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

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

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 system 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.

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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.¹ U.S. opioid consumption peaked in 2012.² 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.³

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,⁴ clinical guidelines and research studies often use MMEs per day or per dose to establish a threshold.⁵ 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).⁶ Clinical guidelines published by the World Health Organization (WHO) and others discourage using high-

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.

² *Ensuring Adequate Access for Medical and Scientific Purposes*, report published by the United International Narcotics Control Board, *Availability of Internationally Controlled Drugs* Nations, New York, NY, January 2016.

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.⁷

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.⁸ MMEs are an opioid's dosage equivalency to morphine, measured in milligrams. MMEs are commonly used with a population metric to create an MME per capita rate.⁹ Although MMEs are commonly used to standardize the potency of opioid medications, published MME conversion tables may vary, depending on the source used.¹⁰ **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 of 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.¹¹ 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.¹²

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

⁷ World Health Organization, *Web statement on pain management guidance*, “Essential medicines and health products,” June 20, 2019.

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

⁹ Centers for Disease Control and Prevention, *CDC Guidelines for Prescribing Opioids for Chronic Pain - United States, 2016*, MMWR vol. 65 no. 1, Atlanta, GA, March 28, 2016, at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>.

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>.

¹¹ See World Health Organization, *Essential Medicines and Health Products/Defined Daily Doses*, at https://www.who.int/medicines/regulation/medicines-safety/toolkit_ddd/en/.

¹² J. Merlo, A. Wessling, and A. Melander, “Comparison of Dose Standard Units for Drug Utilisation Studies,” *Eur J Clin Pharmacol*, vol. 50 (1996), pp. 27-30; and Thomas Grimmsman and Wolfgang Himmel, “Discrepancies between Prescribed and Defined Daily Doses: A Matter of Patients or Drug Classes,” *Eur J Clin Pharmacol*, vol. 67 (2011), pp. 847-854.

management. 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

Low Equivalency (MME factor <1)		Equivalent (MME factor =1)		High Equivalency (MME factor >1)	
Codeine	0.15	Hydrocodone	1	Fentanyl (patch)	2.4
Dihydrocodeine	0.25	Morphine	1	Hydromorphone	4
Tapentadol	0.40	Nalbuphine	1	Oxycodone	1.5
Tramadol	0.10			Oxymorphone	3

Source: Based on Michael Von Korff, Kathleen Saunders, G. Thomas Ray, et al., “Defacto Long-term Opioid Therapy for Non-Cancer Pain,” *Clinical Journal of Pain*, vol. 24, no. 6 (2008), pp. 521-527 (as cited in Centers for Disease Control and Prevention, *CDC Guidelines for Prescribing Opioids for Chronic Pain - United States, 2016*, MMWR vol. 65 no. 1, Atlanta, GA, March 28, 2016, at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>), and Exhibit 37 in IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, Parsippany, NJ, May 2019.

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.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.¹⁴ Opioid use rose precipitously beginning in the late 1990s, corresponding with the introduction of reformulated opioid analgesics such as OxyContin¹⁵ 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,

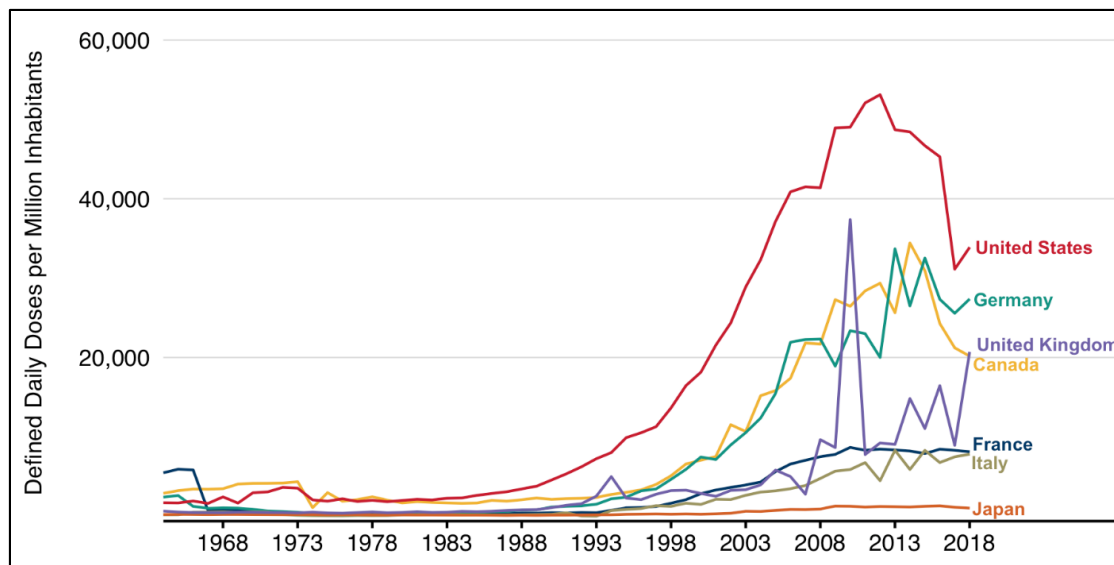
¹⁴ Given that no consensus exists on an appropriate amount of opioids per capita, it is possible that other countries consume fewer opioids than the United States because pain is undertreated there. However, most experts believe that the opioid-related drug overdose epidemic in the United States is due 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,” *Substance Abuse Treatment, Prevention, and Policy*, vol. 9, no. 4 (October 27, 2014), and Organisation for Economic Co-operation and Development (OECD), *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>.

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, *OXYCONTIN*, Medication Guide (Reference ID 3805894), August 2015, <https://www.fda.gov/media/78453/download>.

addiction, and overdose death.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.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.¹⁸ Several experts have identified overutilization of prescription opioids in particular as a key contributing factor to the epidemic of opioid overdose deaths.¹⁹

Figure I. Total Opioid Consumption for G-7 Countries

Defined daily doses per 1 million inhabitants: 1964-2018



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

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 Doses*, at https://www.who.int/medicines/regulation/medicines-safety/toolkit_ddd/en/.

¹⁶ Roger Chou, Rick Deyo, Beth Devine, et al., “The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain,” *Evidence Report/Technology Assessment*, vol. 218 (2014), pp. 1-219, and Charl Els, Tanya Jackson, Diane Knyk, et al., *Adverse Events Associated with Medium- and Long-Term Use of Opioids for Chronic Non-Cancer Pain: An Overview of Cochrane Reviews*, Cochrane Database of Systematic Reviews, 2017.

¹⁷ Leonard Paulozzi, Christopher Jones, Karin Mack, et al., *Vital Signs: Overdoses of Prescription Opioid Pain Relievers: United States, 1999-2008*, Centers for Disease Control and Prevention, National Center for Injury Prevention, Morbidity and Mortality Weekly (MMWR) Early Release, Atlanta, GA, November 4, 2011, at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm>, and OECD, *Addressing Problematic Opioid Use*, 2019.

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

¹⁹ OECD, *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.²⁰ Medical opioid use (separate from use of illicit opioids, such as heroin²¹) has increased in many economically developed countries over the past 25 years.²² 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.²³

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.²⁴ For instance, from 2001 to 2013, prescription opioid use for pain more than doubled globally, most significantly in North America, Europe, and Australia.²⁵ Opioid consumption rose nearly 40% in the European Union (EU) during that time.²⁶ 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%.²⁷ During that same period, prescription opioid sales in Italy and total consumption of opioids in Canada both tripled.²⁸

In the majority of countries, the largest prescription opioid use increases were among patients with chronic noncancer pain.²⁹ One research study found a pronounced trend toward the use of

²⁰ Laxmaiah Manchikanti, Standiford Helm, a Bert Fellows, et al., "Opioid Epidemic in the United States," *Pain Physician*, vol. 15 (2012), pp. ES9-ES38.

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.

²² International Narcotics Control Board, *Narcotic Drugs – Technical Report, 1972-2019*, available at https://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html.

²³ Hydrocodone is a long-acting opioid formulation used to treat severe pain for a prolonged duration, and is taken orally. Oxycodone is a synthetic analgesic drug used to treat moderate to severe pain. International Narcotics Control Board, *Narcotic Drugs: Estimated World Requirements for 2011, Statistics for 2009*, The United Nations, Vienna, Austria, 2010, at https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2010/Narcotic_drugs_publication_2010.pdf.

²⁴ International Narcotics Control Board, *Narcotic Drugs: Estimated World Requirements for 2019, Statistics for 2017*, The United Nations, Vienna, Austria, 2018, at https://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html, and Cristina Bosetti, Claudia Santucci, Silvia Radrezza, et al., "Trends in the Consumption of Opioids for the Treatment of Severe Pain in Europe, 1990-2016," *European Journal of Pain*, vol. 23 (2019), pp. 697-707.

²⁵ See, for instance, Stefano Berterame, Juliana Erthal, Johny Thomas, et al., "Use of and Barriers to Access to Opioid Analgesics: A Worldwide, Regional, and National Study," *The Lancet*, February 3, 2016, and C. Chenaf, J. L. Kabore, J. Delorme, et al., "Prescription Opioid Analgesic Use in France: Trends and Impact on Morbidity -Mortality," *European Journal of Pain*, vol. 23 (2019).

²⁶ From 2005 to 2015. *Ibid.*

²⁷ Jan van Amsterdam and Wim van den Brink, "The Misuse of Prescription Opioids: A Threat for Europe?" *Current Drug Abuse Reviews*, vol. 8 (2015), pp. 3-14.

²⁸ See Chenaf et al., "Prescription Opioid Analgesic Use in France," 2019.

²⁹ S. Mathieson, G. Wertheimer, C.G. Maher, et al., "What Proportion of Patients with Chronic Noncancer Pain are Prescribed an Opioid Medication: Systematic Review and Meta-regression of Observational Studies," *Journal of Internal Medicine*, 2020, pp. 1-17.

stronger, higher-potency opioids (defined in this study as >50 MME per day).³⁰ Another study found that in the United Kingdom (UK) the number of individuals using strong opioids increased nearly fivefold from 2000 to 2010.³¹ The use of oxycodone—considered one of the higher-potency opioids—has increased the most in many countries.³² In France, oxycodone use jumped 1,950% between 2004 and 2017.³³ By 2010, oxycodone was the most widely prescribed opioid in the United States, with an increase in consumption of 1,100% between 1997 and 2010.³⁴ **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.³⁵ In Denmark, Finland, France, Ireland, Switzerland, and Poland, for instance, opioid consumption has leveled off or declined in 2014-2016.³⁶ Israel, Greece, and Portugal, however, experienced increases of more than 50% between 2011 and 2016.³⁷ Similar increases have been reported in Australia and New Zealand.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.³⁹

³⁰ Ibid.

