



July 2017

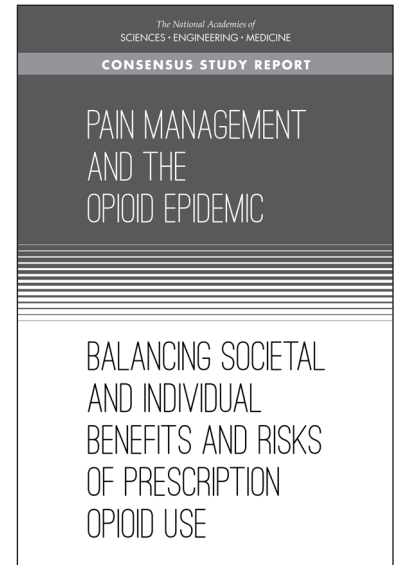
## Pain Management and the Opioid Epidemic Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use

Drug overdose is now the leading cause of death from unintentional injury in the United States, and most of these deaths involve an opioid. The ongoing opioid crisis lies at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the increasing toll of the harms that can arise from use of opioid medications.

On one hand, meeting the needs of tens of millions of U.S. residents suffering from pain (including acute pain, chronic pain, or pain at the end of life) requires access to a broad array of therapies for pain management. On the other hand, harms associated with use of prescription opioids, including misuse, opioid use disorder (OUD, a substance use disorder involving opioids), and overdose, affect not only patients with pain themselves but also their families, their communities, and society at large. Chronic pain and OUD both represent complex human conditions affecting millions of Americans and causing untold disability and loss of function.

Against this backdrop, the U.S. Food and Drug Administration (FDA) asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic.

The resulting report, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, states that a sustained, coordinated effort is necessary to stem the still-escalating prevalence of opioid-related harms, including a culture change in prescribing for chronic noncancer pain, aggressive regulation of opioids by the FDA, and multi-pronged policies by state and local governments. However, the committee also counsels against arbitrary restrictions on access to opioids by suffering patients whose health care providers have prescribed these drugs responsibly.



## STRATEGIES FOR ADDRESSING THE OPIOID EPIDEMIC

A constellation of policies, interventions, and tools related to lawful access to opioids and clinical decision making can help reduce or contain opioid-related harms while meeting the needs of patients with pain. These strategies include: (1) restricting the lawful supply of opioids; (2) influencing prescribing practices; (3) reducing demand; and (4) reducing harm.

### Restricting supply

See Recommendation 5-1

Although more research is needed, limited evidence suggests that state and local interventions aimed at reducing the supply of prescription opioids in the community may help curtail access. Importantly, however, none of these studies investigates the impact of reduced access on the well-being of individuals suffering from pain whose access to opioids was curtailed.

Drug take-back programs allow people with unused medications to bring them in for proper disposal. These programs can increase awareness of the need for the safe disposal or return of many unused drugs. Access to these programs should be expanded, with states convening public-private partnerships to implement take-back programs year-round rather than the standard occasional take-back event.

### Influencing prescribing practices

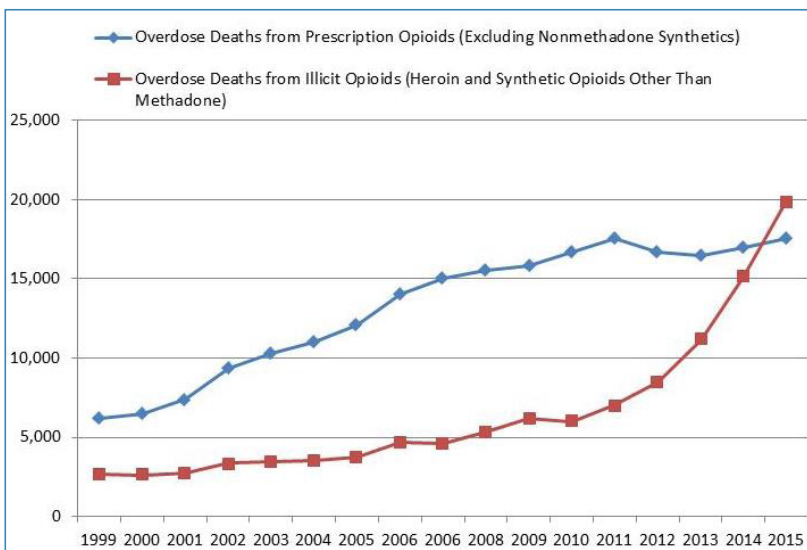
See Recommendations 5-2, 5-3, and 5-4

Many treatments are available to manage pain. Some nonopioid therapies are likely to be as effective as opioids, or even more so, and potentially carry lower risk when used appropriately.

Any meaningful effort to improve pain management will require a basic culture shift in the nation's approach to mandating pain-related education for all health professionals who provide care to people with pain. Prescribing guidelines may be most effective when accompanied by education, and so an evidence-based national approach to pain education, including pharmacologic and nonpharmacologic treatments and materials on opioid prescribing, is needed.

