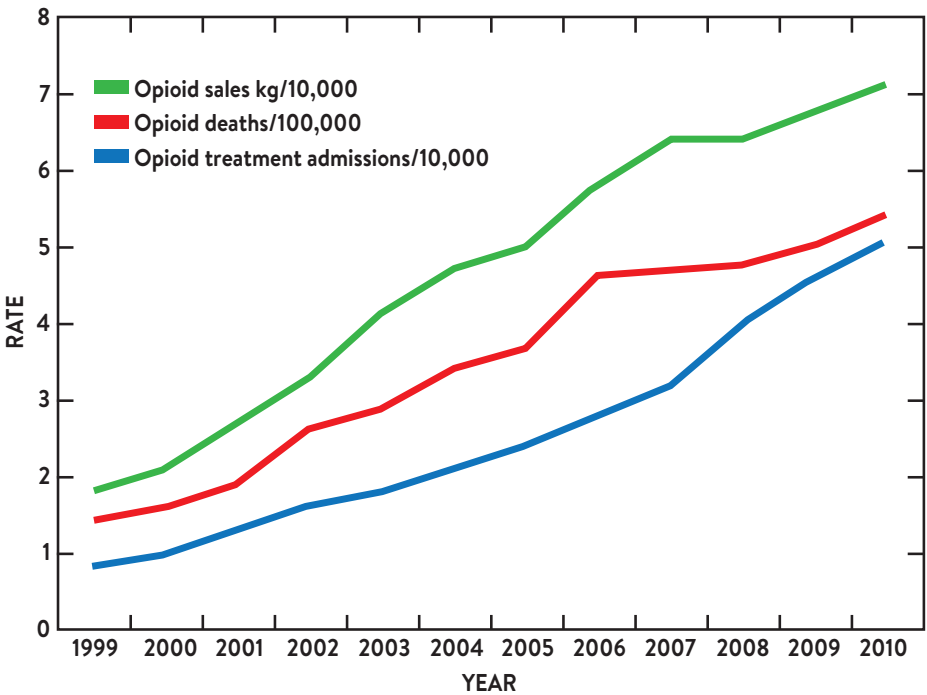


FIGURE 1 | Concurrent increase in opioid sales, deaths, and admissions to treat opioid use disorder.

SOURCE: Kolodny, 2015.

In the following pages, we briefly describe the crisis, its nature and sources, and its consequences for individuals, families, and communities across the nation. We then reflect on the many potential challenges of the opioid epidemic, including the real need to provide relief to those suffering from severe pain. We provide examples of effective strategies for pain management and insights on the work of various organizations who are providing leadership to address the crisis. Finally, we offer a short summary of the key elements and resources essential for every

clinician to have on hand whenever an opioid prescription is considered or a patient presents with a likely opioid use disorder, enabling clinicians to assume their broader leadership responsibility to advance the health of the communities in which they live and serve.

WHAT IS THE MAGNITUDE OF THE OPIOID EPIDEMIC?

In 2015, there were about 20,000 deaths due to opioid pharmaceuticals (including illicit analogs, accounting for much of the recent increase) and another 13,000 deaths from heroin. An estimated 2.5 million Americans now struggle with opioid dependence or use disorder (CBHSQ, 2014), and more than 1,000 people daily present to emergency departments for misusing prescription opioids (CDC, 2017c). With acute capacity pressure on emergency departments and addiction treatment centers, and limited access to office-based treatments, most patients with opioid use disorder have difficulty gaining access to treatment (Saloner and Karthikeyan, 2015).

The term “epidemic” has historically been used to refer to the outbreak and rapid spread, often person-to-person, of an infectious disease, such as smallpox, plague, and cholera. In today’s parlance, the term is frequently used in referring more broadly to any disease or condition that is newly occurring or having newly recognized impact, ascending in prevalence, and presenting a threat to an undetermined but increasingly large population. Defining elements include the number of people affected, the seriousness of the consequences, the certainty that consequences will occur with exposure to the condition, and the rate of spread in the occurrence of those consequences. Chronic conditions such as obesity, diabetes, Alzheimer’s disease, and lung cancer have also been recently characterized as epidemics.

Given the rapid increase in opioid use and related harms, the nation clearly faces an epidemic of opioid use disorder. The relatively young age of those with opioid use disorder—and the wrenching familial, social, and economic consequences on those affected—imparts a particular sense of urgency to the challenge. In a short period, annual deaths from drug overdoses in the United States—with the largest and most rapid increases attributable to opioids—have already come to exceed the peak levels experienced with either HIV infections or automobile fatalities (Katz, 2017). In terms of the combination of numbers, lethality, scale, trajectory, immediacy of impact, and abrupt social disruption, there is no question that opioid use disorder has become the fastest growing, most serious, and furthest reaching public health crisis facing our nation today.

WHICH OPIOIDS ARE MOST COMMONLY INVOLVED IN OVERDOSE DEATHS?

Common to multiple opioid substances is their action at the same receptor sites—the μ opioid receptor—as morphine, which is produced from the resin of the opium poppy. In addition to morphine, opioids include synthetic and semi-synthetic drugs, such as heroin, methadone, oxycodone (e.g., OxyContin®), hydrocodone (e.g., Vicodin®), tramadol, oxymorphone, meperidine, fentanyl, and carfentanil. Nearly two dozen opioids have been approved by the Food and Drug Administration (FDA) for introduction into therapeutic use (FDA, 2017b). Along with their pain-relieving capacity, opioids have been associated with various side effects, including psychoactive changes, respiratory depression, hyperesthesia, and constipation. With chronic exposure, people usually develop a tolerance for opioids—requiring larger doses to achieve the same effects—and become physically dependent, exhibiting withdrawal symptoms with abrupt discontinuation or lowering of doses. The effects also cross the placenta to fetuses, and infants born to women using opioids during pregnancy are at particular risk of neonatal abstinence syndrome.

The inherent potential lethality of opioids is increased by various factors, such as simultaneous use with alcohol or benzodiazepines or use of illicit opioids (often of uncertain content or potency). From 1999 to 2011, deaths from prescribed opioids increased threefold and then began to level off. But from 2011 to 2015, the use of illicit opioids (heroin and fentanyl/fentanyl analogs) was associated with a three-fold increase in deaths (*Figure 2*). Subsequently, overall opioid death rates have continued to increase, driven by increases in supply and availability, and use of relatively affordable heroin—and even greater increases in use of illicit synthetic opioids, especially fentanyl and fentanyl analogs, which now represent the most rapidly growing contributors to overdose deaths.

Increasingly, the heroin sold on the street is combined with the more potent fentanyl and, more recently, with the even more lethal fentanyl analog, carfentanil, used by dealers to increase profitability and ease of transport. Fentanyl is 50 to 100 times more potent, on average, than heroin, and carfentanil is, in turn, 100 times more potent than fentanyl. This underscores the urgency of efforts to reduce importation of heroin and synthetic opioids; improve the accessibility of the opioid antidote, naloxone (Narcan), and of the training in its use; and expand opioid use disorder screening and medication-assisted treatment (MAT) capacity.

WHAT ARE THE ASSOCIATED CHARACTERISTICS OF THOSE WITH OPIOID USE DISORDER?

Persons with opioid use disorder do not fit a generalizable profile. Where studies in the 1970s and 1980s characterized the heroin problem as one primarily of urban minority populations (DuPont, 1971), today's heroin users are more typically white men and women who were introduced to opioids through prescription drugs (Cicero et al., 2014). Overdose rates are higher in non-Hispanic whites than in African Americans or Hispanic Americans (Anderson et al., 2009; Ghandour et al., 2008; HKFF, 2015; Ringwalt et al., 2015). Men were previously more likely than women to die from opioid overdoses, but the gap is narrowing (CDC, 2015). Because the highest rates of overdose deaths occur among those ages 25 to 54, the recent and unexpected increase in death rates and decreases in life expectancy among middle-aged white men and women in the United States is ascribed in part to the rise in drug overdose deaths (Case and Deaton, 2015).

