



EVERFI

The State of Prescription Drug Safety

Understanding How We Got Here
and Where We Go Next

The State of Prescription Drug Safety

Foreword

At the time of this report, America and most of the world are embroiled in a fight to slow the escalation of the coronavirus, or COVID-19. The efforts put in place to prevent the spread of this virus are unprecedented, but not new. They are the basis of a public health approach to prevention: keep healthy people healthy, reduce risk for those who are more vulnerable, and increase the capacity to respond to those who require treatment.

Medical, public health officials, and government leaders are moving quickly to gather data, mobilize resources, and make bold decisions to protect the health and safety of their communities. Success will depend on how we as individuals contribute to collective action. It will require a proactive lens, an understanding of cultural and community challenges, and the ability for everyone to embrace their role as community stewards.

Imagine for a moment if we adopted this same approach to the current prescription drug crisis in America. While the long-term impact of the coronavirus on both public health and our social infrastructure is not yet known, it is worth considering how we might apply the lessons learned during this global crisis to inform next steps in addressing another long-standing crisis that has claimed lives and devastated communities across the US for decades.

A Complex Issue: Prescription Drug Culture in the US

America's current public health crisis related to prescription drug misuse is not the result of a single factor. For over two decades, a complicated mix of social, cultural, and economic factors have collectively contributed to one of the most complex issues of our time. As is the case with many public health issues, the impact varies by age, race, gender, and socioeconomic status.

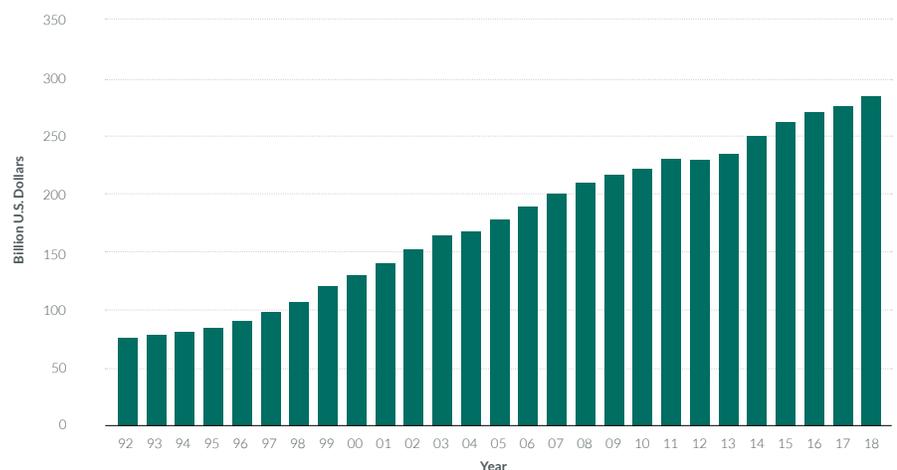
An in-depth exploration of every potential contributing factor is outside the scope of this report. However, some notable points of reference have been identified that have contributed to our understanding of how and why we find ourselves where we are today as well as inform the way forward.

Growing Access to Prescription Drugs

One of the leading contributors to prescription drug misuse is ease of access, a challenge highlighted by the following¹:

- In 2018, there were 5.8 billion prescriptions filled in the United States.²
- Nearly half (48.4%) of the U.S. population has used one or more prescription drugs in the past 30 days³
- 66% of people between the ages of 35-49 (those most likely to have teens and young adults living at home) use an average of 6 prescription medications.⁴
- One in five teens admitted they have used prescription medications written for other people.
- More than half of teens who misused prescription medications accessed the drugs in their family's medicine cabinet, while others obtained the drugs from a friend or relative.⁵
- One in 16 adolescents between 12 to 19 years old are prescribed a stimulant medication to treat attention deficit disorder.⁶

