



ANDREW W. MULCAHY

# Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries

---

For more information on this publication, visit [www.rand.org/t/RRA788-4](http://www.rand.org/t/RRA788-4).

#### **About RAND**

The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest. To learn more about RAND, visit [www.rand.org](http://www.rand.org).

#### **Research Integrity**

Our mission to help improve policy and decisionmaking through research and analysis is enabled through our core values of quality and objectivity and our unwavering commitment to the highest level of integrity and ethical behavior. To help ensure our research and analysis are rigorous, objective, and nonpartisan, we subject our research publications to a robust and exacting quality-assurance process; avoid both the appearance and reality of financial and other conflicts of interest through staff training, project screening, and a policy of mandatory disclosure; and pursue transparency in our research engagements through our commitment to the open publication of our research findings and recommendations, disclosure of the source of funding of published research, and policies to ensure intellectual independence. For more information, visit [www.rand.org/about/research-integrity](http://www.rand.org/about/research-integrity).

RAND's publications do not necessarily reflect the opinions of its research clients and sponsors.

Published by the RAND Corporation, Santa Monica, Calif.

© 2024 RAND Corporation

RAND® is a registered trademark.

#### **Limited Print and Electronic Distribution Rights**

This publication and trademark(s) contained herein are protected by law. This representation of RAND intellectual property is provided for noncommercial use only. Unauthorized posting of this publication online is prohibited; linking directly to its webpage on [rand.org](http://rand.org) is encouraged. Permission is required from RAND to reproduce, or reuse in another form, any of its research products for commercial purposes. For information on reprint and reuse permissions, please visit [www.rand.org/pubs/permissions](http://www.rand.org/pubs/permissions).

## About This Report

---

Some stakeholder groups have raised concerns about the impact of new policies to address high U.S. prescription drug prices on access to new drugs for Americans. In this report, the author compares the availability of new prescription drugs between the United States and other high-income countries.

This research was funded by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation under Contract Number HHSP233201500038I, Task Order Number HHSP23337008T, and carried out within the Payment, Cost, and Coverage Program in RAND Health Care.

RAND Health Care, a division of the RAND Corporation, promotes healthier societies by improving health care systems in the United States and other countries. We do this by providing health care decisionmakers, practitioners, and consumers with actionable, rigorous, objective evidence to support their most complex decisions. For more information, see [www.rand.org/health-care](http://www.rand.org/health-care), or contact

### **RAND Health Care Communications**

1776 Main Street

P.O. Box 2138

Santa Monica, CA 90407-2138

(310) 393-0411, ext. 7775

[RAND\\_Health-Care@rand.org](mailto:RAND_Health-Care@rand.org)

## Acknowledgments

We thank our Office of the Assistant Secretary for Planning and Evaluation (ASPE) colleagues Kenneth Finegold, Bisma Sayed, Arielle Bosworth, Sonal Parasrampuria, and Stephen Murphy for their guidance and input on this report. Amber Jessup, then at ASPE and now at the U.S. Department of Health and Human Services Office of the Inspector General, Jon Oliver at ASPE, and Denis Agniel at RAND provided helpful advice on an earlier version of this analysis. We are also grateful to Mariana Social and Peggy Chen for strengthening the report with their careful review and feedback.

## Summary

---

Prescription drug research and development (R&D) is, particularly in its most expensive later stages, an increasingly global endeavor undertaken by large, multinational firms. However, the availability of the resulting new drugs in individual countries and the timing of their launch can vary because of regulatory differences, business decisions, and other factors (Downing, Zhang, and Ross, 2017; Varol, Costa-Font, and McGuire, 2012; Danzon and Epstein, 2012; Danzon, Wang, and Wang, 2005; Kanavos et al., 2013; Kyle, 2006; Houy and Jelovac, 2015).

The now-enacted Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169, 2022) and other policy proposals aim to lower U.S. prices for brand-name drugs that are between three and four times as expensive as in other higher-income countries (Mulcahy, Schwam, and Lovejoy, 2023). Some stakeholders assert that lower U.S. prices will prevent U.S. patients from accessing some drugs sold in other countries or delay the launch of new drugs in the United States (Haninger, 2019; PhRMA, 2021; PhRMA, 2023; The Exchange, 2023).

Although the Congressional Budget Office and others have modeled the potential implications of changes in U.S. net revenue on drug R&D broadly (Congressional Budget Office, 2022; Adams and Herrnstadt, 2021), few studies have described differences in new drug availability and the timing of new drug launches between the United States and other higher-income countries.

This study presents results from an analysis of the availability and timing of market entry for 287 new drugs launched between 2018 and 2022 in the United States and 26 comparison Organisation for Economic Co-operation and Development (OECD) countries. The results focus both on availability—that is, whether new drugs are available in each individual country by quarter 4 (Q4) 2022—and on the timing of entry, which we (the author, with support from members of the project team) measure in terms of the length of time in quarters from first entry in any country market to entry in each individual country.

## Data and Methods

We used 2017–2022 IQVIA MIDAS data as our primary data source. The IQVIA MIDAS data include country-level, quarterly estimates of total sales and volume for individual drug products and cover a broad range of prescription and non-prescription drugs. We used data for prescription drugs only and identified *new drugs* as those without sales in any of the 27 study countries in 2017 but with sales from 2018 through 2022. Including the United States, we used data from 26 comparison OECD countries with both retail and hospital data available in the IQVIA MIDAS data.<sup>1</sup>

---

<sup>1</sup> Our study countries were Australia, Austria, Belgium, Canada, Czechia, Finland, France, Germany, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, South Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States.

## Results

Of 287 total new drugs, we found that, by Q4 2022,

- 164 (57 percent) were sold in both the United States and at least one other country
- 48 (17 percent) were sold in the United States but not in any of the other study countries
- 75 (26 percent) were sold only outside the United States.

The United States had more total new drugs sold by Q4 2022 (212, or 74 percent of all new drugs) compared with any other individual country. Germany had the second-highest share, with 149 (52 percent of) new drugs.

New drugs sold in both the United States and at least one other country by Q4 2022 accounted for 90 percent of 2022 spending on all new drugs in the United States. This percentage was higher for 2021 (95 percent) and would likely be higher in 2023 given that the “U.S.-only” new drug with the greatest U.S. sales was launched in other countries one quarter after the end of our study period. Of the top ten new drugs available in both the United States and other countries by U.S. sales, nine were sold in 14 or more countries, and six were sold in 23 or more countries.

In terms of launch order and timing, we found that more than half of new drugs were launched first in the United States, and there was an average lag of about one year between launch in the United States and launch in other major OECD markets (Australia, Canada, France, Germany, Italy, Japan, and the United Kingdom). Some new drugs launched in other countries before they were launched in the United States. At any point in time over our study period, we found that the likelihood of launch of a new drug was considerably higher in the United States versus in other countries.

## Conclusion

We found that most new drugs are sold first in the United States, that the United States has access to the largest share of new drugs overall, and that new drugs are typically sold in other major high-income OECD countries about one year after they are launched in the United States. At the same time, our results suggest that the most-important new drugs to industry—those with considerable revenue potential—are ultimately sold broadly across multiple countries. There are likely many reasons why companies launch new products first in the United States and then gradually over time in other countries. For example, countries may launch first in markets where they have more latitude to set prices (namely, in the United States) before launching in countries that use external reference pricing, which ties domestic prices, at least partially, to those in other countries. There are also likely important differences in regulatory approval timelines, whether economic evaluation processes outside the United States run in parallel or in sequence with regulatory approval, supply chain considerations, and other factors. It remains unclear whether increases or decreases in U.S. brand-name drug revenue would substantively affect the availability of new drugs in the United States, the timing of the initial marketing of new drugs globally, or the relative timing of launch in the United States versus other countries.

# Contents

---

About This Report.....	iii
Summary.....	iv
Figures and Tables.....	vii
Chapter 1. Background.....	1
Chapter 2. Data and Methods.....	4
Study Sample.....	4
Methods.....	5
Chapter 3. Results.....	7
Share of Total Prescription Drug Spending on New Drugs.....	7
Availability of New Drugs.....	9
Spending Shares.....	11
U.S. and Other Country–Only Drugs.....	13
First Sales Rank Order.....	15
Chapter 4. Discussion.....	20
Limitations.....	21
Conclusions.....	21
Appendix. Supplemental Results.....	23
Abbreviations.....	27
References.....	28

## Figures and Tables

---

### Figures

Figure 3.1. Spending on New Drugs as a Share of Total Prescription Drug Spending, 2018–2022.....	7
Figure 3.2. Number of Total New Drugs Sold by Q4 2022, Overall and by Country .....	10
Figure 3.3. Number of New 2018 and 2019 Cohort Drugs Sold by Q4 2022, Overall and by Country .....	11
Figure 3.4. Share of New Drugs and Spending on New Drugs from Drugs Sold in the United States and Other Countries, 2022.....	12
Figure 3.5. First Sales Rank Order Descriptive Statistics.....	16
Figure 3.6. Time in Quarters from U.S. to Other-Country Launch of 2018 and 2019 New Drugs.....	17
Figure 3.7. Proportion of New Drugs Sold by Country by Time .....	18
Figure 3.8. Estimated Average Likelihood of a New Drug Launch, Relative to the United States, in Each Calendar Quarter by Country .....	19

### Tables

Table 3.1. Change in 2021 to 2022 Spending for Top U.S. and Other-Country New Drugs .....	9
Table 3.2. Top U.S.-Only and Other Country–Only Drugs by 2022 Spending.....	14
Table A.1. Country-Specific Results, Share of Total Prescription Drug Spending on New Drugs, 2021 and 2022 .....	23
Table A.2. Country-Specific Results, Counts of Total, U.S.-Only, and Other Country–Only New Drugs, Q4 2022 .....	24
Table A.3. Country-Specific Results, Share of U.S.-Only or Other Country–Only New Drugs by Count and Spending, 2021 and 2022 .....	25
Table A.4. Country-Specific Results, Time in Quarters from U.S. to Other-Country Launch of 2018 and 2019 New Drugs .....	26





## Chapter 1. Background

---

Large, multinational pharmaceutical companies often finance the late-stage clinical development of potential new drugs and push candidates through U.S. regulatory approval. These same companies often have the marketing capabilities or partnerships to sell their products worldwide, and, in many cases, they have the financial incentive to do so. However, many factors likely affect whether and when new drugs become available in a country. Prior research suggests these factors include regulatory review requirements and duration (Downing, Zhang, and Ross, 2017; Varol, Costa-Font, and McGuire, 2012), expected revenue (a function of market size, uptake, and price) (Danzon and Epstein, 2012; Danzon, Wang, and Wang, 2005; Kanavos et al., 2013; Kyle, 2006), and strategic considerations related to drug price regulation in different countries (Houy and Jelovac, 2015). Other factors, such as manufacturing capacity, supply chains, marketing capabilities and partnerships, and cultural norms, may also play important roles.