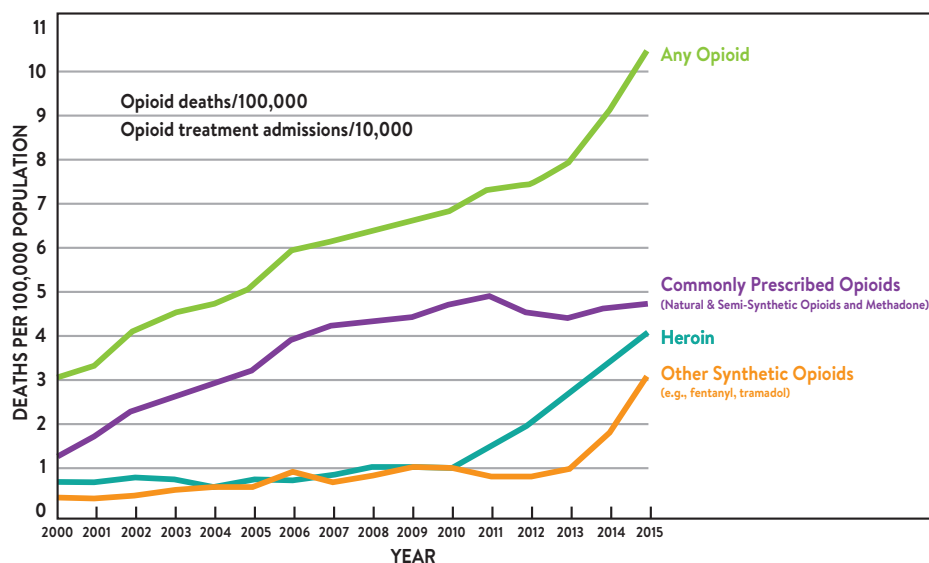


FIGURE 2 | Overdose deaths involving opioids, United States, 2000–2015.

SOURCE: CDC, 2017a.

Previously, deaths involving opioid analgesics in rural areas outpaced those in cities (Keyes et al., 2014; Paulozzi and Xi, 2008), but rates for overdoses overall are beginning to even out. Disparities also exist among populations with respect to access to both pain management and treatment for opioid use disorder, as it

appears that clinicians may provide less aggressive treatment for pain (including opioids) to African Americans and Hispanic Americans, perhaps due to conscious or subconscious biases, or misperceptions that pain is experienced differently according to race (Weisse et al., 2005).

A challenge in understanding the nature and sources of, and trends and shifts in, the use and impact of various categories of opioids has been the inconsistent and inadequate support for monitoring systems. Ironically, as the epidemic was beginning to take form, support for two of the surveillance programs—the DAWN (Drug Abuse Warning Network) and the ADAM (Arrestee Drug Abuse Monitoring) programs—was eliminated, ADAM in 2004 and DAWN in 2011.

Overall, accelerated in part by lack of awareness, misinformation, misperceptions, and misinterpretations, the epidemic has spread so vastly that few families—regardless of ethnicity, age, geographic location, or socioeconomic status—remain untouched in some fashion by the occurrence of opioid use disorder or death among their circle of family members, friends, colleagues, and acquaintances. Along with the rapidly growing numbers, the broad demographics of those suffering from the consequences of opioid use disorder has focused attention on, and shifted prevailing attitudes toward, use of opioids as a public health crisis.

HOW DOES THE OPIOID EPIDEMIC IMPACT OUR FAMILIES AND OUR COMMUNITIES?

The impact of the opioid crisis extends well beyond the mortality tables, deeply impacting lives in communities, schools, and homes. Already shallow addiction treatment capacity in many communities is seriously strained, with waiting lists sometimes comprising hundreds of people. Nationwide, 9 of every 10 persons with opioid use disorder do not receive the treatment they need, and around 80 percent of people ready to accept help for opioid use disorder report an inability to access treatment (Jones et al., 2015; Saloner and Karthikeyan, 2015).

Emergency departments, often representing the front lines of care for overdose victims, are also stretched to the limits of their capacities, their resources diverted by the need to treat rapidly increasing numbers who have overdosed. Between 2009 and 2014, opioid-related emergency department visits nearly doubled. The state of Ohio saw the greatest jump in visits, with a 106 percent increase (Weiss et al., 2016). In Dayton, Ohio, at least 20 percent of emergency department visits have been related to drug or alcohol abuse (Wedell, 2017; Weiss et al., 2016). Overdose occurrences have become so prevalent in

many places that policy makers have been compelled to implement special training programs for the management of overdoses and the administration of the lifesaving antidote naloxone. One Ohio community experiencing a doubled number of overdoses requiring naloxone—and ambulances and medics to provide emergency services—even discussed, alarmingly, a “three strikes” rule, withholding care after the third call to revive the same person (Honig, 2017).

One estimate suggested that the medical costs alone for each case of opioid misuse, dependence, and overdose are greater than \$15,000 annually (Kirson et al., 2017), with indirect costs from lost wages and productivity pushing actual societal costs much higher. Nationally, with the accelerating pace of the epidemic, the overall costs to the nation have not yet been fully assessed, but the societal costs of prescription opioid misuse were estimated in 2013 at \$78.5 billion, inclusive of costs for health care, criminal justice, and lost productivity (Florence et al., 2016). The human and economic consequences of the opioid epidemic are so striking that it is not surprising that the nation’s governors, with their 2016 Compact to Fight Opioid Addiction, positioned combating the opioid epidemic at the top of their states’ agendas.

WHAT HAS DRIVEN THE EPIDEMIC?

Prescribing

Many factors have intersected to drive the rate and reach of the opioid epidemic. Prescribing practices have played a substantial role, but those practices have been shaped, in turn, by circumstances ranging from medical issues—increases in chronic diseases, new surgical interventions, professional calls for better pain management—to the influence of market distortions, including misinterpretation of scientific data, introduction of new products, commercial marketing, and large quantities of unused opioids made easily accessible in the home.

In the 1980s, advocacy groups began raising awareness of inadequate pain treatment for people with cancer (Paice and Roenn, 2014), and the use of opioids for treatment of cancer-related pain soon increased. There were calls to introduce the notion of pain as a “fifth vital sign” (beyond the usual vital signs of body temperature, heart rate, respiratory rate, and blood pressure) that should be inquired about at every clinician–patient encounter. Pharmaceutical companies increased the development and marketing of new opioid products, with FDA approving nearly two dozen new products between 1990 and 2017 (FDA, 2017b). The Joint Commission initiated the requirement of pain assessments

in patients even during routine clinic visits and the organization of pain management educational programs for prescribers (Joint Commission, 2016). As societal pressure increased, many more clinicians became primed for the need to effectively recognize, treat, and, if possible, eliminate pain.

Around the same time, a few observations in the scientific literature suggested that the addictive properties of opioids might have been overstated. A short letter to the editor of a prominent medical journal, for example, reported very low rates of addiction from opioid use among patients recorded in a 40,000-person hospital database (Portenoy and Foley, 1986; Porter and Jick, 1980). Despite the fact that these patients had not been receiving long-term opioids for chronic pain, widely published media reports at the time emphasized strong benefits and low risks from opioids for chronic pain management. Such reports resulted in a greater propensity to prescribe opioids by clinicians and aggressive marketing by pharmaceutical manufacturing companies. Before long, opioids were being aggressively marketed not just for cancer pain, but for treatment of chronic pain in general. With investments in the hundreds of millions of dollars (Van Zee, 2009), and little acknowledgment of side effects, marketing strategies from interested companies included pain-management and clinician speaker-training conferences, the dissemination of potentially misleading information about benefits and risks of opioids, and bonus systems to incentivize sales (Meier, 2007).

Recognition of the emerging crisis has now prompted the development of strong efforts to raise awareness among clinicians of the need for vigilance and counteraction, and these efforts are beginning to take some effect. While opioid prescriptions decreased by 18 percent from 2010 to 2015, prescribing rates today remain at least triple what they were in 1999 and quadruple the opioid prescription rates in Europe (Guy, 2017).

A related element contributing to the lag in recognition of and response to the opioid crisis is the stigma often associated with substance use disorders. There is a pervasive notion among many members of the public and even some clinicians that those who suffer from drug or alcohol dependence may be reaping the consequences of their own choices, and that these are character flaws. The science, however, indicates otherwise. Like any other chronic disease—such as diabetes, hypertension, and cancer—substance use disorder is the product of individual differences in the results of the interplay between biology, behavior, and environment, and requires sustained, multifaceted, and team-oriented treatment regimens. Adequately addressing these issues, individually or societally, requires not their conceptual and practical sequestration, but their integration into the established chronic disease management paradigm.

Illicit and Illegal Opioids

Although studies show that only a relatively small proportion of people who use prescription opioids will subsequently use illicit opioids, both legally obtained and illicit opioids clearly contribute to the epidemic. Individuals who misuse prescription opioids are 19 times more likely to use heroin (Muhuri et al., 2013), and an increasing proportion of the deaths involving opioids are associated with heroin and illegally made fentanyl. In 2015, compared to the previous year, deaths from synthetic opioids, including fentanyl, increased by 72 percent, and deaths from heroin increased by 20 percent (Rudd, 2016). The transition to illicit drugs can often be attributed to their lower costs relative to prescription opioids. A primary factor in the shift in the nature of heroin use now, relative to that in the 1970s, has been the marked decline in its price on the street. Both heroin and illicit fentanyl are readily available and often less expensive than their prescribed counterparts (Compton et al., 2016).