Pharmacy and Drug Store Sales in the United States from 1992 to 2018⁷

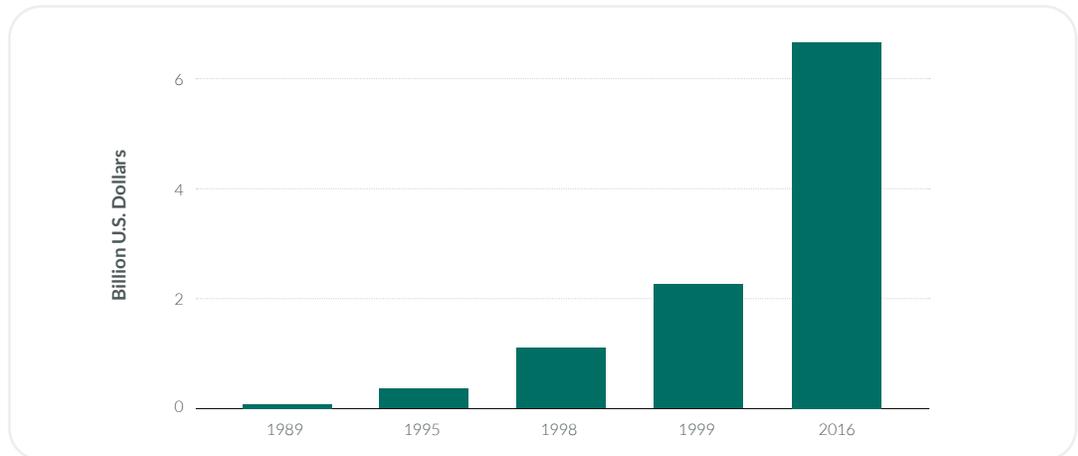


Increasing Visibility and Promotion of Prescription Drugs

Since the 1980's, there has been a progressive easing of regulations by the FDA on direct-to-consumer pharmaceutical advertising ([DTCPA](#)).

- DTCPA is currently America's most visible form of health communication.⁸
- The FDA's 1999 decision to loosen DTCPA broadcast regulations is considered a significant contributing factor to the current proliferation of pharmaceutical ads on television.⁹

Total Spending on Direct-to-Consumer Advertising, 1989-2016^{10,11}



The US is a “quick fix” culture. A pill is less daunting than alternative therapies and this, generally speaking, is attractive to U.S. consumers. American culture values comfort and convenience.¹⁵

Misperceptions of Prescription Drug Risks and Benefits

- Pharmaceutical ads can overemphasize drug benefits, creating the perception that health improvement can be achieved by medication alone, rather than behavior modification, lifestyle changes, or a combination.¹²
- Americans believe that prescription drugs are safe, simply because they are prescribed by a physician, a perspective unique to the U.S. and not shared by our European counterparts.¹³
- Teens and young adults believe that drugs prescribed by a physician are “less risky than drugs obtained from a drug dealer,” and that their parents would not be concerned about their non-medical use of prescription medications.¹⁴
- Misperceptions of safety among youth are shown to result in the abuse of prescription drugs and increased likelihood of developing a substance use disorder later in life.¹⁶

Mental Health Challenges Closely Tied to Prescription Drug Misuse

- Having a mental health disorder in childhood or adolescence can increase the risk of later drug use and the development of a substance use disorder.¹⁷
- Youth develop internalizing disorders, including depression and anxiety, prior to developing substance use disorders.¹⁸
- Feeling depressed or stressed due to school was cited as the greatest problem leading to initiation of drug use.¹⁹
- Prescription opioid medication can ease emotional distress and decrease feelings of worry or sadness, which makes misuse of these medications very appealing.²⁰

Risk is Not Equal for All

- Conditions such as anxiety, depression, or post-traumatic stress disorder increase the odds of developing a substance use disorder.²¹
- Misuse of prescription drugs is highest among young adults ages 18 to 25, with 14.4 percent reporting non-medical use in the past year.²²
- The high rates of multiple (co-morbid) chronic illnesses in older populations, age-related changes in drug metabolism, and the potential for drug interactions make medication (and other substance) misuse more dangerous in older people than in younger populations.²³

Evolution of America's Opioid Crisis

71%

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In 2017, the Office of the Chief Medical Examiner in Washington, DC, reported that 71 percent of overdose deaths in the District involved fentanyl or a fentanyl analog.²⁷

Shortly before the expansion of DTCPA, both the American Pain Society and Veteran's Health Administration developed "pain as the fifth vital sign" campaigns.²⁴ In addition to the objective measures of blood pressure, body temperature, pulse, and respiration rate, health care workers were now asking patients to subjectively rate their level of pain. This - in combination with America's growing reliance on medication as a first-line treatment for any health concern - created the perfect storm that many believe fueled the U.S. opioid crisis.