Prior studies have found that at least some new prescription drugs are sold only in select countries (Lanjouw, 2005), and, for drugs sold more broadly, launch timing is frequently staggered; however, these studies rely on older data for drugs approved prior to 2010 (Verniers, Stremersch, and Croux, 2011). There is some more-recent evidence that major new drugs are ultimately available broadly across at least higher-income countries. One study found that each of the top 50 brand-name drugs sold in the United States, by 2020 net sales,<sup>2</sup> and all insulins were sold in at least four of six high-income comparison countries in 2020. However, this study did not specifically address either drug availability or launch timing (Mulcahy, Whaley, et al., 2021).

The United States pays prices for brand-name retail drugs that are nearly four times as high as those in other high-income countries, even after accounting for rebates and other discounts paid by manufacturers to pharmacy benefit managers (PBMs) (Mulcahy, Schwam et al., 2021). Prescription drug–related provisions of the Inflation Reduction Act of 2022 (IRA) prompted a redesign of the structure of the Medicare Part D benefit, capped Medicare payment growth for prescription drugs at inflation, and introduced a new Medicare drug price negotiation program for older, single-source drugs with the greatest Medicare spending (Pub. L. 117-169, 2022). The Congressional Budget Office (CBO) estimated that the IRA drug price negotiation provisions alone would save the federal government approximately \$100 billion over ten years (CBO, 2022). In terms of impacts on patients, an Office of the Assistant Secretary for Planning and

---

<sup>2</sup> That is, sales at prices adjusting for off-invoice discounts paid by drug companies to drug plan sponsors or their PBMs. Sales at net prices differ from sales at gross prices by the magnitude of these discounts, which are often in the form of rebates.

Evaluation report estimated that the IRA’s broader changes to the Medicare Part D benefit will save 18.7 million enrollees \$7.4 billion in out-of-pocket costs in 2025 (Sayed et al., 2023). Other proposals to address U.S. drug prices and patient out-of-pocket costs, both in Medicare and more broadly, remain under discussion and debate.

Some pharmaceutical industry groups have raised concerns that lower U.S. prices could lead to less innovation and fewer new drugs overall, result in fewer new drugs available in the United States, and slow American patients’ access to new drugs (Haninger, 2019; PhRMA, 2019; PhRMA, 2023; The Exchange, 2023). The same industry groups and some policymakers argue that lower, regulated prices in other countries allow these countries to effectively “free ride” on higher prices and the associated revenue and incentives for research and development (R&D) from the United States (Council of Economic Advisors, 2018).

The impact of Medicare negotiation and other U.S. prescription drug policies on the number of new drugs developed globally, whether new drugs are sold in the United States, and the timing of new drug availability in the United States is uncertain. CBO estimated that the IRA drug price negotiation provisions would lead to 15 fewer new drugs approved by the U.S. Food and Drug Administration (FDA) out of 1,300 new drugs expected to be approved by the FDA over 30 years—a difference of about 1.2 percent (CBO, 2022). CBO’s estimates were from a model linking investment in new drug R&D to the expected return on investment, which, in part, hinges on U.S. prices that may change as a result of the IRA (Adams and Herrnstadt, 2021). CBO’s analysis focused on new drugs approved for marketing in the United States, given the relevance of the analysis for scoring, or projecting costs, for federal legislation. Its analysis did not explicitly differentiate between new drugs never developed at all versus those that were developed but that were not sold in the United States, nor did it directly address launch timing.

To provide context for these policy discussions, we (the author, with support from members of the project team) examine the extent to which the United States had broader and earlier availability of new drugs compared with other countries under the status quo through 2022. More specifically, our analysis aims to answer three main research questions:

1. What share of new drugs is available only in the United States, only in comparator countries, and in both the United States and comparator countries?
2. What share of drug spending does U.S.-only and other country-only drugs capture relative to total spending on prescription drugs, including on drugs available in both the United States and other countries?
3. For drugs that are sold in the United States and in other countries, what is the relative timing of entry in the United States versus in other countries?

Our analysis compares availability and entry timing for 287 new drugs first sold from 2018 through 2022 in the United States and 26 other Organisation for Economic Co-operation and Development (OECD) countries. Although our findings are descriptive in nature, they help quantify the extent of potential broader and earlier availability of new drugs in the United States at a time when the United States paid gross prices for brand-name drugs that were roughly four

times as high, and net prices for brand-name drugs roughly three times as high, as those in other OECD countries (Mulcahy, Schwam, and Lovejoy, 2023).

In Chapter 2, we describe the data we used and our methodology; in Chapter 3, we present the results of our analyses; and in Chapter 4, we discuss the policy implications of our findings and the limitations of the study.

## Chapter 2. Data and Methods

---

We used quarterly 2017–2022 IQVIA MIDAS data for the United States and 26 OECD comparison countries (we refer to all 27 countries collectively as the *study countries*).<sup>3</sup> Although IQVIA MIDAS data include more than 26 OECD countries, we restricted our analysis to countries for which we had access to data covering both retail and hospital distribution channels.<sup>4</sup> IQVIA MIDAS country-level sales and volume estimates are projected from IQVIA’s audits of standardized list prices and manufacturer, wholesaler, and other invoices; they do not reflect net prices realized by the manufacturers. These data are designed to support country-level trend and pattern analyses, but they remain estimates. The IQVIA MIDAS data used in this analysis were obtained under license from IQVIA. Our IQVIA MIDAS extract was prepared on May 19, 2023.

For each combination of country, drug product, and year, IQVIA MIDAS includes an estimate of country-level volume measured in standard units (a count of pills or capsules for oral solid drugs; 5 milliliter increments for liquids; and a count of vials, syringes, and other discrete packages for most other drug forms) and of country-level sales in U.S. dollars at prices from manufacturer invoices. We aggregated sales and volume at the active ingredient level by country and quarter, excluding active ingredients sold exclusively over the counter in all study countries and quarters. Furthermore, for some analyses, we combined sales across all non-U.S. study countries to create an aggregate non-U.S. comparison group.

### Study Sample

We initially identified 334 prescription drugs as “new drugs” if they (a) did not have 2017 sales in any study country but (b) did have sales in any study country from 2018 through 2022. We excluded 39 drugs with sales less than \$1,000,000 across all quarters and countries to focus on drugs likely to have had the most clinical and economic relevance. Because of this criterion, we also excluded older, infrequently sold drugs that happen not to have been sold in 2017 but

---

<sup>3</sup> MIDAS is a registered trademark of IQVIA. This report does not reproduce any IQVIA MIDAS data directly. Our study countries were Australia, Austria, Belgium, Canada, Czechia, Finland, France, Germany, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, the Netherlands, New Zealand, Norway, Poland, Portugal, Slovakia, South Korea, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States.

<sup>4</sup> We excluded data for Chile, Estonia, Greece, Luxembourg, Mexico, Slovenia, and Colombia, for which we had IQVIA MIDAS data on the retail channel but not the hospital channel. We did not have data for Denmark, Iceland, or Israel. Costa Rica became an OECD member in May 2021 but was not included in this analysis because IQVIA MIDAS data do not include Costa Rica as a separate market.

were sold in 2018 through 2022.<sup>5</sup> We also excluded six chimeric antigen receptor (CAR) T-cell drugs listed on FDA’s Approved Cellular and Gene Therapy Products list.<sup>6</sup> Although these products are sold in both the United States and other countries, they do not appear to be consistently reported across countries in IQVIA MIDAS data and, importantly, do not appear in the United States data at all. The uneven inclusion of CAR T-cell therapies across countries in IQVIA MIDAS data could reflect differences in regulation or the extent to which IQVIA’s data collection approaches capture products of this type blending features of both a drug and a medical treatment. We excluded two other drugs (cenegermin and inotersen) without IQVIA MIDAS records of U.S. sales but that we found in company filings with the U.S. Securities and Exchange Commission to be sold in the United States over our study time frame. After discussion with IQVIA, a small number of drug companies chose to exclude their information from IQVIA MIDAS, and we think this is the case for these two drugs.

Our final sample consisted of 287 new drugs. We limited some analyses to 122 new drugs first sold globally in 2018 or 2019 to ensure a minimum three-year period during which we could observe entry in other countries.

## Methods

We defined the first quarter in which a new drug was sold in any study country as the global first sales quarter. We determined whether each new drug was sold in each country at any point between the global first sales quarter and quarter 4 (Q4) 2022, inclusive. For each country and drug pair, we measured the quarters from global first sales to when a new drug was sold in the specific country. The measure equals zero for countries with country-specific first sales in the same quarter as global launch, one for countries with country-specific first sales in the quarter after the global launch quarter, etc. For new drugs sold in both the United States and other countries, we also calculated the difference in calendar quarters between U.S. and other-country first launch. A negative difference in quarters indicates that a drug was first sold in other countries before being sold in the United States, whereas positive differences in quarters indicate the opposite (that is, earlier first sales in the United States than in other countries).

---

<sup>5</sup> Nearly all the remaining new drugs were sold in at least one country annually from the year of first launch through 2022. There were only two exceptions. First, tagraxofusp was first sold in the United States in 2019, was not sold in any country in 2020, and was then sold in the United States, Germany, and Austria in 2021 and 2022. Second, melphalan flufenamide was sold in the United States in 2021 but not in any country during 2022. Both of these drugs are excluded from later analyses because they do not meet one or more other inclusion criteria, which we describe later.

<sup>6</sup> These therapies involve collecting T-cells—an immune system cell—from patients, genetically modifying the T-cells in vitro to add an antigen receptor with a specific target, and then administering the resulting CAR T-cells back to the patient. The excluded six CAR T-cell products were tisagenlecleucel, axicabtagene ciloleuce, idcabtagene vicleucel, lisocabtagene maraleucel, brexucabtagene autoleucel, and betibeglogene autotemcel. See FDA, undated.

We calculated the cumulative probability of entry in each country by quarter after global first sales using the Kaplan-Meier estimator, a nonparametric statistic used to describe the time to an event that allows for right censoring—in other words, observations without an event by the end of the study time frame. We also calculated the average likelihood of a new drug launch in each comparison country versus the United States at any point during our five-year study time frame. For this analysis, we used parametric Cox proportional hazard models that account for the fact that not all drugs were observed for equal lengths of time. Because our interest is in the overall difference in the likelihood of entry, we did not include covariates when estimating either of our models.