In addition, the rapid growth in opioid prescriptions for both acute and chronic pain management has led in the aggregate to large quantities of unused opioid medications being stored insecurely in homes for long periods (Bartels et al., 2016). There, they are available for sharing, trading, sale, or theft by family members, friends, and others (Jones et al., 2014). Among high school seniors, the start of opioid use is often linked to the use of leftover opioids prescribed for another individual.

ARE EFFECTIVE PAIN MANAGEMENT AND OPIOID CRISIS MITIGATION COMPETING PRIORITIES?

In the face of competing clinical obligations—to manage people’s pain effectively and to reduce or eliminate the serious harms associated with opioids—the question before prescribers is how best to improve their approach to both. Some reports suggest that as many as one in four patients may become dependent after the initial use of opioids for noncancer pain management (SAMHSA, 2013; Volkow and McLellan, 2016). High dosages (Chou et al., 2014; Dunn et al., 2010; Larochelle et al., 2016), long-acting formulations (Martin, 2017), treatment by high-intensity prescribers (Barnett et al., 2017), multiple prescription sources (Baumblatt et al., 2014), and a family history of addiction are factors that predict a higher likelihood of transition to long-term use after initial treatment with opioids (Edlund et al., 2014). Risk factors for overdose include high-dose prescriptions and use with certain other medications, such as benzodiazepines and methadone. But reliable, well-designed studies of risk factor identification are lacking. The characteristics of patients who may be most susceptible to

dependence, the likelihood that addiction will result after the initial prescription, and factors associated with increased susceptibility require further study (Minozzi et al., 2013). In the absence of definitive evidence, structured approaches to pain management and substantially enhanced recognition and treatment of opioid use disorder are essential.

Non-Opioid Pain Treatments

After two decades of increasing use of opioids, experts caution that opioid prescribing is greater than what is warranted, based on what we know about the benefits of long-term opioid therapy (Kissin, 2013; Von Korff et al., 2011). Several literature reviews have found that evidence on long-term benefits is insufficient to draw meaningful conclusions (Chaparro et al., 2013; Chou et al., 2014; Martell et al., 2007; McNicol et al., 2013; Noble et al., 2010; Papaleontiou et al., 2010). Initial results from the Strategies for Prescribing Analgesics Comparative Effectiveness trial, the first and only long-term (12-month) randomized controlled trial comparing opioid and non-opioid therapies for chronic pain, found opioids associated with no benefits for either function or pain intensity (Krebs et al., 2017). In fact, some evidence suggests the possibility of *increased* pain sensitivity with opioid use. Alternative medications such as non-opioid analgesics, antidepressants, or anti-seizure drugs are recommended as reasonable alternatives to opioids for certain chronic pain conditions. Though there is still much to learn about long-term benefits of non-opioid interventions, guidelines from the Centers for Disease Control and Prevention (CDC) recommend non-opioid therapies as the preferred therapy for chronic pain, based on evidence showing benefits, with lower (though not absent) risk of harm (Dowell et al., 2016).

Similarly, the American Dental Association now recommends nonsteroidal anti-inflammatory analgesics as first-line therapy for acute pain management for tooth extractions (ADA, 2017). This recommendation is based in part on the increased risk of prescribing opioids to adolescents undergoing third molar extractions as well as on evidence demonstrating that a combination of ibuprofen and acetaminophen is effective at managing pain from tooth extractions (Moore et al., 2015).

The recent National Academies of Sciences, Engineering, and Medicine (the National Academies) report *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use* (NASEM, 2017) challenges clinicians and health care systems to reevaluate how opioids fit into the larger array of pain management strategies. Successful management of painful disorders relies on multiple treatment modalities, underscoring that certain non-opioids can be as effective as opioids in managing pain, with lower risks of harm. Given what is known about how to best treat pain, deemphasizing the use

of opioids is an important consideration that must be a part of efforts to improve chronic pain management.

Nonpharmacologic Pain Treatments

There has been increased emphasis by many clinicians on nonpharmacologic treatments for the management of chronic pain. These are treatments that target important psychosocial contributors to pain or focus on movement and return of function. Nonpharmacologic treatments supported by evidence of effectiveness include exercise therapy (Hayden et al., 2005; Van Middelkoop et al., 2011), psychological interventions (e.g., cognitive behavioral therapy) (Ehde et al., 2014), interventions to improve sleep (Miró et al., 2011; Smith and Haythornthwaite, 2004), mind-body interventions (e.g., yoga, tai chi, meditation, and mindfulness-based stress reduction) (Astin, 2004; Garland et al., 2014), manipulation treatment, acupuncture, massage, and interdisciplinary rehabilitation (Gatchel and Okifuji, 2006). Not all of these interventions, however, are available to all patients with pain. In some cases, those who specialize in these treatments may not be available in all areas, and in other cases they may not be affordable due to high insurance deductibles or lack of health insurance coverage altogether.

Special Considerations

In weighing opioid versus non-opioid management of pain, certain populations warrant additional considerations due to factors that affect the benefit-risk ratio. Active cancer, palliative care, and end-of-life care patients are generally viewed as exceptions in this regard because, even at high doses, the benefits of opioids are generally thought to outweigh the risks in these situations, and because the ethical imperative for rapid relief of suffering is so strong in persons with such serious or fatal conditions.

Persons who merit particular caution before being prescribed opioids include children and young adults, pregnant women, those with medical or psychiatric comorbidities, those with substance use disorders, and those who live in circumstances conducive to misuse. Approaches to prescribing (or continuing to prescribe) opioids to patients in these groups should reflect the understanding that they are potentially at greater vulnerability for harm.

WHAT GUIDANCE AND ASSISTANCE IS AVAILABLE FROM PROFESSIONAL AND POLICY ORGANIZATIONS?

Responses to the wide-ranging implications and impact of the opioid epidemic by professional and policy organizations throughout the nation include

recommendations, guidelines, funding, and other resources to help patients, clinicians, and their communities in their efforts (*Table 1*). These efforts cover many issues and activities, including prescribing recommendations or policies, opioid use disorder treatment payment policies, data and tracking improvements, and drug review and approval processes.

Opioid Prescribing Policies

Various professional, state, and federal health organizations have developed guidance and policies for responsible opioid prescribing practices. *Table 1* provides examples from the American Medical Association (AMA), the Association of American Medical Colleges (AAMC), the Federation of State Medical Boards (FSMB), CDC, FDA, and the Department of Veterans Affairs (VA), which issued its guidance in conjunction with the Department of Defense (DoD). Those from CDC, VA, and the DoD present quantitative guidance regarding appropriate dosing of opioids for chronic pain and duration of opioid therapy for acute pain. The FSMB has played an important role in harmonizing state-level guidance for opioid prescribing. Almost every state also now authorizes first responders and laypersons to use naloxone to reverse suspected opioid overdose.

Opioid Use Disorder Treatment Policies

Various professional, policy, and regulatory authorities have developed guidance on treatment and referral of patients with opioid use disorder, including the use of medication-assisted treatment (MAT) with buprenorphine, Suboxone (buprenorphine co-formulated with naloxone), methadone, and Vivitrol (naltrexone long-acting injectable). To provide buprenorphine-naloxone for treatment of opioid use disorder, physicians, nurse practitioners, and physician assistants can obtain a waiver from the Drug Enforcement Administration (DEA) after 8 hours of training for physicians and 24 hours for nurse practitioners and physician assistants (a waiver program and training is administered by the Substance Abuse and Mental Health Services Administration) (Rapoport and Rowley, 2017; SAMHSA, 2017a; SAMHSA, 2017b). Because currently only about 4 percent of active physicians have obtained such waivers (Rapoport and Rowley, 2017), clinicians can help improve access to treatment either by obtaining the waiver and requisite training or by familiarizing themselves with fellow practitioners who have, to ensure a successful hand-off of patients who need care. Although the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act authorized additional funds to states for prevention and treatment of opioid use disorder, capacity and payments for treatment, in particular, remain inadequate. Insurance and payment policies that incentivize optimal care could support ready

access to well-trained interdisciplinary team approaches, including both MAT and nonpharmacological interventions. Despite the provisions of the Mental Health Parity and Addiction Equity Act of 2008 requiring equitable treatment (see below), procedures and requirements established by many payers often present *de facto* barriers to patients, families, and clinicians seeking payment for substance use disorder treatment.

