

New report presents national strategy to reduce opioid epidemic

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Years of sustained and coordinated efforts will be required to contain and reverse the harmful societal effects of the prescription and illicit opioid epidemics, which are intertwined and getting worse, says a [new report](#) from the National Academies of Sciences, Engineering, and Medicine. The report, requested by the U.S. Food and Drug Administration (FDA), says it is possible to stem the still-escalating prevalence of opioid use disorder and other opioid-related harms without foreclosing access to opioids for patients suffering from pain whose providers have prescribed these drugs responsibly. The committee that conducted the study and wrote the report recommended actions the FDA, other federal agencies, state and local governments, and health-related organizations should take—which include promoting more judicious prescribing of opioids, expanding access to treatment for opioid use disorder, preventing more overdose deaths, weighing societal impacts in opioid-related regulatory decisions, and investing in research to better understand the nature of pain and develop non-addictive alternatives.

"The broad reach of the epidemic has blurred the formerly distinct social boundary between prescribed opioids and illegally manufactured ones, such as heroin," said committee chair Richard J. Bonnie, Harrison Foundation Professor of Medicine and Law and director of the Institute of Law, Psychiatry, and Public Policy at the University of Virginia in Charlottesville. "This report provides an action plan directed particularly at the health professions and government agencies responsible for regulating them. This plan aims to help the millions of people who suffer

from chronic pain while reducing unnecessary opioid prescribing. We also wanted to convey a clear message about the magnitude of the challenge. This epidemic took nearly two decades to develop, and it will take years to unravel."

As of 2015, at least 2 million people in the United States have an opioid use disorder involving [prescription opioids](#)—meaning they are addicted to prescription opioids—and almost 600,000 have an opioid use disorder involving heroin. An average of about 90 Americans die every day from overdoses that involve an opioid. While the annual number of deaths from prescription opioids remained relatively stable between 2011 and 2015, overdose deaths from illicit opioids—including heroin and synthetic opioids such as fentanyl—nearly tripled during this time period, partially in connection to a growing number of people whose use began with prescription opioids. Drug overdose, driven primarily by opioids, is now the leading cause of unintentional injury deaths in the United States, and trends indicate that premature deaths associated with the use of opioids are likely to climb.

Some of the consequences of increased prescribing of opioids over the last few decades have been increases in the use of heroin; overdose deaths; and cases of HIV, hepatitis C, and other injection-related harms. In more recent years, national initiatives to reduce opioid prescribing have modestly decreased the number of prescription opioids dispensed. However, many people who otherwise would have been using prescription opioids have transitioned to heroin use. The declining price of heroin, together with regulatory efforts designed to reduce harms associated with the use of prescription opioids—including the availability of abuse-deterrent formulations—may be contributing to increased heroin use, the report says.

With this in mind, one approach to addressing the opioid epidemic is to have a fundamental shift in the nation's approach to prescribing practices

and improve awareness of the risks and benefits of opioids. To this end, the committee recommended enhancing education for both health professionals and the general public. Such education should involve mandating pain-related education for all health professionals who provide care to people with pain, requiring and providing basic training in the treatment of opioid use disorder for health care providers, and training prescribers and pharmacists to recognize and counsel patients who are at risk for opioid use disorder or overdose. In addition, the committee was struck by the relative lack of attention to educating the general public about the risks and benefits of prescription opioids and called for an evaluation of the impact and cost of an education program that raises awareness among patients with pain and the general public.

The committee stressed that restrictions on lawful access to prescription opioids could have other unintended effects, and any policy designed to curtail legal access to them will inevitably drive some people toward the illegal market. Therefore, a strategy for reducing lawful access to opioids should be coupled with an investment in treatment for the millions who have opioid use disorder. The committee recommended that states—with assistance from relevant federal agencies, particularly the Substance Abuse and Mental Health Services Administration – provide universal access to evidence-based treatment for opioid use disorder in a variety of settings, including hospitals, criminal justice settings, and substance-use treatment programs. Efforts to this end should be carried out with particular intensity in communities with a high burden of opioid use disorder. The U.S. Department of Health and Human Services (HHS) and state health financing agencies should also remove impediments to full coverage of medications approved by the FDA for treatment of opioid use disorder.

In addition, preventing [overdose deaths](#) and other opioid-related harms should be substantially and immediately elevated as a public health priority. The committee recommended improving access to the

medication naloxone, which blocks or reverses the effects of opioids, as well as safe injection equipment to reduce transmission of HIV and hepatitis C. Providers and pharmacists should be permitted to prescribe, dispense, or distribute naloxone to laypersons, third parties, and first responders. Additionally, prescribers should be immune from civil liability or criminal prosecution for prescribing, dispensing, or distributing naloxone, and laypersons should be ensured immunity for possessing or administering it. The sale or distribution of syringes should be permitted, exempting syringes from laws that prohibit the sale or distribution of drug paraphernalia, and syringe exchanges should be authorized.

Another key element to the strategic response is weighing societal, not just the individual, impacts of opioids. The FDA traditionally has taken a product-specific approach to drug approval decisions by focusing on the data generated and submitted by a drug's manufacturer and balancing the benefits against the known risks to the individual patient. While this approach works well in most cases, it is necessary to view regulatory oversight of opioid medications differently from that of other drugs, because these medications can have a number of consequences not only at the individual level but also at the household and societal levels. Therefore, the FDA should incorporate public health considerations into opioid-related regulatory decisions, including during the clinical development stage.

Several other strategies that the committee recommended are that:

- the FDA should complete a review of the safety and effectiveness of all approved opioids;
- states should convene a public-private partnership to implement drug take-back programs that allow drugs to be returned to any pharmacy on any day, rather than relying on occasional take-back events;

- public and private payers, including insurance companies, should develop reimbursement models that support evidence-based and cost-effective comprehensive pain management, including both drug and non-drug treatments for pain;
- HHS, in concert with state organizations, should conduct or sponsor research on how data from prescription drug monitoring programs can be better leveraged to track opioid prescribing and dispensing information; and
- the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, the U.S. Department of Veterans Affairs, and industry should invest in research that examines the nature of pain and **opioid** use disorder, as well as develop new non-addictive treatments for pain.

Provided by National Academies of Sciences, Engineering, and Medicine

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