³¹ C.S. Zin, L.C. Chen, and R.D. Knaggs, “Changes in Trends and Pattern of Strong Opioid Prescribing in Primary Care,” *European Journal of Pain*, vol. 18 (2014), pp. 1343-1351.

³² IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, Parsippany, NJ, May 2019; Chenaf et al., “Prescription Opioid Analgesic Use in France,” 2019; and van Amsterdam et al., “The Misuse of Prescription Opioids,” 2015.

³³ Chenaf et al., “Prescription Opioid Analgesic Use in France,” 2019.

³⁴ International Narcotics Control Board, *Narcotic Drugs: Estimated World Requirements for 2011, Statistics for 2009*, The United Nations, Vienna, Austria, 2010, and International Narcotics Control Board, *Narcotic Drugs: Estimated World Requirements for 2003, Statistics for 2001*, The United Nations, Vienna, Austria, 2002, at https://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html. An exploration of the factors explaining these different trajectories is beyond the scope of this report.

³⁵ OECD, *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.

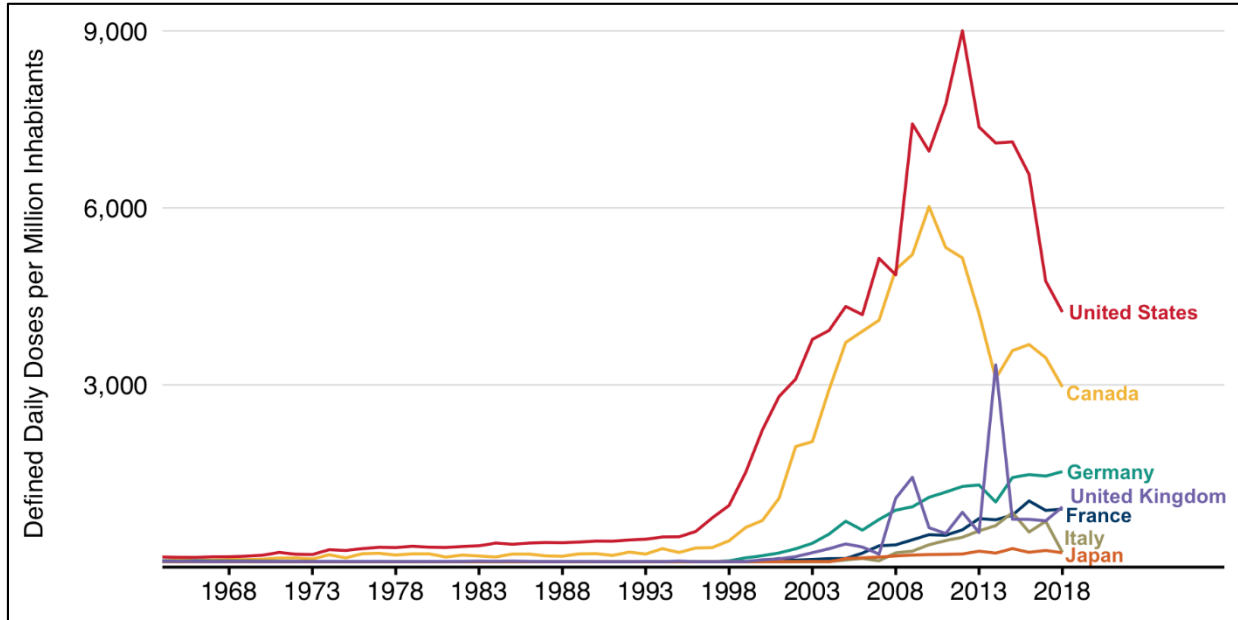
³⁶ Cristina Bosetti, Claudia Santucci, Silvia Radrezza, et al., “Trends in the Consumption of Opioids for the Treatment of Severe Pain in Europe, 1990-2016,” *European Journal of Pain*, vol. 23 (2019), pp. 697-707.

³⁷ Karima Hider-Mlynarz, Philippe Cavalie, and Patrick Maison, “Trends in Analgesic Consumption in France Over the Last 10 Years and Comparison of Patterns across Europe,” *British Journal of Clinical Pharmacology*, vol. 84 (2018), pp. 1324-1334, and OECD, *Addressing Problematic Opioid Use*, 2019.

³⁸ Bosetti et al., “Trends in the Consumption of Opioids,” 2019.

³⁹ G.T. Helmerhorst, T. Teunis, S.J. Janssen, et al., “An Epidemic of the Use, Misuse, and Overdose of Opioids and Deaths Due to Overdose, in the United States and Canada,” *The Bone and Joint Journal*, vol. 99-B (2017), pp. 856-864.

Figure 2. Oxycodone Consumption in G-7 Countries
Defined daily doses per 1 million inhabitants: 1964-2018



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 2010.⁴⁰ In some years, prescription opioid use in the United States was as much as four times higher than in Western European countries.⁴¹

Prescription opioid use peaked in the United States in 2012, with decreases in the years that followed.⁴² The overall national opioid prescribing rate declined from 81.3 prescriptions per 100

⁴⁰ CDC, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999–2008*, MMWR 60(43):1487-92, 2011. Of note, studies examining opioid consumption often cover different time periods, making it difficult to compare certain trends.

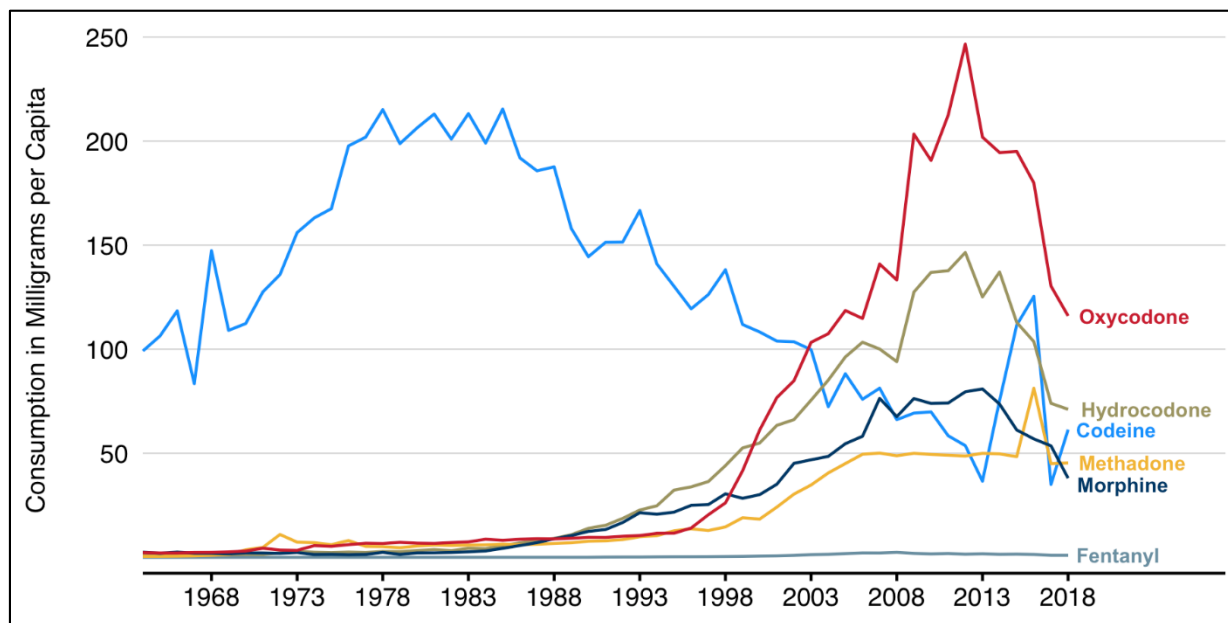
⁴¹ Benedikt Fischer, Annette Keates, Gerhard Buhner, et al., “Non-medical Use of Prescription Opioids and Prescription Opioid-Related Harms: Why So Markedly Higher in North America Compared to the Rest of the World?,” *Addiction*, vol. 109 (2013), pp. 177-181; Chenaf et al., “Prescription Opioid Analgesic Use in France,” 2019; van Amsterdam et al., “The Misuse of Prescription Opioids,” 2015; and INCB, *Narcotic Drugs – Technical Report*, 2011-2019.

⁴² Wenjia Zhu, Michael Chernen, Tismarie Sherry, et al., “Initial Opioid Prescriptions among U.S. Commercially Insured Patients, 2012-2017,” *New England Journal of Medicine*, March 14, 2019.

persons in 2012 to 51.4 prescriptions per 100 persons in 2018 (from 255 million total opioid prescriptions to 168 million).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. **Figure 3** displays opioid consumption over time from 1964 to 2018 in the United States.

Figure 3. Opioid Consumption in the United States, by Opioid

Consumption in milligrams per capita: 1964-2018



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

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 **Figure 1**).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.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.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.⁴⁷ Other studies report similar findings, showing that a relatively small

⁴³ Ibid.

⁴⁴ **Figure 1** refers to opioid consumption per capita. The United States also leads in total annual opioid consumption by weight.

⁴⁵ Zhu et al., "Initial Opioid Prescriptions among U.S. Commercially Insured Patients," 2019.

⁴⁶ Centers for Disease Control and Prevention, *Opioid Overdose/Data/U.S. Opioid Prescribing Rate Maps*, 2019, <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>.

⁴⁷ Gery Guy, Kun Zhang, and Michele Bohm, *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.⁴⁸

Factors Influencing Medical Opioid Consumption

Several factors may influence differences in opioid-prescribing practices among developed countries.⁴⁹ 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:⁵⁰

- **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).⁵¹

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.⁵²

2015, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR) vol. 66, no.26, July 7, 2017, pp. 697-704, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm#contribAff>.