Opioid Use Data Improvement

Improving quality of care requires data of a better quality to understand the problems and guide decisions, even beyond results of the inaccessibility of information about illicit and diverted opioid supplies. Although various research organizations and local, state, and federal health agencies are actively engaged in collecting data on opioid prescribing and use patterns, the fragmented nature of the data collection efforts imposes substantial limitations. At a minimum, efforts to restore and build improved data collection and analysis from ongoing activities within health systems (e.g., care delivery, care improvement, performance transparency, patient registries, patient-powered research networks and online forums) could lay the groundwork for more effective and safer pain care tailored to circumstances, and to enhanced effectiveness of policy initiatives, public education efforts, and targeted treatment (Bruehl et al., 2013; Etheredge, 2007; Reid et al., 2011).

Opioid Product Review, Approval, Use, and Marketing Regulation

Part of the challenge of the over-prescribing of opioids is related to the development, introduction, and marketing of opioid formulations. Typically, FDA reviews proposed products based on documentation of their safety and effectiveness performance under expected dose and duration patterns for individuals. But opioids have generally been approved on the basis of short-term trials in highly selected populations at low risk for opioid use disorder and with few psychiatric and medical comorbidities. Indeed, for products such as opioids, with their considerable potential for use (and misuse) in patterns departing from those commonly expected, the public health implications should also be considered in the review and approval process. Recommendations of this sort were advanced in the 2017 National Academies' report (NASEM, 2017), and the recommendations' adoption would have bearing on the variety of formulations entered into the market, their approved doses, and the requirements related to their use. On the research front, FDA and the National Institutes of Health are actively encouraging the development of abuse-deterrent formulations (FDA, 2017c; Volkow and Collins, 2017), although there are potential complications with this dimension

as well. Some individuals may carry the unintended consequence of increasing the use of substitute drugs, including heroin and fentanyl (Alpert et al., 2017; Volkow and Collins, 2017).

TABLE 1 | Organizational Commentaries and Recommendations

AUDIENCE	AMA ^A	AAMC ^B	FSMB ^C	CDC ^D	FDA ^E	VA/DOD ^F
Physicians	++	+	+	++	++	++
All clinicians	+	+	+	+	++	++
Clinicians in training	++	++		+	+	+
State medical boards			++			
Local health departments				+		
Pharmaceutical manufacturers					+	
Patients	+		+			+
Policy makers	+					
SCIENTIFIC CONCLUSIONS						
Opioids of epidemic-level concern	++	++	++	++	++	++
Opioids useful for chronic pain	+/-		+/-	+/-	-	-
Short-acting opioids for acute pain	+/-		+	+		+
Non-opioid analgesics for chronic pain	++	+	++	++		++
Usefulness of pain assessment tools	+/-	++	+/-	+		
RECOMMENDATIONS ON THERAPEUTIC OPIOID USE						
Cancer/palliative care	+		+			+
Chronic pain management	-	-	-	-	-	-
Need for social assessment						+
Role for urine/blood tests	+/-	++	+		++	+
Check state PDMP	++	+	++	+	++	++
Articulate treatment goals	+	+	+	+		+
Written treatment agreement	+/-		++	+		+/-
Lowest possible dose at first use	+		++	++		++
Dosing caution for long-acting				++		++
Naloxone co-prescribed for home use	++		++		++	++
Mention of non-opioid analgesics	++	++	++		++	+

Mention nonpharmacologic options	++	++	++	++		++
RECOMMENDATIONS ON TREATMENT OF OPIOID USE DISORDER						
Use of medications	++		+	++	+	++
Referral to specialty care	+			+		++
EDUCATION RECOMMENDATIONS						
Improve prescriber education	++	++	++	++	++	++
Improve patient education	++		++	++	++	++

SOURCES: a = AMA, 2017; b = AAMC, 2017; c = FSMB, 2017; d = Dowell et al., 2016; e = FDA, 2017a; f = VA/DoD, 2017.

NOTES: ++ = yes or recommended; + = positive; +/- = equivocal; - = evidence lacking.

WHAT ARE PRIMARY CLINICIAN OPPORTUNITIES TO COUNTER THE EPIDEMIC AND ITS CONSEQUENCES?

Just as *primum non nocere* is the foundation for clinician action, it primarily serves as obligatory prelude to the primary duty, *deinde benefacere* (then, do some good). The opportunities are abundant. Approximately 5 million clinicians are actively delivering patient care in communities throughout the nation. The largest group is nurses, and the most referenced in the context of clinician engagement in pain management are physicians (there are 950,000 licensed physicians) and nurse practitioners (about 220,000). But the pool of skilled and dedicated health professionals providing capacity and leadership to health initiatives in pain management and opioid crisis mitigation also includes dentists, psychologists, pharmacists, physician assistants, registered nurses, physical therapists, podiatrists, occupational therapists, dental hygienists, paramedical assistants, emergency medical technicians, and social workers, as well as others who assist them.

All are important to successfully countering the opioid epidemic, whether through caring for persons prescribed opioid medications, providing assistance to those who need it, or rallying community action. In carrying out their respective daily roles, as well as through their community activities, each clinician—and their other colleagues in the health professions—has access to numerous frontline and supportive opportunities to help turn the tide, including:

- Using a team-based approach to care, especially important in substance use disorders

- Emphasizing that substance use disorders are treatable chronic neurologic conditions, requiring the sustained, multifaceted approach typical of managing any chronic disease
- Precautionary prescribing that accounts for individual risk factors and social circumstances
- Counseling of patients and caregivers regarding secure storage and proper disposal of unused opioids
- Prescription Drug Monitoring Program (PDMP) cross-checking to identify unsafe drug use behaviors
- Systematic followup by the care team for signs of opioid misuse or opioid use disorder
- Co-prescribing naloxone to patients at risk of overdose
- Facilitating use of medication (e.g., buprenorphine/naloxone), as indicated, for opioid use disorder, including obtaining training and authority for MAT
- Referral for treatment assistance, as indicated, including follow-up with the referral team
- Community engagement to promote the availability of necessary substance use disorder treatment resources

Optimal management of opioid use disorder is facilitated through effective coordination as a team. Although the role of individual team members will vary, each clinician involved in the care of people who are prescribed opioids bears responsibility to ensure optimal pain management and safety of their patients. Similarly, they have an opportunity to promote awareness and stewardship in the performance of each component of the system.

BOX 1

Opportunities for Clinicians to Counter the Opioid Epidemic

Opportunities for All Clinicians

- Ensure that all who interact with the patient are working as informed team members.
- Ensure patient engagement in options, protocols, and plans in pain management.
- Precautionary pain prescribing: PDMP check, urine test, benefit-risk discussion, start low/go slow, reassess.
- Have conversations about limits and risks of opioids in chronic pain management.
- Counsel patients and caregivers regarding secure storage and proper disposal of unused opioids.

- Emphasize that substance use disorders are treatable chronic neurologic conditions, requiring the sustained, multifaceted approach typical in managing any chronic disease.
- Reduce stigma: Understand, emphasize, and reinforce the chronic disease nature of addiction.
- Remain alert for early signs of opioid use disorder and candidates for naloxone co-prescription.
- Keep current on use of office-based treatments for opioid use disorder (e.g., buprenorphine, Suboxone).
- Keep current on cognitive behavioral treatments for opioid use disorder.
- Promote individual and community awareness of treatment needs, services, and access.

Particular Opportunities for Clinician Groups

Primary Care Physicians

- Establish communication pathways for seamless, multi-party team treatment and referral as needed.
- Exercise chronic pain precautions: PDMP check, urine test, benefit-risk discussion, start low/go slow, reassess.
- Reduce high-risk prescribing practices, (e.g., use of high doses or co-prescribing of opioids with benzodiazepines).
- Co-prescribe naloxone to patients at risk of overdose.
- Provide office-based, medication-assisted treatment of opioid use disorder (e.g., buprenorphine/naloxone).

Dentists

- Emphasize use of non-opioid analgesics post-procedure.
- Employ all precautionary protocols, such as use of the PDMP, counseling on risks and benefits, and assessment of patients for baseline risk of opioids complications such as baseline comorbid substance use disorders in selection of acute pain management plan.

Pharmacists

- Dispense naloxone under standing orders or similar procedures.
- Be alert to use patterns, dosage and duration factors, prescription interactions (e.g., sedative-opioids).
- Undertake PDMP checks in dispensing opioids.
- Notify primary care clinicians of concerning behaviors (e.g., early refill requests, multiple providers).
- Provide community leadership for needed service coordination and capacity.

Pain Specialists

- Support primary care physicians and others providing frontline pain management.
- Maintain particular vigilance for dependence and provide links to treatment services.

Psychiatrists and Addiction Medicine Physicians

- Steward and educate in the provision of medication-assisted treatment.
- Ensure closely coordinated communication with primary care team.