Simultaneously, oxycodone was introduced to the American consumer in 1996 and promoted as "a medication capable of relieving pain for up to 12 hours."²⁵ The new medication was labeled as "non addictive," leaving the public unaware of its high potential for overdose, as well as risk of dependency and subsequent substance use disorder.²⁶

Shortly after its distribution and subsequent widespread use, "Oxy" - as it came to be known - was linked to increases in overdose deaths. This realization prompted limitations on pain medication prescriptions in order to limit access, and reformulations of the medication to decrease its effects. These efforts were mostly successful, but individuals with an opioid use disorder were in need of a replacement, which they found in the more readily available drug, heroin.²⁸

Today, drug enforcement and health care officials are struggling to respond to the latest threat in the opioid epidemic: increasing rates of overdose deaths related to illicit fentanyl and fentanyl analogs, powerful synthetic opioids similar to morphine but 50 to 100 times more potent.²⁹

A Nation Responds

During the past decade, there have been increasing numbers of policies and programs established to address prescription drug safety in the United States. Medical professionals and their associations, public health officials, government agencies, and private retail industries have all contributed individually to the growing inventory of strategies.

Though not an exhaustive list, the examples provided here represent a snapshot of America's efforts to reduce the threat of prescription drug misuse. It is worth mentioning that this snapshot does not include the numerous national awareness campaigns and self-guided online resources that have proliferated over time, nor does it speak to all of the ongoing research initiatives and systems for data gathering and review that have informed the critical work in this space.

Evolving Perspectives on Pain

Removal of Vital Sign Designation

In 2016, the AMA removed the 5th vital sign designation and has been working in partnership with researchers to help better understand pain and identify alternative pain therapies, some of which include topical agents, nerve blocks (injections that block pain signals), and non-medication interventions such as acupuncture, meditation, physical therapy, or a combination of medical and non-medical approaches.^{30,31}

Better Guidelines for Healthcare Professionals

Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain provides recommendations for the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing).

Limiting Access

Prescription Drug Monitoring Program (PDMP)

These state-run electronic databases track prescribing and dispensing of controlled substances, enabling healthcare providers to make more informed prescribing decisions after reviewing their patients' prescribing histories.²⁷

Drug Take-Back Programs

National Prescription Drug Take-Back Days are coordinated by the Drug Enforcement Agency and involve over 5000 collection sites.³³

Expanding Role of the Private Sector

CEOs Pledge to Take Action

More than 90 executives signed the Leidos Pledge, committing to take action in their local communities to end the opioid crisis.

Educating Patients and Their Caregivers

Pharmaceutical companies and leading retail pharmacies are increasingly offering patients, caregivers, and employees access to no-cost personalized digital learning modules that provide critical information about their prescribed medications.

Supporting Safe Disposal

Increasing numbers of national retail pharmacies are providing programs similar to Walgreens' safe medication disposal kiosks, which populate over 500 of their stores across 43 states.³⁴

Treatment and Response

Affordable Care Act (ACA)

The ACA required coverage of, and expanded access to, substance use disorder treatment.

Comprehensive Addiction and Recovery Act (CARA)

In 2016, CARA sought to address the full continuum of care from primary prevention to recovery support, including expanded access to addiction treatment services and overdose reversal medications, as well as criminal justice and law enforcement-related provisions.³⁶

President's Commission on Combating Drug Addiction and the Opioid Crisis

Convened in 2017 to create a policy blueprint to address the epidemic, they released a report later that year which included recommendations for efforts to prevent, screen, and treat substance use disorders, expand recovery programs, and more effectively coordinate federal drug policy.³⁷

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment

The 2018 (SUPPORT) for Patients and Communities Act, is a bipartisan bill that includes provisions to teach addiction medicine to providers, standardize the delivery of addiction medicine, expand access to evidence-based care, and cover addiction medicine to ensure coordinated and comprehensive treatment.³⁸

