Consumption of Prescription Opioids for Pain: A Comparison of Opioid Use in the United States and Other Countries

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Beginning in the late 1990s, the consumption of medical opioids used to treat pain increased in many countries worldwide. Since that time, the United States has outpaced every other country in per capita opioid consumption. Most research suggests that high levels of prescription opioid consumption in the United States have contributed to the current epidemic of opioid misuse and overdose deaths.

In response, several states and the U.S. federal government have demonstrated an interest in reducing opioid misuse and overdose deaths through legislation and executive initiatives. Understanding why the United States consumes more opioids per capita than other countries may help Congress construct effective legislation to reduce inappropriate or excess opioid consumption and mitigate related consequences, such as opioid misuse and overdose deaths. In addition, lawmakers in the United States could examine policies in peer countries for possible approaches to curb excessive prescription opioid use.

A review of the scientific literature through February 2020 on international opioid consumption and prescribing practices pointed to several possible underlying reasons explaining the difference in opioid consumption per capita in the United States.

Prescribing practices and drug potency. At the most basic level, the difference in consumption of opioids reflects the prescribing practices of health care providers. U.S. health care providers prescribe opioids more frequently, at higher doses, and throughout more stages of pain treatment—including as a first-line treatment—than their international counterparts. Use of higher-potency opioids appears particularly high in the United States compared with other countries. Nearly all published clinical guidelines discourage use of high-potency opioids, and opioids as a first-line treatment, for managing long-term chronic noncancer pain.

Prevalence of pain and approaches to pain management. It is possible the United States has a greater prevalence of pain, and that Americans experience—or at least self-report—more intense pain. Americans may receive more opioids at more points in care at the expense of more comprehensive pain therapies. Higher opioid prescribing practices may be influenced by insurance reimbursement systems that incentivize opioids over alternative pain treatments, cost structures that promote more efficient care, or evaluations that conflate patient satisfaction with effective pain management.

Health care systems structures. The U.S. health care system and regulatory structure may have had more risk factors—such as permissive marketing laws and a decentralized oversight system—compared with European or other countries. Conversely, countries with nationalized health care systems and centralized regulation of health care practices may have had more protective factors that prevented an increase in overprescribing. Compared with its European counterparts, the U.S. medical system permits more autonomy for health care providers, imposes fewer national regulations on health care practices, and allows more direct-to-provider marketing practices. U.S. prescription drug monitoring programs (PDMPs), which track prescriptions for narcotic drugs such as opioids, are decentralized and generally structured to monitor bad actors; PMDPs are not always designed to promote best practices aligned with clinical guidance.

Cultural differences and access to care. More broadly, cultural differences, such as expectations about pain relief and entitlements to opioid treatment, may also explain the greater reliance on pharmacological treatments in the United States. In addition, health care systems that provide more expansive access to care and broader options for pain management—including many in Western Europe—may enable greater preventive care and more multimodal approaches to pain, in part because there may be fewer barriers to accessing these types of treatments. Countries with nationalized health care systems and centralized regulation of health care practices also may have had protective factors that prevented an increase in overprescribing.
This report describes trends in opioids use across industrialized countries and identifies possible factors explaining the disproportionate use of prescription opioids in the United States. The main findings in this report appear in the “Key Takeaways” text box.
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Overview

Beginning in the late 1990s, many countries saw increases in consumption of medical opioids used to treat pain. Opioids are substances that act on receptors in the brain, particularly those involved in pain regulation and emotion. Opioids are used in the medical field as analgesics, meaning to treat pain. From the mid-1990s through 2019, the United States outpaced every other country in opioid consumption per capita, including all other Organisation for Economic Co-operation and Development (OECD) and Group of 7 (G-7) member countries. U.S. opioid consumption peaked in 2012. Since then—and after historic levels of misuse and overdose deaths—the United States has witnessed a decline in opioid prescribing. Despite this decline, the United States continues to consume more opioids per capita than any other country in the world, including its G-7 counterparts.

Policymakers interested in addressing the opioid epidemic may want to understand why the United States consumes a disproportionate amount of opioids. The scientific evidence suggests that many factors may influence this disparity between the United States and other economically advanced countries. This report synthesizes the scientific research to explain relevant factors regarding the difference between opioid consumption in the United States and other comparable industrialized countries, such as the G-7 countries.

A review of scientific literature on international and domestic opioid use pointed to several factors affecting the difference in consumption per capita. Prescribing practices of health care providers appear to be a primary factor affecting consumption. U.S. health care providers prescribe opioids more frequently, at higher doses, and throughout more stages of pain treatment—including as a first-line treatment—than their European counterparts. Use of higher-potency opioids—with greater morphine milligram equivalents (MMEs) per dose—appears especially high in the United States compared with other countries. Although there is generally no agreed upon threshold value of what constitutes a “high potency” opioid, clinical guidelines and research studies often use MMEs per day or per dose to establish a threshold. The MME metric allows for standardization of dose across different opioid analgesics. Table 1 lists the MME conversion factors of several commonly used opioid analgesics, as defined by the U.S. Centers for Disease Control and Prevention (CDC). Clinical guidelines published by the World Health Organization (WHO) and others discourage using high-

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1 The Organisation for Economic Co-operation and Development (OECD) and Group of 7 (G7) are international intergovernmental economic organizations of economically developed countries. The G-7 consists of Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States. For a list of the 36 member countries of the OECD, see https://www.oecd.org/about/members-and-partners/. All G-7 countries are members of the OECD. This report compares opioid consumption across the United States and other OECD countries, with an emphasis on the G-7 countries for simplicity.


3 Literature review reflects scientific literature through February 2020. Data used in the figures reflect the most recent complete annual data (2019) as obtained August 2020.

4 FDA Briefing Document, Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC), June 11-12, 2019, p. 34, https://www.fda.gov/media/127780/download.

5 Different research studies define “high potency” or “strong” in varying ways. See the specific journal articles for details regarding how these terms were defined in the studies.

6 Published MME conversion tables may vary, depending on the source.
potency opioids and opioids as a first-line treatment for long-term chronic noncancer pain management.  

### Measuring Opioid Consumption

Opioid consumption on a national scale is measured in a variety of ways. The most common metrics include (1) total weight (in kilograms) or weight per capita, (2) morphine milligram equivalents (MMEs) per capita, (3) total number of individual prescriptions, and (4) defined daily doses (DDD). These metrics are used in research on opioid consumption and are defined below.

**Total weight** refers to the amount of an opioid consumed by a country in kilograms. Total weight on its own does not factor in potency of the opioid or per capita rate of use. It is most useful for comparing opioid use within a country over time rather than between countries in a single year. When comparing opioid use within a single country over several decades, weight per capita can help account for population change in that country over time.

**Morphine milligram equivalents (MMEs)** is a value assigned to an opioid to reflect its potency compared with morphine—one of the first modern opioid analgesics used medically to treat pain. MMEs are used to standardize the potency of opioid medications, published MME conversion tables may vary, depending on the source used. Table 1 displays the MME conversion factors of several commonly used opioid analgesics.

**Number of prescriptions** refers to the amount of individual opioid prescriptions issued in a country. The number of prescriptions does not always factor in the length of the prescription, specific medication, number of pills, or potency of the medication, especially since countries differ in average number of pills and potency per prescription. Number of prescriptions more often serves as an indicator of provider and patient behavior rather than opioid consumption.

** Defined daily dose (DDD)** is “the assumed average maintenance dose per day” for an opioid used for “its main indication in adults” according to the World Health Organization. DDDs are units of measurement used to provide an estimate of drug consumption. DDDs do not necessarily reflect the prescribed therapeutic dose, which is based on individual patient characteristics (e.g., age, weight). DDDs are useful as a standard measure of drug use in national and international comparison studies at the population level because one DDD per day is implied.

Several additional factors besides higher prescribing practices may explain the higher relative use of opioids in the United States. It is possible the United States has a greater prevalence of pain, and that Americans experience, or at least self-report, more intense pain. Americans may receive more opioids at more frequent points in care rather than more comprehensive approaches to pain management, such as those that use combinations of pharmaceutical, psychological, and physical therapies. Higher opioid-prescribing practices may be driven by insurance reimbursement systems that incentivize opioids over alternative pain treatments, cost structures that promote more efficient care, or evaluations that prioritize patient satisfaction and conflate it with pain.

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8 *Morphine* also refers to the molecule isolated from opium that serves as the foundation for natural and semisynthetic opioid analgesics.


10 FDA Briefing Document, Joint Meeting of the Drug Safety and Risk Management (DSaRM) Advisory Committee and Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC), June 11-12, 2019, p. 34, https://www.fda.gov/media/127780/download.


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Compared with most of its European counterparts, the U.S. medical system allows for more autonomy for health care providers, imposes fewer national government regulations on health care practices, and permits more direct-to-provider marketing practices. In addition, prescription drug monitoring programs (PDMPs) in the United States are decentralized. PDMPs in the United States are generally structured to monitor bad actors and generally not designed to promote best practices aligned with clinical guidance. More broadly, cultural differences, such as expectations about pain relief and entitlements to opioid treatment, may also explain the greater reliance on pharmacological treatments in the United States.

### Table 1. Morphine Milligram Equivalent (MME) Conversion Factors of Commonly Used Opioid Analgesic Drugs

<table>
<thead>
<tr>
<th>Low Equivalency (MME factor &lt;1)</th>
<th>Equivalent (MME factor =1)</th>
<th>High Equivalency (MME factor &gt;1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>Hydrocodone</td>
<td>Fentanyl (patch)</td>
</tr>
<tr>
<td>0.15</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>Morphine</td>
<td>Hydromorphone</td>
</tr>
<tr>
<td>0.25</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>Nalbuphine</td>
<td>Oxycodone</td>
</tr>
<tr>
<td>0.40</td>
<td>1</td>
<td>1.5</td>
</tr>
<tr>
<td>Tramadol</td>
<td>Oxymorphone</td>
<td></td>
</tr>
<tr>
<td>0.10</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>


Notes: Conversion factors are for oral administration (with the exception of fentanyl). To determine the dose of an opioid in MMEs, the dose is multiplied by the conversion factor for that opioid. For example, oxycodone 80 mg multiplied by the conversion factor of 1.5 would be equivalent to 120 MME per dose; taken twice a day (160 mg), this would be equal to 240 MME/day.

The MME factor of fentanyl varies depending on the formulation for this drug. The most commonly prescribed fentanyl formulation (transdermal patch) has an MME factor of 100; however, here the fentanyl conversion to morphine equivalents is based on the assumption that one patch delivers the dispensed micrograms per hour over a 24-hour day and remains in place for three days. Other forms of licit fentanyl used to treat pain, including injectables and oral formulations (spray, buccal, sublingual, lozenges), have MME factors with scale based on strength from 10 to over 200.