Social Workers and Other Behavioral Specialists

- Assess and ensure optimal teamwork in identifying and treating opioid use disorder.
- Ensure closely coordinated communication with primary care team.

Nurses

- Assess and ensure optimal teamwork in identifying and treating opioid use disorder.
- As indicated, facilitate access to opioid overdose education, naloxone prescription, and MAT (e.g., buprenorphine-naloxone).

Physician Assistants and Nurse Practitioners

- Assess and ensure optimal teamwork in identifying and treating opioid use disorder.
- As indicated, facilitate access to opioid overdose education, naloxone prescription, and MAT (e.g., buprenorphine-naloxone).

First Responders and Emergency Department Clinicians

- Exercise training, skills, and outreach to improve access to naloxone for emergencies.
- Be aware of—and link patients to, when possible—community capacity and services for opioid use disorder treatment.

SUMMARY MESSAGES: CALLING THE NATION'S CLINICIANS TO ACTION

Throughout this paper, and summarized below, are the core messages important for the successful marshaling of clinician leadership for progress against a health challenge that poses a formidable threat to the nation. These messages are anchored in certain key actions: work to reduce stigma by routinely emphasizing that substance use disorders are chronic neurologic conditions that require the sustained, multifaceted team approach typical for other chronic diseases; understand and prioritize non-opioid analgesics and other treatment options in a multi-modal approach to pain management; when opioids are indicated, employ conservative dosage regimens; review PDMP data; offer naloxone to reduce risk of unintentional overdose; have a clear treatment plan including steps

to slowly taper and discontinue therapy when indicated; and, for patients who do develop opioid use disorder, provide access to treatment with buprenorphine, methadone, or naltrexone and other forms of MAT, including direct provision through clinician training and waiver authority under the Drug Addiction Treatment Act of 2000.

Prioritize non-opioid strategies for chronic pain management. Except for conditions such as cancer, palliative care, and end-of-life care, look first to non-opioid approaches proven effective for most patients in need of chronic pain control. If the realistic benefits are thought to outweigh the serious risks of opioids for a given patient, clinicians should use them in combination with other modalities, as appropriate, to provide greater benefits to patients in improving pain and function.

Follow five basic axioms of responsible opioid prescribing. The following principles of responsible opioid prescribing are anchored in the science and the ethics of the circumstances:

1. **Tailor the treatment for each patient.** Thoroughly understanding the full range of factors in play is especially critical in pain management. As the golden rule of medicine, “first do no harm,” conveys an inherently complicated challenge to execute, its successful application requires full accounting for the patient’s circumstances, clinically and socially; a full discussion of relevant issues of concern; and emphasis on vigilance for dependence as a routine element of the care process.
2. **Employ precautionary protocols.** Standard precautionary protocols for treatment with opioids include obtaining a thorough, targeted medical history; checking the state PDMP database for dangerous drug combinations (e.g., benzodiazepine) or dosages (CDC recommends that physicians review PDMP data before every opioid prescription, or at least every three months); obtaining urine drug screens prior to initiating opioids and periodically in persons prescribed opioids; thoroughly discussing with patients the nature, expected course, risks, and management of the medication; initiating opioid therapy using short-acting formulations at low doses and titrating slowly. “Start low and go slow” is recommended for any new opioid prescription—VA/DoD recommends a starting dose of less than 20 morphine milligram equivalents (MME); CDC recommends increased vigilance at doses greater than 50 MME and employing doses greater than 90 MME only in unusual circumstances.
3. **Actively manage and monitor.** Treatment merely begins with the opioid prescription and the requisite protocols and counseling. A mutually

agreed-upon therapeutic plan and dosing timetable should be developed prior to initiating opioids and should be accompanied by actively monitoring the patient against the plan for tapering the medications, assessment for signs of opioid use disorder, and preparation to refer patients to addiction expertise, as indicated.

4. **Work as a team.** Health care is ever-increasing in complexity, requiring the adoption of a team approach in most circumstances. This is especially the case for management of chronic conditions such as opioid use disorder, and each clinician should prepare for the likelihood of encountering patients with opioid use disorder. This requires building an in-practice team orientation, including patients and family as team members, developing contingency alternatives for treatment referral, and, as possible, obtaining training and DEA waiver authority to use buprenorphine–naloxone in treatment. At the practice level, each team member should be familiar with the characteristics and risks of relevant medications, with the availability of addiction treatment opportunities, and with naloxone intervention use.
5. **Treat and link to treatment services.** With the complexities of managing opioid dependence—including provision and education on naloxone, and counseling and MAT for long-term care—a team-based, intensively patient-centered approach may require accessing skills and experience from elsewhere in the community. Operational familiarity and interfaces with available opioid use disorder treatment options in the community are essential and should include arrangements for continuity of hand-offs and followup. The “hub and spoke” approach to opioid use disorder treatment is one such model that integrates centers with expertise in the care of people with complex addictions and co-occurring substance abuse and mental health conditions (hubs) with nonspecialty settings (spokes) that can manage patients with opioid use disorder who are less complex or who have been stabilized in a hub.

Promote policies that stimulate and support action on the evidence we have. Clinician action and leadership is core to a community’s success in building the needed access to treatment for misuse and addiction. Beyond educating themselves on the availability of treatment opportunities and working to ensure access for our patients, clinicians have broader leadership opportunities.

1. **Education and training.** Apart from ensuring individual and team awareness, skill levels, and continuity strategies necessary for successful efforts, clinicians can work within their communities and professional

organizations to promote targeted curricular and continuing education practices that convey the foundational concepts emphasizing substance use disorder as a treatable chronic neurologic condition requiring long-term and ongoing management with medication and psychosocial interventions; evidence-based best practices in prescribing and risk mitigation strategies for opioids; and use of non-opioid analgesics and nonpharmacological therapies to manage pain.

2. **Treatment.** Knowledge alone is not sufficient to address the challenge of the opioid epidemic. Capacity and commitment from all sectors to support needed treatment is also essential. In addition to improving opioid prescribing practices, established national priorities include expanded access to MAT for opioid use disorder and increased use of naloxone to reverse overdoses. The most important rate-limiting factor in the response capacity to opioid use disorder is the ability of those who need it to access treatment, including the range of services of proven efficacy in different circumstances and the availability of clinicians with the necessary authority to provide MAT. These are efforts that require access, capacity, and support, as well as a level of communication that does not currently exist among all relevant elements of the broader health care system.
3. **Payment.** Reimbursement is a core issue for the development and operation of necessary capacity. The Mental Health Parity and Addiction Equity Act of 2008 requires coverage of mental health and substance use disorder treatment, in both the public and private health insurance markets, using benefit determination standards that match equitably to the standards for other evidence-based medical and surgical treatment benefits. However, its enforcement has largely been limited to responses to complaint and appeal/complaint processes that often present formidable barriers to those needing services and their families. The fact that only about one-tenth of people who need substance use treatment receive it is testament to the fact that a multifaceted initiative is needed to drive support for adequate financial support and funding, with inclusion in value-based initiatives and accountability metrics.
4. **Monitoring.** Reliable profession- and community-wide information on opioid prescribing—especially through technology and software that is integrated into an electronic health record and is easy to access by clinicians and their duly designated and trained staff—is central to effective cooperation among clinicians in stemming the tide of dangerous and illicit use of opioids. To ensure the effective use of PDMPs, all prescribing clinician teams should employ and promote active use of PDMPs for each opioid

prescription for chronic pain, bolstered by support for clinical registries and educational initiatives to improve overall community support for cooperative initiatives.

5. **Recovery support.** Not only is treatment of opioid use disorder under-engaged and less supported in its acute phase, but so is the provision of longer-term supportive services. Long-term management of opioid use disorder should be undertaken like management of any other chronic disorder. Just as ongoing support is provided to those with hypertension, diabetes, heart disease, and cancers—because those patients need ongoing monitoring and support—such is the case in those with chronic substance use disorders. Care delivery, reimbursement, and support approaches should be accordingly structured.

Clinicians should not be expected to make these sorts of changes alone. To truly have maximum impact on the health of their communities, clinicians must work with community leaders, elected officials, and the business community, and vice versa. Facilitative cooperation is important for identifying educational materials and strategies, compelling stories, community implications, barriers and opportunities, and useful guidance for policy initiatives. All clinicians, regardless of their focus or specialty, are interested in the same goal of patient health and well-being. With interaction of colleagues across fields and specialties, and leadership in efforts to shape clinical practice and policy, the potential exists to effect the transformative changes necessary to alleviate the devastating pain, suffering, and death this epidemic imposes on individuals, families, and communities across the nation.