Expanding Access to Naloxone

In April 2019, the FDA approved the first generic naloxone nasal spray to treat opioid overdose, a move supported by national medical and pharmacy organizations to make the drug more readily available to both reduce overdose deaths, and as a way to expand the role of pharmacists in direct patient care.^{39,40}

Abuse-Deterrent Formulations (ADF)

ADF are designed to prevent misuse of prescription medications, such as opioids and stimulants, by snorting or injection (e.g., barriers to prevent crushing, slower release of the drug, unpleasant sensations when used inappropriately).⁴¹



The 2018 fiscal year drug budget included a **\$27 billion** funding request across various federal agencies aimed at reducing both the demand and supply of all drugs.³⁵

Trending Positive



Physicians have a responsibility to help end the opioid epidemic, and they are taking steps: more judicious prescribing that has resulted in a dramatic decline in opioid prescriptions, enhanced education and lobbying for policies based on clinical evidence.”

Patrice A. Harris, MD, MA,
President of the American Medical Association

The risk in highlighting any forward movement is that it will lead to complacency, so it should be emphasized that progress does not signal victory and does not imply that it is safe to take a step back or redirect energies elsewhere. But signs of progress, however small, should be recognized in order to inform next steps and continuing efforts.

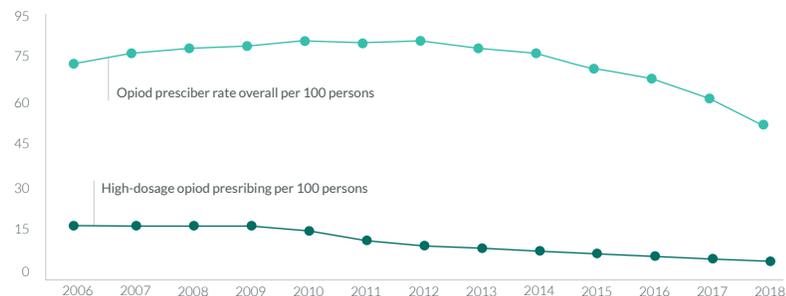
Fewer Prescriptions

Between 2006 and 2018, the annual rate for filling high dosage opioid prescriptions decreased from 11.5 to 3.9 prescriptions per 100 persons, an overall relative reduction of 66.1%.⁴²

In 2018, the average prescription rate was 17.6 medications per person, representing a 2.7% increase from just a year earlier, with one exception: a 17% decline in opioid prescriptions. This marked the largest single-year drop – 43% – since the peak in 2011.⁴³

This suggests that programs like PDMP, changes in regulations and clinical guidelines, coupled with increased public awareness are driving change. Importantly, decreases in hydrocodone prescribing were not replaced by increased prescribing of other opioids.⁴⁴

Total Number and Rate of Opioid Prescriptions Dispensed, United States



Source: www.cdc.gov/drugoverdose/maps/rxrate-maps.html

First Signs of Decline in Overdose-Related Deaths

For the first time in decades, overdose-related deaths in the United States for all drugs, as well as opioids specifically, have declined slightly since the previous year.⁴⁵

As a review of these activities suggests, universal prevention approaches - strategies delivered to broad populations regardless of identified risk level - have not been prioritized. Government funding has been largely allocated to treatment and response, specifically in relation to opioids. Even at that, while overall opioid funding increased \$3.3 billion from 2017 to 2018 - a victory for public health funding - these monies were not prioritized around strategies to prevent opioid misuse which represented only 23% of the total appropriations.^{46,47} While investments in treatment and response programs are necessary and life-saving, we will only get ahead of this issue by keeping individuals from initiating prescription drug misuse to begin with.

The Path Forward: Broadening the Scope of Prevention

Preventing the initiation of drug misuse - including prescription drug misuse - “is a common-sense, cost-effective approach to promoting safe and healthy communities.”⁴⁸ For a number of years, America’s prescription drug misuse prevention strategies have fallen under the areas of surveillance, clinical interventions, regulatory and oversight activities, and overdose prevention. But a recent report from the Department of Health and Human Services (HHS) makes clear that in addition to such approaches, prescription drug misuse and abuse activities must include a focus on public education, with a particular emphasis on patient-directed efforts.⁴⁹

This will require broadening the scope of prescription drug prevention to include more “upstream” initiatives; shifting the balance to prioritize primary prevention - activities intended to prevent initiation of misuse. Understanding the history and current landscape of prescription drug misuse brings to light several considerations that can serve as a guide in developing effective primary and population-level prevention efforts moving forward.