⁴⁸ See, for example, Zhu et al., “Initial Opioid Prescriptions among U.S. Commercially Insured Patients,” 2019.

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.

⁵⁰ Mark Sullivan and Catherine Howe, “Opioid Therapy for Chronic Pain in the U.S: Promises and Perils,” *Pain*, vol. 154, no. 01 (December 2013).

⁵¹ See Winfried Hauser, Frank Petzke, Lukas Radbruch, et al., “The Opioid Epidemic and the Long-term Opioid Therapy for Chronic Noncancer Pain Revisited: A Transatlantic Perspective,” *Pain Management*, vol. 6, no. 3 (2016), pp. 249-263.

⁵² Factors are grouped generally, though many of the factors are interrelated and some categories may overlap.

Key Takeaways

Key findings from this section are as follows:

- Research consistently shows that U.S. health care providers prescribe a greater number of opioids per capita, at higher doses, throughout more stages of treatment of various conditions compared with providers in other countries.
- A few studies suggest that U.S. citizens may self-report higher levels of pain than citizens in other countries, which may increase demand for and subsequent use of opioids. International reviews of pain prevalence are incomplete, though possible explanations for a greater prevalence 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.
- The United States uses opioids for pain management more frequently than other economically advanced countries, which frequently offer a wider variety of pharmacological and nonpharmacological interventions for pain.
- Increases in opioid use for chronic noncancer pain in some countries—such as the United States—were parallel to an emergent pain advocacy movement and the intensified marketing campaigns of the pharmaceutical industry. While much of this activity originated in the United States—and may have been concentrated there due to factors such as market share—some evidence suggests that U.S. prescribing practices may have been more susceptible to these outside influences than in other countries.
- Clinical guidance for opioid use in the United States is nonbinding for health care providers. Some other countries tie clinical guidelines more closely to their national policies.
- Differences in health care systems may influence rates of opioid use in medical care. The historical predominance of a fee-for-service model in the United States may incentivize the use of opioids. 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.
- Payment systems for opioid and nonopioid pain interventions, and their respective costs, may influence the frequency of opioid use—particularly in the United States, where not all pain management treatments are reimbursed equally.
- The ability of oversight or regulatory bodies to monitor opioid use may affect consumption.
- 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.

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

⁵³ Laxmaiah Manchikanti, Standiford Helm, Bert Fellows, et al., “Opioid Epidemic in the United States,” *Pain Physician*, vol. 15 (2012), pp. ES9-ES38; Luca Miceli, Rym Bednarova, Alessandro Rizzardo, et al., “Opioids Prescriptions in Pain Therapy and Risk of Addiction: A One-Year Survey in Italy. Analysis of National Opioids Database,” *Ann Ist Super Sanita*, vol. 54, no. 4 (2018), pp. 370-374; and Heather Tick, Arya Nielson, and Kenneth Pelletier, “Evidence-Based Nonpharmacologic Strategies for Comprehensive Pain Care: The Consortium Pain Task Force White Paper,” *Explore*, vol. 14, no. 3 (May/June 2018), pp. 177-211.

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.⁵⁵ Research shows that U.S. providers generally use higher doses of opioids,⁵⁶ higher-potency opioids (meaning higher MMEs per dose or per day),⁵⁷ and opioids at more stages of treatment than health care providers in other countries.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.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**).⁶⁰ ACDC study found that the percentage of adults in the United States

324.

⁵⁵ Manchikanti et al., “Opioid Epidemic in the United States,” 2012, and INCB, *Narcotic Drugs – Technical Report, 2011-2020*, available at https://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html. This includes opioid use per capita, total weight, and number of prescriptions

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 hydrocodone-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 Stevens, 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.

⁵⁹ El-Amin et al., “International Differences in Outpatient Pain Management,” 2019.

⁶⁰ See, for instance, Sairam Atluri, Gururau Sudarshan, and Laxmaiah Manchikanti, “Assessment of the Trends in Medical Use and Misuse of Opioid Analgesics from 2004 to 2011,” *Pain Physician*, vol. 17 (2014), pp. E119-E128; and Denise Boudreau, Michael Von Korff, Carolyn Rutter, et al., “Trends in De-Facto Long-Term Opioid Therapy for Chronic Non-Cancer Pain,” *Pharmacoepidemiol Drug Saf*, vol. 18, no. 12 (December 2009), pp. 116-175. In the latter study, “high potency” opioids were defined as schedule II opioids. For more information on scheduling opioid medications, see U.S. Drug Enforcement Administration (DEA), *Drug Scheduling*, available at <https://www.dea.gov/>

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%.⁶¹ 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.⁶²

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.⁶³ 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.⁶⁴ Long-term use can also result in hyperalgesia—a heightened sensitivity to pain that can result in more opioid use.⁶⁵ In this way, opioid consumption often begets more opioid consumption.⁶⁶

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).⁶⁷ Germany, for instance, is a top global consumer of opioids but has low rates of opioid-related overdose deaths compared with the United States.⁶⁸ 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.⁶⁹ As one study

drug-scheduling; DEA, *The Controlled Substances Act*, available at <https://www.dea.gov/controlled-substances-act>; and European Union, European Monitoring Centre for Drugs and Drug Addiction, *Classification of Controlled Drugs*, available at http://www.emcdda.europa.eu/publications/topic-overviews/classification-of-controlled-drugs/html_en.

⁶¹ Steven Frenk, Kathryn Porter, and Leonard Paulozzi, *Prescription Opioid Analgesic Use Among Adults: United States, 1999-2012*, CDC, National Center for Health Statistics, NCHS Data Brief No. 189, Hyattsville, MD, February 2015, at <https://www.cdc.gov/nchs/data/databriefs/db189.pdf>.

⁶² Laxmaiah Manchikanti, Bert Fellows, Hary Ailinani, et al., “Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten Year Perspective,” *Pain Physician*, vol. 13 (2010), pp. 401-435.

⁶³ In one study, for example, roughly 10% of Swedish patients filled an opioid prescription within the first seven days after discharge for any procedure, compared with over 75% of U.S. and Canadian patients. Ladha et al., “Opioid Prescribing After Surgery in the United States, Canada, and Sweden,” 2019. Canadian patients in the study filled prescriptions at similar rates as Americans, though the average dose of opioids was higher in the United States.

⁶⁴ Deborah Dowell, Tamara Haegerich, and Roger Chou, *CDC Guidelines for Prescribing Opioids for Chronic Pain - United States, 2016*, Centers for Disease Control and Prevention, Recommendations and Reports, Atlanta, GA, March 18, 2016. See also, Manchikanti et al., “Therapeutic Use, Abuse, and Nonmedical Use of Opioids,” 2010; Okie, “A Flood of Opioids,” 2010; and Anuj Shah, Corey Hayes, and Bradley Martin, “Factors Influencing Long-Term Opioid use Among Opioid Naïve Patients: An Examination of Initial Prescription Characteristics and Pain Etiologies,” *The Journal of Pain*, vol. 18, no. 11 (November 2017), pp. 1374-1383.

⁶⁵ L. Chen, M. Sein, T. Vo, et al., “Clinical Interpretation of Opioid Tolerance versus Opioid-Induced Hyperalgesia,” *Journal of Opioid Management*, vol. 10, no. 6 (2014), pp. 383-393.

⁶⁶ See, for example, Sebastiano Mercadante, Edoardo Arcuri, and Angela Santoni, “Opioid-Induced Tolerance and Hyperalgesia,” *CNS Drugs*, vol. 33 (2019), pp. 943-955; and Lesley Colvin, Fiona Bull, and Tim Hales, “Perioperative Opioid Analgesia-When is Enough Too Much: A Review of Opioid-Induced Tolerance and Hyperalgesia,” *Lancet*, vol. 393 (2019), pp. 1558-1568.

⁶⁷ Bastian Rosner, Jessica Neicun, Justin Christopher Yang, et al., “Opioid Prescription Patterns in Germany and the Opioid Epidemic: Systematic Review of Available Evidence,” *PLoS ONE*, vol. 14, no. 8 (2019).

⁶⁸ U. Marschall, H. L’hoest, L. Radbruch, et al., “Long-term Opioid Therapy for Chronic Non-Cancer Pain in Germany,” *European Journal of Pain*, 2015.

⁶⁹ Keith Humphreys, Jonathan P. Caulkins, and Vanda Felbab-Brown, *What the U.S. and Canada Can Learn From Other Countries to Combat the Opioid Crisis*, the Brookings Institution, Order from Chaos Blog, Washington, DC, January 13, 2020, at <https://www.brookings.edu/blog/order-from-chaos/2020/01/13/what-the-us-and-canada-can-learn-from-other-countries-to-combat-the-opioid-crisis/>.

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.”⁷⁰ 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 with other countries.⁷¹

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.⁷²

In 2016, CDC estimated that 20.4% of U.S. adults experienced chronic pain.⁷³ 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).⁷⁴ 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 versus 50% and 43% in France and Italy, respectively)—but has a higher prevalence than others, such as Germany (32%) and Japan (28%).⁷⁵

Pain is one of the most common reasons for seeking medical care in the United States.⁷⁶ Population-level studies of U.S. citizens indicate that pain prevalence may have increased during

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 Buhringer, 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?,” *Addiction*, 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.

⁷² See, for instance, N. Torrance, R. Mansoor, and H. Wang, et al., “Association of Opioid Prescribing Practices with Chronic Pain and Benzodiazepine Co-Prescription: A Primary Care Data Linkage Study,” *British Journal of Anaesthesia*, vol. 120, no. 6 (June 2018), pp. 1345-1355; and Geana Paula Kurita, Per Sjogren, and Knud Juel, et al., “The Burden of Chronic Pain: A Cross-Sectional Survey Focusing on Disease, Immigration, and Opioid Use,” *Pain*, vol. 153, no. 12 (December 2012), pp. 2332-2338.