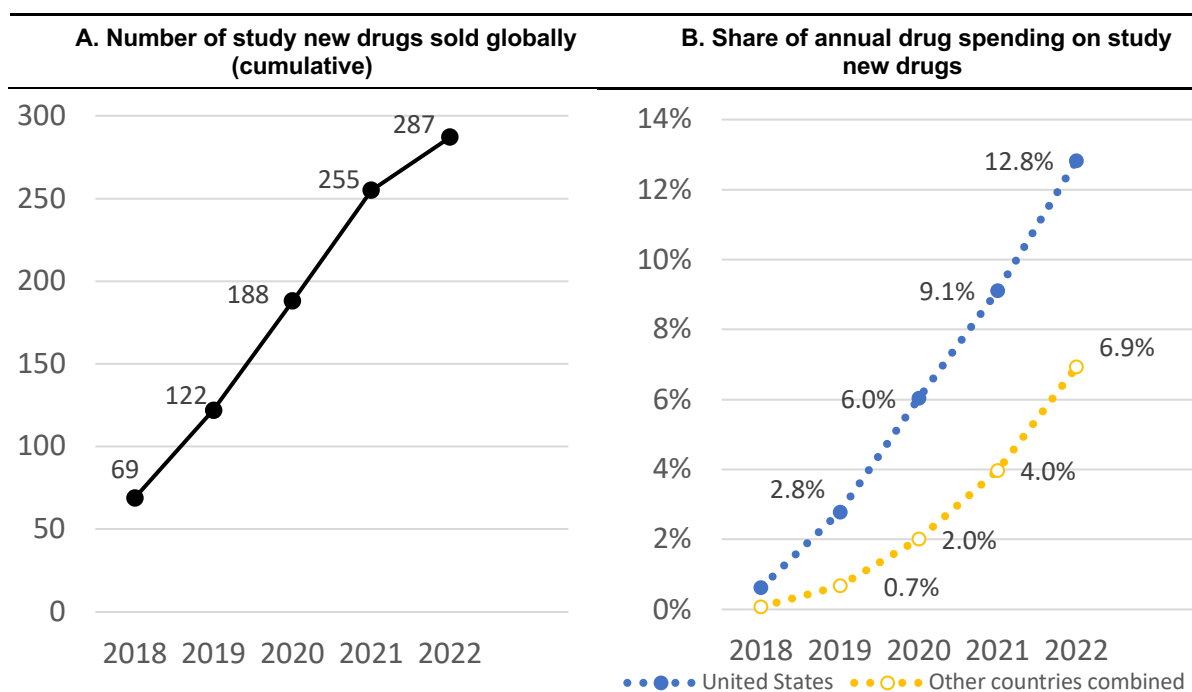
## Chapter 3. Results

In this chapter, we compare the availability of new prescription drugs in the United States and other countries, the share of spending on new drugs, and the timing of the initial launch of new drugs in the United States and comparison countries.

### Share of Total Prescription Drug Spending on New Drugs

The number of new drugs sold globally increased gradually over time, from 69 new drugs introduced globally in 2018 to 287 study new drugs sold in 2022 (see Figure 3.1, left panel). Annual spending on study new drugs increased correspondingly over time, with quicker growth and highest share in the United States compared with comparison countries.

**Figure 3.1. Spending on New Drugs as a Share of Total Prescription Drug Spending, 2018–2022**



SOURCE: Analysis of 2017–2022 IQVIA MIDAS data (run date: May 19, 2023) (IQVIA, undated).

NOTE: *Other countries combined* refers to the 26 comparison countries (but not the United States) considered as a single aggregate market.

Of total spending on prescription drugs (including on older drugs), the 287 study new drugs accounted for 12.8 percent of spending in the United States by 2022, the end of our study period, compared with 6.9 percent for other countries combined (see Figure 3.1 right panel and Table

A.1 for full country-level results for 2021 and 2022).<sup>7</sup> The substantial differences between U.S. and other-country shares of total spending by 2022 could reflect greater use of new drugs, quicker uptake, higher manufacturer gross prices for new drugs in the United States compared with other countries, or a combination of these factors.<sup>8</sup>

There was a notable increase in the share of total spending on new drugs from 2021 to 2022 in both the United States and in other countries. Similar drugs and similar relative changes in drug-level spending drove this increase globally (Table 3.1). For example, spending on semaglutide (sold under Ozempic and other brand names, a drug to treat diabetes that is also used for weight loss) increased by roughly 80 percent in both the United States and other countries. Of the top ten new drugs by U.S. sales in 2022, eight were also in the top ten by other-country sales (the other two top ten new drugs in other countries were numbers 13 and 14 in the United States). Two of the top ten new drugs by 2022 spending in the United States were not available as of 2022 in other countries: tirzepatide (brand name Mounjaro, an antidiabetic) and ubrogepant (brand name Ubrelvy, for migraines). Of the new drugs in Table 3.1, remdesivir, an antiviral used to treat coronavirus disease 2019 (COVID-19), was the only drug to decline in spending between 2021 and 2022. This decrease could reflect changes in the severity of the COVID-19 pandemic, availability of vaccines and therapy treatment alternatives, and other factors.

---

<sup>7</sup> We focus on estimated new drugs' share of all prescription drug spending in 2021 and 2022 specifically to allow time for new drugs to be launched across study countries. All 287 study new drugs were sold in one or more countries in 2021 through 2022.

<sup>8</sup> Conceptually, relatively higher U.S. prices for new, brand-name drugs could also dampen demand from consumers in the United States compared with other countries. However, drug coverage likely shields patients from the full manufacturer gross prices, and in practice insurers and their PBMs are sometimes able to negotiate substantial discounts paid as rebates by drug companies.



**Table 3.1. Change in 2021 to 2022 Spending for Top U.S. and Other-Country New Drugs**

Generic Name (Brand Name; Primary Clinical Use)	Spending Rank, 2022		Change in Spending, 2021 to 2022	
	United States	Other Countries Combined	United States	Other Countries Combined
semaglutide (Ozempic and others; diabetes and weight loss)	1	1	79.2%	77.0%
bictegravir, emtricitabine, tenofovir (Biktarvy; antiretroviral)	2	2	19.8%	18.5%
risankizumab (Skyrizi; autoimmune disorders)	3	3	87.9%	81.4%
daratumumab, vorhyaluronidase (Darzalex; multiple myeloma)	4	5	62.3%	67.5%
tirzepatide (Mounjaro; diabetes)	5	N/A	N/A	N/A
elexacaftor, ivacaftor, tezacaftor (Trikafta, Kaftrio; cystic fibrosis)	6	4	11.8%	42.8%
rimegepant (Nurtec; migraine)	7	8	101.5%	101.5%
upadacitinib (Rinvoq; autoimmune disorders)	8	6	54.1%	66.1%
ubrogepant (Ubrovelvy; migraine)	9	N/A	47.9%	N/A
remdesivir (Veklury; antiviral)	10	7	-55.6%	-31.0%
dolutegravir, lamivudine (Dovato; antiretroviral)	13	10	56.7%	49.6%
apalutamide (Erleada; prostate cancer)	14	9	31.4%	51.1%

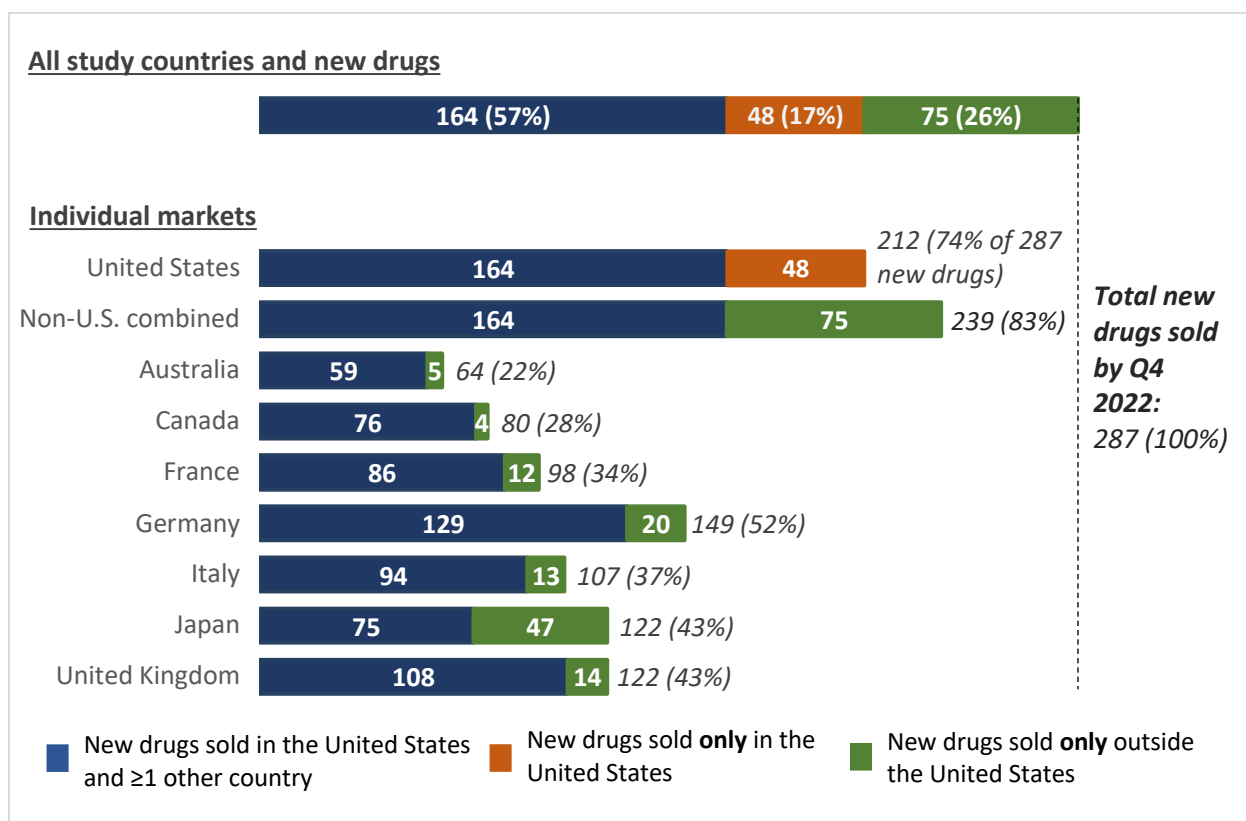
SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: Rows are sorted by U.S. new drug spending rank through the tenth drug. Two drugs in the top ten new drugs by spending outside the United States were added for completeness. Tirzepatide was sold in the United States in 2022 but not in 2021 and was not sold in any other country in 2021 or 2022. Ubrogepant was not sold outside the United States in 2021 or 2022. N/A = not applicable. Other countries combined = the 26 comparison countries (but not the United States) considered as a single aggregate market.

## Availability of New Drugs

Of the 287 new prescription drugs, 164 (57 percent) were sold in both the United States and other countries by Q4 2022. Another 48 (17 percent) were sold in the United States but not in any of the other study countries by Q4 2022, for a total of 212 (74 percent) sold in the United States by Q4 2022 (see the top row under Individual markets in Figure 3.2). The remaining 75 new drugs (26 percent of the total 287 new drugs) were sold only in other countries and not the United States by Q4 2022. Compared with the United States, the total numbers of new drugs sold in individual countries were lower, ranging from 149 in Germany to just 12 for Turkey (see key countries in Figure 3.2 and Table A.2 for full results).

**Figure 3.2. Number of Total New Drugs Sold by Q4 2022, Overall and by Country**



SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: See Table A.2 for full country-level results. Bar labels note the count (and, in parentheses, the share) of all study new drugs sold in the given market by Q4 2022. Non-U.S. combined = the 26 comparison countries (but not the United States) considered as a single aggregate market.