I. **Prioritize Evidence-Informed Approaches**

There is limited research on the effectiveness of education-based prevention initiatives. However, that should not preclude us from blending thoughtful approaches that utilize relevant behavior change theories and frameworks and that are grounded in currently available evidence on effective prevention practice. These approaches might focus on engaging the healthy majority who do not misuse prescription medication as a way to challenge misperceptions about the prevalence and social acceptance of misuse. They would incorporate strategies designed to help individuals not only recognize the signs of misuse, but develop the skills to effectively assist someone who may be struggling or at risk of an overdose.

They would educate on the dangers of non-medical use of prescription drugs, while empowering individuals to confidently refuse an offer or a request to share medication. Such approaches would be considered evidence-informed and would have a greater potential for impact beyond that of awareness campaigns and public service announcements.



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Given the links between mental health and prescription drug misuse among adolescents and young adults, we must incorporate strategies to help young people develop a deeper understanding of their personal mental well-being.

II. Build Consensus About What Exactly We Are Trying to Prevent

While there is consensus about the risks of prescription drug misuse, there is a lack of consensus about what to do when it comes to effective prevention. In many cases, this ambivalence has led either to inaction or reaction to a specific concern, such as overdose. We must do all we can to continue to train and equip communities with the life-saving drug Naloxone, but lessening the impact of overdose of any drug requires that we identify the most effective way to prevent it from happening in the first place. Other than preventing opioid-related overdose, efforts to effectively educate individuals and communities on prescription drug misuse have been limited in scope and impact.

A singular focus on overdose prevention, coupled with a lack of effective public education about the risks and proper use of medications has led to one of two extreme viewpoints: fear of all prescribed medications or misperceptions of safety. Neither perspective will lead to the outcomes we are seeking.

III. Misuse is Not Exclusive to Prescription Opioids

“Substance abuse does not discriminate,” the Addiction Center warns. “No one, regardless of whether they come from a good family or have a high GPA, is immune to drug abuse.” Tragically, illegal drugs continue to plague our communities, none more so than heroin and other opioid-based substances. This cannot be overstated or disregarded. However, prescriptions of all kinds are being misused and diverted. Young people erroneously believe that non-medical use of medications prescribed for cognitive disabilities will boost their academic performance. Benzodiazepines (“benzos”) like Valium, that are used to relieve symptoms of anxiety, are some of the most commonly prescribed medications in the United States and also some of the most commonly abused.⁵⁰ This is not to suggest that opioids be deprioritized. Instead, it is a call to broaden the lens through which we view the prescription drug threat and create consistent messaging about the risks associated with the non-medical use of any prescription drug.

IV. Effective Education Must Begin Early and with a Focus on Shifting Misperceptions

A review of research conducted by the National Institutes of Health (NIH) suggests that certain educational efforts are effective in reducing prescription drug misuse during adolescence and young adulthood. Specifically, it points to the effectiveness of population-level strategies that are implemented at the middle-school level.⁵¹ Such strategies should be designed to help youth develop the necessary skills to continue making healthy decisions, as well as challenge current unhealthy behavior and support intentions to change that behavior. This requires an environment where those skills and intentions can be reinforced and is best accomplished through shifting normative behavior, that is, correcting misperceptions about the prevalence and social acceptance of prescription drug misuse. Shifting what is accepted as “normal” or “typical” behavior involves challenging students’ perceived versus actual peer actions and attitudes about prescription drug use.

V. Don't Overlook the Mental Health Landscape

Among the current generation of young adults, Gen Z, 91 percent report experiencing physical or emotional symptoms due to stress. More than half of these symptoms include feelings of depression, sadness, lack of motivation, and energy.⁵² Considering this, plus what we know about the links between mental health and prescription drug misuse among adolescents and young adults, we must explore opportunities not only to educate on prescription drug safety, but to incorporate strategies to help young people develop a deeper understanding of their personal mental well-being. This is especially true of young people who are prescribed medications to treat conditions like ADHD, anxiety, and depression.