Health care systems that provide more expansive access to care may allow for greater preventive care and more multimodal approaches to pain, in part because there may be fewer barriers to using these types of treatments. Moreover, providers operating in highly regulated systems may be less susceptible to the direct and indirect influences experienced by American providers, such as profit-driven fee-for-service incentives or direct-to-provider pharmaceutical marketing. The U.S. federal government leaves the majority of medical practice regulation to individual states. This decentralized system may impose rules governing prescribing practices (e.g., those instituted in European countries to prevent adverse outcomes of opioid use) at a slower pace than those imposed by centrally governed health care systems.\(^\text{13}\)

\[^{13}\] In general, the decentralized regulation of the practice of medicine may provide several benefits to health care in the United States. Evaluating the benefits and drawbacks of the federalized structure of the regulation of medicine in the United States is beyond the scope of this report. Notably, this decentralized structure may contrast with some other countries and may contribute to differences in opioid consumption overall. The health care system in the United States is not exclusively decentralized, however. Some aspects, such as Medicare or the Veteran’s Health Administration, offer more centralized regulatory controls.
Taken together, the evidence suggests that numerous factors may influence the relatively disproportionate amount of opioids consumed by the United States.\textsuperscript{14} Opioid use rose precipitously beginning in the late 1990s, corresponding with the introduction of reformulated opioid analgesics such as OxyContin\textsuperscript{15} and intensified marketing of these drugs. Due to several of the aforementioned factors, the United States may have been more susceptible to petitions from the pain advocacy community and the aggressive marketing campaigns of the pharmaceutical industry than other countries. The U.S. health care system and regulatory structure may have had more risk factors—such as permissive marketing laws and a decentralized oversight system—compared with European or other countries. Conversely, countries with nationalized health care systems and centralized regulation of health care practices may have had more protective factors that prevented an increase in overprescribing.

Although regulating the practice of medicine is mostly left up to the states, Congress may have a number of options to reduce the overutilization of opioids for pain. For example, the federal government plays a role in establishing the annual quotas for opioid production, specifying storage and dispensing rules, defining training requirements for health care providers, and regulating federal health care programs such as Medicare and Medicaid. Congress might also consider policies instituted in peer countries for possible approaches to curb excessive prescription opioid use.

This report discusses these points in further detail. More specifically, it

- identifies several factors that may influence the differences between opioid consumption in the United States and other developed countries;
- describes related empirical research and summarizes findings from a literature review;
- provides an overview of opioid use internationally and in the United States, along with factors that may influence differences between the United States and other economically advantaged countries; and
- discusses issues related to this topic that may interest Congress.

Global Medical Opioid Use

Nearly all countries use opioids as medicines to manage or treat pain, typically under the supervision of a health care provider. In the United States, for instance, opioids are legally available only by prescription. Opioids can pose significant dangers, including addiction and overdose resulting in death. Most research suggests that long-term opioid use, in particular, increases risks for several adverse events, including gastrointestinal distress, dizziness, fatigue,

\textsuperscript{14} Given that no consensus exists on an appropriate amount of opioids per capita, it is possible that other countries consume fewer opioids than the United States because pain is undertreated there. However, most experts believe that the opioid-related drug overdose epidemic in the United States is due in part to overprescribing practices. See, for instance, Sameer Imtiaz, Kevin Shield, Benedikt Fischer, et al., “Harms of Prescription Opioid Use in the United States,” \textit{Substance Abuse Treatment, Prevention, and Policy}, vol. 9, no. 4 (October 27, 2014), and Organisation for Economic Co-operation and Development (OECD), \textit{Addressing Problematic Opioid Use in OECD Countries}, OECD Health Policy Studies, Paris, France, June 11, 2019, at https://www.oecd.org/health/addressing-problematic-opioid-use-in-oecd-countries-a18286f0-en.htm.

\textsuperscript{15} OxyContin is the brand-name extended-release formulation of oxycodone manufactured by Purdue Pharma L.P. For more information, see U.S. Food and Drug Administration, \textit{OXYCONTIN}, Medication Guide (Reference ID 3805894), August 2015, https://www.fda.gov/media/78453/download.
addiction, and overdose death.\textsuperscript{16} Since the 1990s, opioid misuse and overdose deaths have increased significantly in many countries, particularly in the United States. In some countries—including the United States—the increase in adverse outcomes has corresponded with the increase in opioids prescribed to treat pain.\textsuperscript{17} Most data suggest that high levels of prescription opioid consumption in the United States have contributed to the current epidemic of misuse and overdose deaths in the country.\textsuperscript{18} Several experts have identified overutilization of prescription opioids in particular as a key contributing factor to the epidemic of opioid overdose deaths.\textsuperscript{19}

**Figure 1. Total Opioid Consumption for G-7 Countries**

Defined daily doses per 1 million inhabitants: 1964-2018

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1}
\caption{Total Opioid Consumption for G-7 Countries}
\end{figure}


\textbf{Notes:} The opioids included in the total are hydrocodone, oxycodone, morphine, methadone, dextropropoxyphene, dihydrocodeine, diphenoxylate, ethylmorphine, pethidine, pholcodine, tilidine, hydromorphone, and fentanyl. Defined daily doses (DDD) are "the assumed average maintenance dose per day" for an opioid used for "its main indication in adults," according to the World Health Organization. DDDs are commonly used as a standard measure of drug use in national and international comparison studies at the population level because one DDD per day is implied. DDDs do not necessarily reflect the prescribed therapeutic dose, which is based on individual patient characteristics (age, weight, etc.). See World Health Organization, "Essential Medicines and Health Products/Defined Daily Dose," at https://www.who.int/medicines/regulation/medicines-safety/toolkit_ddd/en/.

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\textsuperscript{18} For example, see Sameer Imtiaz, Kevin Shield, Benedikt Fischer, et al., "Harms of Prescription Opioid Use in the United States," \textit{Substance Abuse Treatment, Prevention, and Policy}, vol. 9, no. 4 (October 27, 2014).

\textsuperscript{19} OECD, \textit{Addressing Problematic Opioid Use}, 2019.
Despite general acceptance in the medical field that opioids are effective treatments for acute pain, no medical consensus exists regarding the appropriate amount of opioid consumption per capita in a country. Medical opioid use (separate from use of illicit opioids, such as heroin) has increased in many economically developed countries over the past 25 years. However, per capita opioid consumption differs substantially among countries. The United States has less than 5% of the world’s population but consumed roughly 30% of the world’s opioids in 2009, including more than 99% of the world’s hydrocodone and 80% of the world’s oxycodone. Figure 1 displays trends in the use of the most common opioids in the G-7 countries over the past several decades.

Global Trends

Global opioid use has increased over the past 25 years. For instance, from 2001 to 2013, prescription opioid use for pain more than doubled globally, most significantly in North America, Europe, and Australia. Opioid consumption rose nearly 40% in the European Union (EU) during that time. Several individual countries experienced substantial growth in opioid consumption in the early 2000s. In the decade from 2000 to 2010, for example, the proportion of individuals in Germany with at least one opioid prescription increased by 37%. During that same period, prescription opioid sales in Italy and total consumption of opioids in Canada both tripled. In the majority of countries, the largest prescription opioid use increases were among patients with chronic noncancer pain. One research study found a pronounced trend toward the use of

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21 The term “opioid use” in this report refers to medical opioid use only, not illicit opioid use (e.g., heroin or illicit fentanyl use). Likewise, except where noted, the term “opioids” denotes opioids used medically to treat pain. Statistics describing the consumption of opioids likewise refer to those used medically—not to illicit opioids.
26 From 2005 to 2015. Ibid.
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stronger, higher-potency opioids (defined in this study as >50 MME per day).\textsuperscript{30} Another study found that in the United Kingdom (UK) the number of individuals using strong opioids increased nearly fivefold from 2000 to 2010.\textsuperscript{31} The use of oxycodone—considered one of the higher-potency opioids—has increased the most in many countries.\textsuperscript{32} In France, oxycodone use jumped 1,950% between 2004 and 2017.\textsuperscript{33} By 2010, oxycodone was the most widely prescribed opioid in the United States, with an increase in consumption of 1,100% between 1997 and 2010.\textsuperscript{34} Figure 2 illustrates oxycodone use in the United States compared with the other G-7 members over the past several decades.

Since the early to mid-2010s, European countries and other developed economies have experienced different trajectories of opioid use. Some continue to see increases in the dose and quantity of prescriptions, while others have seen level use or declines.\textsuperscript{35} In Denmark, Finland, France, Ireland, Switzerland, and Poland, for instance, opioid consumption has leveled off or declined in 2014-2016.\textsuperscript{36} Israel, Greece, and Portugal, however, experienced increases of more than 50% between 2011 and 2016.\textsuperscript{37} Similar increases have been reported in Australia and New Zealand.\textsuperscript{38} During that time, some countries, such as France and Canada, have experienced a surge in adverse effects associated with increased opioid prescriptions, such as opioid misuse, doctor shopping, opioid-related hospitalizations, and overdose deaths.\textsuperscript{39}

\textsuperscript{30} Ibid.
\textsuperscript{33} Chenaf et al., “Prescription Opioid Analgesic Use in France,” 2019.
\textsuperscript{35} OECD, \textit{Addressing Problematic Opioid Use}, 2019. A full comparison of the different trajectories of use across countries and an exploration of the factors contributing to these differing rates are beyond the scope of this report.
**Figure 2. Oxycodone Consumption in G-7 Countries**
Defined daily doses per 1 million inhabitants: 1964-2018

![Graph showing oxycodone consumption in G-7 countries from 1964 to 2018.](image)

**Source:** International consumption of narcotic drugs, 1964-2018, data provided to CRS by the International Narcotics Control Board (August 2020).

**Notes:** Defined daily doses (DDD) are “the assumed average maintenance dose per day” for an opioid used for “its main indication in adults” according to the World Health Organization. DDDs are commonly used as a standard measure of drug use in national and international comparison studies at the population level because one DDD per day is implied. DDDs do not necessarily reflect the prescribed therapeutic dose, which is based on individual patient characteristics (age, weight, etc.). See World Health Organization, *Essential Medicines and Health Products/Defined Daily Doses*, found at https://www.who.int/medicines/regulation/medicines-safety/toolkit_ddd/en/.

**U.S. Trends**

Although opioid consumption has increased in many countries, the United States continues to outpace its European counterparts in opioid consumption (see **Figure 1**). Research from CDC shows that overall opioid sales in the United States quadrupled from 1999 to 2010. In some years, prescription opioid use in the United States was as much as four times higher than in Western European countries.

Prescription opioid use peaked in the United States in 2012, with decreases in the years that followed. The overall national opioid prescribing rate declined from 81.3 prescriptions per 100

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persons in 2012 to 51.4 prescriptions per 100 persons in 2018 (from 255 million total opioid prescriptions to 168 million).\textsuperscript{43} Data from the International Narcotics Control Board (INCB) showed a 50% decrease in the consumption of both hydrocodone and oxycodone from 2012 to 2018. \textbf{Figure 3} displays opioid consumption over time from 1964 to 2018 in the United States.

\textbf{Figure 3. Opioid Consumption in the United States, by Opioid}

\begin{center}
\includegraphics[width=\textwidth]{figure3.png}
\end{center}


\textbf{Notes:} Consumption in milligrams per capita accounts for population change over time but does not factor in the potency of the opioid.