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APPENDIX A

Action Resources

Detailed Prescribing Guidelines

- *CDC (Centers for Disease Control and Prevention). Guideline for Prescribing Opioids for Chronic Pain.* <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.
- *Department of Veterans Affairs. Management of Opioid Therapy for Chronic Pain.* <https://www.healthquality.va.gov/guidelines/pain/cot>.

Prescription Drug Monitoring Programs

- *Brandeis University PDMP Training and Technical Assistance Center. Resources.* <http://www.pdmpassist.org/content/resources>.
- *National Alliance for Model State Drug Laws. States That Require Prescribers and/or Dispensers to Access PMP Database in Certain Circumstances.* <http://www.namsdl.org/library/4475CD3E-1372-636C-DD2E5186156DFB6F>.

Opioid Use Disorder Treatment References

Locate treatment providers

- *SAMHSA (Substance Abuse and Mental Health Services Administration). Behavioral Health Treatment Services Locator.* <https://findtreatment.samhsa.gov>.

Co-prescribing naloxone

- *American Medical Association Opioid Task Force. Help Save Lives: Co-prescribe Naloxone to Patients at Risk of Overdose.* <https://www.end-opioid-epidemic.org/wp-content/uploads/2017/08/AMA-Opioid-Task-Force-naloxone-one-pager-updated-August-2017-FINAL.pdf>.

Medically Assisted Treatment waiver training

- *Providers' Clinical Support System for Medication Assisted Treatment. Training.* <http://pcssmat.org/>.

- *AAAP (American Academy of Addiction Psychiatry)*. Education and Training. <https://www.aaap.org/education-training/buprenorphine>.
- *ASAM (American Society of Addiction Medicine)*. Waiver Qualifying Training. <https://www.asam.org/education/live-online-cme/buprenorphine-course>.

Screening, Brief Intervention, and Referral to Treatment (SBIRT) resources

- SAMHSA. Resources for Screening, Brief Intervention, and Referral to Treatment (SBIRT). <https://www.samhsa.gov/sbirt/resources>.
- *National Institute on Drug Abuse*. Screening for Drug Use in General Medical Settings. https://www.drugabuse.gov/sites/default/files/resource_guide.pdf.
- *SBIRT Training*. Improve Clinical Skills. <https://www.sbirtraining.com>.

Education and Training

- *American College of Physicians*. SAFE Opioid Prescribing. <https://www.acponline.org/meetings-courses/focused-topics/safe-opioid-prescribing-strategies-assessment-fundamentals-education>.
- *AAAP*. Continuing Medical Education Opportunities. <https://www.aaap.org/education-training/cme-opportunities>.
- *ASAM*. Opioid Prescribing: Safe Practice, Changing Lives. <https://www.asam.org/education/resources/Opioid-Prescribing>.
- *American Association of Nurse Practitioners*. Continuing Education Center. <https://aanp.inreachce.com/SearchResults?q=opioid&searchType=1>.
- *American Medical Association (AMA)* education and training resources: <https://www.end-opioid-epidemic.org>.
- *APNA (American Psychiatric Nurses Association)*. e-Learning Center. Medical Assisted Treatment Waiver Training for APRNs. <https://www.apna.org/i4a/pages/index.cfm?pageid=6197>.
- *APNA*. Effective Treatments for Opioid Use Disorders. <https://www.apna.org/i4a/pages/index.cfm?pageid=6088>.
- *CDC*. Interactive Training Series: Applying CDC's Guidelines for Prescribing Opioids: An Online Training Series for Healthcare Providers. <https://www.cdc.gov/drugoverdose/training/online-training.html>.
- *CDC*. Webinar Series: COCA (Clinician Outreach and Communication Activity) Call Webinar Series. <https://www.cdc.gov/drugoverdose/training/webinars.html>.
- *Food and Drug Administration*. Introduction for the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. <https://www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm515636.pdf>.

- *Providers' Clinical Support System for Opioid Therapies*. Training. <http://pcss-o.org>.

Related Publications from the National Academies

- NASEM (National Academies of Sciences, Engineering, and Medicine). 2017. *Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use*. Edited by R. J. Bonnie, M. A. Ford, and J. K. Phillips. Washington, DC: The National Academies Press.
- NASEM. 2016. *Pain management and prescription opioid-related harms: Exploring the state of the evidence: Proceedings of a workshop—in brief*. Edited by E. H. Forstag. Washington, DC: The National Academies Press.
- IOM (Institute of Medicine). 2011. *Relieving pain in America: A blueprint for transforming prevention, care, education, and research*. Washington, DC: The National Academies Press.
- NRC (National Research Council). 2010. *Understanding the demand for illegal drugs*. Edited by P. Reuter. Washington, DC: The National Academies Press. 2010.
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APPENDIX B

Author Biosketches

Susan M. Adams, PhD, RN, PMHNP, FAANP, is a professor of nursing and faculty scholar for community-engaged behavioral health at Vanderbilt University School of Nursing. A respected advanced-practice psychiatric nurse and educator, Dr. Adams served as program director for Vanderbilt's PMHNP program for almost two decades, developing a modified distance option program and overseeing its sustained growth and national recognition. Her research with community partners such as The Next Door, an agency that serves women who have substance abuse problems and are reentering the community from incarceration, informs agency development and evaluation of new service lines, including trauma-informed care, onsite psychiatric medication management, supported employment, housing options, and family reintegration. Since 1997, Dr. Adams has served on the board of the Mental Health Cooperative, a multisite network that provides a continuum of services for individuals with serious mental illness and their families. She has been a leader in clinical practice, education, and innovative models of care, with recent efforts in integration of primary care and behavioral health care. She has served on national panels and initiatives for the American Nurses Association, American Nurses Credentialing Center, National Organization of Nurse Practitioner Faculties, American Psychiatric Nurses Association (APNA), and International Society of Psychiatric-Mental Health Nurses (developing PMHNP competencies, the initial PMHNP certification exam, nurse practitioner faculty and program standards, and the PMH workforce). A frequent speaker at national conferences, Dr. Adams shares her expertise on co-occurring mental health and substance use disorders, screening and brief intervention for alcohol and drug abuse, fetal alcohol spectrum disorders (FASDs), PMHNP education for full scope of practice, and PMHNP certification review courses. Her recent publications address treatment outcomes for co-occurring disorders, predictors of treatment retention, and training for nurses regarding FASD screening and prevention. She has also authored book chapters in widely used nursing texts on psychotherapeutic approaches for

addictions and related disorders and on evidence-based practice. As president of the APNA (2014–2015), Dr. Adams is focused on collaboration initiatives that facilitated integrated models of care, interprofessional education, and research.

Carlos Blanco, MD, PhD, MS, is the director of the Division of Epidemiology, Services, and Prevention Research at the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health. Dr. Blanco is a nationally known expert in the epidemiology and treatment of addictive disorders with and without comorbid disorders. His accomplishments include a detailed examination of the course and stages of substance use disorders, the development of methods to quantify the generalizability of clinical trials, the development and testing of interventions that combine motivational interviewing with cognitive behavioral therapy to improve retention and outcome in individuals with addictive disorders, and the creation of a virtual map of psychiatric disorders, based on empirical data, to guide research into the causes of mental disorders. Prior to joining NIDA, Dr. Blanco was professor of psychiatry at Columbia University Medical Center and a research psychiatrist at New York State Psychiatric Institute. He is a graduate of Universidad Autónoma de Madrid (Spain) and completed his psychiatry residency at Columbia University, where he also completed a research fellowship. Dr. Blanco has authored more than 200 peer-reviewed publications.

Humayun J. Chaudhry, DO, MACP, is the president and CEO of the Federation of State Medical Boards (FSMB) of the United States, a position he undertook in October 2009. The FSMB is a national nonprofit organization, founded in 1912, that represents the 70 state medical and osteopathic licensing boards of the United States and its territories and cosponsors the United States Medical Licensing Examination. Dr. Chaudhry graduated from the College of Osteopathic Medicine of New York Institute of Technology (NYIT), where he received a doctor of osteopathic medicine degree. He completed residency training in internal medicine at NYU Winthrop Hospital in Mineola, New York, where he was chief medical resident. He has also earned a master's degree in anatomy from NYU and a master's degree in health care management from the Harvard T. H. Chan School of Public Health. Prior to joining FSMB, he was commissioner of health services for Suffolk County, New York, home of the ninth-largest health department in the United States. Dr. Chaudhry served in the US Air Force Reserve, rising to the rank of major and serving as a flight surgeon with the 514th Air Mobility Wing at McGuire Air Force Base in New Jersey. He is a member of the American Medical Association, the American

Osteopathic Association, the American College of Physicians, the Medical Society of the State of New York, and the Harvard Club of New York City. He is a former president of the American College of Osteopathic Internists, the Association of Osteopathic Directors and Medical Educators, and the NYIT College of Osteopathic Medicine Alumni Association. He served on the journal advisory board of *The New Physician*, a publication of the American Medical Student Association.