Using Germany as an example:

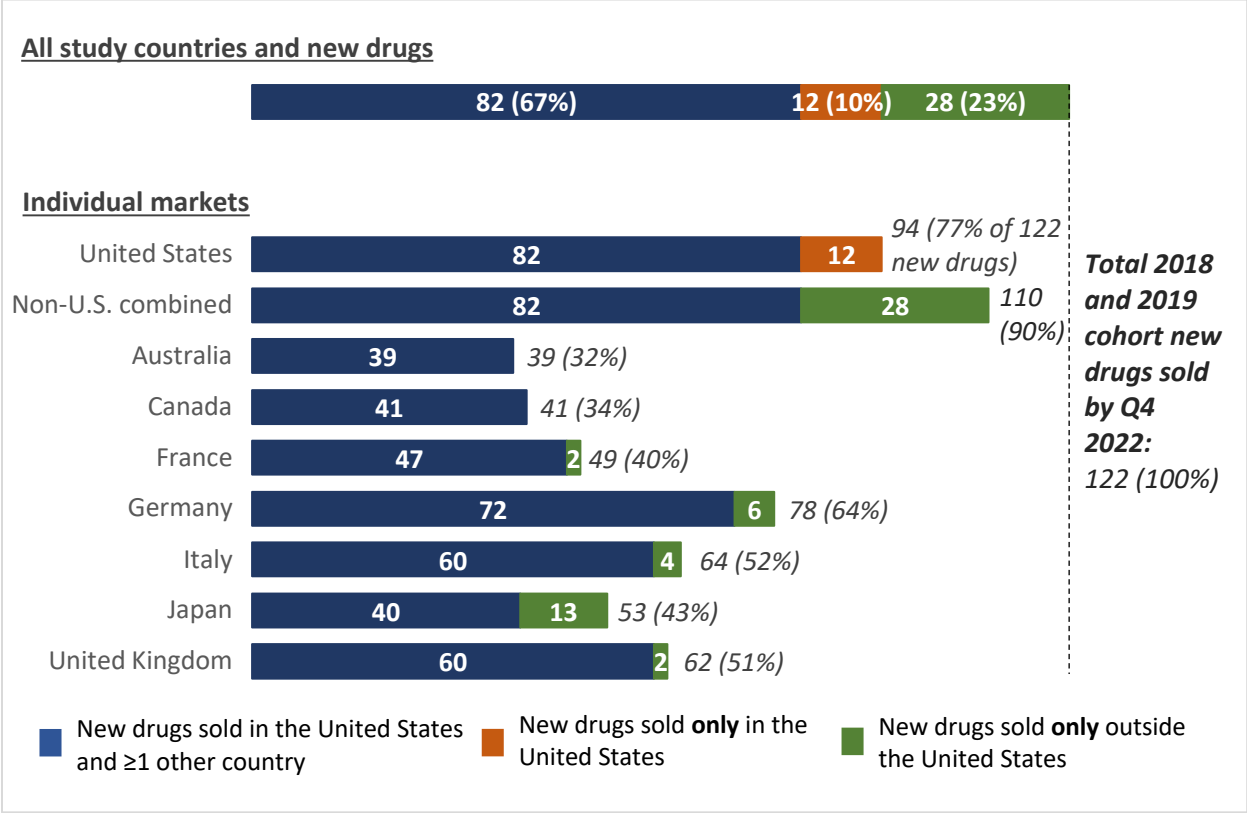
- Of the 164 new drugs sold in the United States and at least one other study country, 129 (79 percent) were sold in Germany by Q4 2022 while the other 35 (21 percent) were not.
- By definition, none of the 48 U.S.-only new drugs were sold in Germany by Q4 2022.
- Of the 75 new drugs sold only outside the United States, 20 (27 percent) were sold in Germany by Q4 2022 while the remaining 55 (73 percent) were not.

New drugs sold only outside the United States accounted for a small share of total new drugs sold in most countries. Japan was a notable exception with 39 percent of new drugs (47 of 122 new drugs) sold in Japan by Q4 2022 unavailable in the United States. In contrast, all but four of the 80 new drugs sold in Canada were also sold in the United States.

We reproduced Figure 3.2 using a subset of new drugs first sold in 2018 or 2019 only (Figure 3.3). Should the timing of entry differ between the United States and other countries (which we address in later sections), this smaller subset of new drugs allows at least three full years of runout for new drugs to be introduced in different country markets. Of the 122 total new drugs in the 2018 and 2019 first global marketing year cohorts, two-thirds (82 of 122 new drugs)

were sold in the United States by Q4 2022; 12 new drugs (10 percent) sold only in the United States. The U.S.-only share of new drugs was smaller (versus 26 percent in Figure 3.2), while the overlap in new drugs sold in the United States and other countries was higher for most countries than in Figure 3.2. The remaining 28 of 122 (23 percent of) new drugs first sold in 2018 or 2019 were sold only in countries other than the United States by Q4 2022.

**Figure 3.3. Number of New 2018 and 2019 Cohort Drugs Sold by Q4 2022, Overall and by Country**



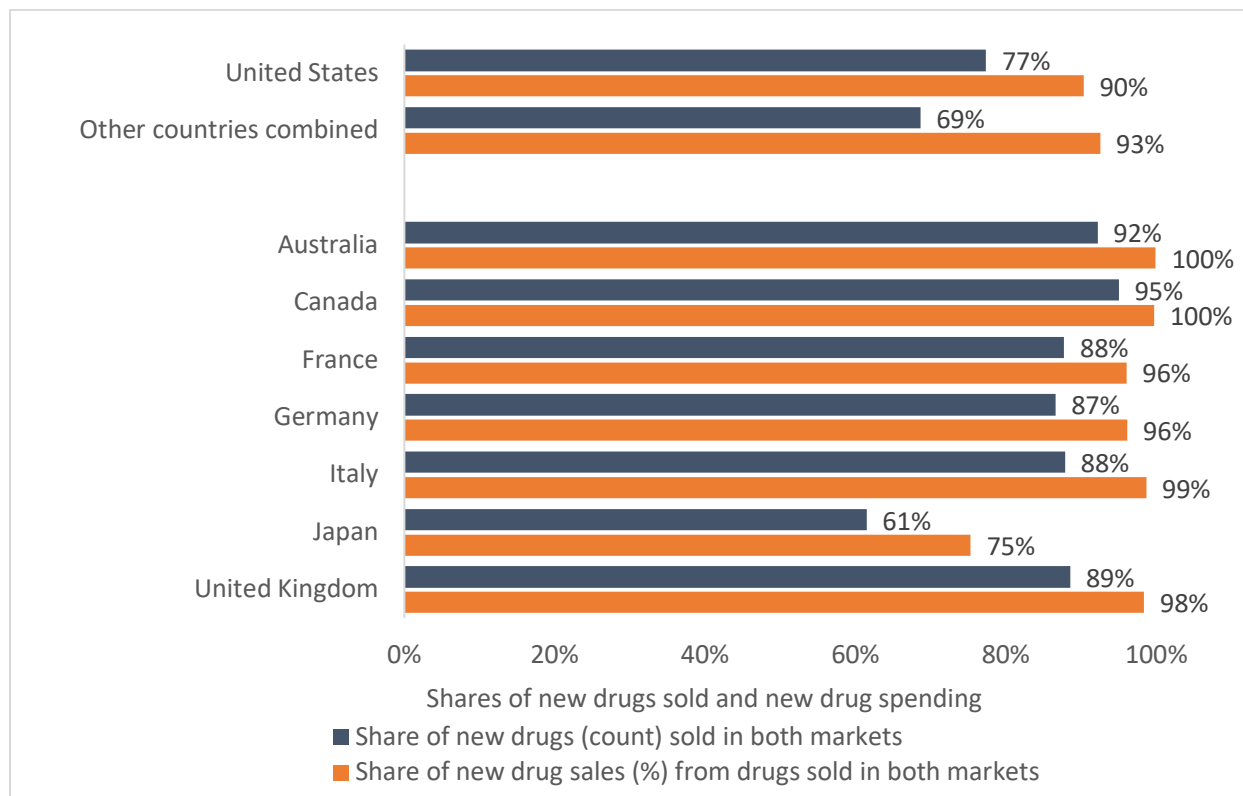
SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).  
 NOTE: See Table A.2 for full country-level results. Non-U.S. combined = the 26 comparison countries (but not the United States) considered as a single aggregate market.

### Spending Shares

As described earlier, we found that nearly half of new drugs (123 of 287 total new drugs) were sold only in the United States (48 of 287 new drugs) or only in other countries (75 of 287 new drugs). However, spending on new drugs was concentrated on the new drugs that were sold more broadly across the United States and other countries. Although over three-fourths of new drugs that were sold in the United States by Q4 2022 were also sold in other countries (164 of 212 new drugs sold in the United States by Q4 2022), these overlapping drugs accounted for over 90 percent of total U.S. spending on new drugs (see Figure 3.4 for key countries and Table

A.3 for all study countries). New drugs sold in both the United States and other countries accounted for over 90 percent of total spending on new drugs in other countries.

**Figure 3.4. Share of New Drugs and Spending on New Drugs from Drugs Sold in the United States and Other Countries, 2022**



SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: See Table A.3 for full country-level results. The denominator used for each listed market is the total number of new drugs sold in that market in 2022 or the total sales on new drugs sold in that market in 2022. The denominators therefore change from market to market. For example, of the 64 new drugs sold in Australia in 2022 (from Figure 3.2), 92 percent were also sold in the United States; the denominator is higher for Japan (with 122 new drugs sold in Japan by 2022 per Figure 3.2) such that even with a smaller share of new drugs also sold in the United States (61 percent per Figure 3.4), there were still more new drugs sold in both the United States and Japan (61 percent of 122 or 75 new drugs, again per Figure 3.2) than in the United States and Australia (92 percent of 64, or 59 new drugs). Other countries combined = the 26 comparison countries (but not the United States) considered as a single aggregate market.

In 2022, only Japan, South Korea, Lithuania, and Latvia had a share of spending on drugs sold only outside the United States that was greater than 10 percent. Japan is again an outlier among the countries illustrated in Figure 3.4 in terms of relatively small shares of drugs sold in Japan and in the United States (only 61 percent) and spending on those new drugs (nearly 75 percent).

These findings suggest that the most economically important drugs are more likely to be sold in multiple countries. If Figure 3.4 had analyzed 2021 rather than 2022 data, the U.S. share of

new drug spending on U.S.-only drugs would have been only 5 percent rather than 10 percent, and the share of other-country spending on new drugs not sold in the United States would have been about the same (9 percent in 2021 versus 8 percent in 2022). These differences could reflect year-on-year changes in the specific new drugs sold in both markets. As we describe below, tirzepatide (Mounjaro)—a diabetes drug first sold in the United States in 2022 but not in other countries prior to the close of Q4 2022—contributed to much of the increase in spending on U.S.-only new drugs from 2021 to 2022. Tirzepatide was subsequently approved in late 2022 in the European Union, Japan, Canada, and Australia and first sold in multiple comparison countries in early 2023.<sup>9</sup>

## U.S. and Other Country–Only Drugs

Table 3.2 lists the top ten new drugs sold only in the United States and only in comparison countries based on 2022 global sales. New drugs that were sold only in the United States or only in other countries covered a wide variety of clinical conditions. In the United States, three U.S.-only drugs (tirzepatide for diabetes, ubrogepant for migraines, and ategepant for migraines) accounted for over two-thirds of spending on U.S.-only new drugs. As noted earlier, the top U.S.-only new drug by 2022 sales, tirzepatide (Mounjaro) was sold in multiple comparison countries in early 2023. Of the top ten new drugs sold only in other countries, six were sold only in a single country (Japan or South Korea).