Despite the decrease in opioid prescriptions since 2012, the United States remains the top consumer of prescription opioids globally, followed by Germany, the United Kingdom, and Canada (see \textbf{Figure 1}).\textsuperscript{44} In addition, the rates of lengthy prescriptions (more than three days) for high-potency opioids have remained high. From 2012 to 2017, prescriptions for more than a three-day supply or for a dose of 50 MMEs per day or higher persisted in United States, even as overall consumption declined.\textsuperscript{45} CDC has noted that prescribing rates remain especially high in certain areas of the country. The agency reported annual prescribing rates of over 350 prescriptions per 100 people in some areas, with 11% of U.S. counties having enough opioid prescriptions for each inhabitant.\textsuperscript{46} In 2015, average per capita amounts of opioids prescribed in the top-prescribing counties were approximately six times the amounts prescribed in the lowest prescribing counties.\textsuperscript{47} Other studies report similar findings, showing that a relatively small

\textsuperscript{43} Ibid.

\textsuperscript{44} \textbf{Figure 1} refers to opioid consumption per capita. The United States also leads in total annual opioid consumption by weight.


\textsuperscript{47} Gery Gey, Kun Zhang, and Michele Bohm, \textit{Vital Signs: Changes in Opioid Prescribing in the United States: 2006-}
percentage of U.S. providers prescribe a disproportionate amount of opioid prescriptions to U.S. patients.  

Factors Influencing Medical Opioid Consumption

Several factors may influence differences in opioid-prescribing practices among developed countries. Comparing global opioid consumption is a challenge. Economic, social, and health care systems in G-7 and other economically developed countries vary. Excluding these broader discussions, public health experts have identified three key factors shaping opioid consumption:

- **physician behavior** (e.g., influence by pharmaceutical marketing, inadequate training on opioid pharmacology and risks, lack of access to multimodal pain treatments, and the ease of prescribing opioids compared with other pain therapies);
- **patient-related factors** (e.g., awareness of pain management options, attitudes toward pain, an emphasis on pain relief in treatment as opposed to underlying mental health, more value placed on pain relief than on functional improvement, and susceptibility to direct-to-consumer advertising); and
- **sociocultural factors** (e.g., beliefs about pain and the right to pain treatments, such as opioid therapy; health care coverage for opioid medications and alternative therapies; direct-to-provider and direct-to-consumer marketing rules; and opioid-prescribing regulations).

This section describes how these key factors might explain the differences in opioid consumption between the United States and other developed countries. These factors are organized into two general categories: (1) physician behavior and patient-related factors, and (2) sociocultural factors.

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49 Medical treatment and the use of certain health care services such as prescription opioids are complex. A combination of many factors likely influences use. The goal of this report is to provide as many possible reasons as are supported by the scientific literature. It is possible that other factors exist but are not identified in this report.


52 Factors are grouped generally, though many of the factors are interrelated and some categories may overlap.
Physician Behavior and Patient-Related Factors

Prescribing Practices

Prescribing practices influence opioid use, and research consistently shows that U.S. health care providers prescribe more opioids, at higher doses, more frequently during more stages of care for acute and chronic pain conditions than health care providers in other countries.53 Most governments regulate medical opioid use, often requiring permission for use—such as a prescription—from a health care provider.54 From 1995 through 2019, the United States

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54 Some countries, such as Canada, allow a select few opioids with low morphine equivalent levels such as codeine, to be available over the counter without a prescription. See, for example, Jesse MacKinnon, “Tighter Regulations Needed for Over-the-Counter Codeine in Canada,” Canadian Pharmacists Journal, vol. 149, no. 6, (November 2016), pp. 322-
prescribed more opioids than any other country in the world.\textsuperscript{55} Research shows that U.S. providers generally use higher doses of opioids,\textsuperscript{56} higher-potency opioids (meaning higher MMEs per dose or per day),\textsuperscript{57} and opioids at more stages of treatment than health care providers in other countries.\textsuperscript{58}

Attitudes toward opioids may affect prescribing practices. According to several studies, U.S. providers are more likely to report being “very comfortable” prescribing opioids, compared with non-U.S. prescribers.\textsuperscript{59}

Use of higher-potency opioids may explain relatively higher national consumption of opioids in the United States. Multiple studies have found that long-term use of more potent opioids—such as oxycodone and hydromorphone—increased substantially in the United States from the mid-1990s through 2011, while the use of codeine—an opioid with comparatively low potency—decreased (see Figure 3).\textsuperscript{60} ACDC study found that the percentage of adults in the United States

324.


56 For example, one study found that the average MME for a postoperative opioid prescription was higher in the United States compared with Canada and Sweden. See Karim Ladha, Mark Neuman, Gabriella Broms, et al., “Opioid Prescribing After Surgery in the United States, Canada, and Sweden,” JAMA Network Open, vol. 2, no. 9 (September 4, 2019). Opioid users in the United States are also more likely to use immediate-release opioid medications—as opposed to extended-release opioids—which may require more frequent dosing (e.g., every 4–6 hours instead of every 12 hours) and a greater overall number of pills. See Catherine Hwang, Elizabeth Kang, Yulan Ding, et al., “Patterns of Immediate-Release and Extended-Release Opioid Analgesic Use in the Management of Chronic Pain, 2003–2014,” JAMA Network Open, vol. 1, no. 2 (June 1, 2018).

57 For example, one study found that American patients were more likely to receive opioids the day after surgery than European patients. Another study examining opioid-prescribing practices among providers treating sickle cell disease in the United States and internationally found that U.S. providers tend to prescribe more tablets of stronger opioids per patient than non-U.S. physicians. Another study comparing opioid-prescribing practices between dentists in the United States and England during calendar year 2016 found that U.S. dentists prescribed opioids at a rate 37 times higher than dentists in England. This study also found that U.S. dentists prescribed a wider variety of opioids, including hydromorphone-based opioids and oxycodone, compared with England, where the only opioid prescribed by dentists was dihydrocodeine, a codeine derivative and less potent opioid. See C. Richard Chapman, Duncan Sevens, and Arthur Lipman, “Quality of Postoperative Pain Management in America versus European Institutions,” J Pain Palliat Care Pharmacother, vol. 27, no. 4 (December 2013); Nadirah El-Amin, Paul Nietart, and Julie Kanter, “International Differences in Outpatient Pain Management: A Survey of Sickle Cell Disease,” Journal of Clinical Medicine, vol. 8, no. 2136 (December 2019); and Katie Suda, Michael Durkin, Gregory Calip, et al., “Comparison of Opioid Prescribing by Dentists in the United States and England,” JAMA Network Open, vol. 2, no. 5 (May 24, 2019).

58 For example, one study comparing the United States with 13 European countries found that U.S. patients received opioids more frequently at every treatment phase (except for during an operation), including before admission to the hospital and after discharge. See R. Zaslansky, W. Meissner, and C.R. Chapman, “Pain After Orthopaedic Surgery: Differences in Patient Reported Outcomes in the United States vs Internationally. An Observational Study from the PAIN OUT Dataset,” British Journal of Anaesthesia, vol. 120, no. 4 (2018), pp. 790–797. Another study found that most American patients attending a pain management clinic had been receiving opioids prior to specialized pain care, suggesting that opioids may be frequently used as first-line pain treatments. See L. Manchikanti, K.S. Damron, C.D. McManus, et al., “Patterns of Illicit Drug Use and Opioid Abuse in Patients with Chronic Pain at Initial Evaluation: A Prospective, Observational Study,” Pain Physician, vol. 7, no. 4 (September 30, 2004), pp. 431–437.


who used only a weaker-than-morphine opioid in the past 30 days declined from 42.4% in 1999–2002 to 20.0% in 2011–2012, while the percentage who used a stronger-than-morphine opioid increased from 17.0% to 37.0%. This finding suggests that increases in opioid consumption rates may be partially due to higher-potency opioids replacing those of lower potency, resulting in more MMEs per capita in the United States.

Patient attitudes toward opioids may also affect opioid consumption rates. Some studies indicate that American patients are more likely to fill and use prescriptions compared with their European counterparts. In addition, American patients may be more likely to use opioids in long-term treatment for pain (the majority of which is chronic noncancer pain), which can lead to tolerance, leading in turn to use of more opioids. Long-term use can also result in hyperalgesia—a heightened sensitivity to pain that can result in more opioid use. In this way, opioid consumption often begets more opioid consumption.

Several countries demonstrate high rates of opioid consumption, including long-term use for chronic noncancer pain, yet most do not experience comparable adverse outcomes (e.g., high overdose deaths). Germany, for instance, is a top global consumer of opioids but has low rates of opioid-related overdose deaths compared with the United States. This difference may be partially due to the amount of opioids that are used in institutional settings, compared with outpatient settings away from provider supervision, where most U.S. use occurs. As one study...
noted, “The international data thus suggest that it’s not just the volume of opioid prescribing that matters, but where and how opioids are prescribed and used.” The higher rate of opioid prescribing by health care providers in the United States may not be limited to opioids. Other studies have shown that U.S. providers rely more heavily on pharmacotherapy in medical treatment compared to other countries.

Pain Rates among Select Countries

International reviews of pain prevalence are sparse and often incomparable, though a few studies suggest that U.S. citizens may experience higher levels of pain (or higher subjective self-reported pain) than citizens in some other countries, which may increase demand and subsequent use of opioids.

In 2016, CDC estimated that 20.4% of U.S. adults experienced chronic pain. Estimates of chronic pain in Europe typically range from 11% to 20% of the population (though some research has estimated that in some European countries as much as 50% of the population experienced chronic pain). One study comparing the prevalence of common chronic pain conditions across a number of countries found that the United States has a similar prevalence as some developed countries—such as France and Italy (44% prevalence in the U.S. population vs 50% and 43% in France and Italy, respectively)—but has a higher prevalence than others, such as Germany (32%) and Japan (28%).

Pain is one of the most common reasons for seeking medical care in the United States. Population-level studies of U.S. citizens indicate that pain prevalence may have increased during

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70 Ibid.
71 The use of psychotropic medications for mental disorders, for example, is substantially higher in North America compared to most other regions. See, for instance, Benedikt Fischer, Annette Keates, and Gerhard Bühringer, et al., “Non-medical Use of Prescription Opioids and Prescription Opioid-Related Harms: Why So Markedly Higher in North America Compared to the Rest of the World?” Addictio, vol. 109 (2013), pp. 177-181. A comparison of use across classes of medications is beyond the scope of this report, though it is notable that higher rates of prescription medication use by the United States is not solely confined to opioids.
75 Tsang et al., “Chronic Pain Conditions in Developed and Developing Countries,” 2008.
76 See, for instance, Jennifer St. Stauver, David Warner, Barbara Yawn, et al., “Why Do Patients Visit Their Doctors?
the past several decades. Although this jump may have contributed to an increase in opioid use for pain, it may not fully explain international differences; other studies suggest that pain conditions may have increased in other countries as well. Some research suggests that Americans may experience pain at more intense levels than residents of other countries. Possible explanations for a greater prevalence (or intensity) of pain in the United States may include more frequent assessments of pain during medical care or more risk factors for pain, such as undertreated mental illness, greater income inequality, or higher rates of other socio-economic stressors.

American patients receive more frequent assessments of pain compared with patients in other countries. A body of research suggests that these assessments do not necessarily result in more effective pain management, and may even increase self-reported pain levels. For example, repeated assessments may heighten patient awareness of pain, making patients hypervigilant and increasing their perceptions of pain severity. Conversely, infrequent assessments of pain may lead to worse pain management for certain patient populations.