Insurance-based policies have substantial potential to reduce the use of specific prescription drugs. Coverage for and access to comprehensive pain management that includes both pharmacologic and nonpharmacologic options should be expanded.

Prescription drug monitoring programs (PDMPs) can help address the opioid epidemic by enabling prescribers and other stakeholders to track prescribing and dispensing information, but PDMP data currently are not being used to their full potential. This



Number of overdose deaths from prescription and illicit opioids, United States, 1999–2015

## BACKGROUND

Over the past 25 years, the United States has experienced a dramatic increase in deaths from opioid overdose, opioid use disorder (OUD), and other harms in parallel with increases in the prescribing of opioid medications for pain management.

*From 1999 to 2011, the annual number of overdose deaths from prescription opioids nearly tripled.*

*From 2011 to 2015, the annual number of deaths from prescription opioids remained relatively stable, but overdose deaths from illicit opioids (including heroin and synthetic opioids) nearly tripled, driven in part by a growing number of people whose use began with prescription opioids.*

*As of 2015, 2 million Americans ages 12 or older had an OUD involving prescription opioids, and nearly 600,000 had an OUD involving heroin.*

information could be better leveraged for patient safety, monitoring of policy interventions, and health service planning, among other uses.

### **Reducing demand**

See Recommendations 5-5 through 5-8

The committee's recommended changes to provider education and payer policy should be accompanied by a change in patient expectations with respect to the treatment and management of chronic pain. Attention is not being paid to educating the general public on the risks and benefits of opioid therapy, or the comparative effectiveness of opioids with nonopioid or nonpharmacologic therapies.

Medication-assisted treatment for OUD is the standard of care, but it is underused. Evidence-based treatment for OUD should be expanded by states, and barriers to coverage for these medications should be removed.

### **Reducing harm**

See Recommendations 5-9 and 5-10

Life-saving medication for treating opioid overdose, called naloxone, is available, but its high and unpredictable cost impedes its use. Prescribers and pharmacists can help address OUD and opioid overdose by counseling patients who may be at risk and offering naloxone when an opioid is prescribed or when opioid-related treatment is sought.

States can improve access to naloxone and safe injection equipment by implementing laws and policies to remove existing barriers.

## **THE ILLICIT MARKET**

See Recommendation 4-1

The prescription and illicit opioid epidemics are intertwined. Indeed, most heroin users report that their opioid misuse or OUD began with prescription opioids. The declining price of heroin and regulatory efforts designed to reduce harms associated with the use of prescription opioids may be contributing to increased heroin use. The FDA and other agencies should consider the potential effects on illicit markets in designing and implementing all interventions to address the epidemic.

## **OPIOID APPROVAL AND MONITORING BY THE FDA**

See Recommendations 6-1 through 6-7

Unlike the product-specific approach to the drug approval process usually taken by the FDA, the committee recommends a systems approach for analyzing the benefits and risks of opioid medications to more comprehensively assess the public health consequences of opioids. This approach should incorporate public health considerations, including benefits and risks to individual patients, their family members, and the broader community, as well as effects on the overall legal and illicit markets. Public health considerations should also be incorporated into clinical development and into opioid scheduling decisions.

Transparency is critical to maintain public trust and to find the balance between preserving access to opioids when needed and mitigating opioid-related harms. Therefore, the committee recommends that FDA increase the transparency of its regulation of opioid medications.

The FDA should also strengthen the post-approval oversight of opioids and conduct a full review of currently marketed or approved opioids.

## **THE NEED FOR MORE RESEARCH**

See Recommendation 3-1, 4-2, and 4-3

Little is known about why people who use prescribed opioids to alleviate pain develop opioid dependence or OUD, but these outcomes have become a driving force in the opioid epidemic. Better identification of individuals at risk of OUD requires a better understanding of the neurobiological interaction between chronic pain and opioid use.

Despite the costs to society of both chronic pain and OUD, research on pain is poorly resourced. More research is needed to better understand pain and OUD.

Gaps exist in the data describing the epidemiology of pain, OUD, and other opioid-related harms in the United States. Closing these data gaps through improved reporting of data on pain and OUD and investing in data and research would improve understanding and enable more effective and measurable policy interventions.

## Committee on Pain Management and Regulatory Strategies To Address Prescription Opioid Abuse

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## CONCLUSION

Access to evidence-based treatment for OUD should be substantially and immediately increased as a public health priority. Action by the nation's political and public health leadership is also needed to reduce new cases of prescription opioid-induced OUD. Scientifically grounded policies and clinical practices to promote responsible opioid prescribing are needed, along with research to identify and develop nonaddictive alternatives to opioids for treatment of pain.

Years of sustained and coordinated effort will be required to contain the current opioid epidemic and stem its harmful effects on society.

To read the full report and to view related resources, please visit [nationalacademies.org/OpioidStudy](http://nationalacademies.org/OpioidStudy)

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