⁷³ James Dahlhamer, Jacqueline Lucas, and Carla Zelaya, et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR), Atlanta, GA, September 14, 2018. Other surveys of the U.S. population have estimated anywhere from a tenth of the U.S. adult population, to a third, to over half report experiencing pain. See Jochen Hardt, Clemma Jacobsen, and Jack Goldberg, et al., “Prevalence of Chronic Pain in a Representative Sample in the United States,” *Pain Medicine*, vol. 9, no. 7 (2008); Russell Portenoy, Carlos Ugarte, and Ivonne Fuller, et al., “Population-based Survey of Pain in the United States: Differences among White, African American, and Hispanic Subjects,” *The Journal of Pain*, vol. 5, no. 6 (August 2004), pp. 317-328; and Committee on Advancing Pain Research, Care, and Education, *Relieving Pain in America*, Institute of Medicine of the National Academies, A Blueprint for Transforming Prevention, Care, Education, and Research, Washington, DC, 2011, at https://www.ncbi.nlm.nih.gov/books/NBK91497/pdf/Bookshelf_NBK91497.pdf.

⁷⁴ O. van Hecke, N. Torrance, and B.H. Smith, “Chronic Pain Epidemiology and Its Clinical Relevance,” *British Journal of Anaesthesia*, vol. 111, no. 1 (2013), pp. 13-18; P. Croft, A.S. Rigby, and R. Boswell, et al., “The Prevalence of Chronic Widespread Pain in the General Population,” *The Journal of Rheumatology*, vol. 20, no. 4 (March 31, 1993), pp. 710-713; and Bosetti et al., “Trends in the Consumption of Opioids,” 2019.

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.⁷⁷ 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.⁷⁸ Some research suggests that Americans may experience pain at more intense levels than residents of other countries.⁷⁹ 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.⁸⁰ 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.⁸¹ For example, repeated assessments may heighten patient awareness of pain, making patients hypervigilant and increasing their perceptions of pain severity.⁸² Conversely, infrequent assessments of pain may lead to worse pain management for certain patient populations.⁸³

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

Assessing the Most Prevalent Conditions in a Defined US Population,” *Mayo Clinic Proceedings*, vol. 88, no. 1 (January 2013), pp. 56-67.

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).

⁷⁸ See E.F. Harkness, G.J. Macfarlane, A.J. Silman, et al., “Is Musculoskeletal Pain More Common Now Than 40 Years Ago?: Two Population-Based Cross-Sectional Studies,” *Rheumatology*, vol. 44, no. 7 (2005), and J.K. Freburger, G.M. Holmes, R.P. Agans, et al., “The Rising Prevalence of Chronic Low Back Pain,” *Arch Intern Med*, vol. 169 (2009), pp. 251-258. There is a dearth of research monitoring global prevalence of pain over time, which may impede making accurate comparisons of international trends or identifying how the United States compares to other countries. See, for example, Fischer et al., “Non-medical Use of Prescription Opioids and Prescription Opioid-Related Harms,” 2013.

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.

⁸⁰ *Ibid.* In U.S. health care institutions, patient pain is assessed routinely and these assessments factor in to hospital accreditation. The Joint Commission, *Pain Assessment and Management Standards*, Oakbrook Terrace, IL, 2019, at <https://www.jointcommission.org/en/resources/patient-safety-topics/pain-management-standards-for-accredited-organizations/>.

⁸¹ See, for example, Richard Mularski, Foy White-Chu, Deborah Overbay, et al., “Measuring Pain as the 5th Vital Sign Does Not Improve Quality of Pain Management,” *Journal of General Internal Medicine*, vol. 21 (June 2006); Charles E. Lucas, Angie L. Vlahos, and Anna M. Ledgerwood, “Kindness Kills: The Negative Impact of Pain as the Fifth Vital Sign,” *Journal of the American College of Surgeons*, vol. 205, no. 1 (July 2007), pp. 101-107; Jane C. Ballantyne and Mark D. Sullivan, “Intensity of Chronic Pain - The Wrong Metric,” *The New England Journal of Medicine*, vol. 373, no. 22 (November 26, 2015); and Clara Scher, Lauren Meador, and Janet H. Van Cleave, “Moving Beyond Pain as the Fifth Vital Sign and Patient Satisfaction Scores to Improve Pain Care in the 21st Century,” *Pain Management Nursing*, vol. 19, no. 2 (April 2018), pp. 125-129.

⁸² Arnoud Arntz, Laura Dreessen, and Harald Merckelbach, “Attention, Not Anxiety, Influences Pain,” *Behaviour Research and Therapy*, vol. 29, no. 1 (1991), pp. 41-50.

⁸³ Sarah Spilman, Lisa Baumhover, Cheryl Lillegraven, et al., “Infrequent Assessment of Pain in Elderly Trauma Patients,” *Journal of Trauma Nursing*, vol. 21, no. 5 (September/October 2014), pp. 229-235.

survivorship after injury and cancer, and increasing frequency and complexity of surgery.⁸⁴ 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.⁸⁵

Other risk factors may contribute to, or exacerbate, the experience of pain. These include sociodemographic, clinical, psychological, and biological determinants.⁸⁶ For example, large-scale national surveys indicate that pain is more common among people who report a history of abuse and interpersonal violence.⁸⁷ 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.⁸⁸ Some research suggests that economic insecurity might increase physical pain sensations.⁸⁹ In the United States, certain sociodemographic factors, such as socioeconomic status and race/ethnicity, may result in disparities in chronic pain across subgroups.⁹⁰ Similarly, sociodemographic factors may predict opioid-prescribing rates, with higher prescribing found in lower-income counties in the United States, for example.⁹¹ 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.⁹²

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.⁹³ Of the G-7 countries, the United States

⁸⁴ Nabarun Dasgupta, Leo Beletsky, and Daniel Ciccarone, "Opioid Crisis; No Easy Fix to Its Social and Economic Determinants," *American Journal of Public Health*, vol. 108, no. 2 (2018), pp. 182-186.

⁸⁵ Thomas Weisner, Alex Haynes, and George Molina, et al., *Size and Distribution of the Global Volume of Surgery in 2012*, World Health Organization, Bulletin of the World Health Organization Vol. 94, No.3, Geneva, Switzerland, March 2016, at <https://www.who.int/bulletin/volumes/94/3/BLT-15-159293-table-T3.html>.

⁸⁶ van Hecke, "Chronic Pain Epidemiology and Its Clinical Relevance," 2013. Physical health conditions and health behaviors may also influence opioid consumption for example. See Anne Nitter, Are Pripp, and Karin Forseth, "Are Sleep Problems and Non-specific Health Complaints Risk Factors for Chronic Pain? A Prospective Population-based Study with 17 year Follow-Up," *Scandinavian Journal of Pain*, 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).

⁸⁷ Ibid., and Clare Dominick, Fiona Blyth, and Michael Nicholas, "Unpacking the Burden: Understanding the Relationships between Chronic Pain and Comorbidity in the General Population," *Pain*, vol. 153 (2012), pp. 293-304.

⁸⁸ CDC, "Prevalence of Chronic Pain," 2018.

⁸⁹ Eileen Chou, Bidhan Parmar, and Adam Galinsky, "Economic Insecurity Increases Physical Pain," *Psychological Science*, vol. 27, no. 4 (2016), pp. 443-454.

⁹⁰ See, for instance, Molly Fuentes, Tamera Hart-Johnson, and Carmen Green, "The Association Among Neighborhood Socioeconomic Status, Race, and Chronic Pain in Black and White Older Adults," *Journal of the National Medical Association*, vol. 99, no. 10 (October 2007); and Joseph Riley, James Wade, and Cynthia Myers, et al., "Racial/Ethnic Differences in the Experience of Chronic Pain," *Pain*, vol. 100 (2002), pp. 291-298.

⁹¹ Douglas McDonald, Kenneth Carlson, and David Izrael, "Geographic Variation in Opioid Prescribing in the U.S.," *The Journal of Pain*, vol. 13, no. 10 (October 2012).

⁹² Kelly M. Hoffman, Sophie Trawalter, and Jordan R. Axt, et al., "Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites," *PNAS*, vol. 113, no. 16 (April 19, 2016), p. 4296-4301.

⁹³ Rebeca Rios and Alex Zautra, "Socioeconomic Disparities in Pain: The Role of Economic Hardship and Daily Financial Worry," *Health Psychology*, vol. 30, no. 1 (2011), pp. 58-66.

has the highest level of income inequality.⁹⁴ 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.⁹⁵ In the United States, individuals with a mental health condition are twice as likely to be prescribed opioids.⁹⁶ Mental illness rates do not differ substantially between the United States and other G-7 countries.⁹⁷ 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%.⁹⁸

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.⁹⁹ Widespread focus in the United States on treating pain rather than underlying psychological distress may contribute to higher opioid demand and consumption rates.¹⁰⁰ 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.¹⁰¹ In addition, poor physical health and certain health behaviors may be associated with higher rates of pain and opioid use.¹⁰²

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>.

⁹⁵ See, for example, Oye Gureje, Michael Von Korff, and Gregory Simon, et al., “Persistent Pain and Well-Being: A World Health Organization Study in Primary Care,” *JAMA*, vol. 280, no. 2 (July 8, 1998); D. von der Windt, T. Kuijpers, and P. Jellema, et al., “Do Psychological Factors Predict Outcome in Both Low-Back Pain and Shoulder Pain?,” *Annals of Rheumatic Diseases*, vol. 66 (2007), pp. 313-319; and Ramune Jacobsen, Claus Moldrup, and Lona Christrup, “Psychological and Behavioural Predictors of Pain Management Outcomes in Patients with Cancer,” *Scandinavian Journal of Caring Sciences*, vol. 24 (November 9, 2010).

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.⁹⁶ 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 Surgery in U.S. Adults,” *JAMA Surgery*, vol. 152, no. 6 (June 21, 2017).

⁹⁷ Institute for Health Metrics and Evaluation, *Global Health Data Exchange*, Seattle, WA, 2019, at <http://ghdx.healthdata.org/>.

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

⁹⁹ Robert Kohn, Shekhar Saxena, and Itzhak Levav, et al., *The Treatment Gap in Mental Health Care*, World Health Organization, Bulletin of the World Health Organization Vol.82 Ref No. 03-005736, Geneva, Switzerland, 2003, pp. 858-866, at <https://www.who.int/bulletin/volumes/82/11/en/858.pdf>.

¹⁰⁰ Winfried Hauser, Stephan Schug, and Andrea Furlan, “The Opioid Epidemic and National Guidelines for Opioid Therapy for Chronic Noncancer Pain: A Perspective from Different Continents,” *Pain Around the World*, vol. 2, no. e599 (2017).