Different experiences of pain between individuals in the United States and other countries may be genuine, perhaps the product of increased risk factors for pain conditions. One report attributed the rise in chronic pain prevalence in the United States to several factors, including greater patient expectations for pain relief, musculoskeletal disorders of an aging population, obesity, increased

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77 One study found that the proportion of adults in the United States reporting painful health conditions increased from 32.9% (120 million adults) in 1998 to 41.0% (178 million adults) in 2014. See R.L. Nahin, B. Sayer, B.J. Stussman, et al., “Eighteen-Year Trends in the Prevalence of, and Health Care Use for, Noncancer Pain in the United States: Data from the Medical Expenditure Panel Survey,” Journal of Pain, vol. 20, no. 7 (January 15, 2019).


79 For example, in one study comparing patients’ preoperative pain scores across countries, researchers found that, U.S. patients reporting chronic pain before hospital admission reported higher worst pain scores. See Zaslansky et al., “Pain After Orthopaedic Surgery,” 2018.


survivorship after injury and cancer, and increasing frequency and complexity of surgery. These factors may explain only some of the differences between countries, however, as other developed countries have experienced similar increases in life expectancy, use comparable advanced treatments, and, in some cases, perform more surgeries per capita than the United States.

Other risk factors may contribute to, or exacerbate, the experience of pain. These include sociodemographic, clinical, psychological, and biological determinants. For example, large-scale national surveys indicate that pain is more common among people who report a history of abuse and interpersonal violence. CDC has reported that chronic pain is more prevalent among adults living in poverty, adults with less than a high school education, and adults with public health insurance. Some research suggests that economic insecurity might increase physical pain sensations. In the United States, certain sociodemographic factors, such as socioeconomic status and race/ethnicity, may result in disparities in chronic pain across subgroups. Similarly, sociodemographic factors may predict opioid-prescribing rates, with higher prescribing found in lower-income counties in the United States, for example. U.S. providers may assess a patient’s pain differently based on sociodemographic characteristics such as race, which can lead to systematic undertreatment of pain and other adverse outcomes.

Socioeconomic disparities may partially explain higher opioid consumption in the United States. The United States is a high-income nation overall, but disparities in income within the U.S. population may explain, in part, higher levels of pain in certain subpopulations. Some research has identified economic stress as a contributor to pain. Of the G-7 countries, the United States

has the highest level of income inequality. Some economics researchers have labelled the increase in opioid-related overdose deaths in the United States “deaths of despair” due to declining economic conditions and poor economic prospects for certain populations. Income inequality and poor economic prosperity for some groups in the United States may equate to a greater experience of pain across the population, and a higher demand for opioids.

Mental health issues, such as anxiety and depression, have been associated with higher levels of physical pain. In the United States, individuals with a mental health condition are twice as likely to be prescribed opioids. Mental illness rates do not differ substantially between the United States and other G-7 countries. However, in a study comparing the prevalence of chronic pain conditions and comorbid depression and anxiety, the United States ranked first (23%) in the percentage of people with depression or anxiety who also reported a pain condition. This percentage was higher than other G-7 countries, which ranged from 6% to 15%.

Although research has shown that mental health disorders are undertreated globally, European countries tend to treat mental illness at higher rates—something WHO has primarily attributed to wider availability of health care in Western Europe. Widespread focus in the United States on treating pain rather than underlying psychological distress may contribute to higher opioid demand and consumption rates. Placing a greater value on pain relief than on functional improvement may not effectively address the underlying conditions—such as mental health issues—that influence pain. In addition, poor physical health and certain health behaviors may be associated with higher rates of pain and opioid use.

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94 As measured by the Gini coefficient, an economic index of income inequality. By OECD country, the United States is ranked seventh globally, above all of Europe and other G-7 countries. See https://data.oecd.org/inequality/income-inequality.htm.


96 OECD, Addressing Problematic Opioid Use, 2019; and Kern, et al., “Treatment Patterns, Healthcare Utilization, and Costs of Chronic Opioid Treatment,” 2015. One study found that 18.7% of all patients with mental health conditions receive 51.4% of the total opioid prescriptions distributed each year. See Matthew Davis, Lewei Lin, and Haiyin Liu, et al., “Prescription Opioid Use among Adults with Mental Health Disorders in the United States,” Journal of the American Board of Family Medicine, vol. 30, no. 4 (July 2017), pp. 407-417. Another study found that patients with mental health disorders were more likely to continue opioid use after a surgery than individuals without a mental health diagnosis. See Chad Brummet, Jennifer Waljee, and Jenna Goesling, et al., “New Persistent Opioid Use after Minor and Major Survey in U.S. Adults,” JAMA Surgery, vol. 152, no. 6 (June 21, 2017).


98 Tsang et al., “Common Chronic Pain Conditions in Developed and Developing Countries,” 2008. Prevalence was compared across 18 countries.


101 Ibid.

Opioid Use in Japan

Japan consistently has some of the lowest annual per capita opioid consumption in the developed world. The Japanese population is aging faster than any other nation, and 26% of Japan's population is over the age of 65. Some reports indicate that demand for opioids in Japan is growing, as Japanese baby boomers deal with diseases and ailments of aging, such as arthritis, diabetic nerve damage, and cancer.

Most research on opioid use and chronic pain in Japan has found that medical practice norms influence opioid prescribing and therefore opioid use:

- The Japanese national insurance system does not provide coverage for most opioids for nonchronic cancer pain, which is perhaps a leading factor contributing to Japan’s low prescription and use rates.
- Per-capita use of opioids is 26 times higher in the United States, compared with Japan.
- Japanese providers generally prescribe opioids for chronic noncancer pain at a much lower rate than their American counterparts.
- In 2019, approximately 45.2% of Japanese adults suffered from chronic pain.

Low opioid-use rates in Japan may stem from certain sociocultural factors:

- “Opioids are frowned on both culturally and socially.”
- “Japanese patients may be less likely to complain about pain because of strong cultural mores regarding self-attention, a dynamic far less pervasive in the United States.”

Recently, opioid indications in Japan were expanded to include chronic noncancer pain. Experts in Japan have predicted that yearly opioid consumption will begin to increase due to this expansion.

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vol. 3, no. 4 (October 1, 2012); and Dasgupta et al., “Opioid Crisis: No Easy Fix,” 2018. One UK study found that people who reported “very bad” or “bad” health status used opioids 14% and 6% more, respectively, compared with those who reported “very good” health status. This suggests that the burden of certain chronic diseases and other health behaviors may affect rates of opioid use. See Adam Todd, Nasima Akhter, and Joanne-Marie Cairns, et al., “The Pain Divide: A Cross-sectional Analysis of Chronic Pain Prevalence, Pain Intensity, and Opioid Utilisation in England,” BMJ Open, vol. 8, no. 7 (2018).


Ibid.


Ibid.


Ibid.
Medical Treatment of Pain

Variance in pain management practices may contribute to differences in prescribed opioid use worldwide. Pain treatment in the United States frequently includes opioids, whereas other countries may embrace a wider variety of pharmacological and nonpharmacological interventions for pain.

The medical field continues to identify the most effective treatments for various chronic pain conditions (e.g., neuropathic versus musculoskeletal), and a consensus on how to best treat chronic pain conditions has not been reached. Current medical research reveals that a chronic pain treatment regimen involving nonopioid medications, such as nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, and psychotherapeutic interventions like cognitive-behavioral therapy and meditation, can often be used effectively to treat pain. According to some research, using opioids to treat chronic pain over the long term results in limited effectiveness.

Much of the scientific literature appears to indicate that European countries tend to use nonopioid treatment regimens more frequently than the United States does. For instance, in Europe, about two-thirds of patients with persistent pain take a prescription medication, but only a third of those medications are opioids.

As demonstrated by the higher per capita opioid consumption rates, the medical field in the United States tends to use opioids as a standard, and often first-line, treatment for both acute and chronic noncancer pain. Some experts have observed that before the recent rise of U.S. opioid use, chronic pain was managed largely with nonopioid pain medications, psychotherapies such as cognitive behavioral therapy, and alternative therapies like hypnosis. Other evidence shows that when opioid prescription rates were rising in the early 2000s, referrals to alternative treatments for pain, such as physical therapy, remained stagnant.

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115 International patients appear to receive more nonopioids during and after surgery than American patients (see Zaslansky et al., “Pain After Orthopaedic Surgery,” 2018). In studies in Norway and Germany, the prevalence of long-term opioid treatment for chronic noncancer pain was found to be less than 1.5%. See Olav Magnus Fredheim, Milada Mahic, Svetlana Skurtveit, et al., “Chronic Pain and Use of Opioids: A Population-Based Pharmacoepidemiological Study from the Norwegian Prescription Database and the Nord-Trøndelag Health Study,” Pain, vol. 155, no. 7 (July 2014), pp. 1213-1221. Other studies had similar findings, showing that European patients were most frequently treated with NSAIDs and other nonopioid medications. See Kim Reid, Julie Harker, Malgorzata Bala, et al., “Epidemiology of Chronic Non-Cancer Pain in Europe: Narrative Review of Prevalence, Pain Treatments, and Pain Impact,” Current Medical Research and Opinion, vol. 27, no. 2 (2011).


119 Patricia Zheng, Ming-Chih Kao, Nicholas Karayannis, et al., “Stagnant Physical Therapy Referral Rates Alongside
Few studies directly compare nonopioid treatments between the United States and European countries. However, some literature seems to indicate that European countries use a wider range of nonpharmacologic treatments to address pain conditions in patients, whereas U.S. health providers more commonly use opioids to treat chronic noncancer pain conditions.120 Some experts have suggested that this usage may be partially due to more expansive health care coverage of such treatments in European countries.121

**Optimal Pain Treatment**

Although clinical practice guidelines provide best practices for opioid use in pain management, no consensus exists in the global medical community regarding the appropriate amount of per capita opioid consumption. The international differences in opioid consumption, however, may be due to the undertreatment of pain in some places.122

Some experts have argued that pain remains undertreated, even in G-7 or other countries with adequate access to opioid analgesics.123 Many believe that the movement to increase the use of opioid medications worldwide by WHO and others began as a compassionate effort to reduce undertreated pain.124 However, a specific figure for safe and effective opioid consumption per capita may not exist. Instead, countries may have to find a balance between use of opioids for pain treatment and a reduction in their misuse and abuse. Few analyses of need and availability for opioids exist; however, according to some estimates, the United States distributes more than enough opioids in total to meet palliative pain needs, for example.125

**External Influences on Health Care Practices**

U.S. prescribing practices may have been more susceptible to outside influences—such as the pain advocacy movement and marketing campaigns of the pharmaceutical industry—than prescribing practices in other countries, resulting in higher rates of opioid use. For example, the OECD, U.S. Government Accountability Office, U.S. Surgeon General, and other experts believe that differences in drug advertising regulations have had a direct effect on opioid prescription practices and opioid use.126 In the United States, advertisers are allowed to market directly to market

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121 See, for example, Miceli et al., “Opioids Prescription in Pain Therapy,” 2018. See the “Health Care Systems” section below.
Beginnings in the 1990s, several pharmaceutical companies downplayed the addictiveness of opioids and promoted them as low-risk medications in marketing campaigns. Several studies have shown that these practices directly influenced prescribing patterns and provider behavior, subsequently increasing U.S. opioid use. The pharmaceutical industry encouraged opioid use through direct funding to private hospital systems (see the text box below). Moreover, these marketing and lobbying campaigns seem to have relegated alternative or complementary pain interventions to the sidelines.


