Cornell University

Pharmaceutical and Biotech Policy Issues

PUBPOL 2350

October 31, 2023

JOIN THE CORNELL DEMOCRATS FOR

A CONVERSATION WITH CORNELL ALUM JENNY YANG

CORNELLDEMS

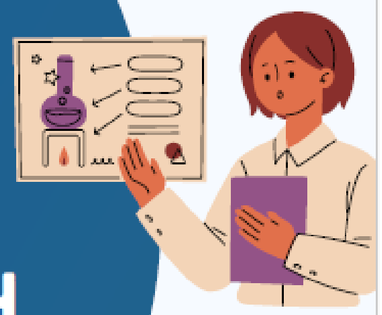
Deputy Director of the Domestic Policy Council for Racial Justice & Equity

November 3, 2023
Goldwin Smith Hall 142
5:30PM-6:30PM

REGISTER HERE:

Cornell University

THE COLLEGE OF HUMAN ECOLOGY'S DEAN UNDERGRADUATE ADVISORY COUNCIL PRESENTS...



CORNELL HUMAN ECOLOGY UNDERGRADUATE RESEARCH CAREER FAIR

JOIN US FOR A SHOWCASE OF HUMAN ECOLOGY-FOCUSED RESEARCH.

TALK TO LAB REPRESENTATIVES + LEARN ABOUT AVAILABLE RESEARCH POSITIONS WITHIN HUMAN ECOLOGY.

PERFECT TO DEVELOP A FOUNDATION FOR YOUR RESEARCH CAREER.

WHEN :
NOVEMBER 7, 2023
TUESDAY

WHERE:
MVR COMMONS

PLEASE RVSP USING THE QR CODE PROVIDED. LIMITED SPOTS AVAILABLE

BIG RED THON

BIG RED THON
DANCE MARATHON

Big Red Thon is Cornell's largest student-run non-profit organization!

We raise funds for Children's Miracle Network Hospitals, specifically Upstate Golisano (right here in New York!) to help provide kids with lifesaving treatments and the best quality care.

Every year, we host an annual **DANCE MARATHON** at Barton Hall as our main fundraising event, with games, prizes, food, and more! Your participations and contributions go directly to Upstate Golisano, so sign up now to show your support and save your spot at the event!

SCAN ME

REGISTER FOR THE EVENT!

WHEN: SATURDAY, NOVEMBER 11TH, 2-7PM

WHERE: BARTON HALL (CENTRAL CORNELL CAMPUS)

EMAIL US AT BIGREDTHON@GMAIL.COM

SCAN BELOW TO REGISTER!

Global Health

EXPERIENTIAL LEARNING SYMPOSIUM

Hosted by the GHSAB and DNS

FRIDAY, NOV 3RD

Physical sciences Building

4:30 PM - 6:00 PM

At the Experiential Learning Symposium you'll:

- Learn about students' ELOs
- Participate in the Health Humanities Contest

THE GLOBAL HEALTH STUDENT ADVISORY BOARD PRESENTS:
THE THIRD ANNUAL

HEALTH HUMANITIES CONTEST

2023 THEME: TOPICS IN GLOBAL AND PUBLIC HEALTH

HELD AT THE 2023 EXPERIENTIAL LEARNING SYMPOSIUM

NOVEMBER 3, 2023 FROM 4:30 - 6:00 PM AT THE PHYSICAL SCIENCES BUILDING (PSB) SOUTH PASSAGEWAY AND CLARK ATRIUM

DEADLINE: OCTOBER 30TH AT 11:59 PM

Application and guidelines here:

NOVEMBER 1ST, 2023 AT 6:30 PM
ROCKEFELLER 104

GRADUATE SCHOOL DEMYSTIFIED: HUMANITIES

Meet current Cornell Graduate Students in the Humanities and Social Sciences Fields

Learn about applying to and attending grad school!
Ask your own questions!

Contact Eva Weiner (ekw43) and Daniel Zhang (drz23) with any questions

CORNELL UNDERGRADUATE RESEARCH BOARD
CURB
Established in 1985

Cornell Brooks
Public Policy

Are you enjoying this course?

The Brooks School may be right for you!