Not only do they need to understand how to safely and effectively use their prescription to manage their symptoms, they must also develop self-awareness and the ability to recognize when they are struggling to manage those symptoms and when to reach out for support, rather than attempting to manage it on their own.

VI. Help Patients Become Informed Consumers of Prescription Drugs

Patient-directed education goes well beyond what can be gleaned from pharmaceutical ads. It is the result of effective education programs designed and delivered to patients and their caregivers, and is especially important for individuals who are prescribed medications that are associated with greater levels of misuse and increased risk of harm (e.g., opioids, stimulants, and depressants). Prescription drugs are designed to improve quality of life for people who suffer from various physical and emotional illnesses. For the majority of these drugs, the benefits can outweigh the risks when they are taken as directed, under the care of a healthcare professional, and by the individual for which they were prescribed. This is an important part of the conversation, as we don't want the outcome of our efforts to make anyone fearful of using drugs that are appropriately prescribed by their physician and safely used. By becoming informed consumers of prescription medications, patients - and their caregivers - can significantly impact the prescription drug landscape.

Effective education will vary in terms of how the information is presented, what format is used, its length, and its tone. Patient education will look very different from education efforts directed at young adults. But any primary prevention curriculum should include important information on critical topics, including:

- Potential side effects and precautions, including the potential for misuse, developing a substance use disorder, and overdose.
- For patients: how a given medication can be used effectively to treat a diagnosed condition.
- The importance of reading prescription and warning labels in order to understand risk factors.
- The legal and personal implications of sharing prescribed medication or using someone else's medication.
- How to safely store and dispose of unused medication.
- For opioids: alternative pain treatments.
- How to recognize signs and symptoms of dependency and potential substance use disorder.
- How to recognize signs and symptoms of any drug overdose.
- How to respond to a drug overdose, and for opioids specifically, information on Naloxone, including what it is, how it works, and where to obtain it.
- For parents/caregivers: how to talk to a young person about prescription drug misuse.
- The risks associated with mixing prescription and non-prescription drugs.
- Warnings about counterfeit pills and analogues that are marketed as prescription drugs, such as the increasingly common example of pills labeled Xanax that may actually be fentanyl, a powerful synthetic opioid up to 100 times more potent than morphine.
- Information on state and local laws related to seeking medical intervention, for example, community or state-sponsored Good Samaritan policies.
- Suggestions for ways that anyone can contribute to reducing prescription drug misuse in their community.

Conclusion

Prescription medicines play a critical role in healthcare. Advances in drug discovery and development help millions of people live longer and healthier lives. But any medication, when misused, can also cause harm. Driven by multiple factors, the misuse of prescription medications - particularly opioids - has become one of the most critical public health challenges in the U.S. But there is also some evidence to suggest that the policies and programs that have been put into place over the past decade may be helping to make inroads on this complex social issue. While promising, these trends are not an indication that we can afford to take our foot off the gas when it comes to education and prevention. In fact, it provides a call to action to continue, enhance and expand current educational efforts to build and sustain well communities across the country.



PRESCRIPTION DRUG SAFETY NETWORK

powered by EVERFI

In 2017, EVERFI created a blueprint for addressing the challenges identified in this report by developing a first-of-its-kind public-private partnership, the Prescription Drug Safety Network (PDSN). This Network is a national coalition of healthcare organizations, pharmaceutical manufacturers, distributors, pharmacies, foundations, and state leaders committed to empowering Americans to make safe and healthy decisions about prescription medications.

With support and funding from members of the Prescription Drug Safety Network, EVERFI is deploying evidence-informed digital courses in schools across the country, including some of the most at-risk communities. Since the launch of the Network in 2017, prevention education has been delivered to nearly 200,000 students across 1,500 high schools and 70 colleges and universities.

EVERFI makes digital prescription drug education available to pharmacies and other retailers, enabling them to provide just-in-time learning to patients, their caregivers, and employees.

For more information on becoming a part of PDSN, visit prescriptiondrugsafetynetwork.com

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