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Consumption of Prescription Opioids for Pain

**Effectiveness of Pain Advocacy and Pharmaceutical Marketing**

Some researchers posit that the pain treatment campaign and pharmaceutical marketing practices of the 1980s and 1990s may have had a greater effect on U.S. health care providers when compared with their European counterparts. Multinational opioid manufacturers, such as Purdue Pharma and Janssen Pharmaceuticals, funded pain advocacy organizations, medical societies, clinical practice guideline development efforts, and medical education in the United States. In turn, advocacy groups, including the American Academy of Pain Management and the Academy of Integrative Pain Management, issued guidelines recommending opioid use for pain management, and opposed efforts to monitor and regulate opioid overprescription. One report found that opioid manufacturers contributed $9 million to 14 third-party advocacy organizations between 2012 and 2017, and allocated $1.6 million in payment to physicians affiliated with these advocacy groups. A U.S. Surgeon General report found that physicians who received any opioid-related payments from industry had 9.3% more opioid prescription claims compared with physicians who received no such payments.

Many experts contend that the international opioid promotion campaign was more effective in the United States because of cultural and systemic factors. For example, European countries may have had protective factors against some of the influence of these campaigns, such as cultural stigma and stricter prescribing regulations that kept opioid use low. The United States may have had risk factors that made health care system and providers more vulnerable to the influence of such campaigns. Of note, recent reports indicate that as opioid-prescribing rates in the United States decline, opioid manufacturers and distributors—such as Purdue Pharma—are promoting broader use of painkillers in low- and middle-income countries using similar marketing tactics.

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**Attention to Clinical Guidance**

Adherence to clinical guidance for opioid use for chronic pain varies, potentially resulting in the contrasting use of opioids across countries. Several professional, national, and international health organizations have issued guidance on best practices for effective and safe management of pain. However, adherence to this guidance appears to differ by country, with European

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136 Ibid.

137 HHS, Facing Addiction in America, 2016. See also footnote 132 and footnote 126.


139 For example, research shows that U.S. health providers may be more responsive to expectations for treatment or patient demands than providers in other countries. Survey data have shown that because patients’ satisfaction ratings of hospitals decreased when they were not prescribed opioids, opioids were prescribed for minor procedures. In addition, licensing requirements by state medical boards include criteria for supportive and appropriate pain control, which experts believe have likewise influenced prescribing practices. Prescribing opioids or other drugs for many ailments may be the feasible or incentivized intervention for care providers, but it is also viewed by many patients as an expected, satisfactory form of medical care. See, for instance, Koichiro Otani, Neale R. Chumbler, Patrick A. Herrmann, et al., “Impact of Pain on Patient Satisfaction Integration Process,” Health Services Research and Managerial Epidemiology, November 3, 2015, and B.M. Kuehn, “Major disparities in opioid prescribing among states: some states crack down on excess prescribing,” Journal of the American Medical Association, vol. 312 (2014).


141 According to the WHO’s three-step pain ladder, pain analgesics should be prescribed in the following order: first, nonopioids (e.g., acetaminophen and NSAIDs); then, if necessary, weak opioids (e.g., tramadol and codeine); and then strong opioids (e.g., oxycodone and morphine). See World Health Organization, WHO’s Cancer Pain Ladder for Adults, 1986, at https://www.who.int/cancer/palliative/painladder/en/; T. O’Brien, L.L. Christup, A.M. Drewes, et al., “European Pain Federation Position Paper on Appropriate Opioid Use in Chronic Pain Management,” European Journal of Pain, vol. 21 (2017), pp. 3-19; World Health Organization, Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines, Geneva, Switzerland.
countries more apt to follow the guidance closely compared with the United States. In European countries with high levels of prescription opioid use, such as Germany, clinical guidelines and practice appear to impose greater restrictions on the use of opioids (especially of higher-potency opioids), limiting their use compared with North American countries. Many other OECD member countries have implemented clinical practice guidelines at the national level. Some research suggests that national clinical guideline implementation is associated with fewer adverse outcomes. In addition, many European countries use national stewardship programs to train medical practitioners, review prescribing practices, and provide feedback to health care professionals. The United States relies primarily on states to institute these programs.

In the United States, national clinical guidance for opioid use was published by CDC in 2016 and is nonbinding for health care providers. The decision to enact laws consistent with CDC guidelines is left to the discretion of individual states. Several states have opted to institute policies that align with the recommendations, and research suggests that compliance with CDC guidelines has helped curb overprescribing practices. Overall, U.S. opioid use patterns through

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144 In addition to the WHO guidelines, 15 other Organization for Economic Co-operation and Development (OECD) member countries have produced their own opioid clinical practice guidelines. Most of these guidelines agree on several opioid risk-mitigation strategies, such as upper dosing thresholds, cautions with certain medications, attention to potential drug interactions, and use of risk assessment tools such as urine drug testing. See Teryl Nuckols, Laura Anderson, Ioana Popescu, et al., “Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain,” Annals of Internal Medicine, vol. 160, no. 1 (January 7, 2014). OECD, Addressing Problematic Opioid Use, 2019. In some countries, such as Germany, national prescribing laws are closely tied to clinical guidelines. See Rosner et al., “Opioid Prescription Patterns in Germany,” 2019.

145 OECD, Addressing Problematic Opioid Use, 2019. This study points to smaller percentages of patients taking high-dose opioids, more providers avoiding long-acting opioids, fewer co-prescriptions with other potentially dangerous drugs such as benzodiazepines, and physicians more likely to use drug screens in patients with substance use disorders.

146 OECD, Addressing Problematic Opioid Use, 2019.

147 Some experts have observed that slow adoption of the CDC guidelines may be attributed to opposition to the recommendations by some patient advocacy and industry groups, particularly those with a financial stake in continued opioid use. See, for example, Dora Lin, Eleanor Lucas, and Irene Murimi, “Financial Conflicts of Interest and the Centers for Disease Control and Prevention’s 2016 Guidance for Prescribing Opioids for Chronic Pain,” JAMA Internal Medicine, vol. 177, no. 3 (2017), pp. 427-428.

148 CDC reported that opioid prescribing decreased at a faster rate after the agency released the guidelines in 2016, for
the mid-2010s suggest that health care providers have not adhered to international guidelines such as those released by WHO.\textsuperscript{149}

**Sociocultural Factors**

**Health Care Systems**

Differences in the structure and financing mechanisms of health care systems may influence rates of opioid use in medical care.\textsuperscript{150} The United States uses a number of payers for health care, both public and private. The historical predominance of a retrospective cost-based, fee-for-service (FFS) model in the United States (in which providers are paid [reimbursed] according to the amount of activities they conduct or number of patients they treat) may incentivize the use of opioids. Without other parallel constraints on services or costs, an FFS model (and other profit-driven forces in the private sector) may create financial incentives for more care and more profitable procedures, such as surgeries.\textsuperscript{151} Treating pain with opioids may lead to shorter visits with patients and, as a consequence, enable health providers to treat more patients and bill for more services.\textsuperscript{152} In addition, time constraints may drive providers to prescribe opioids for pain management rather than provide comprehensive pain care, which is more time- and resource-intensive and may be considered less efficient. Medical care in European systems is often funded before the point of service (e.g., through taxes) and is less likely to rely exclusively on FFS models in favor of other funding structures, such as pay-for-performance or diagnostic-related group payments.\textsuperscript{153}

In addition, the federalized regulatory model in the United States (which leaves many regulations to the states) may result in a slower, less direct ability to govern the use of opioids compared with the more centralized systems in many European countries and elsewhere. A centralized, publicly


\textsuperscript{150} A full discussion of the many differences between the health care systems of the United States and other countries is beyond the scope of this report. However, as described in this report, research suggests that a few notable differences may particularly affect opioid use.


\textsuperscript{153} Naoki Ikegami, “Fee-for-Service Payment—An Evil Practice That Must Be Stamped Out?” \textit{International Journal of Health Policy Management}, vol. 4, no. 2 (February 2015), and Jacqueline O’Reilly, Reinhard Basse, Unto Hakkinen, et al., “Paying for Hospital Care: The Experience With Implementing Activity-Based Funding in Five European Countries,” \textit{Health Economics, Policy and Law}, vol. 7, no. 1 (January 2012).
administered health care system may permit greater control over medical practices and facilitate a faster response to problematic trends—such as the overprescribing of opioids—compared with the U.S. system.

In the United States, health care is regulated on multiple governmental levels. The majority of European countries, including those in the G-7, operate various nationalized health care system models. According to research, many of the regulatory responses that mitigated prescription opioid misuse were implemented in Europe sooner than in the United States (see Appendix A for more information on government regulations affecting opioid use). Centralized health care may pose other tradeoffs, such as less efficiency in other areas, reduced innovation, less regional flexibilities, and less responsiveness to patient needs.

The specialization of medicine in the United States—and the lack of coordination among medical specialties—may have also influenced high opioid prescription rates. Patients frequently access care through a specialist, visiting multiple providers for a variety of health issues, which can make coordinating care difficult. Siloed specializations may contribute to fragmented care and create obstacles for streamlined provider communication (such as through synchronized Electronic Health Records). By contrast, in the UK’s National Health System (NHS), for example, patients receive coordinated care through their general practitioner (GP). When patients are referred to a specialist, their GP continues to coordinate their care, and related information (e.g., prescriptions) is centralized and accessible to other providers. Such coordinated care reduces duplicative services (or prescriptions) and may lead to more effective, efficient medical care.

Some research suggests that U.S. patients often delay seeking care due to cost, and will frequently wait until a health condition (such as chronic pain) becomes severe. More widespread and coordinated health care coverage may lead to more preventive treatments, reducing the amount or severity of health complications and thus reducing subsequent demand for opioid medications.

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154 Many European countries have vertically integrated health care regulatory systems that have imposed restrictions on the prescribing and accessibility of prescription opioids. A vertically integrated health care system is an arrangement whereby a health care organization offers, either directly or through others, a broad range of patient care and support services. Evidence suggests that some European health systems are shifting toward more decentralization. See, for example, *Federalism and Decentralization in European Health and Social Care*, ed. Joan Costa-Greer (Palgrave Macmillan, 2013). In the United States, medical practice regulations differ by state.

155 One study noted that the consumption of opioids has leveled off in recent years in many Western and Northern European countries, suggesting “that the measures being implemented by governments may prevent the development of an opioid crisis.” See Bosetti et al., “Trends in the Consumption of Opioids,” 2019, and van Amsterdam et al., “The Misuse of Prescription Opioids,” 2015. Notably, the U.S. Veteran’s Health Administration—a vertically integrated health system for military veterans—achieved a significant reduction in opioid prescribing after instituting several system-wide safety and pain management initiatives, such as the Opioid Safety Initiative. See U.S. Department of Veterans Affairs, VHA Pain Management/Opioid Safety Initiative, available at https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp.