Harry L. Chen, MD, served as commissioner of the Vermont Department of Health from 2011 to 2017. Dr. Chen was appointed acting secretary of the Vermont Agency of Human Services by Governor Peter Shumlin and served from August 2014 to January 2015. Prior to his appointment as commissioner, Dr. Chen worked as an emergency physician at Rutland Regional Medical Center for more than 20 years and served as medical director from 1998 to 2004. He is on the clinical faculty at the University of Vermont Larner College of Medicine and served as vice chair of the University of Vermont board of trustees. Dr. Chen earned his medical degree and completed his residency in emergency medicine at the Oregon Health and Science University School of Medicine, serving as chief resident. He worked at and was on the faculty of the George Washington University School of Medicine and Health Sciences, Department of Emergency Medicine, from 1983 to 1988. From 2004 to 2008, Dr. Chen was a member of the Vermont House of Representatives and was vice chair of the Health Care Committee during his final term. In 2008, Dr. Chen received the Vermont Medical Society's Physician Award for Community Service. He has served on numerous statewide boards addressing health care and medical issues, including service as vice chair of the Vermont Board of Medical Practice. From June to September 2010, Dr. Chen served as interim executive director of the Vermont Program for Quality in Health Care, Inc., where he had been a board member since 2006. In addition, Dr. Chen is a member of the Board of Scientific Counselors of the Centers for Disease Control and Prevention Office of Infectious Diseases, and a member of the Prevention Committee of the Association of State and Territorial Health Officials. Dr. Chen has spoken on the issue of health care reform nationally and regionally, including presentations to the US Senate Health, Education, Labor and Pension Committee, the New Mexico legislature's Health & Human Services Committee, and the New England Medical Society Leadership Conference.

Roger Chou, MD, is a professor in the Departments of Medicine, and Medical Informatics and Clinical Epidemiology at Oregon Health and Science University

(OHSU) School of Medicine, and staff physician in the Internal Medicine & Geriatrics Clinic at OHSU. He has served as director of the Pacific Northwest Evidence-Based Practice Center since 2012. Dr. Chou's research interests are systematic review methodology, meta-analysis, screening and preventive services, guideline development, and drug effectiveness. He has conducted systematic reviews in a number of areas, including chronic pain and musculoskeletal conditions, screening and prevention, diagnostic testing, and prognosis. He has served as director of the American Pain Society clinical guidelines program and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodologist for the World Health Organization's Division of Reproductive Health, and is a member of the *Cochrane Back and Neck Review* editorial board and cochair of the National Quality Forum Musculoskeletal Standing Committee. Dr. Chou is on several journal editorial boards and is the author of numerous scientific articles published in peer-reviewed journals.

Melissa L. D. Christopher, PharmD, is currently the national director for the Veterans Affairs (VA) Academic Detailing Service, which services providers and clinical staff in VA health care systems. She received her doctor of pharmacy from Duquesne University, Pittsburgh Pennsylvania. She completed a post-graduate year 1 pharmacy practice residency and post-graduate year 2 in pharmacoconomics and formulary management at VA San Diego Healthcare System. Dr. Christopher conducts research in health outcomes and pharmaco-economic analysis for several chronic disease management areas. Until 2014, she practiced as a clinical pharmacy specialist, providing medication management in diabetes and metabolic syndrome while expanding efforts to develop new programs for educational outreach by clinical pharmacists in mental health. Most of her Academic Detailing Program efforts focus on development of educational materials, outcome monitors, provider-specific electronic audits, and feedback tools to trend practice patterns for mental health and pain management. The Academic Detailing Program focuses on engaging system solutions for health care teams to act on evidence-based practice recommendations.

Patrice A. Harris, MD, MA, a psychiatrist from Atlanta, Georgia, has diverse experience as a private practicing physician, public health administrator, patient advocate, and medical society lobbyist. She was elected to the American Medical Association board of trustees (AMA-BOT) in June 2011. Active in organized medicine her entire career, Dr. Harris has served on the board of the American Psychiatric Association (APA) and was an APA delegate to the AMA. She has also been a member of the governing council of the AMA Women Physicians

Congress; testified before and served on AMA reference committees; and served on AMA work groups on health information technology, SGR, and private contracting. The AMA-BOT appointed her to the AMA Council on Legislation in 2003 and she was elected by the council in 2010 to serve as its chair. Dr. Harris has also held many leadership positions at the state level, including serving on the board and as president of the Georgia Psychiatric Physicians Association, and on the Medical Association of Georgia's Council on Legislation, its Committee on Constitution and Bylaws, and its Membership Task Force. She was also the founding president of the Georgia Psychiatry Political Action Committee. In 2001, Dr. Harris was selected Psychiatrist of the Year by the Georgia Psychiatric Physicians Association. In 2007, she was inducted into the West Virginia University Academy of Distinguished Alumni. Governing themes in Dr. Harris's professional life are a passion to improve the lives of children and service to others. Starting with medical school at West Virginia University—followed by a psychiatry residency and child psychiatry and forensics fellowships at Emory University and a tenure as the Barton senior policy fellow at the Emory University School of Law—she has worked for children both as a clinician and an advocate. At Emory, she addressed public policy for abused and neglected children before the Georgia legislature and in public education programs. Dr. Harris has also given invited lectures and presentations on children's mental health, childhood trauma, integration of health services, health equity, and the intersection of athletics and health. As past director of health services for Fulton County, Georgia, which includes Atlanta, Dr. Harris was the county's chief health officer, overseeing all county health-related programs and functions, including a wide range of public safety, behavioral health, and primary care treatment and prevention services. She spearheaded the county's efforts to integrate public health, behavioral health, and primary care services. Dr. Harris also served as medical director for the Fulton County Department of Behavioral Health and Developmental Disabilities. Currently, Dr. Harris continues in private practice and consults both public and private organizations on health service delivery and emerging trends in practice and health policy. She is an adjunct assistant professor in the Emory University Department of Psychiatry and Behavioral Sciences.

Saul M. Levin, MD, MPA, is the chief executive officer and medical director of the American Psychiatric Association. Prior to assuming this role in October 2013, Dr. Levin served as interim director of the District of Columbia Department of Health (DOH). There, Dr. Levin was responsible for emergency preparedness and planning, and for coordinating alongside dozens of federal and local agencies to ensure the public's health during major events, such as former

president Obama's second inauguration. Moreover, he promoted the development of a citywide health information exchange that connects health care providers, shares critical information to promote patient care, tracks outcomes, prepares for disasters, and provides public health surveillance. Dr. Levin also served on the D.C. Health Exchange board and chaired the Essential Health Benefits Package Subcommittee, where he successfully led the effort to ensure that residents of the District of Columbia had access to a full range of substance abuse and mental health services. He also cochaired the committee that oversaw the merger of substance abuse and mental health services into the new Department of Behavioral Health. In 2012, Dr. Levin served briefly as senior deputy director of DOH's Addiction Prevention and Recovery Administration. During his tenure, Dr. Levin promoted substance abuse prevention efforts in all eight wards of the city through the work of Prevention and Access to Recovery teams, assessed and referred an increasing number of individuals into treatment services, and connected more clients to recovery support services. Dr. Levin has long been involved in organized medicine and psychiatry. He served as vice president for science, medicine, and public health at the American Medical Association. Among the positions Dr. Levin has held is special expert appointee in the Substance Abuse and Mental Health Services Administration, where he led the initiative to integrate primary care, substance abuse, mental health, and HIV/AIDS response. While serving as president for Access Consulting International Inc., he worked with federal, state, and local governments and private companies to provide health policy, program, and research and evaluation services.

Sean Mackey, MD, PhD, is Chief of the Division of Pain Medicine and Redlich Professor of Anesthesiology, Perioperative and Pain Medicine at Stanford University. Dr. Mackey received his BSE and MSE in Bioengineering from the University of Pennsylvania and his PhD in Electrical and Computer Engineering, as well as his MD, from the University of Arizona. He completed his residency and Pain Medicine fellowship at Stanford and joined the faculty in 1999. Under Dr. Mackey's leadership, the Stanford Pain Management Center has been twice designated a Center of Excellence by the American Pain Society for the Center's innovative approach in comprehensive, interdisciplinary, and outcomes-based care. He has served as principle investigator on multiple NIH awards where he has overseen efforts to map the specific regions of the brain and spinal cord that perceive and process pain. Dr. Mackey is author of more than 200 journal articles and book chapters in addition to numerous national and international lectures. Currently, he is developer of a free, open-source learning health system—CHOIR (<http://choir.stanford.edu>)—to transform the care of people

with pain, and serve as a platform for research in real-world clinic patients. Dr. Mackey is past president of the American Academy of Pain Medicine (AAPM). He coauthored the Institute of Medicine's report on *Relieving Pain in America*. He was co-chair of the Oversight Committee for the HHS/NIH *National Pain Strategy (NPS)*, an effort to establish a national health strategy for pain care, education, and research. He has received multiple awards for leadership, teaching, research, and clinical care. In the last two years he has received the American Pain Society Wilbert E. Fordyce Clinical Investigator Award; the AAPM Pain Medicine Fellowship Award and Distinguished Service Award, and the NIH Director's Award for his efforts on the NPS.