---

<sup>9</sup> “Eli Lilly and Mitsubishi Tanabe Launch New Diabetes Treatment in Japan,” 2023; Government of Canada, undated; Australian Government, Department of Health and Aged Care, 2022.

**Table 3.2. Top U.S.-Only and Other Country-Only Drugs by 2022 Spending**

<b>Active Ingredient (Brand Name)</b>	<b>Countries Sold by Q4 2022</b>	<b>Primary Clinical Use</b>	<b>2022 U.S. Sales (\$ billions)</b>	<b>2022 Non-U.S. Sales (\$ billions)</b>
<b>Both U.S. and other countries</b>				
<i>(of 27, including the United States)</i>				
semaglutide (Ozempic, Wegovy, Rybelsus)	24	Diabetes, weight loss	18.87	2.54
bictegravir, emtricitabine, tenofovir (Biktarvy)	24	antiretroviral	11.25	1.78
risankizumab (Skyrizi)	25	autoimmune disorders	4.79	0.69
elexacaftor, ivacaftor, tezacaftor (Trikafta, Kaftrio)	19	cystic fibrosis	2.28	2.34
daratumumab, vorhyaluronidase (Darzalex)	2 (United States, Japan)	multiple myeloma	3.52	0.29
upadacitinib (Rinvoq)	24	autoimmune disorders	1.94	0.78
remdesivir (Veklury)	15	antiviral	1.54	1.03
rimegepant (Nurtec)	14	migraine	2.07	<0.01
apalutamide (Erleada)	25	prostate cancer	1.04	0.94
dolutegravir, lamivudine (Dovato)	24	antiretroviral	1.12	0.76
<b>All other drugs sold in the United States and other countries</b>			19.15	10.54
<b>U.S.-only drugs</b>				
tirzepatide (Mounjaro)	1 (United States)	diabetes	2.72	N/A
ubrogepant (Ubrelvy)	1 (United States)	migraines	1.66	N/A
atogepant (Qulipta)	1 (United States)	migraines	0.53	N/A
lumateperone (Caplyta)	1 (United States)	antipsychotic	0.30	N/A
revefenacin (Yupelri)	1 (United States)	COPD	0.26	N/A
nivolumab, relatlimab (Opdivo)	1 (United States)	melanoma	0.23	N/A
clascoterone (Winlevi)	1 (United States)	acne	0.20	N/A
netarsudil (Rhopressa)	1 (United States)	glaucoma	0.19	N/A
viloxazine (Qelbree)	1 (United States)	ADHD	0.14	N/A
omadacycline (Nuzyra)	1 (United States)	antibiotic	0.10	N/A
<b>All other U.S.-only new drugs</b>			0.88	N/A
<b>Other country-only</b>				
<i>(of 26, excluding the United States)</i>				
mirogabalin (Tarlige)	3	neuropathic pain	N/A	0.25
filgotinib (Jyseleca)	13	rheumatoid arthritis	N/A	0.15
pemafibrate (Parmodia)	1 (Japan)	hyperlipidemia	N/A	0.10
elobixibat (Goofice)	1 (Japan)	IBS	N/A	0.10
ipragliflozin, sitagliptin (Suglat)	1 (Japan)	diabetes	N/A	0.09
tegoprazan (K-CAB)	1 (South Korea)	acid blocker	N/A	0.07
evocalcet (Orkedia)	1 (Japan)	hyperparathyroidism	N/A	0.07
bulevirtide (Hepcludex)	5	antiviral	N/A	0.06
tirabrutinib (Velebru)	1 (Japan)	autoimmune disorders	N/A	0.05
glycopyrronium, indacaterol, mometasone (Enerzair)	21	asthma	N/A	0.05
<b>All other country-only new drugs</b>			N/A	0.74

SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

## First Sales Rank Order

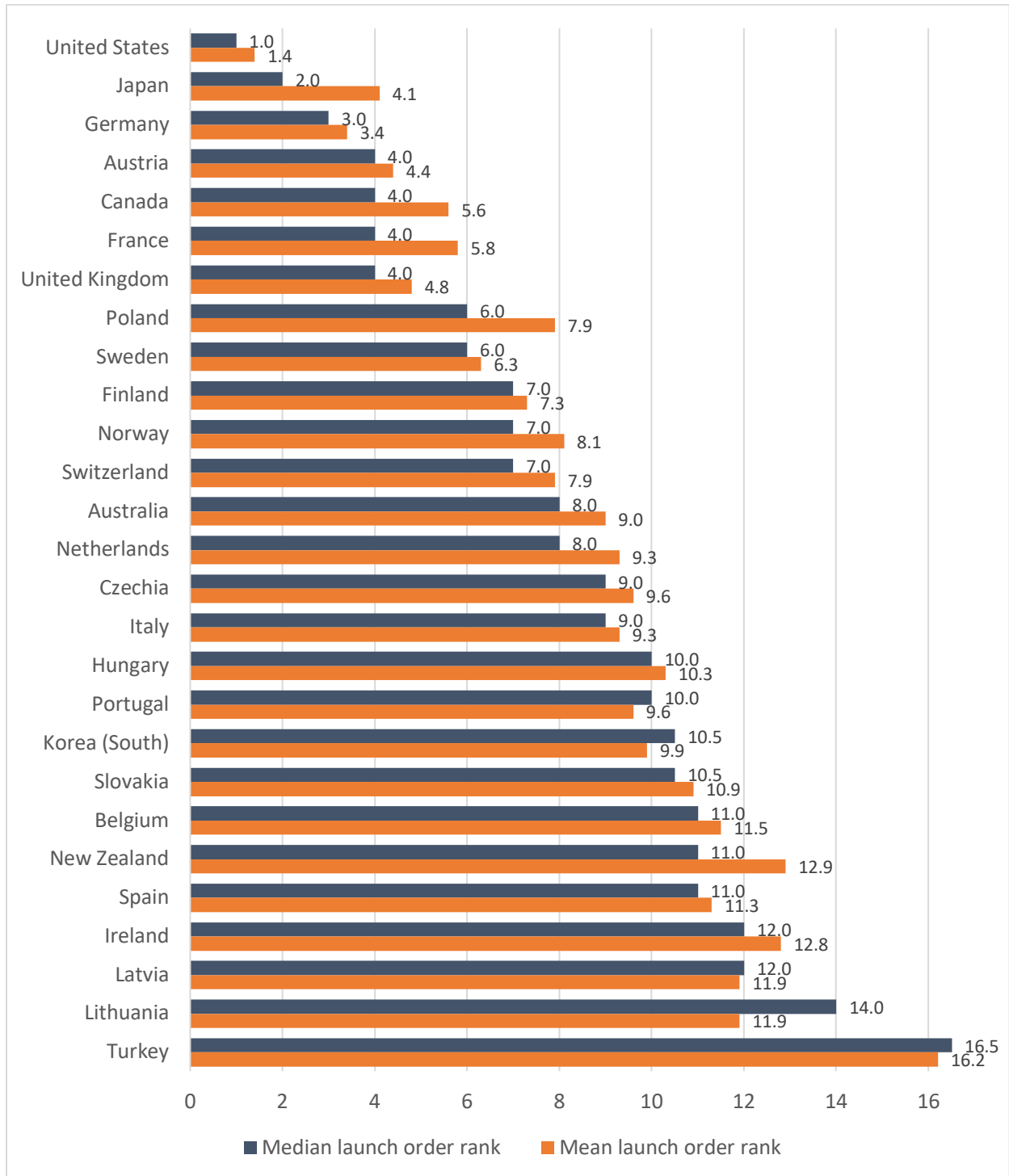
Of the 212 total new drugs sold in the United States by Q4 2022, 180 drugs (84.9 percent) were sold in the United States either first or in the same quarter that they were first introduced in other countries.<sup>10</sup> Japan (54 drugs) and Germany (23 drugs) were the next most common countries for initial sales (or ties). See Figure 3.5 for first sales rank order summary statistics for all countries. A median rank order of 1 for the United States indicates that at least half of new drugs were launched first in the United States; the higher mean rank of 1.4 indicates that some drugs are not launched first in the United States. As another example, across the new drugs launched in France by Q4 2022, the median launch order for France was fourth (or a tie for fourth place). In other words, the median new drug sold in France was first sold in three other countries before being sold in France. Some countries (notably Japan, but also Canada, France, Poland, and New Zealand) had higher mean versus median ranks, which suggests a right-skewed distribution of first sales rank order with relatively few new drugs first sold in the market considerably later than other new drugs. Mean ranks were lower than median ranks for Latvia, Lithuania, and Turkey, suggesting a very low rank (that is, late entry) for most new drugs but with a few new drugs with much higher ranks (that is, earlier entry).

Figure 3.6 reports summary statistics on the measured time span in quarters between U.S. and international first sales for the other Group of Seven countries, plus Australia, limited to the 122 new drugs first sold from 2018 through 2019 to address right-censoring concerns with later cohorts (see Table A.4 for complete country-level results). Positive numbers indicate earlier U.S. launches, and negative numbers indicate earlier launches in the comparison country. The median lag between U.S. and other-country launches ranged from three quarters (for the United States compared with Japan) to seven quarters (for the United States compared with Italy). Several of the countries shown (Canada, France, Germany, and the United Kingdom) had a median lag of four quarters. Interquartile ranges were roughly four years—including cases in which drugs were first sold in other countries years earlier than in the United States. Figure 3.6 shows a single new drug was sold in Germany nine quarters prior to its launch in the United States (the outside value “dot” at the left of Figure 3.6). In Japan, the bottom quartile of new drugs was first sold in Japan between one and ten quarters prior to being sold in the United States.

---

<sup>10</sup> When including new drugs not sold in the United States by Q4 2022 in the denominator, 62.7 percent of new drugs were sold in the United States first or in the same quarter that they were first sold in other countries.