158 Martin Roland, Bruce Guthrie, and David Colin Thome, “Primary Medical Care in the United Kingdom,” *Journal of the American Board of Family Medicine*, vol. 25 (March 2012), pp. 6-11.

159 Ibid.


161 Institute of Medicine Committee on the Consequences of Uninsurance, “Effects of Health Insurance on Health,” in *Care Without Coverage: Too Little, Too Late* (Washington, DC: National Academies Press, 2002), and Substance
Cost of and Payment for Pain Treatment

Cost structures and payment systems for pain treatments may explain international differences in prescription opioid use. How various pain therapies are paid for—and whether they are reimbursed under health insurance systems—likely affects how frequently patients and providers use them, especially compared with other possible approaches (see, for example, the text box on Japan above).162

According to some research, payment structures for health care in the United States often incentivize the use of prescription opioids over other pain management alternatives.163 Evidence suggests that policies adopted by some payers, such as Medicaid, have encouraged providers to prescribe opioids due, in part, to their comparatively low cost.164 Although coverage of opioid pain medications by commercial insurers—including those participating in the Medicare and Medicaid programs—is common, reimbursement for nonopioid pain interventions is less consistent.165

Some effective nonopioid treatments for chronic pain management have been identified, though they may remain underutilized in the United States due in part to insurance coverage policies.166 Utilization of nonopioid interventions has decreased in the United States since the early 2000s, primarily due to inconsistent coverage by insurers.167 Some nonpharmacological treatments for pain, such as physical therapy, are frequently covered by commercial and Medicare insurers.168 Other treatments, like steroidal injections, are sometimes covered, while treatments such as acupuncture do not appear to be covered often, if at all.169

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162 Toby Gosden, Frode Forland, Ivar Kristiansen, et al., *Capitation, Salary, Fee-for-Service and Mixed Systems of Payment: Effects on the Behaviour of Primary Care Physicians*, Cochrane Database of Systematic Reviews, Cochrane Systematic Review - Intervention, July 24, 2000, at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD002215/abstract. One study revealed that oxycodone consumption in Poland, for instance, was negligible until 2011 when it gained reimbursement status by the National Health Fund. In the years following, oxycodone use grew substantially: by 2015, oxycodone ranked fourth among opioids used in the country. Another study found a similar pattern in Italy, with the increase in use of specific opioids corresponding to changes in reimbursement structures. See Tomasz Dzierzanowski and Aleksandra Cialkowska-Rysz, “Accessibility of Opioid Analgesics and Barriers to Optimal Chronic,” *Support Care Cancer*, vol. 25 (2017); and Umberto Maria Musazzi, Paolo Rocco, Cinzia Brunelli, et al., “Do Laws Impact Opioid Consumption? A Breakpoint Analysis Based on Italian Sales Data,” *Journal of Pain Research*, vol. 11 (2018), pp. 1665-1672.


169 Ibid. One commentary on pain treatment in the United States proposed that the displacement of nonpharmacological
Some experts have suggested that the limited insurance coverage of alternative pain treatments—primarily for “cost-containment and profitability” reasons—has contributed to overuse of opioids for chronic pain management. The disproportionate coverage for some treatments, such as opioids, but not others, such as acupuncture, may have a trickle-down effect on chronic pain management. The absence of financial incentives to treat pain in a comprehensive manner may in turn produce a health care system with fewer providers learning about and using these therapies effectively.

Recent changes in health care coverage suggest that more insurers—both public and private—may be limiting payments based on the dosage in opioid prescriptions. In addition, more insurers may be moving to offer comprehensive pain treatments. For example, the Centers for Medicare & Medicaid Services announced in 2019 that Medicare would cover some (but not all) possible nonopioid interventions as part of a comprehensive pain treatment regimen.

Other characteristics of health care systems, such as provider and patient knowledge of insurance coverage, may affect opioid use. Insurance coverage may not be obvious to providers coordinating care, and the system may be challenging for patients to navigate. If coverage of opioid medications is common and well-known, providers may default to pharmacological treatment over nonpharmaceutical interventions.

Medication costs may also play a role. One study examining opioid purchases and expenditures across Europe found that the same drug costs different amounts in different countries. The researchers noted that costs to purchasers—such as hospitals and patients—differed between countries, and that pricing may factor into differential opioid use. The reasons behind different costs for identical opioid medications are complex and beyond the scope of this report. What is notable is that the costs of opioids differ across countries, and it is possible that these disparities affect use.

treatments in favor of greater opioid use was not coincidental, noting that “as insurers limited coverage of behavioral pain therapy, biopharmaceutical manufacturers sensed an opportunity. Pharmaceutical innovation propagated extended-release formulations, transdermal patches, nasal sprays, and oral dissolving strips. Medical device manufacturers drove a proliferation of novel pain modulating implants.”


171 The lack of coverage for nondrug and nonmedical treatments may contribute to a dearth of providers who are knowledgeable and willing to provide these services for people with chronic pain, particularly in the rural United States (including in some areas disproportionately affected by the opioid crisis). See Gross et al., “The Strengths and Weaknesses of Current US Policy to Address Pain,” 2019, and Schatzman, “Role of Health Insurance Industry,” 2011.


Government Regulations

National policies likely influence prescribing practices for opioids, particularly in Europe, where many governments have instituted national-level regulations on opioid prescribing. Many European regulations are more stringent than those in the United States; possibly because many European countries have public health care systems that, generally speaking, can be regulated more uniformly.\textsuperscript{178} European governments use a variety of regulatory restrictions, including\textsuperscript{179}

- the requirement for permission to prescribe or receive opioids;
- limitations on the amount to be prescribed;
- restrictions regarding dispensing privileges;\textsuperscript{180}
- national formularies to regulate which opioids can be prescribed under what conditions;\textsuperscript{181}
- requirements for a permit or license to prescribe; and
- restrictions regarding the authorization to prescribe, administrative provisions, and requirements for the storage of controlled medicines or prescription forms.\textsuperscript{182}

Dispensing rules include

- stipulations for the pharmacies authorized to dispense,
- limitations on the dispensing of controlled medicines, and
- administrative requirements, storage requirements, and delivery restrictions.\textsuperscript{183}

For example, several countries restrict opioid prescriptions to less than three weeks’ supply. Germany and other countries specify dose limits and require that opioids be prescribed in duplicate or triplicate using special forms (see the text box below).\textsuperscript{184}

Global health experts have noted that several European countries introduced stricter control measures in response to the increase in deaths due to oxycodone overdose reported in North America.\textsuperscript{185} Recent observations indicate that, in some countries, regulations on opioid prescribing may becoming more permissive.\textsuperscript{186}


\textsuperscript{182} Vranken et al., “Barriers to Access to Opioid Medicines,” 2016.

\textsuperscript{183} Ibid.


| Table A-1 identifies several common legal or regulatory provisions regarding opioid distribution and prescribing practices in G-7 and other economically advanced countries.

Public policies governing opioid use in the United States differ from most European countries in a number of ways. At the federal level, the United States does not impose limits on the daily dose of opioids a person can receive, place caps on long-term use, or restrict who can receive opioids, among other regulations commonly seen abroad. Federal programs such as the FDA’s Risk Evaluation and Mitigation Strategies (REMS) institute risk-mitigation procedures to promote the safe use of medications, although questions remain about the effectiveness of these policies.

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188 Ibid.


191 Ibid.


194 For more information on REMS, see CRS Report R44810, FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development.

Although other restrictions, such as medication storage and frequency of patient visits to receive prescriptions are imposed on the national level, most prescribing practices are regulated at the state level. At the national level, the U.S. system governing opioid prescriptions appears to allow for more provider autonomy than in many European countries. Several states have instituted opioid-prescribing regulations similar to those in Western Europe, though there is substantial variation between states. This decentralized system may create oversight challenges, making it more difficult to consistently monitor safe prescribing, enforce laws, and identify bad actors.

**Prescription Drug Monitoring**

The ability of national governments and other oversight or regulatory bodies to monitor the use of controlled substances used in medicine—such as opioids—may affect national consumption rates. Prescription drug-monitoring programs consist of electronic databases that track prescriptions for controlled medicines such as opioids. PDMPs are designed to provide health authorities with timely information about prescribing patterns and patient behaviors. Evaluations suggest that such programs have a positive impact in controlling problematic drug use by influencing both health care and law enforcement systems. Recent studies in the United States have shown that prescription opioid misuse increased more slowly in states with PDMPs than in states without them, and that states with more robust PDMPs have fewer prescription opioid overdose deaths.

Most economically advanced countries use PDMPs to monitor opioid prescribing, but to varying degrees. Compared with PDMPs in the United States and Canada, most European countries use PDMPs to assert more control over prescribing practices. The North American PDMPs appear primarily designed to detect individual instances of inappropriate prescribing rather than to promote safe and effective prescribing practices. In addition, the United States lacks a systematic post-dispensing control mechanism. Although the Drug Enforcement Administration

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196 See, for example, Title II of P.L.91-513, The Controlled Substances Act, as amended; 21 C.F.R. §1301.71 et seq.; and 21 U.S.C. §823.
202 Australia and the Netherlands appear to have robust national systems, for instance, while France’s program is limited in its ability to identify and monitor national trends over time. See OECD, *Addressing Problematic Opioid Use*, 2019, and Chenaf et al., “Prescription Opioid Analgesic Use in France,” 2019.
(DEA) oversees one-day prescription drug take-back events biannually (with the first occurring in 2010), no coordinated system exists to manage prescription opioid supply after dispensing.\(^{204}\)

The absence of a mandated centralized PDMP may contribute to higher rates of opioid use in the United States. Although states are not required to operate PDMPs, all 50 states, the District of Columbia, and two territories (Guam and Puerto Rico) have operational PDMPs.\(^{205}\) How PDMPs are organized and operated varies among states, which can slow interoperability and coordination.\(^{206}\) The decentralized nature of PDMPs in the United States may explain some of the differences in opioid consumption compared with European countries that have uniform national programs designed to promote, or ensure, safe prescribing practices.

### Cultural Factors\(^{207}\)

Cultural differences surrounding experiences of pain, expectations of pain remediation, and the use of medical care may explain higher rates of opioid use in the United States compared with other countries. A full exploration of all of the cultural factors that may explain differences in opioid consumption is beyond the scope of this report. Instead, this section identifies certain cultural factors commonly highlighted in existing research that may affect opioid consumption rates.\(^{208}\)

Social, cultural, and educational factors “influence illness behaviour in a number of ways including defining what is regarded as ‘normal’ and ‘abnormal,’ determining the cause of illness, influencing the decision-making control in healthcare settings and impacting on health-seeking behaviour.”\(^{209}\)

Research indicates that culture likely influences

- communication about pain between patients and physicians;\(^{210}\)

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\(^{204}\) Okie, “A Flood of Opioids,” 2010. Section 3032(a) of the SUPPORT Act (P.L. 115-271) allows the HHS Secretary to require, as part of a REMS for a drug that has a serious risk of abuse or overdose, that the drug be dispensed with a safe disposal packaging or safe disposal system. This provision did not require such packaging or disposal system, however, and it is unclear whether the provision has had any effect on drug disposal practices.