¹⁰¹ *Ibid.*

¹⁰² Anne Nitter, Are Pripp, and Karin Forseth, “Are Sleep Problems and Non-specific Health Complaints Risk Factors for Chronic Pain? A Prospective Population-based Study with 17 year Follow-Up,” *Scandinavian Journal of Pain*,

Opioid Use in Japan

Japan consistently has some of the lowest annual per capita opioid consumption in the developed world.¹⁰³ 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.¹⁰⁴
- Per-capita use of opioids is 26 times higher in the United States, compared with Japan.¹⁰⁵
- Japanese providers generally prescribe opioids for chronic noncancer pain at a much lower rate than their American counterparts.¹⁰⁶
- In 2019, approximately 45.2% of Japanese adults suffered from chronic pain.¹⁰⁷

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

- "Opioids are frowned on both culturally and socially."¹⁰⁸
- "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."¹⁰⁹

Recently, opioid indications in Japan were expanded to include chronic noncancer pain.¹¹⁰ Experts in Japan have predicted that yearly opioid consumption will begin to increase due to this expansion.¹¹¹

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).

¹⁰³ Kanoko and Matsuyama, "Japan Is Discovering the Power of Painkillers," September 21, 2017; and International Narcotics Control Board, *Narcotic Drugs: Estimated World Requirements for 2019, Statistics for 2017*, Table XIV.1.a, The United Nations, Vienna, Austria, 2018, at https://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html.

¹⁰⁴ Committee for the Guidelines for Prescribing Opioid Analgesics for Chronic Noncancer Pain of Japanese Society of Pain Clinicians, *Guidelines for Prescribing Opioid Analgesics for Chronic Noncancer Pain*, Japan Society of Pain Clinicians, 2012.

¹⁰⁵ Richard A. Deyo, Michael Von Korff, and David Duhkoop, "Opioids for Low Back Pain," *British Medical Journal*, vol. 350 (January 5, 2015).

¹⁰⁶ Yukari Shindo, Soushi Iwasaki, and Michiaki Yamakage, "Efficacy and Practicality of Opioid Therapy in Japanese Chronic Noncancer Pain Patients," *Pain Management Nursing*, vol. 20, no. 3 (June 2019).

¹⁰⁷ *Ibid.*

¹⁰⁸ Eriko Onishi, Tadashi Kobayash, Miguel Marino, et al., "Comparison of Opioid Prescribing Patterns in the United States and Japan: Primary Care Physicians' Attitudes and Perceptions," *Journal of the American Board of Family Medicine*, vol. 30, no. 2 (March 2017), pp. 248-54.

¹⁰⁹ *Ibid.*

¹¹⁰ Yukio Suga, Mayako Uchida, Shunya Suzuki, et al., "Current Status of Adverse Events Related with Opioid Analgesics in Japan: Assessment Based on Japanese Adverse Drug Event Report Database," *Biol. Pharm. Bull.*, vol. 42, no. 5 (2019), pp. 801-809.

¹¹¹ *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.¹¹² 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.¹¹³ According to some research, using opioids to treat chronic pain over the long term results in limited effectiveness.¹¹⁴

Much of the scientific literature appears to indicate that European countries tend to use nonopioid treatment regimens more frequently than the United States does.¹¹⁵ 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.¹¹⁶

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.¹¹⁷ 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.¹¹⁸ 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.¹¹⁹

¹¹² Jacob Gross and Debra Gordon, “The Strengths and Weaknesses of Current US Policy to Address Pain,” *American Journal of Public Health*, vol. 109, no. 1 (January 2019).

¹¹³ Hauser et al., “The Opioid Epidemic and National Guidelines,” 2017, National Academies of Sciences, Engineering, and Medicine, *The Role of Nonpharmacological Approaches to Pain Management: Proceedings of a Workshop*, Washington, DC, 2019.

¹¹⁴ See, for instance, Andrea Trescot, Scott Glaser, Hans Hansen, et al., “Effectiveness of Opioids in the Treatment of Chronic Non-Cancer Pain,” *Pain Physician*, vol. 11 (2008), pp. S181-S200.

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).

¹¹⁶ Harald Breivik, Beverly Collett, and Vittorio Ventafridda, “Survey of Chronic Pain in Europe: Prevalence, Impact on Daily Life, and Treatment,” *European Journal of Pain*, vol. 10 (2006), pp. 287-333. Of note, CRS identified few studies that examined the use of interdisciplinary approaches to pain treatment in Europe.

¹¹⁷ Fred Finney, Timothy Gossett, Hsueh Mei Hu, et al., “Rate of Opioid Prescriptions for Patients with Acute Ankle,” *Annals of Internal Medicine*, vol. 171, no. 6 (2019), pp. 441-443. See the “Prescribing Practices” section in this report.

¹¹⁸ Dasgupta et al., “Opioid Crisis: No Easy Fix,” 2018. Currently, in some U.S. health care institutions, as many as 90% of patients receive opioids for chronic pain management. See Manchikanti et al., “Patterns of Illicit Drug use and Opioid Abuse,” 2004.

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

Rising Opioid Prescription Rates in Patients With Low Back Pain in the United States 1997-2010,” [JD: Missing journal/periodical title?] vol. 42, no. 9 (May 1, 2017), pp. 670-674.

¹²⁰ Hauser et al., “The Opioid Epidemic and Long-Term Opioid Therapy,” 2016.

¹²¹ See, for example, Miceli et al., “Opioids Prescription in Pain Therapy,” 2018. See the “Health Care Systems” section below.

¹²² See, for instance, World Health Organization, *The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences*, Technical Report prepared for the Ministers Summit, Geneva, Switzerland, 2012.

¹²³ See, for instance, Michael Zenz, Thorsten Zenz, Michael Tryba, et al., “Severe Undertreatment of Cancer Pain: A 3-year Survey of the German Situation,” *Journal of Pain and Symptom Management*, vol. 10, no. 3 (April 1995), pp. 187-191.

¹²⁴ World Health Organization, *Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines*, Geneva, Switzerland, 2011, at <https://apps.who.int/iris/handle/10665/44519>.

¹²⁵ Felicia Marie Knaul, Paul Farmer, and Erik Krakauer, “Alleviating the Access Abyss in Palliative Care and Pain Relief—An Imperative of Universal Health Coverage: the Lancet Commission Report,” *Lancet*, vol. 391 (2018), pp. 1391-1454.

¹²⁶ See, for instance, Art Van Zee, “The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,” *American Journal of Public Health*, vol. 99, no. 2 (2009); OECD, *Addressing Problematic Opioid Use in OECD Countries*, 2019; U.S. Government Accountability Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110, December 19, 2003, <https://www.gao.gov/products/gao-04-110>;

providers.¹²⁷ In the European Union, direct-to-provider marketing is discouraged, with enforcement of national and international policies delegated to professional groups and self-regulatory bodies.¹²⁸ The European Union bans direct-to-consumer marketing explicitly,¹²⁹ while the United States allows such practices—one of two countries in the world to do so.¹³⁰

Beginning in the 1990s, several pharmaceutical companies downplayed the addictiveness of opioids and promoted them as low-risk medications in marketing campaigns.¹³¹ Several studies have shown that these practices directly influenced prescribing patterns and provider behavior, subsequently increasing U.S. opioid use.¹³² The pharmaceutical industry encouraged opioid use through direct funding to private hospital systems (see the **text box** below).¹³³ Moreover, these marketing and lobbying campaigns seem to have relegated alternative or complementary pain interventions to the sidelines.¹³⁴

Substance Abuse and Mental Health Services Administration, Office of the Surgeon General, U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, Washington, DC, November 2016; and Scott Hadland, Magdalena Cerda, Yu Li, et al., "Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing," *JAMA Internal Medicine*, vol. 178, no. 6 (June 2018).

¹²⁷ Section 502(n) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352(n)) and U.S. Food & Drug Administration (FDA) regulations at 21 C.F.R. 202.1 address prescription drug advertising. When advertising to the public, drug companies must comply with various requirements in statute and FDA regulations; however, no federal law has ever banned direct-to-consumer advertising. For more information, see the FDA webpage *Background on Drug Advertising*: <https://www.fda.gov/drugs/prescription-drug-advertising/background-drug-advertising>.

¹²⁸ The requirements and procedures for marketing authorization are primarily laid down in Directive 2001/83/EC and in Regulation (EC) No 726/2004. For more information, see European Commission, *Legal Framework for Governing Medicinal Products for Human Use in the EU*, available at https://ec.europa.eu/health/human-use/legal-framework_en.

¹²⁹ Publications Office of the European Union, *Council Directive 89/552/EEC of 3 October 1989 on the Coordination of Certain Provisions Laid Down by Law, Regulation, or Administrative Action in Member States concerning the Pursuit of Television Broadcasting Activities*, <https://op.europa.eu/en/publication-detail/-/publication/63084a3f-be4a-4415-bf02-ac5f76524348/language-en>. See also, World Health Organization, *Direct-to-Consumer Advertising Under Fire*, Bulletin of the World Health Organization, vol. 87, no. 8, Geneva, August 2009, <https://www.who.int/bulletin/volumes/87/8/09-040809/en/>.

¹³⁰ New Zealand is the only other country to allow such marketing practices. Tim Reed, Ancel la Santos, et al., "What Healthcare Professionals Need to Know About EU Pharmaceutical Marketing," Health Action International and Universities Allied for Essential Medicines, Galway, Ireland, September 2016; and Mareen Poser, "DTCA of Prescription Medicines in the European Union: Is There Still a Need for a Ban?," *European Journal of Health Law*, vol. 17, no. 5 (December 2010), pp. 471-484.

¹³¹ OECD, *Addressing Problematic Opioid Use in OECD Countries*, 2019, p. 20, and Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," *American Journal of Public Health*, September 20, 2011.

¹³² The increases in opioid consumption differ by opioid type, suggesting that the marketing campaigns for specific drugs may be at least partially responsible. The timing of the precipitous rise in opioid use—especially in the United States—aligns with the introduction of new opioid formulations such as OxyContin and the corresponding upsurge in marketing practices by Purdue Pharma and other pharmaceutical manufacturers. See, for example, Substance Abuse and Mental Health Services Administration, Office of the Surgeon General, U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, Washington, DC, November 2016; and U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic, Exposing the Financial Ties between Opioid Manufacturers and Third-Party Advocacy Groups: Minority Staff Report*, 2018.