**Figure 3.5. First Sales Rank Order Descriptive Statistics**

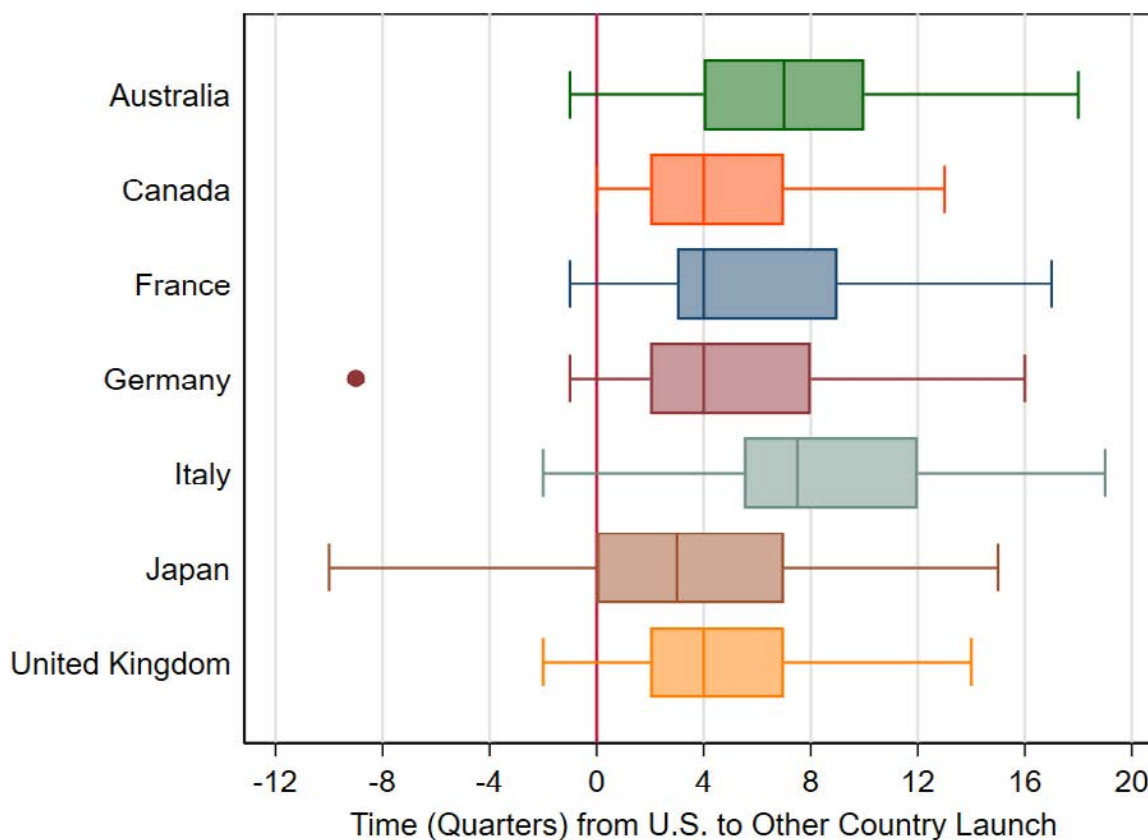


SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: Medians tied between two values reported with a value ending in 0.5.



**Figure 3.6. Time in Quarters from U.S. to Other-Country Launch of 2018 and 2019 New Drugs**

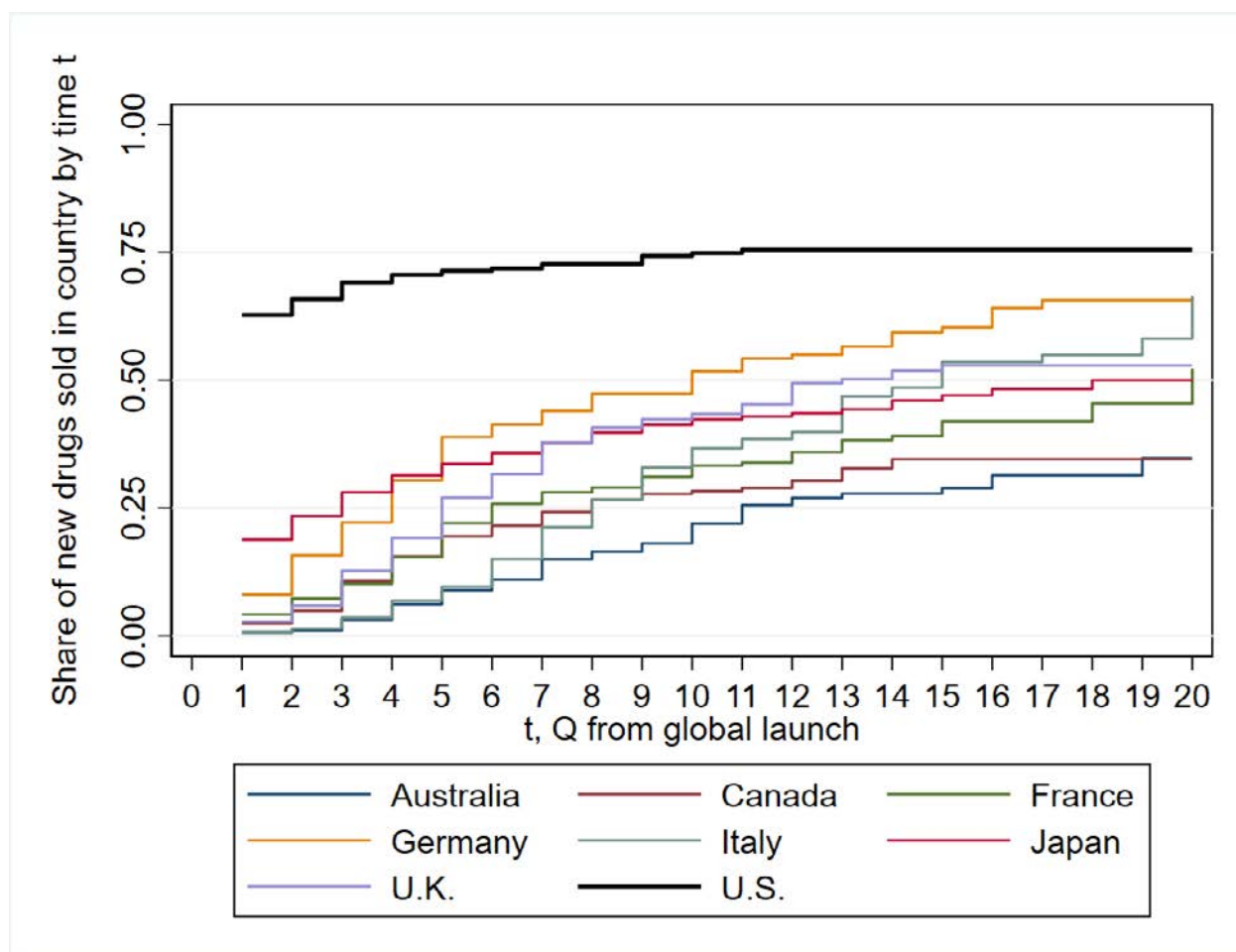


SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: The vertical line through the solid box represents the median rank for each comparison country. The extent of the solid box marks the interquartile range. The whiskers are adjacent values, which are defined as the largest and smallest data points within 1.5 times the interquartile range. The single dot to the left of the whiskers for Germany is an outlier value.

At any given time, the proportion of all new drugs sold in the United States was considerably higher than the proportion sold in other countries (Figure 3.7). Japan had the next-highest likelihood of new drug entry initially but was replaced by Germany about four quarters after initial sales. At the end of the five-year period, the cumulative probability of entry was greater than or equal to 50 percent in France, Germany, Italy, Japan, and the United Kingdom; the share in the United States was roughly 75 percent. Australia was consistently below the other countries shown. Canada, although initially in line with the United Kingdom and France, later lagged behind those other countries and finished on par with Australia at the end of the five-year period.

Figure 3.7. Proportion of New Drugs Sold by Country by Time

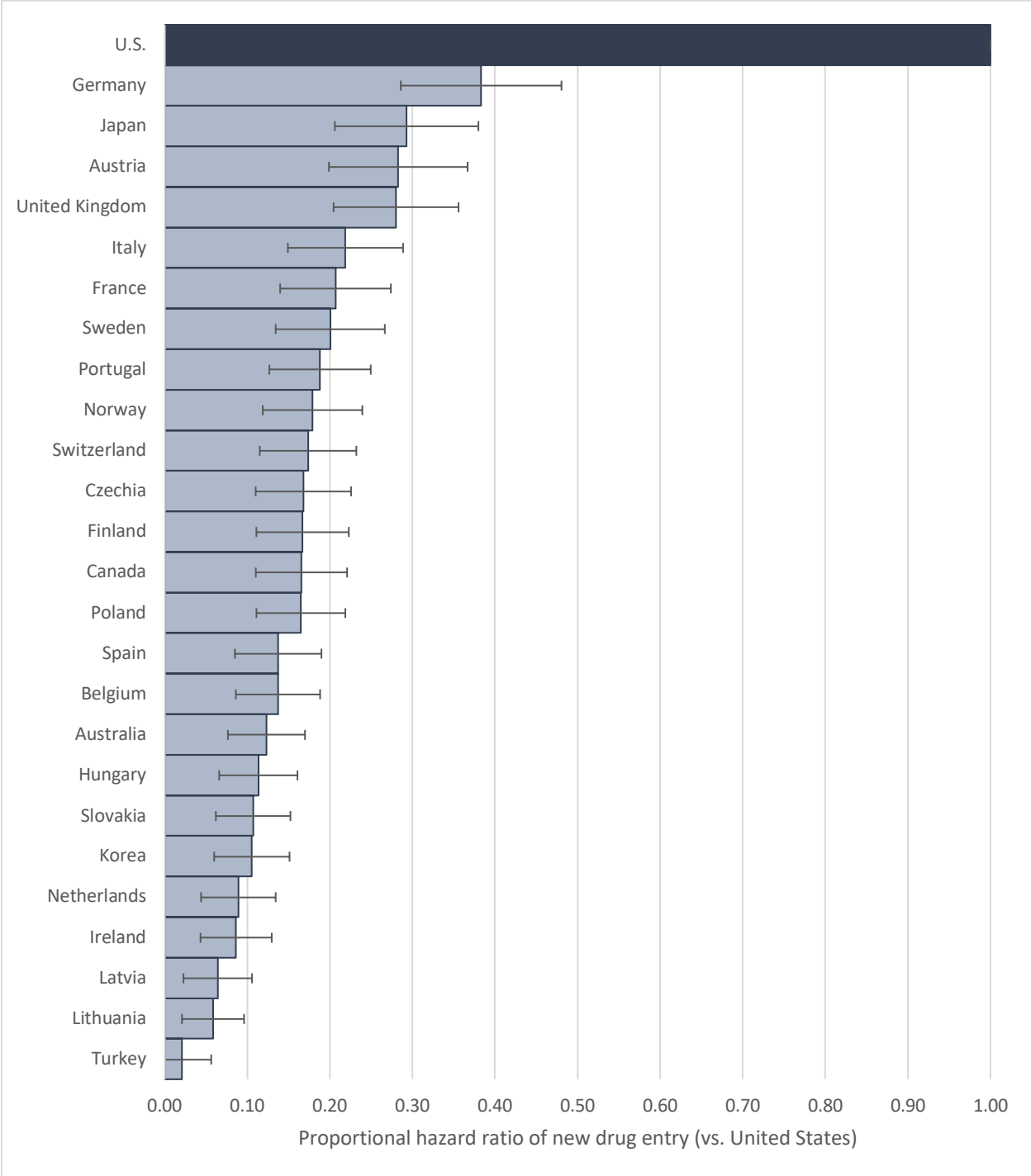


SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: t = time; Q = quarter; U.K. = United Kingdom.