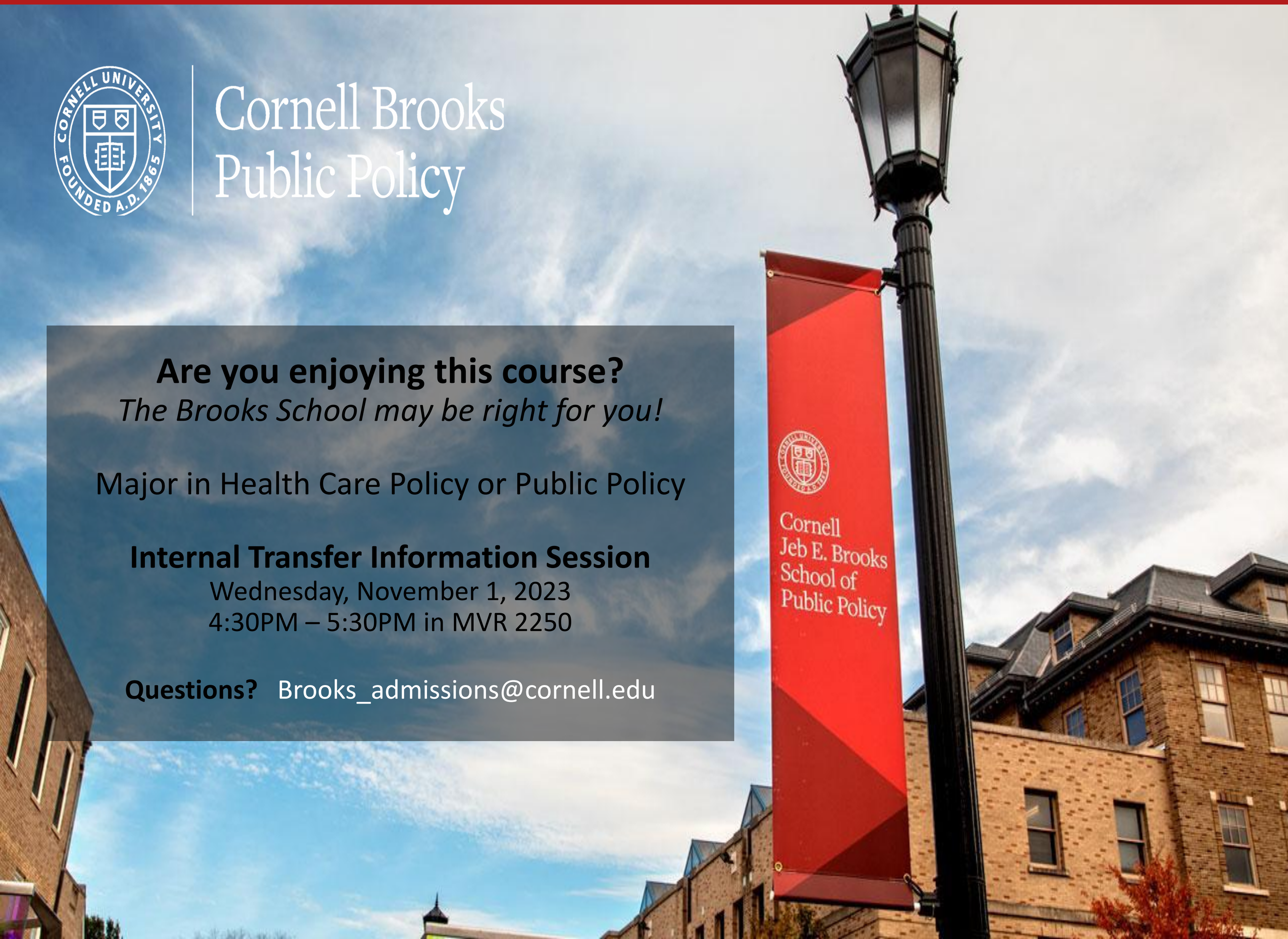
Major in Health Care Policy or Public Policy