¹³³ Andrew Joseph, "'A Blizzard of Prescriptions': Documents Reveal New Details about Purdue's Marketing of OxyContin," *STAT News*, January 15, 2019.

¹³⁴ Dasgupta et al., "Opioid Crisis: No Easy Fix," 2018, and Fischer et al., "Non-medical Use of Prescription Opioids," 2013.

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.¹³⁵ 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.¹³⁶ 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.¹³⁷

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.¹³⁸ The United States may have had risk factors that made health care system and providers more vulnerable to the influence of such campaigns.¹³⁹ 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.¹⁴⁰

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.¹⁴¹ However, adherence to this guidance appears to differ by country, with European

¹³⁵ Liz Whyte, Geoff Mulvihill, and Ben Wieder, “Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis,” *Center for Public Integrity*, September 18, 2016, and U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic, Exposing the Financial Ties between Opioid Manufacturers and Third-Party Advocacy Groups: Minority Staff Report*, 2018.

¹³⁶ *Ibid.*

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

¹³⁸ Bosetti et al., “Trends in the Consumption of Opioids,” 2019.

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).

¹⁴⁰ See, for example, Keith Humphreys, Jonathan Caulkins, and Vanda Felbab-Brown, “Opioids of the Masses: Stopping an American Epidemic from Going Global,” *Foreign Affairs*, May/June 2018; and Harriet Ryan, Lisa Girion, and Scott Glover, “OxyContin goes global—‘We’re only just getting started,’” *Los Angeles Times*, December 18, 2016.

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.¹⁴² 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.¹⁴³ Many other OECD member countries have implemented clinical practice guidelines at the national level.¹⁴⁴ Some research suggests that national clinical guideline implementation is associated with fewer adverse outcomes.¹⁴⁵ 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.¹⁴⁶

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.¹⁴⁷ 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.¹⁴⁸ Overall, U.S. opioid use patterns through

2011, at <https://apps.who.int/iris/handle/10665/44519>; INCB, *Narcotic Drugs: Estimated World Requirements for 2019, Statistics for 2017*, 2018; and Helmerhorst et al., “An Epidemic of the Use, Misuse, and Overdose,” 2017. The WHO recommendations were primarily designed for treating pain in palliative cancer care, but they provide a framework for treating other pain conditions. See also 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 (2014), pp. 38-47.

¹⁴² See for instance, OECD, *Addressing Problematic Opioid Use*, 2019; and Fischer et al., “Non-medical Use of Prescription Opioids,” 2013. 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, 2011, at <https://apps.who.int/iris/handle/10665/44519>; INCB, *Narcotic Drugs: Estimated World Requirements for 2019, Statistics for 2017*, 2018; and Helmerhorst et al., “An Epidemic of the Use, Misuse, and Overdose,” 2017. Most of the world currently adheres to this step ladder in some form, and several countries (e.g., Italy) have enacted national regulations that align with the WHO recommendations for pain management. Bosetti et al., “Trends in the Consumption of Opioids,” 2019.

¹⁴³ See, for instance, Ingrid Schubert, Peter Ihle, and Rainer Sabatows, “Increase in Opiate Prescription in Germany Between 2000 and 2010,” *Deutsches Ärzteblatt International*, vol. 110, no. 4 (January 25, 2013), pp. 45-51, and Fischer et al., “Non-medical Use of Prescription Opioids,” 2013.

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 Guideline 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.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.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.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.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.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

instance. See Amy Bohnert, Gery Guy, and Jan Losby, “Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention’s 2016 Opioid Guideline,” *Annals of Internal Medicine*, vol. 169, no. 16 (September 18, 2018), pp. 367-375.

¹⁴⁹ For instance, one study found that one-third of all patients who visited an emergency department in the United States had opioids prescribed at discharge. See Maryann Mazer-Amirshahi, Peter Mullins, Irit Rasooly, et al., “Rising Opioid Prescribing in Adult U.S. Emergency Department Visits: 2001-2010,” *Academic Emergency Medicine*, vol. 21, no. 3 (March 13, 2014), pp. 236-243. Another study found that 80% of patients undergoing relatively minor surgery in the United States received a prescription for an opioid. See Hannah Wunsch, Duminda Wijeyesundera, Molly Passarella, et al., “Opioid Prescribed After Low-Risk Surgical Procedures in the United States, 2004-2012,” *Journal of the American Medical Association*, vol. 315, no. 15 (April 19, 2016), pp. 1654-1656.

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.

¹⁵¹ See Steven A. Schroeder and William Frist, “Phasing Out Fee-for-Service Payment,” *New England Journal of Medicine*, vol. 368, no. 21 (May 23, 2013), pp. 2029-2032; Miriam J. Laugesen and Sherry Glied, “Higher Fees Paid To US Physicians Drive Higher Spending For Physician Services Compared To Other Countries,” *Health Affairs*, vol. 30, no. 9 (September 2011); and U.S. Congress, Office of Technology Assessment, *Medicare’s Prospective Payment System: Strategies for Evaluating Cost, Quality, and Medical Technology*, OTA-H-262, Washington, DC, October 1985.

¹⁵² DR Oyler, KS Deep, and PK Chang, “Opioid Use in the Acute Setting: A Survey of Providers at an Academic Medical Setting,” *Journal of Opioid Management*, vol. 14, no. 3 (May/June 2018), pp. 203-210.

¹⁵³ Naoki Ikegami, “Fee-for-Service Payment—An Evil Practice That Must Be Stamped Out?” *International Journal of Health Policy Management*, vol. 4, no. 2 (February 2015), and Jacqueline O’Reilly, Reinhard Busse, Unto Hakkinen, et al., “Paying for Hospital Care: The Experience With Implementing Activity-Based Funding in Five European Countries,” *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.¹⁵⁴ 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).¹⁵⁵ 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.¹⁵⁶

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.¹⁵⁷ 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).¹⁵⁸ 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.¹⁵⁹ 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.¹⁶⁰ 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.¹⁶¹

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-Font and Scott L. 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.

¹⁵⁶ See, for instance, Richard B. Saltman and Joseph Figueras, “Analyzing the Evidence on European Health Care Reforms,” *Health Affairs*, vol. 17, no. 2 (March/April 1998).

¹⁵⁷ Gross et al., “The Strengths and Weaknesses of Current U.S. Policy to Address Pain,” 2019.

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.*

¹⁶⁰ Sora Al Rowas, Michael Rothberg, and Tara Lagu, “The Association between Insurance Type and Cost-Related Delay in Care: A Survey,” *The American Journal of Managed Care*, vol. 23, no. 7 (July 2017), pp. 435-442.

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

Abuse and Mental Health Services Administration, Office of the Surgeon General, U.S. Department of Health and Human Services, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, Washington, DC, November 2016.

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.

¹⁶³ Nicoleta Stoicea, Andrew Costa, Luis Periel, et al., “Current Perspectives on the Opioid Crisis in the US Healthcare System: A Comprehensive Literature Review,” *Medicine*, vol. 98, no. 20 (2019).

¹⁶⁴ Lynn Webster, Susan Cochella, Naburan Dasgupta, et al., “An Analysis of the Root Causes for Opioid-Related Overdose Death in the United States,” *Pain Medicine*, vol. 12, suppl_2 (June 13, 2011), and OECD, *Addressing Problematic Opioid Use*, 2019.

¹⁶⁵ Haiden Huskamp, Lauren Riedel, Colleen Barry, et al., “Coverage of Medications that Treat Opioid Use Disorder and Opioids for Pain Management in Marketplace Plans, 2017,” *Med Care*, vol. 56, no. 6 (June 2018).

¹⁶⁶ Agency for Healthcare Research and Quality, *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review*, Comparative Effectiveness Review Number 209, Rockville, MD, June 2018.

¹⁶⁷ Michael Schatman and Lynn Webster, “The Health Insurance Industry: Perpetuation the Opioid Crisis through Policies of Cost-Containment and Profitability,” *Journal of Pain Research*, vol. 8 (March 18, 2015), pp. 153-158, and Stoicea et al., “Current Perspectives on the Opioid Crisis in the US Healthcare System,” 2019.

¹⁶⁸ James Heyward, Christopher Jones, and Wilson Compton, “Coverage of Nonpharmacologic Treatments for Low Back Pain Among US Public and Private Insurers,” *JAMA Network Open*, vol. 1, no. 6 (October 5, 2018).

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.¹⁷⁰ The disproportionate coverage for some treatments, such as opioids, but not others, such as acupuncture, may have a trickledown effect on chronic pain management.¹⁷¹ 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.¹⁷²

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.¹⁷³ 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.¹⁷⁴

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.¹⁷⁵ 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.¹⁷⁶ The researchers noted that costs to purchasers—such as hospitals and patients—differed between countries, and that pricing may factor into differential opioid use.¹⁷⁷ 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.”

¹⁷⁰ See, for example, Michael Schatman, “The Role of the Health Insurance Industry in Perpetuating Suboptimal Pain Management,” *Pain Medicine*, vol. 12 (2011), pp. 415-426.

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 Schatman, “Role of Health Insurance Industry,” 2011.

¹⁷² Gross et al., “The Strengths and Weaknesses of Current US Policy to Address Pain,” 2019.

¹⁷³ Stephen Bernard, Paul Chelminski, and Timothy Ives, “Management of Pain in the United States—A Brief History and Implications for the Opioid Epidemic,” *Health Services Insights*, vol. 11 (2018), pp. 1-6, and Dora H. Lin, Christopher M. Jones, Wilson M. Compton, et al., “Prescription Drug Coverage for Treatment of Low Back Pain Among US Medicaid, Medicare Advantage, and Commercial Insurers,” *JAMA Network Open*, vol. 1, no. 2 (2018).

¹⁷⁴ Centers for Medicare and Medicaid Services, *Medicare Coverable Services for Integrative and Non-pharmacological Chronic Pain Management*, MLN Matters Number: SE19008, August 19, 2019. For more information on Medicare and Medicaid, see CRS Report R40425, *Medicare Primer*, and CRS Report R43357, *Medicaid: An Overview*.