\(^{205}\) Each state determines which agency houses the PDMP; which controlled substances must be reported; which types of dispensers (e.g., pharmacies) are required to submit data; how often data are collected; who may access information in the PDMP database (e.g., prescribers, dispensers, or law enforcement); the circumstances under which the information may (or must) be accessed; and what enforcement mechanisms are in place for noncompliance. For more information on prescription drug-monitoring programs in the United States, see CRS Report R42593, *Prescription Drug Monitoring Programs*, by Lisa N. Sacco, Johnathan H. Duff, and Amanda K. Sarata. See also, Office of National Drug Control Policy, *Prescription Drug Monitoring Programs*, Fact Sheet, Washington, DC, April 2011, at https://www.ncjrs.gov/pdfiles1/ondcp/pdmp.pdf; and Dianne Goede and Scott Joy, “It Is Past Time for A National Prescription Drug Monitoring Program,” *SGIM Forum*, vol. 41, no. 7 (July 2018). There may be benefits to having different state PDMPs; however, evaluating the benefits and drawbacks is beyond the scope of this report. What is notable is that the partitioned structure of the PDMP system in the United States may explain some differences in opioid consumption compared with other countries.

\(^{206}\) The state of Missouri does not have a state-wide system. It is operated on the county level, with some counties opting to collaborate with one another.

\(^{207}\) For the purposes of this report, “culture” refers to the customary beliefs and social norms of a particular racial, religious, or social group, and the set of shared attitudes, values, and practices that characterizes a group of people.


\(^{210}\) For example, one study of pain in minority populations found that if clinicians and patients were of different ethnic backgrounds, the patients were less likely to be fully honest about the intensity of their physical pain. Shaurab Sharma, J. Abbott, and Mark Jensen, “Why clinicians should consider the role of culture in chronic pain,” *Brazilian Journal of*
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• beliefs about the cause of physical pain, and a focus on physical pain as opposed to psychological distress caused by the pain; 211
• expectations and acceptance of pain (e.g., as a normal part of life or as a medical problem that needs clinical intervention);
• displays of emotion or verbal expression in response to pain or injury; 212 and
• pain intensity and tolerance.

Other research demonstrates that established attitudes and beliefs about pain are important predictors in identifying who is likely to develop long-term and disabling pain. 213 For example, some researchers note that Americans believe pain can be controlled, and thus they may have lower pain tolerance and more permissive attitudes toward pain treatment and human intervention in the treatment of pain, compared with some of their European counterparts. 214

Further research highlights the way national laws and regulations may influence cultural beliefs about pain and an individual’s expectations of pain management. For example, U.S. health care providers can be held personally liable for pain control; patients can sue a practitioner if they perceive pain control to be inadequate. 215 One study found that as medical care has increasingly been viewed as a consumer good (including, in this case, advertisements that contain subjective information about pain relief), more individuals believe there should be a quick solution to pain—ideas that may have permeated American culture. 216

Issues for Congress

Congress has demonstrated continued interest in addressing the opioid epidemic in the United States. The 114th and 115th Congresses enacted several laws addressing opioid use, such as the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198), the 21st Century Cures Act (P.L. 114-255), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271). These laws included provisions specifically designed to address widespread overprescribing and abuse of opioids in the United States. 217 Future efforts by Congress could continue to address the United States’ comparatively high use of prescription opioids through oversight, hearings, or legislation on this topic. As described below, Congress could consider several options when addressing opioid consumption in the United States.

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212 Ibid.
213 See, for example, Van Hecke, “Chronic Pain Epidemiology and Its Clinical Relevance,” 2013.
216 Ibid.
217 For more information on the SUPPORT Act, see CRS Report R45405, The SUPPORT for Patients and Communities Act (P.L. 115-271): Food and Drug Administration and Controlled Substance Provisions.
Policy Options for Congress

Congress may have a number of options in seeking to reduce the overutilization of opioids for pain. Although regulating the practice of medicine is mostly left up to the states, Congress has several policy levers at its disposal to influence opioid-prescribing practices. The federal government is involved in multiple aspects of regulating the use of scheduled drugs in medicine, for example, such as establishing annual quotas for production, specifying storage and dispensing rules, requiring certain training for health care providers, and regulating federal health care programs such as Medicare and Medicaid. The federal government—often through the annual appropriations process—provides substantial funding to states specifically for opioid-related activities. Congress has sometimes linked states’ receipt of discretionary funding with their employment of certain policies or practices aimed at reducing prescription opioid use.

Congress could consider using mandatory or discretionary funding for innovative activities designed to promote best clinical practices. For example, research has shown that default settings in electronic medical record systems can influence lower opioid utilization for pain without compromising the quality of pain care. Sometimes referred to as “nudges” in the scientific literature, these default settings could promote alignment with clinical guidelines without any additional burdens to health care providers or additional costs to the system.

Reducing Opioid Consumption

Congress could also consider other policy or program strategies to reduce consumption of opioids. For example, lawmakers in the United States could look to policies in peer countries for possible approaches to curb excessive prescription opioid use. Congress could consider broadly applying some strategies from the Veterans Health Administration’s Opioid Safety Initiative, which, according to the VA, reduced prescription opioid use in patients within the VA health care system by 64%. Possible strategies for reducing prescription opioid use are discussed further below.

Prescription Drug-Monitoring Programs and Electronic Medical Records

Congress funds state prescription drug-monitoring programs (PDMPs) through initiatives such as the Harold Rogers grant program. Although the current authorizing statute outlines best practices for PDMPs, states must meet few requirements—none of which mandate state PDMPs to interact with other electronic medical record (EMR) systems. Congress could use the PDMP

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220 See, for example, 21 U.S.C. §823.
225 42 U.S.C. 280g-3.
grant program to encourage states to integrate their PDMPs with EMRs, for example. Congress could also revise the grant stipulations for PDMPs to encourage, or require, use of PDMPs in promoting best clinical practices, rather than primarily for diversion enforcement. In its toolkit outlining state strategies to improve PDMPs, the National Governors Association recommended integrating PDMPs with EMRs, using PDMPs to support clinical decision-making, and providing PDMP data access to health care institution leadership to facilitate oversight and best practices. Integrating PDMPs with EMRs may be challenging and burdensome. EMRs have substantial financial costs and are often not interoperable across systems, among other possible drawbacks. Further federal regulation on EMRs could actually restrict operability and curb innovation, having a counterproductive effect on opioid-related clinical practices.

As mentioned above, opioid-prescribing rates are not equally distributed across geographic areas in the United States. A relatively small percentage of health care providers are responsible for a disproportionate amount of opioid prescriptions. Congress could encourage the use of PDMPs to target regions or providers for education campaigns, training programs, or other PDMP-related interventions shown to curb excessive opioid use.

### Setting Annual Quotas for Controlled Substances

The Controlled Substances Act (CSA) includes a production quota system that requires the DEA to establish the total amount of each basic class of Schedule I and II controlled substances and listed chemicals that may be manufactured in a given calendar year “to provide for the estimated medical, scientific, research, and industrial needs of the United States for lawful export requirements, and for the establishment and maintenance of reserve stocks.” Many prescription opioids are Schedule II controlled substances under the CSA. The DEA establishes aggregate production quotas (APQs) and then assigns individual production quotas to manufacturers that

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227 For more detailed information on health information technology and EMRs, see, for example, Committee on Patient Safety and Health Information Technology, Institute of Medicine, *Health IT and Patient Safety: Building Safer Systems for Better Care*, Washington, DC, November 10, 2011, https://www.ncbi.nlm.nih.gov/books/NBK189661/.


230 These listed chemicals are ephedrine, pseudoephedrine, and phenylpropanolamine, which are ingredients commonly found in over-the-counter cold medicines that may be used in the production of methamphetamine and amphetamine. See Drug Enforcement Administration, *CMEA (Combat Methamphetamine Epidemic Act) Questions & Answers*, https://www.deadiversion.usdoj.gov/meth/q_a_cmeea.htm.


232 For more information on the CSA, see CRS Report R45948, *The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress*. 

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prevent the APQ from being exceeded. Registrants may not manufacture a Schedule I or II controlled substance that is (1) not expressly authorized by their registration and by the individual quota assigned to them by the DEA, or (2) in excess of that quota.

For any year in which the approved APQ for a covered controlled substance is higher than in the previous year, the Attorney General, in consultation with the HHS Secretary, includes in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

In trying to control the opioid supply and reduce opioid abuse, Congress has imposed tighter oversight of opioid production and distribution, including through oversight of annual APQs for opioids quotas. For example, Section 3282 of the SUPPORT Act strengthened considerations for DEA’s opioid quotas. Congress may consider further amending the quota process to control the nation’s opioid supply. For instance, Congress could amend data considerations for the DEA in its annual APQ determinations. In the annual APQ notices, the DEA has stated that it has difficulty relying on overdose death data provided by CDC because the data do not distinguish between, for instance, licit fentanyl and illicit fentanyl. Congress could diversify the quota process and involve other federal agencies, such as the FDA, in the decisionmaking process. The DEA has often stated that the quota decision is a careful balance between providing an adequate supply to those who need such substances for medical care and limiting the supply to prevent diversion to unlawful users.

**Prescription Drug-Marketing Practices**

Congress could look to peer countries for examples of national policies that appear to reduce opioid prescribing. The United States, for example, is the only country in the world besides New Zealand that allows direct-to-consumer marketing for prescription drugs, including opioids.

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233 Statement for the record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the U.S. Congress, United States Senate Caucus on International Narcotics Control, *Improving Management of the Controlled Substances Quota Process*, 114th Cong. 1st sess., May 5, 2015; and 21 U.S.C. §826(b). By regulation, the DEA Administrator must consider specific factors in making APQ determinations. See 21 C.F.R. §§1303.11(b)(1)-(5). In establishing quotas for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone, the Attorney General estimates the amount of diversion that occurs in the United States. In estimating such diversion, the Attorney General must consider, in consultation with the HHS Secretary, information they determine to be reliable on rates of overdose deaths and abuse and overall public health impact related to the substance, along with whatever other sources of information the Attorney General determines reliable. After estimating the amount of diversion, the Attorney General makes appropriate reductions from the quota that would have otherwise been established had such diversion not been considered.

234 Under the CSA, every person who manufactures, distributes, or dispenses any controlled substance, or who proposes to engage in any of those activities, must register with DEA, unless an exemption applies. See 21 U.S.C. §822 and 21 C.F.R. Part 1301.

235 21 U.S.C. §§842(b). The CSA allows registrants to apply for an increase in individual manufacturing quota if it is necessary “to meet … estimated disposal, inventory, and other requirements during the remainder of that year.” See 21 U.S.C. §826(b) and (c).