Elinore McCance-Katz, MD, PhD, FAAAP, is now the Assistant Secretary for Mental Health and Substance Abuse at the Department of Health and Human Services. Previously, and during the authorship of this paper, she was the chief medical officer of the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals. Previously, Dr. McCance-Katz served as the Substance Abuse and Mental Health Services Administration's (SAMHSA) first chief medical officer, where she provided medical, scientific, and psychiatric advice on the development and implementation of SAMHSA policies. Dr. McCance-Katz came to SAMHSA from the University of California, San Francisco (UCSF), where she was a professor of psychiatry and the state medical director for the California Department of Alcohol and Drug Programs. She is board-certified in general psychiatry and addiction psychiatry, and is a distinguished fellow of the American Academy of Addiction Psychiatry. Dr. McCance-Katz has been working in the field of addiction medicine for 22 years as a clinician, teacher, and clinical researcher. Her specialty areas include pharmacotherapy for substance use disorders; clinical pharmacology of drugs of abuse; drug interactions; cocaine, alcohol, and opioid medications development; and co-occurring HIV disease and addiction. Her clinical interests are in the treatment of those with co-occurring substance use disorders, infectious diseases (including HIV and HCV), and mental illness. She is also interested in the treatment of those with chronic pain who have developed problems with opioid analgesic overuse or misuse, often with co-occurring mental illness. Dr. McCance-Katz worked on several SAMHSA projects prior to coming to SAMHSA as the chief medical officer. She was the medical director of the Physicians' Clinical Support System for Buprenorphine and the Prescribers' Clinical Support System for Opioid Therapies, which are Center for Substance Abuse Treatment- and SAMHSA-sponsored national training and peer-support programs for physicians and clinicians treating patients with clinical needs for opioid medications. Dr. McCance-Katz has also helped

to develop educational curricula to assist with the integration of substance use screening, brief intervention and referral to treatment (SBIRT) into primary care settings through an SBIRT grant to UCSF. Internationally, she has been part of a World Health Organization (WHO) committee to develop guidelines on the treatment of drug users living with HIV/AIDS and has reviewed and contributed to WHO white papers on methadone and buprenorphine treatment of opiate addiction. She participated in the United States President's Emergency Plan for AIDS Relief, where she assisted with the development of methadone maintenance programs in Vietnam. Most recently, Dr. McCance-Katz has conducted studies of drug-drug interactions between opioids or alcohol and HIV therapeutics through research studies funded by the National Institute on Alcohol Abuse and Alcoholism and the National Institutes of Health (NIH), and drug interactions between disulfiram and HIV therapeutics funded by the National Institute on Drug Abuse and NIH.

Paul A. Moore, DMD, PhD, MPH, received his DMD and a PhD in pharmacology from the University of Pittsburgh School of Dental Medicine (UPSDM). His professional career has included private practice in Oakmont, Pennsylvania; a hospital residency in dental anesthesiology at the Presbyterian Hospital Medical Center in Pittsburgh; a postdoctoral fellowship in chronic pain management at the University of North Carolina; and faculty appointments at Harvard School of Dental Medicine, University of Massachusetts Medical Center, and Forsyth Dental Center. During his extensive academic career, Dr. Moore has served as director of the Oral Health Science Institute; director of research, director of graduate education, and chair of the Department of Dental Anesthesiology at UPSDM. He is a member of the editorial boards of several journals, including *The Journal of American Dental Association*. He has recently been asked to serve on the US Surgeon General's Expert Panel of Prescription Drug Abuse. Dr. Moore is active in clinical dental research, having served as the principal investigator of more than 40 clinical research projects sponsored by the National Institutes of Health and the pharmaceutical industry. Additionally, he has authored more than 250 scientific articles on clinical pharmacology and dental therapeutics in peer-reviewed journals, and has presented more than 150 invited lectures throughout the world on the topics of local anesthetics, antibiotics, analgesics, sedation, drug interactions, and oral complications of diabetes. Dr. Moore has been honored extensively over his professional career, receiving the Harold Loe National Scholars Award in 2000, the Distinguished Alumnus Award for Advanced Education at the UPSDM in 2005, and the Distinguished Scientist Award of the International Association for Dental Research PTTG section in

2006—and most recently, the Heidbrink Award for lifetime achievement from the American Dental Society of Anesthesiology and the Norton M. Ross Award for Excellence in Clinical Research from the American Dental Association in 2013.

James P. Rathmell, MD, is the chair of the Department of Anesthesiology, Perioperative and Pain Medicine at Brigham and Women's Health Care (BWHC), which includes Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital. Dr. Rathmell is an established leader in pain medicine who has devoted much of his time to the care of patients with acute, chronic, and cancer-related pain. He has been recognized for enhancing medical education for physicians and trainees through direct teaching in the classroom, for strengthening continuing medical education activities around the world, and for publishing original research and textbooks. His research will focus on emerging pain treatments and the evaluation of the safety and effectiveness of specific interventions for pain, with the goal of improving the care of patients with painful disorders. Dr. Rathmell comes to BWHC from Massachusetts General Hospital (MGH), where he was executive vice chair and chief of the Division of Pain Medicine in the MGH Department of Anesthesia, Critical Care and Pain Medicine. In Massachusetts, he was also Henry Knowles Beecher Professor of Anesthesia at Harvard Medical School. At MGH, Dr. Rathmell guided the Center for Pain Medicine into becoming a successful patient-centered clinical operation and a top-tier fellowship training program. Among other local and national leadership roles, he serves as a director for the American Board of Anesthesiology and recently served on the National Pain Strategy taskforce of the National Institutes of Health's Interagency Pain Research Coordinating Committee. Dr. Rathmell received his master's in biochemistry and his medical degree at Wake Forest University in Winston-Salem, North Carolina. He completed his internship, residency, and research fellowship at Wake Forest Baptist Medical Center. Dr. Rathmell also received accolades for excellence in teaching and exceptional care delivery. For three consecutive years, he received the Resident/Fellow Teaching Award from the American Society of Regional Anesthesia and Pain Medicine for his role as teacher and mentor; the Bonica Award from the World Institute of Pain for clinical excellence and education; and the Phillip M. Lippe Award from the American Academy of Pain Medicine for outstanding contributions to the social and political aspects of pain medicine.

Travis Rieder, PhD, is the assistant director for education initiatives, director of the master of bioethics degree program, and research scholar at the Johns Hopkins Berman Institute of Bioethics. Dr. Rieder's work tends to fall into two

distinct research programs. The first concerns ethics and policy questions about sustainability and planetary limits. Much of this research has been on issues in climate change ethics and procreative ethics, with a particular focus on the intersection of the two—that is, on the question of responsible procreation in the era of climate change. The second research program concerns ethical and policy issues surrounding America’s opioid epidemic. In addition to his more scholarly writing, Dr. Rieder is strongly committed to communicating on bioethics with the public, and to that end, he writes and interviews regularly for the popular media. His work has appeared in many high-impact publications, including *The Guardian*, *The Washington Post*, and NPR’s *All Things Considered*. He writes regularly for *The Conversation* and blogs occasionally at *The Huffington Post* and the *Berman Institute Bioethics Bulletin*.

Bob Twillman, PhD, is the executive director for the Academy of Integrative Pain Management. In that capacity, Dr. Twillman is responsible for overseeing federal and state pain policy developments and advocating for those supporting an integrative approach to managing pain. He also serves as chair of the Prescription Monitoring Program Advisory Committee for the Kansas Board of Pharmacy. Dr. Twillman received his Ph.D. in clinical psychology at the University of California, Los Angeles, and maintains a volunteer faculty appointment as clinical associate professor of psychiatry and behavioral sciences at the University of Kansas School of Medicine in Kansas City. Prior to taking his current position, Dr. Twillman was a full-time faculty member at the University of Kansas Medical Center, where he founded and directed the inpatient pain management program and was a cofounder of the hospital’s Palliative Care Team. He has been actively involved in pain policy through his work with the Alliance of State Pain Initiatives and the American Pain Society for many years.