¹⁷⁵ Gross et al., “The Strengths and Weaknesses of Current US Policy to Address Pain,” 2019.

¹⁷⁶ Franco De Conno, Carla Ripamonti, and Cinzia Brunelli, “Opioid Purchases and Expenditures in Nine Western European Countries: ‘Are We Killing Off Morphine?’” *Palliative Medicine*, vol. 19 (2005), pp. 179-184.

¹⁷⁷ De Conno et al., “Opioid Purchases and Expenditures in Nine Western European Countries,” 2005, p. 184.

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.¹⁷⁸ European governments use a variety of regulatory restrictions, including¹⁷⁹

- the requirement for permission to prescribe or receive opioids;
- limitations on the amount to be prescribed;
- restrictions regarding dispensing privileges;¹⁸⁰
- national formularies to regulate which opioids can be prescribed under what conditions;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.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.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).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.¹⁸⁵ Recent observations indicate that, in some countries, regulations on opioid prescribing may becoming more permissive.¹⁸⁶

¹⁷⁸ Christopher Adolph, Scott L. Greer, and Elize Massard da Fonseca, "Allocation of Authority in European Health Policy," *Social Science & Medicine*, vol. 75, no. 9 (2012), pp. 1595-1603; and U.S. Congress, Office of Technology Assessment, *Medicare's Prospective Payment System*, 1985.

¹⁷⁹ Van Amsterdam et al., "The Misuse of Prescription Opioids," 2015.

¹⁸⁰ Marjolein Vranken, John Lisman, and Aukje Mantel-Teeuwisse, "Barriers to Access to Opioid Medicines: Results of a Review of National Legislation and Regulations of 11 Central and Eastern European Countries," *The Lancet Oncology*, vol. 17, no. 1 (2016), pp. e13-e22.

¹⁸¹ Aiden Meyer, Cheryl LeClair, and James McDonald, "Opioid Prescribing in Western Europe and the United States," *Rhode Island Journal of Medicine*, March 2020.

¹⁸² Vranken et al., "Barriers to Access to Opioid Medicines," 2016.

¹⁸³ Ibid.

¹⁸⁴ N.I. Cherny, J. Baselga, F. de Conno, et al., "Formulary Availability and Regulatory Barriers to Accessibility of Opioids for Cancer Pain in Europe: A Report from the ESMO/EAPC Opioid Policy Initiative," *Annals of Oncology*, vol. 21 (2010), pp. 615-626.

¹⁸⁵ Bosetti et al., "Trends in the Consumption of Opioids," 2019.

¹⁸⁶ Humphreys et al., "What the US and Canada Can Learn," 2020.

Opioid-Prescribing Regulations in Germany

Germany has the largest population and the largest economy in the EU, and it has the second-highest opioid consumption rate in the world.¹⁸⁷ Opioid prescription in Germany is strictly regulated by the Narcotic Drugs Prescription Ordinance (Betäubungsmittel-Verschreibungsverordnung, BtMVV) and by the German Narcotic Drugs Act (Betäubungsmittelgesetz, BtMG), which entered into force in 1992.¹⁸⁸ The BtMVV established detailed prescription guidelines, which, among other things, regulate

- the maximum quantities of opioids that can be prescribed within a certain timeframe, and
- the maximum amount of different opioids prescribed during one visit to a health care provider/prescriber.

In Germany, every opioid dispensed requires a prescription by a physician. Under the BtMG, all opioids classified as “strong” and “intermediate”—except Tramadol and Codeine, which are classified as “weak” opioids and do not need a special prescription—require a specific narcotic prescription known as a “BtM” prescription.

The majority of opioid prescription regimens in Germany are based on the WHO guidelines for cancer pain treatments published in 1986 (and updated in 2019) and follow the WHO’s pain treatment ladder.¹⁸⁹ These guidelines also apply to acute pain conditions. In 2008, a separate guideline for long-term treatment of chronic noncancer pain (CNCP) was published. The guideline established rules for long-term use of opioids (four weeks or longer) and treatment methodology.¹⁹⁰ Some observers have noted that having multiple guidelines governing opioid prescribing practices in different health care settings may have myriad unintentional outcomes, such as increasing opioid prescription rates and sowing confusion among providers.¹⁹¹ Though German guidelines do not recommend opioids as the first-line treatment for CNCP, since the early 2000s Germany has seen an increase in the prevalence of “strong” opioid prescriptions.¹⁹² Although prescription opioid use in Germany has increased significantly since 2000, the prescription opioid overdose death rate has not increased at a comparable rate.¹⁹³ In comparison, in the United States, adverse events such as opioid overdose deaths paralleled increased prescription opioid use from 1996 to 2010.

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)¹⁹⁴ institute risk-mitigation procedures to promote the safe use of medications, although questions remain about the effectiveness of these policies.¹⁹⁵

¹⁸⁷ Bastian Rosner, Jessica Neicun, Justin Yang, et al., “Opioid Prescription Patterns in Germany and the Global Opioid Epidemic: Systematic Review of Available Evidence,” *Plos One*, August 28, 2019; and International Narcotics Control Board, *Narcotic Drugs: Estimated World Requirements for 2019, Statistics for 2017*, The United Nations, Vienna, Austria, 2018, at https://www.incb.org/incb/en/narcotic-drugs/Technical_Reports/narcotic_drugs_reports.html.

¹⁸⁸ Ibid.

¹⁸⁹ World Health Organization, *WHO Guidelines for the Pharmacological and Radiotherapeutic Management of Cancer Pain in Adults and Adolescents*, January 2019.

¹⁹⁰ Rosner et al., “Opioid Prescription Patterns in Germany,” 2019.

¹⁹¹ Ibid.

¹⁹² I. Schubert, P. Ihle, and R. Sabatowski, “Increase in Opiate Prescription in Germany between 2000 and 2010,” *Dtsch Arztebl International*, vol. 110, no. 4 (2013), pp. 45-51. A. Werber, U. Marschall, H. L’hoest, et al., “Opioid Therapy in the Treatment Of Chronic Pain Conditions in Germany,” *Pain Physician*, vol. 18, no. 3 (May-June 2015).

¹⁹³ European Monitoring Centre for Drugs and Drug Addiction, *Germany, Country Drug Report*, 2019.

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

¹⁹⁵ Suzanne Murrin, *FDA’s Risk Evaluation and Mitigation Strategies: Uncertain Effectiveness in Addressing the Opioid Crisis*, U.S. Department of Health and Human Services Office of Inspector General, OEI-01-17-00510, Washington, DC, September 2020; and James Heyward, Lily Olsen, Joshua Sharfstein, et al., “Evaluation of the

Although other restrictions, such as medication storage and frequency of patient visits to receive prescriptions are imposed on the national level,¹⁹⁶ 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.¹⁹⁷

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.¹⁹⁸ 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.¹⁹⁹ Recent studies in the United States have shown that prescription opioid misuse increased more slowly in states with PDMPs than in states without them,²⁰⁰ and that states with more robust PDMPs have fewer prescription opioid overdose deaths.²⁰¹

Most economically advanced countries use PDMPs to monitor opioid prescribing, but to varying degrees.²⁰² 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.²⁰³ In addition, the United States lacks a systematic post-dispensing control mechanism. Although the Drug Enforcement Administration

Extended-Release/Long-Acting Opioid Prescribing Risk Evaluation and Mitigation Strategies by the US Food and Drug Administration,” *JAMA Internal Medicine*, December 30, 2019, pp. E1-E9.

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.

¹⁹⁷ Sara Imhof and Brian Kaskie, “How Can We Make the Pain Go Away? Public Policies to Manage Pain at the End of Life,” *The Gerontologist*, vol. 48, no. 4 (2008), pp. 423-431.

¹⁹⁸ OECD, *Addressing Problematic Opioid Use*, 2019.

¹⁹⁹ U.S. Government Accountability Office, *State Monitoring Programs Provide Useful Tool to Prevent Diversion*, GAO-02-634, May 2002, at <https://www.gao.gov/new.items/d02634.pdf>. One review noted that PDMPs effectively reduced “doctor shopping” strategies, curbed prescription misuse, and improved physicians’ prescribing practices. See Julie Worley, “Prescription Drug Monitoring Programs, a Response to Doctor Shopping: Purpose, Effectiveness, and Directions for Future Research,” *Issues in Mental Health Nursing*, vol. 33, no. 5 (2012), pp. 319-328.

²⁰⁰ See, for example, Liza Reifler, Danna Droz, and J. Elise Bailey, “Do Prescription Monitoring Programs Improve State Trends in Opioid Abuse/Misuse?” *Pain Medicine*, vol. 13, no. 3 (March 2012), pp. 434-442.

²⁰¹ Bryce Pardo, “Do More Robust Prescription Drug Monitoring Programs Reduce Prescription Opioid Overdose?” *Addiction*, vol. 112, no. 10 (October 2017), pp. 1773-1783.

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.

²⁰³ *Ibid.*, and Cherny et al., “Formulary Availability and Regulatory Barriers,” 2010.

(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 Factors²⁰⁷

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

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 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.

²⁰⁶ 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/pdffiles1/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.

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.

²⁰⁸ Bosetti et al., “Trends in the Consumption of Opioids,” 2019.

²⁰⁹ Sue Peacock and Shilpa Patel, “Cultural Influences on Pain,” *British Journal of Pain*, vol. 1, no. 2 (2008).

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*

- 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.

Physical Therapy, vol. 22, no. 5 (Sept.-Oct. 2018).

²¹¹ Hauser et al., "The Opioid Epidemic and Long-Term Opioid Therapy," 2016.

²¹² *Ibid.*

²¹³ See, for example, Van Hecke, "Chronic Pain Epidemiology and Its Clinical Relevance," 2013.

²¹⁴ *Ibid.*, and R. Zaslansky, W. Meissner, and C.R. Chapman, "Pain After Orthopaedic Surgery: Differences In Patient Reported Outcomes In The United States Versus Internationally," *British Journal of Anaesthesiology*, vol. 120, no. 4 (February 2, 2018). Proditia Sabarini, "How Different Cultures Experience and Talk About Pain," *The Conversation*, 2015.

²¹⁵ Van Amsterdam et al., "The Misuse of Prescription Opioids," 2015.