238 For more information, see Lisa Schwartz and Steven Woloshin, “Medical Marketing in the United States, 1997-
The pharmaceutical industry in the United States spends over $20 billion annually on marketing to health care professionals.239 These expenditures are generally tax deductible as business expenses.240 Many other countries either prohibit direct-to-provider marketing or place limitations on such practices. As examples, Congress might consider

- imposing a moratorium on advertising of certain prescriptions drugs;
- expanding FDA’s authority to review advertisements for drugs with high risk of abuse;
- eliminating tax deductions for the costs of advertising of certain prescription drugs;241 or
- limiting certain types of marketing practices, such as gifts to providers.242

Reducing direct-to-provider marketing could have drawbacks, such as practitioners being less informed about available medications or the proper use of certain formulations. In addition, a complete ban on direct-to-consumer (or health care provider) advertising may raise First Amendment issues.243

**Clinical Best Practices**

National-level policies do not need to be purely restrictive to effectively reduce unnecessary opioid prescribing. Several other countries—such as Japan—operate national provider training curriculums or stewardship programs designed to help practitioners learn and employ best clinical practices. In the United States, such programs are primarily instituted by states, if at all. FDA’s opioids REMS requires pharmaceutical companies that market opioids to make training available to prescribers. Prescribers are encouraged to participate in training, but they are not required to do so as a condition of prescribing.244 Congress could consider instituting national training programs similar to those of other countries, or international training and mentorship exchange programs, such as international twinning programs, where U.S. providers and public health professionals shadow counterparts in other countries to learn certain best practices.245

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241 For more information on this issue, see CRS Report R40590, *Direct-to-Consumer Advertising of Prescription Drugs*.


243 CRS Report R40590, *Direct-to-Consumer Advertising of Prescription Drugs*.

244 For a list of FDA REMS opioid-related continuing education resources, see https://search.opioidanalgesicrems.com/RPC-RMS-PROD/Guest/GuestPageExternal.aspx. For more information on REMS, see CRS Report R44810, *FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development*.

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National consumer education campaigns warning of the dangers of opioid use are another way to reduce inappropriate demand for these drugs. The federal government could encourage providers to discuss the risks of opioid use by reimbursing these conversations through Medicare—an activity currently not reimbursed, nor required. Recently, Medicare began reimbursing providers for similar nonclinical activities (such as conversations surrounding advanced care planning). In a recent survey of 1,000 Americans, most respondents were unable to correctly identify opioid medications. Of respondents prescribed opioids, less than a quarter of them stored them in a locked cabinet as recommended. Medicare rules—or other policies related to health insurance coverage and payment—could promote strategies to reduce opioid use and promote best practices, such as conversations about risks or alternative treatments for pain.

Prescribing Rules

Special prescription forms—required in some states domestically—are common internationally and have been shown to reduce opioid prescribing. Other countries have instituted national-level restrictions on the duration, number of pills, or dose in a single prescription. This practice has been adopted by about half of U.S. states to reduce excessive opioid pills in circulation and to align clinical best practices with law. Congress may consider federal-level legislation restricting the duration, number of pills, or dose in a single prescription. Considerable federal requirements would deviate from convention; the practice of medicine is mostly regulated at the state level. Additional regulations could add burdens to practitioners and affect pain care. Congress could consider removing certain high-potency opioids from the market, though doing so could have negative consequences for some pain patients.

Access to Other Pain Treatments

Reducing opioid use may involve a challenging balance: providing pain relief while limiting adverse consequences of excessive opioid use. Restricting access to opioids—or otherwise reducing their use—could have consequences for pain patients. Without comparable and effective pain treatments to replace opioids, some pain patients may experience increased pain if opioids are restricted. Reducing opioid use does not necessarily translate to poor pain treatment, however.


247 DrFirst, DrFirst Survey: Americans Think They Know Whether or Not They Are Prescribed an Opioid, But They're Wrong, Press Release, Rockville, MD, August 20, 2020, https://drfirst.com/press-releases/drfirst-survey-americans-prescribed-opioids/.


Although some patients may benefit from an opioid medication regimen for chronic noncancer pain, many may not need to initiate opioids if they use other treatments first.

Congress may seek to ensure that as opioids are reduced, access to other treatments are increased, so that nonopioid replacement therapies prevent a gap in pain treatment. For example, to facilitate access to nonaddictive pain products, the SUPPORT Act directed FDA to hold at least one public meeting with stakeholders and subsequently issue at least one guidance document addressing the challenges of developing nonaddictive medical products for the treatment of pain or addiction.\textsuperscript{250} In response to this directive, FDA convened both an advisory committee meeting and a public meeting and issued draft guidance.\textsuperscript{251} Congress may consider creating new incentives aimed at encouraging the development and use of new nonopioid or nonaddictive therapies.\textsuperscript{252} In addition, Members of Congress could consider tasking the U.S. Preventive Services Task Force with evaluating the efficacy of nonopioid pain treatments for potential reimbursement by the Centers for Medicare & Medicaid Services, for example. Of note, comprehensive, multidisciplinary pain management would likely result in increased financial costs for treatment.

### Comorbid Opioid Use and Mental Health Issues

Congress could seek to address the apparent underlying factors related to high opioid use, such as undertreated mental health disorders. Pain and subsequent opioid use are correlated with mental health conditions such as depression and anxiety.\textsuperscript{253} Moreover, comorbid and untreated mental health disorders are associated with substance use disorders, such as opioid use disorder.\textsuperscript{254} The mental health treatment system in the United States is largely segregated from mainstream medicine.\textsuperscript{255} Yet, many individuals presenting to medical providers may be experiencing underlying mental health conditions causing or exacerbating their physical pain.\textsuperscript{256} Integrating mental health care into mainstream medical care could be one approach to using multimodal approaches to improving pain care and reducing opioid use. Screening for these mental health issues, and subsequently treating them, could reduce the demand for opioids.\textsuperscript{257}

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\textsuperscript{250} Section 3001 of P.L. 115-271.


\textsuperscript{252} The National Institutes of Health (NIH) operates the Helping to End Addiction Long-term (HEAL) Initiative, which includes supporting research on, among other things, the management and treatment of pain without the use of opioids. For more information, see https://heal.nih.gov/.


\textsuperscript{254} See, for example, Lynn Webster, “Risk Factors for Opioid-Use Disorder and Overdose,” \textit{Anesth Analg.}, vol. 125, no. 5 (2017), pp. 1741–1748.


\textsuperscript{257} Few prospective longitudinal studies examining the relationship between mental health interventions and subsequent opioid use exist; however, some studies suggest adequate mental health treatment could potentially reduce future opioid use. See, for example, Mark Sullivan, Mark Edlund, Lily Zhang, et al., “Association Between Mental Health Disorders,
mental health care would likely involve initial financial costs, and the effectiveness of integrated care for chronic pain awaits further research. Congress may consider funding research examining comorbid pain and mental health conditions that might provide insights into effective approaches to care.

## Appendix A. International Opioid-Prescribing Regulations

### Table A-1. Common National Regulatory Systems for Medical Opioid Use in OECD Countries

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>National clinical practice guidelines</td>
<td>Recommendations for the appropriate use of prescription opioids in the treatment of pain. Guidelines may be issued by governmental bodies, professional organizations, or other stakeholders. For example, most guidelines agree on several opioid risk-mitigation strategies, including upper dosing thresholds, cautions with certain medications, attention to drug-drug and drug-disease interactions, use of risk assessment tools, treatment agreements, and urine drug testing.</td>
</tr>
<tr>
<td>National provider training and stewardship programs</td>
<td>Didactic programs that include specific evidence-based guidelines combined with educational initiatives and direct training curriculums and activities for prescribing health care professionals. Outreach campaigns promote judicious use of opioids and access to trainings and resources.</td>
</tr>
<tr>
<td>Special permit/license required for prescribing</td>
<td>National laws limit the competence to prescribe controlled medicines to certain specified medical specialists; designated institutions and/or providers are allowed to prescribe controlled medicines if a special permit or license is obtained.</td>
</tr>
<tr>
<td>Special prescription forms required/prescribing in multiple copies required</td>
<td>Special forms or multiple copies are required and/or other administrative requirements for health care professionals prescribing opioids.</td>
</tr>
<tr>
<td>Limited prescription validity</td>
<td>Prescriptions for some controlled medicines expires within a certain time after issuance.</td>
</tr>
<tr>
<td>Amount of controlled medicine to be prescribed is limited</td>
<td>Restrictions on the duration, number of pills, or total MMEs in a single prescription.</td>
</tr>
<tr>
<td>Daily dosage is limited</td>
<td>Limits on the maximum daily dosage for an opioid prescription.</td>
</tr>
<tr>
<td>National prescription drug monitoring program</td>
<td>National electronic databases that track prescriptions for controlled medicines, such as opioids.</td>
</tr>
<tr>
<td>National prescription drug adverse-events tracking system</td>
<td>National electronic databases that track adverse events for medical products and controlled medicines, such as opioids.</td>
</tr>
<tr>
<td>Disciplinary action for overprescribers</td>
<td>Deliberate or unintended violation of administrative requirements and regulations may result in sanctions for health care providers.</td>
</tr>
<tr>
<td>Marketing restrictions</td>
<td>Limits on allowable marketing practices for the pharmaceutical industry, including constraints or prohibitions on direct-to-consumer or direct-to-provider activities.</td>
</tr>
<tr>
<td>Consumer warning systems</td>
<td>Labels on medications contain warnings regarding possible adverse outcomes associated with use.</td>
</tr>
<tr>
<td>Consumer education campaigns</td>
<td>Messaging campaigns that seek to inform the public about the possible dangers associated with opioid use and misuse.</td>
</tr>
<tr>
<td>Postdispensing control mechanisms</td>
<td>Widespread and systematic mechanisms to safely collect or dispose of excess medications.</td>
</tr>
</tbody>
</table>

**Source:** CRS analysis. See table notes below for selected citations.


Appendix B. Methodology and Search Strategy

To gather relevant articles and information for this report, CRS research librarians conducted literature searches in February 2020. One search was for literature on pain management practices in the United States and comparisons with other countries within PubMed, the National Library of Medicine’s online database of biomedical literature. The other search was for global and international (non-U.S.) comparisons of pain management practices within The Lancet Global Health, a peer-reviewed medical journal focusing on global health issues. Terms used in both searches included geographic terms (i.e., United States, America, Europe, international, global, country names) in combination with the following clinical words and their variants, listed alphabetically:

- Chronic pain
- Complementary
- Integrative
- Nonaddictive
- Noncancer pain
- Noninvasive
- Nonnarcotic
- Nonpharmacologic
- Opioid/Nonopioid
- Pain
- Pain Management
- Palliative
- Prescribe
- Prescription
- Surgical/nonsurgical
- Treatment/intervention/therapy

This search initially identified 108 scientific articles and government reports. CRS reviewed this literature to identify information that offered insight into differences in opioid consumption globally. References, additional citations, and primary sources from the initial articles were reviewed when appropriate—including several published throughout 2020. In total, over 200 journal articles, white papers, and government, agency, or scientific reports were reviewed. The information collected from these sources was then organized into themes surrounding possible explanations for international differences.258 CRS identified 10 themes based on analysis of the literature. Each theme represents a possible reason the United States consumes more opioids than other countries.

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258 Identification and classification of themes followed principles of content analysis; however, no formal coding occurred. For more on content analysis, see Robert Philip Weber, Basic Content Analysis (Newbury Park, CA: Sage Publications, 1990).
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