Figure 3.8 presents estimated hazard ratios comparing the likelihood (*hazard*) of a new drug launch at any point in time from the first quarter of 2018 through Q4 2022 in each comparison country versus the United States (with a fixed likelihood of 1 for comparison). The average likelihood of new drug entry at any point in time was 0.38 in Germany relative to the United States at 1. Japan, Austria, the United Kingdom, Italy, France, and Sweden each had an estimated average likelihood of a new drug launch between 0.2 and 0.3 (again relative to the United States fixed at 1). All other countries included in the study had average likelihoods of a new drug launch less than one-fifth of the U.S. rate.

**Figure 3.8. Estimated Average Likelihood of a New Drug Launch, Relative to the United States, in Each Calendar Quarter by Country**



SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).  
 NOTE: Analysis includes all 287 new drugs. Whiskers indicate 95 percent confidence intervals. New Zealand is not included because it did not have entry over the five-year period.

## Chapter 4. Discussion

---

Our study included 287 new drugs first marketed in the United States and/or 26 other OECD countries from 2018 through 2022. We found that over half of new drugs were launched in both the United States and at least one other country by Q4 2022. These new drugs sold both inside and outside the United States accounted for 90.4 percent of U.S. spending and 95.4 percent of other-country spending on new drugs in 2022. Although some new drugs were sold only in the United States, and a larger number were sold only in comparison countries (meaning they were not sold in the United States), these mismatching new drugs represented small shares of spending on new drugs in their respective markets.

We found that over half of new drugs were launched first in the United States, and that the likelihood of launch was on average lower for comparison countries than for the United States. For new drugs sold in both the United States and a comparison country, entry in the United States was typically about one year prior to entry in the comparison country. This average launch timing difference could reflect timing differences in regulatory approval and, in other countries, economic evaluation requirements.<sup>11</sup> It could also reflect business decisions on the part of drug companies to launch first in the United States, where they are able to set list prices freely, prior to the development of regulated launch prices in other countries. For example, several European Union countries reference each other's prices. The result is a complex set of pricing relationships and considerable strategy on the part of manufacturers around launch timing and launch order across countries to maximize prices and revenue.

Our results suggest that the most important new drugs to industry—those with considerable revenue potential—are ultimately sold broadly across multiple countries. Of the top ten new drugs in terms of spending that were sold in the United States and at least one other country, six were sold in 23 or 24 of the 26 total comparison countries by Q4 2022, and another three were sold in 13 to 18 comparison countries. This finding is consistent with the recent finding that all U.S. insulins and the top 50 brand-name drugs by 2020 U.S. net sales were sold in at least four of the six reference countries in the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3, 2019). The international reference pricing bill was passed by the U.S. House of Representatives in 2019, but with no action taken in the Senate (Mulcahy, Whaley, et al., 2021).<sup>12</sup>

---

<sup>11</sup> Regulatory bodies in many countries outside the United States require formal economic evaluations of new drugs. The specific requirements for these reviews vary, but they can include cost-effectiveness analysis, comparisons of a new drug to existing therapies, and analysis relevant to coverage and pricing decisions in other countries. This economic evaluation runs either in parallel to or after regulatory review (which focuses on safety and efficacy).

<sup>12</sup> H.R. 3 was passed in the House on December 16, 2019, and read in the Senate in August 2020 and again in September 2020. It was reintroduced in the House in April 2021.

The Inflation Reduction Act drug price negotiation provisions apply to drugs that have been on the market for seven years (for small-molecule drugs) or 11 years (for biologics). It is unclear whether these provisions will affect the availability of new drugs or launch strategy. The effects of hypothetical, broader policies to address high U.S. brand-name drug prices are difficult to predict. These effects would depend on the responses of manufacturers; nongovernmental U.S. payers, such as employer plans and the PBMs with whom they work; and foreign governments. New strategies would likely evolve gradually, and different manufacturers, payers, PBMs, and foreign governments might take different approaches. However, given the size of the U.S. population (more than twice that of any other OECD country) and its relatively high per capita income, the United States will likely remain a large and important market compared with other, smaller countries, even with lower prices.

## Limitations

There are several limitations to our analysis. First, we used international prescription drug sales data, and we assumed the first observed sale of a drug within a country represented the launch of a new drug in that country. However, the first sales quarter is not necessarily the same quarter in which a drug received marketing approval or was first used by patients. Although we expect that these dates are highly correlated, there may be differences stemming from country-specific regulatory approval, price regulation, use in clinical research, and other factors. Second, sales in IQVIA MIDAS reflect manufacturer prices from invoice audits rather than net prices after off-invoice discounts and rebates, which are not available broadly across drugs and countries. Using sales at manufacturer prices inflates spending, particularly in the United States where rebates and other off-invoice discounts are common. Although this affects our estimates of new drug sales, it does not affect our analyses related to new drug availability or launch timing. Third, although IQVIA MIDAS covers nearly all drugs sold worldwide, some manufacturers choose not to contribute to IQVIA MIDAS in certain markets, resulting in the possible omission of some new drugs entirely or in certain countries. Finally, our descriptive analyses do not address right censoring, and our results would change as additional quarters of data are available. We addressed this concern by focusing on the subset of new drugs approved in 2018 and 2019, where there are at least three years of runout before our study time frame ends, for some analyses. Our formal models of entry over time (that is, results presented in Figures 3.7 and 3.8) do account for right censoring and therefore include all 287 new drugs.

## Conclusions

Although we found that a larger share of new drugs is sold in the United States than in any other country, our results suggest several avenues for further investigation focusing on opportunities to increase access to new drugs in the United States. We found that 26 percent of new drugs (75 of 287 new drugs) were not sold in the United States by Q4 2022; there were

relatively large shares of such drugs available in Japan and South Korea where domestic R&D players and regulatory approval differences may have created a niche market. Although new drugs sold only in other countries but not in the United States tended to account for a small share of other-country sales, Japan and South Korea were an exception, with 36 percent and 54 percent of 2022 new drug spending on drugs not sold in the United States, respectively. Relatedly, some new drugs available in the United States by Q4 2022 were launched earlier in other countries. These later U.S. launches could be due to sponsor business decisions, unanticipated developments during regulatory review (or both), or other factors. These other country-only drugs and earlier launches outside the United States may offer treatment opportunities that are not available to U.S. patients or lower prices from expanded competition. Although our study listed top drugs sold only in other countries (and only in the United States), we did not explicitly assess the clinical benefit or incremental improvement in value from any of these drugs.

We found that most new drugs were sold in both the United States and at least one other country; that these overlapping new drugs accounted for more than 90 percent of spending on new drugs; and that, on average, new drugs were sold in the United States roughly one year earlier than in any other country. Although some new drugs are launched only in the United States, these drugs account for a small share of overall U.S. spending on new drugs and on all prescription drugs. Some new drugs are not available in the United States within five years of their launch elsewhere, but these drugs similarly account for small shares of spending or volume in the countries where they are available.

Our study does not address questions as to the relationship, if any, between revenue and investments in R&D. On the issues of new drug availability and launch timing, however, we found only small differences between the United States and other countries—providing a sharp contrast to the roughly threefold difference in manufacturer net prices for brand-name drugs between the United States and those countries.

## Appendix. Supplemental Results

---

Tables A.1, A.2, and A.3 present selected results for the United States, for all 26 comparison countries combined, and for each of the 26 comparison countries individually, respectively.

**Table A.1. Country-Specific Results, Share of Total Prescription Drug Spending on New Drugs, 2021 and 2022**

	Share of Total Rx Spending on New Drugs, 2021	Share of Total Rx Spending on New Drugs, 2022
United States	9.1%	12.8%
Other countries combined	4.0%	6.9%
Australia	3.6%	10.8%
Austria	4.6%	8.2%
Belgium	2.1%	4.5%
Canada	4.2%	6.9%
Czechia	4.4%	5.3%
Finland	3.4%	5.4%
France	3.5%	6.3%
Germany	6.2%	8.6%
Hungary	2.9%	3.8%
Ireland	1.5%	2.9%
Italy	3.1%	5.9%
Japan	4.1%	8.7%
Korea (South)	1.4%	2.3%
Latvia	2.6%	3.9%
Lithuania	2.0%	3.3%
Netherlands	3.3%	7.3%
New Zealand	0.1%	7.0%
Norway	3.9%	6.7%
Poland	1.3%	2.6%
Portugal	3.1%	6.4%
Slovakia	1.6%	4.0%
Spain	4.3%	6.7%
Sweden	3.2%	5.5%
Switzerland	3.5%	6.0%
Turkey	0.3%	0.5%
United Kingdom	5.2%	7.8%

SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: Other countries combined = the 26 comparison countries (but not the United States) considered as a single aggregate market.

**Table A.2. Country-Specific Results, Counts of Total, U.S.-Only, and Other Country–Only New Drugs, Q4 2022**

	All New Drugs			New Drugs First Sold in 2018 or 2019		
	Total New Drugs Sold by Q4 2022 (count [% of 287 total new drugs])	New Drugs Sold in the United States and Other Country (count [% of country total new drugs])	New Drugs Sold Only in the United States or Other Country, but Not the Other	Total New Drugs Sold by Q4 2022 (count [% of 122 total new drugs])	New Drugs Sold in the United States and Other Country (count [% of country total new drugs])	New Drugs Sold Only in the United States or Other Country, but Not the Other
United States	212 [74%]	164 [77%]	48 [23%]	94 [77%]	82 [87%]	12 [13%]
Other countries combined	239 [83%]	164 [69%]	75 [31%]	110 [90%]	82 [75%]	28 [25%]
Australia	64 [22%]	59 [92%]	5 [8%]	39 [32%]	39 [100%]	0 [0%]
Austria	122 [43%]	108 [89%]	14 [11%]	63 [52%]	60 [95%]	3 [5%]
Belgium	71 [25%]	64 [90%]	7 [10%]	49 [40%]	46 [94%]	3 [6%]
Canada	80 [28%]	76 [95%]	4 [5%]	41 [34%]	41 [100%]	0 [0%]
Czechia	85 [30%]	73 [86%]	12 [14%]	50 [41%]	45 [90%]	5 [10%]
Finland	82 [29%]	75 [91%]	7 [9%]	51 [42%]	49 [96%]	2 [4%]
France	98 [34%]	86 [88%]	12 [12%]	49 [40%]	47 [96%]	2 [4%]
Germany	149 [52%]	129 [87%]	20 [13%]	78 [64%]	72 [92%]	6 [8%]
Hungary	59 [21%]	52 [88%]	7 [12%]	42 [34%]	39 [93%]	3 [7%]
Ireland	47 [16%]	40 [85%]	7 [15%]	33 [27%]	31 [94%]	2 [6%]
Italy	107 [37%]	94 [88%]	13 [12%]	64 [52%]	60 [94%]	4 [6%]
Japan	122 [43%]	75 [61%]	47 [39%]	53 [43%]	40 [75%]	13 [25%]
Korea (South)	56 [20%]	40 [71%]	16 [29%]	36 [30%]	29 [81%]	7 [19%]
Latvia	35 [12%]	31 [89%]	4 [11%]	28 [23%]	25 [89%]	3 [11%]
Lithuania	32 [11%]	25 [78%]	7 [22%]	25 [20%]	20 [80%]	5 [20%]
Netherlands	48 [17%]	45 [94%]	3 [6%]	29 [24%]	28 [97%]	1 [3%]
New Zealand	13 [5%]	13 [100%]	0 [0%]	7 [6%]	7 [100%]	0 [0%]
Norway	87 [30%]	80 [92%]	7 [8%]	52 [43%]	50 [96%]	2 [4%]
Poland	83 [29%]	75 [90%]	8 [10%]	51 [42%]	48 [94%]	3 [6%]
Portugal	94 [33%]	84 [89%]	10 [11%]	52 [43%]	47 [90%]	5 [10%]
Slovakia	56 [20%]	47 [84%]	9 [16%]	41 [34%]	35 [85%]	6 [15%]
Spain	71 [25%]	63 [89%]	8 [11%]	49 [40%]	46 [94%]	3 [6%]
Sweden	95 [33%]	87 [92%]	8 [8%]	52 [43%]	51 [98%]	1 [2%]
Switzerland	85 [30%]	77 [91%]	8 [9%]	49 [40%]	47 [96%]	2 [4%]
Turkey	12 [4%]	10 [83%]	2 [17%]	12 [10%]	10 [83%]	2 [17%]
United Kingdom	122 [43%]	108 [89%]	14 [11%]	62 [51%]	60 [97%]	2 [3%]

SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: Other countries combined = the 26 comparison countries (but not the United States) considered as a single aggregate market.