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,²¹⁸ specifying storage and dispensing rules,²¹⁹ requiring certain training for health care providers,²²⁰ 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.²²¹ 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.²²²

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,²²³ which, according to the VA, reduced prescription opioid use in patients within the VA health care system by 64%.²²⁴ 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.²²⁵ 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

²¹⁸ 21 U.S.C. §826.

²¹⁹ 21 U.S.C. §826 and 21 C.F.R. §1301.71 et seq.

²²⁰ See, for example, 21 U.S.C. §823.

²²¹ Alexander Chiu, Raymond Jean, Jessica Hoag, et al., “Association of Lowering Default Pill Counts in Electronic Medical Record Systems With Postoperative Opioid Prescribing,” *JAMA Surgery*, vol. 153, no. 11 (July 18, 2018).

²²² Mitesh Patel, Kevin Volpp, David Asch, et al., “Nudge Units to Improve the Delivery of Health Care,” *New England Journal of Medicine*, vol. 378, no. 3 (January 18, 2018).

²²³ U.S. Department of Veterans Affairs, *VHA Pain Management/Opioid Safety Initiative (OSI)*, https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp.

²²⁴ U.S. Department of Veterans Affairs, Office of Public and Intergovernmental Affairs, “VA Reduces Prescription Opioid Use by 64% during the Past Eight Years,” press release, July 30, 2020, <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5492#:~:>.

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.²²⁶ 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.²²⁷ 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.²²⁸ 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.²²⁹

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 chemicals²³⁰ 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.”²³¹ Many prescription opioids are Schedule II controlled substances under the CSA.²³² The DEA establishes aggregate production quotas (APQs) and then assigns individual production quotas to manufacturers that

²²⁶ National Governors Association, *State Strategies to Improve the Use of Prescription Drug Monitoring Programs to Address Opioid and other Substance Use Disorders*, Washington, DC, July 2020, https://www.nga.org/wp-content/uploads/2020/07/NGA_PDMP_Toolkit-July-2020.pdf.

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/>.

²²⁸ Guy et al., *Vital Signs: Changes in Opioid Prescribing in the United States: 2006-2015*, 2017; and Zhu et al., “Initial Opioid Prescriptions among U.S. Commercially Insured Patients,” 2019.

²²⁹ Centers for Disease Control and Prevention, *CDC/Opioid Information/State Information/State Successes*, 2019, <https://www.cdc.gov/drugoverdose/policy/successes.html>.

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.dea diversion.usdoj.gov/meth/q_a_cmea.htm.

²³¹ 21 U.S.C. §826(a).

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

prevent the APQ from being exceeded.²³³ Registrants²³⁴ 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.²³⁵

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.²³⁶ 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.²³⁷ 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.²³⁸

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 (e).

²³⁶ 21 U.S.C. §826.

²³⁷ See Drug Enforcement Administration, “Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021,” 85 *Federal Register* 54407-54414, September 1, 2020; and Drug Enforcement Administration, “Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2020,” 84 *Federal Register* 48170-48177, September 12, 2019.

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 prescription 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

2016,” *JAMA*, vol. 321, no. 1 (2019), pp. 80-96.

²³⁹ Lisa M. Schwartz and Steven Woloshin, “Medical Marketing in the United States, 1997-2016,” *JAMA*, vol. 321, no. 1 (January 2019).

²⁴⁰ Richard Frank, Keith Humphreys, and Harold Pollack, “Policy Responses to the Addiction Crisis,” *Journal of Health Politics, Policy, and Law*, vol. 8970796 (January 22, 2021). See §162 and Rev. Rul. 92-80, 1992-2 C.B. 57, September 11, 1992, and 26 U.S.C. §162.

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

²⁴² Matthew D. Eisenberg, Elizabeth M. Stone, Harlan Pittell, et al., “The Impact of Academic Medical Center Policies Restricting Direct-To-Physician Marketing on Opioid Prescribing,” *Health Affairs*, vol. 39, no. 6 (June 2020).

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*.

²⁴⁵ See, for example, European Commission, *Twinning*, European Neighbourhood Policy and Enlargement Negotiations, August 10, 2020, https://ec.europa.eu/neighbourhood-enlargement/tenders/twinning_en; and Centers for Disease Control and Prevention, *Clinical Mentors Make a Real Difference in Training New Frontline Health Workers in South Africa*, Global Health Stories, February 16, 2017, <https://www.cdc.gov/globalhealth/stories/clinical-mentors-health-workers-in-south-africa.htm>.

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).²⁴⁶ In a recent survey of 1,000 Americans, most respondents were unable to correctly identify opioid medications.²⁴⁷ 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.²⁴⁸ 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.²⁴⁹ 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.

²⁴⁶ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule,” 80 *Federal Register* 41773, July 15, 2015; and Centers for Medicare & Medicaid Services, *Advance Care Planning*, Medicare Learning Network (MLN) Fact Sheet, August 2019, pp. 1-6, <https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/advanccareplanning.pdf>.

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/>.

²⁴⁸ See, for instance, Leonard Paulozzi and Daniel Stier, “Prescription Drug Laws, Drug Overdoses, and Drug Sales in New York and Pennsylvania,” *Journal of Public Health Policy*, vol. 31 (2010), pp. 422-432; and Linda Wastila and Christine Bishop, “The Influence of Multiple Copy Prescription Programs on Analgesic Utilization,” *Journal of Pharmaceutical Care in Pain & Symptom*, February 17, 2010, pp. 3-19.

²⁴⁹ Corey Davis, Amy Judd Lieberman, Hector Hernandez-Delgado, et al., “Laws Limiting the Prescribing or Dispensing of Opioids for Acute Pain in the United States: A National Systematic Legal Review,” *Drug and Alcohol Dependence*, vol. 194 (2018), pp. 166-172. States that have imposed restrictions on the duration, number of pills, or dose in a single prescription include Alaska, Connecticut, Delaware, Hawaii, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Maine, Minnesota, Missouri, North Carolina, New Hampshire, New Jersey, Nevada, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Virginia, and Vermont. The specific restrictions vary by state.

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.²⁵⁰ In response to this directive, FDA convened both an advisory committee meeting and a public meeting and issued draft guidance.²⁵¹ Congress may consider creating new incentives aimed at encouraging the development and use of new nonopioid or nonaddictive therapies.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.²⁵³ Moreover, comorbid and untreated mental health disorders are associated with substance use disorders, such as opioid use disorder.²⁵⁴ The mental health treatment system in the United States is largely segregated from mainstream medicine.²⁵⁵ Yet, many individuals presenting to medical providers may be experiencing underlying mental health conditions causing or exacerbating their physical pain.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.²⁵⁷ Integrating

²⁵⁰ Section 3001 of P.L. 115-271.

²⁵¹ FDA, “Statement on agency’s first year accomplishments implementing SUPPORT Act authorities to address the opioids crisis,” October 24, 2019, <https://www.fda.gov/news-events/press-announcements/statement-agencys-first-year-accomplishments-implementing-support-act-authorities-address-opioids>.

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/>.

²⁵³ See, for example, Anke Hinrichs-Rocker, Kerstin Schulz, Imke Jarvinen, et al., “Psychosocial Predictors and Correlates for Chronic Post-Surgical Pain (CPSP)—A Systematic Review,” *European Journal of Pain*, vol. 13, no. 7 (August 2009), pp. 719-730; and Danielle Reddi and Natasha Curran, “Chronic Pain After Surgery: Pathophysiology, Risk Factors, and Prevention,” *Postgraduate Medical Journal*, vol. 90, no. 1062 (2014).

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

²⁵⁵ Thomas W. Croghan and Jonathan D. Brown, *Integrating Mental Health Treatment Into the Patient Centered Medical Home*, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, AHRQ Publication No. 10-0084-EF, Rockville, MD, June 2010, <https://pcmh.ahrq.gov/page/integrating-mental-health-treatment-patient-centered-medical-home>.

²⁵⁶ Natalie Sachs-Ericsson, Kiara Cromer, Anya Hernandez, et al., “A Review of Childhood Abuse, Health, and Pain-Related Problems: The Role of Psychiatric Disorders and Current Life Stress,” *Journal of Trauma & Dissociation*, vol. 10, no. 2 (2009).

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.

Problem Drug Use, and Regular Prescription Opioid Use,” *Arch Internal Medicine*, vol. 166, no. 19 (2006), pp. 2087-2093.

Appendix A. International Opioid-Prescribing Regulations

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

Regulation	Description
National clinical practice guidelines	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. ^a
National provider training and stewardship programs	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. ^b
Special permit/license required for prescribing	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. ^c
Special prescription forms required/prescribing in multiple copies required	Special forms or multiple copies are required and/or other administrative requirements for health care professionals prescribing opioids. ^d
Limited prescription validity	Prescriptions for some controlled medicines expires within a certain time after issuance. ^d
Amount of controlled medicine to be prescribed is limited	Restrictions on the duration, number of pills, or total MMEs in a single prescription. ^d
Daily dosage is limited	Limits on the maximum daily dosage for an opioid prescription. ^d
National prescription drug monitoring program	National electronic databases that track prescriptions for controlled medicines, such as opioids. ^a
National prescription drug adverse-events tracking system	National electronic databases that track adverse events for medical products and controlled medicines, such as opioids. ^b
Disciplinary action for overprescribers	Deliberate or unintended violation of administrative requirements and regulations may result in sanctions for health care providers. ^e
Marketing restrictions	Limits on allowable marketing practices for the pharmaceutical industry, including constraints or prohibitions on direct-to-consumer or direct-to-provider activities. ^f
Consumer warning systems	Labels on medications contain warnings regarding possible adverse outcomes associated with use. ^g
Consumer education campaigns	Messaging campaigns that seek to inform the public about the possible dangers associated with opioid use and misuse. ^h
Postdispensing control mechanisms	Widespread and systematic mechanisms to safely collect or dispose of excess medications. ⁱ

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

Notes: Table format and information based on those provided in Marjolein Vranken, John Lisman, and Aukje Mantel-Teeuwisse, "Barriers to Access to Opioid Medicines: Results of a Review of National Legislation and Regulations of 11 Central and Eastern European Countries," *The Lancet Oncology*, vol. 17, no. 1 (2016), pp. e13-e22, and OECD, *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>.

- a. OECD, *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>.
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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.

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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