**Table A.3. Country-Specific Results, Share of U.S.-Only or Other Country–Only New Drugs by Count and Spending, 2021 and 2022**

	Share of New Drugs Sold Only in the United States or Other Country		Share of Spending on New Drugs Sold Only in the United States or Other Country	
	2021	2022	2021	2022
United States	21.3%	22.7%	4.6%	9.6%
Other countries combined	33.5%	32.2%	9.2%	7.5%
Australia	5.1%	6.6%	0.1%	0.1%
Austria	10.7%	10.7%	3.5%	3.9%
Belgium	12.2%	9.9%	1.8%	3.0%
Canada	3.5%	5.1%	0.0%	0.3%
Czechia	12.0%	13.2%	1.6%	2.6%
Finland	9.3%	7.4%	0.4%	0.6%
France	13.4%	12.4%	5.7%	4.0%
Germany	14.7%	13.0%	2.8%	3.9%
Hungary	9.5%	12.3%	1.1%	1.2%
Ireland	15.4%	16.3%	0.8%	1.3%
Italy	13.4%	11.3%	0.8%	1.3%
Japan	40.9%	39.2%	35.8%	24.7%
Korea (South)	36.8%	28.6%	54.1%	48.6%
Latvia	22.2%	11.8%	17.1%	12.3%
Lithuania	25.0%	17.9%	14.2%	9.5%
Netherlands	12.0%	6.5%	0.1%	0.1%
New Zealand	0.0%	0.0%	0.0%	0.0%
Norway	8.8%	8.3%	2.4%	5.5%
Poland	12.2%	11.4%	1.2%	1.5%
Portugal	9.1%	10.6%	1.2%	1.8%
Slovakia	16.7%	13.7%	1.3%	1.0%
Spain	13.3%	11.3%	0.7%	1.0%
Sweden	10.0%	8.5%	0.1%	1.3%
Switzerland	5.5%	8.4%	0.3%	0.3%
Turkey	14.3%	16.7%	6.5%	5.4%
United Kingdom	10.2%	10.8%	0.5%	1.6%

SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

**Table A.4. Country-Specific Results, Time in Quarters from U.S. to Other-Country Launch of 2018 and 2019 New Drugs**

	<b>Number of New Drugs Contributing to Analysis</b>	<b>Minimum</b>	<b>25th Percentile</b>	<b>Median</b>	<b>75th Percentile</b>	<b>Maximum</b>
Australia	39	-1	4	7	10	18
Austria	60	-9	2	4	5.5	14
Belgium	46	2	5	9	11	16
Canada	41	0	2	4	7	13
Czechia	44	-7	4.5	6.5	9	17
Finland	49	-5	3	6	9	17
France	46	-1	3	4	9	17
Germany	72	-9	2	4	8	16
Hungary	39	-9	4	6	10	18
Ireland	29	2	4	9	12	14
Italy	60	-2	5.5	7.5	12	19
Japan	39	-10	0	3	7	15
Korea (South)	29	3	5	10	12	19
Latvia	25	-5	5	6	10	17
Lithuania	20	2	4.5	7.5	11	14
Netherlands	28	1	3.5	6.5	11	16
New Zealand	5	2	5	8	10	15
Norway	50	-3	3	5	9	15
Poland	45	-3	3	6	12	17
Portugal	47	-8	5	7	11	18
Slovakia	35	-4	5	7	10	15
Spain	46	1	5	8	11	14
Sweden	51	0	3	4	9	16
Switzerland	47	-5	4	6	8	17
Turkey	10	4	10	12	13	15
United Kingdom	59	-2	2	4	7	14

SOURCE: Analysis of 2017–2022 data from IQVIA, undated (run date: May 19, 2023).

NOTE: “Number of new drugs contributing to analysis” is the number of new drugs (1) first launched globally in 2018 or 2019 and (2) launched in both the indicated country and the United States by Q4 2022. We found 122 new drugs first launched globally in 2018 or 2019.

## Abbreviations

---

CAR	chimeric antigen receptor
CBO	Congressional Budget Office
FDA	U.S. Food and Drug Administration
IRA	Inflation Reduction Act of 2022
OECD	Organisation for Economic Co-operation and Development
PBM	pharmacy benefit manager
Q4	quarter 4
R&D	research and development

## References

---

- Adams, Christopher, and Evan Herrstadt, “CBO’s Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act,” Working Paper 2021-01, Congressional Budget Office, February 2021.
- Australian Government, Department of Health and Aged Care, “MOUNJARO Tirzepatide 15 mg/0.5 mL Solution for Injection Pre-Filled Pen,” December 23, 2022.
- CBO—*See* Congressional Budget Office.
- Centers for Medicare & Medicaid Services, “Most Favored Nation Model,” webpage, undated. As of August 1, 2023:  
<https://innovation.cms.gov/innovation-models/most-favored-nation-model>
- Congressional Budget Office, “Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act,” December 10, 2019.
- Congressional Budget Office, “Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation, as Posted by the Senate Committee on Finance on July 6, 2022,” revised July 13, 2022.
- Council of Economic Advisors, “*Reforming Biopharmaceutical Pricing at Home and Abroad*,” white paper, February 2018.
- Danzon, Patricia M., and Andrew J. Epstein, “Effects of Regulation on Drug Launch and Pricing in Interdependent Markets,” in Kristian Bolin and Robert Kaestner, eds., *The Economics of Medical Technology*, Vol. 23, Emerald Group Publishing Limited, 2012.
- Danzon, Patricia M., Y. Richard Wang, and Liang Wang, “The Impact of Price Regulation on the Launch Delay of New Drugs—Evidence from Twenty-Five Major Markets in the 1990s,” *Health Economics*. Vol. 14, No. 3, 2005.
- Downing, Nicholas S., Audrey D. Zhang, and Joseph S. Ross, “Regulatory Review of New Therapeutic Agents—FDA Versus EMA, 201—2015,” *New England Journal of Medicine*, Vol. 376, No. 14, 2017.
- “Eli Lilly and Mitsubishi Tanabe Launch New Diabetes Treatment in Japan,” *BioSpectrum Asia*, April 21, 2023.
- The Exchange [@CNBCTheExchange], “The first ever Medicare drug price negotiation will come with unintended consequences warns @ScottGottliebMD . . .,” post on the X platform, August 29, 2023. As of September 4, 2023:  
<https://twitter.com/CNBCTheExchange/status/1696606430868934910>

FDA—See U.S. Food and Drug Administration.

Government of Canada, “Drug Health Product Submissions Under Review (SUR): New Drug Submissions Completed,” webpage, undated. As of September 18, 2023:

<https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review/new-drug-submissions-completed.html>

Haninger, Kevin, “Setting the Record Straight on International Reference Pricing,” PhRMA, July 16, 2019.

Houy, Nicolas, and Izabela Jelovac, “Drug Launch Timing and International Reference Pricing,” *Health Economics*, Vol. 24, No. 8, 2015.

IQVIA, “MIDAS,” webpage, undated. As of May 19, 2023:

<https://www.iqvia.com/solutions/commercialization/geographies/midas>

Kanavos, Panos, Alessandra Ferrario, Sotiros Vandoros, Gerard F. Anderson, “Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs,” *Health Affairs*, Vol. 32, No. 4, 2013.

Kyle, Margaret K., “The Role of Firm Characteristics in Pharmaceutical Product Launches,” *RAND Journal of Economics*, Vol. 37, No. 3, 2006.

Lanjouw, Jean O., “Patents, Price Controls, and Access to New Drugs: How Policy Affects Global Market Entry,” National Bureau of Economic Research, May 2005.

Mulcahy, Andrew W., Daniel Schwam, and Susan L. Lovejoy, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, RAND Corporation, RR-A788-3, 2023.

Mulcahy, Andrew W., Daniel Schwam, Preethi Rao, Stephanie Rennane, and Kanaka Shetty, “Estimated Savings from International Reference Pricing for Prescription Drugs,” *JAMA*, Vol. 326, No. 17, 2021.

Mulcahy, Andrew W., Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, and Alejandro U. Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corporation, RR-2956-ASPEC, 2021. As of August 1, 2023:  
[https://www.rand.org/pubs/research\\_reports/RR2956.html](https://www.rand.org/pubs/research_reports/RR2956.html)

Office of Management and Budget, “The President’s FY 2022 Discretionary Request,” April 9, 2021.

PhRMA, “Government-Mandated Price Controls Harm Patients and Undermine Innovation,” fact sheet, July 17, 2019.

PhRMA, “Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments,” response to solicitation of comments, April 14, 2023.

Public Law 117-169, Inflation Reduction Act of 2022, 2022.

Sayed, Bisma A., Kenneth Finegold, T. Anders Olsen, Kaavya Ashok, Sarah Schutz, Steven Sheingold, Nancy De Lew, and Benjamin D. Sommers, “Inflation Reduction Act Research Series: Medicare Part D Enrollee Out-of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act,” Office of the Assistant Secretary for Planning and Evaluation, July 6, 2023.

U.S. Food and Drug Administration, “Approved Cellular and Gene Therapy Products,” webpage, undated. As of May 19, 2023:  
<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>

Varol, Nebibe, Joan Costa-Font, and Alistair McGuire, “Do International Launch Strategies of Pharmaceutical Corporations Respond to Changes in the Regulatory Environment?” in Alistair McGuire and Joan Costa-Font, eds., *The LSE Companion to Health Policy*, Edward Elgar Publishing, 2012.

Verniers, Isabel, Stefan Stremersch, and Christophe Croux, “The Global Entry of New Pharmaceuticals: A Joint Investigation of Launch Window and Price,” *International Journal of Research in Marketing*, Vol. 28, No. 4, 2011.