Internal Transfer Information Session

Wednesday, November 1, 2023

4:30PM – 5:30PM in MVR 2250

Questions? Brooks_admissions@cornell.edu

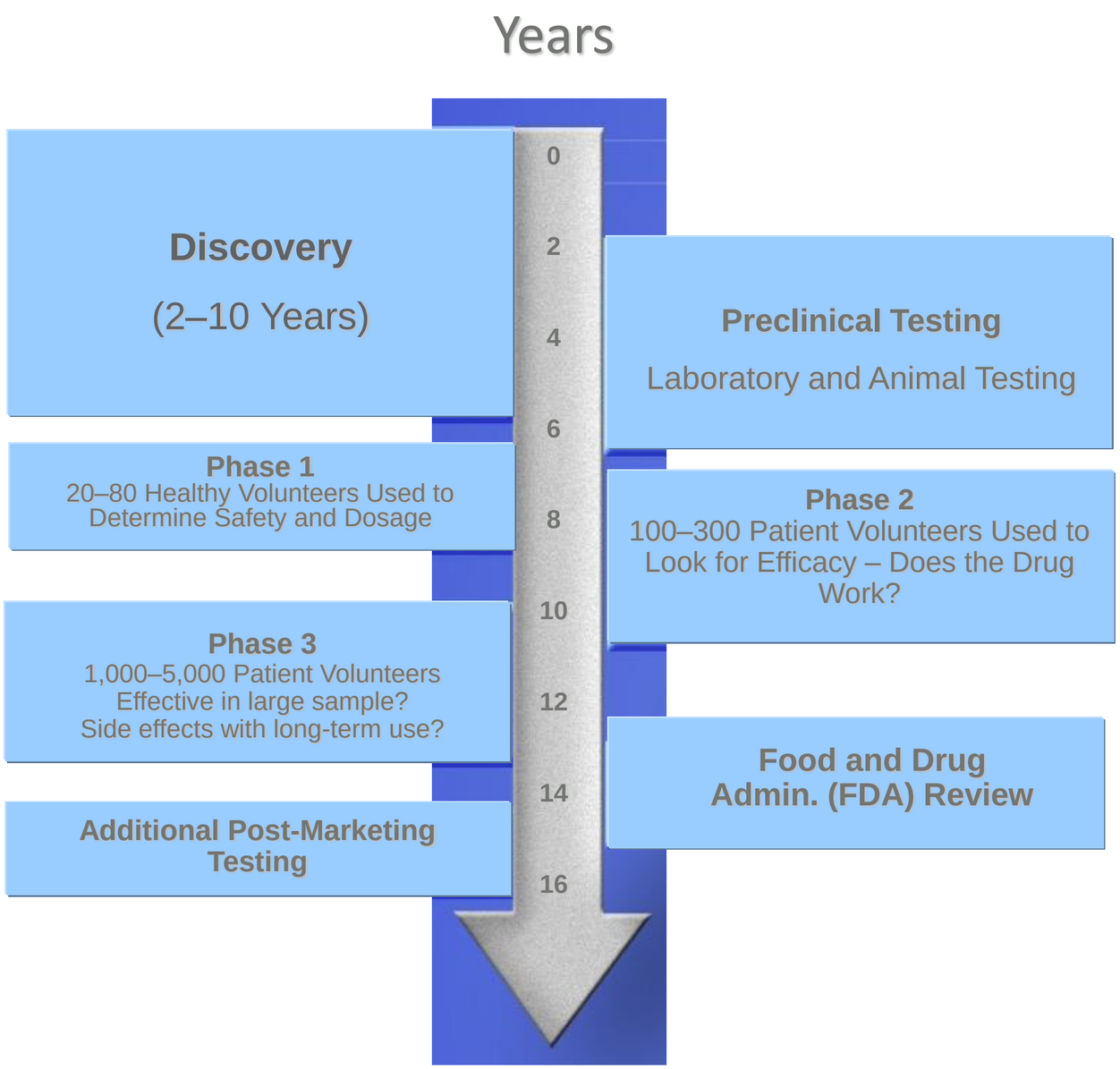


Today's Topics

1. **Development and Approval:** Discuss how new drugs are developed. How long does it take and how much money is required, on average?
2. **What happens when a drug patent expires and generic firms enter?**
3. **Marketing:** Why do biotech and pharmaceutical firms spend so much money marketing drugs?
4. **Drug Prices**: Why are prescription drug prices so much lower in other high-income countries than in the U.S.?
5. **Policies to Reduce U.S. Drug Prices**: discuss the impact of allowing the U.S. government (Medicare) negotiate drug prices with biopharmaceutical firms, beginning in 2026.

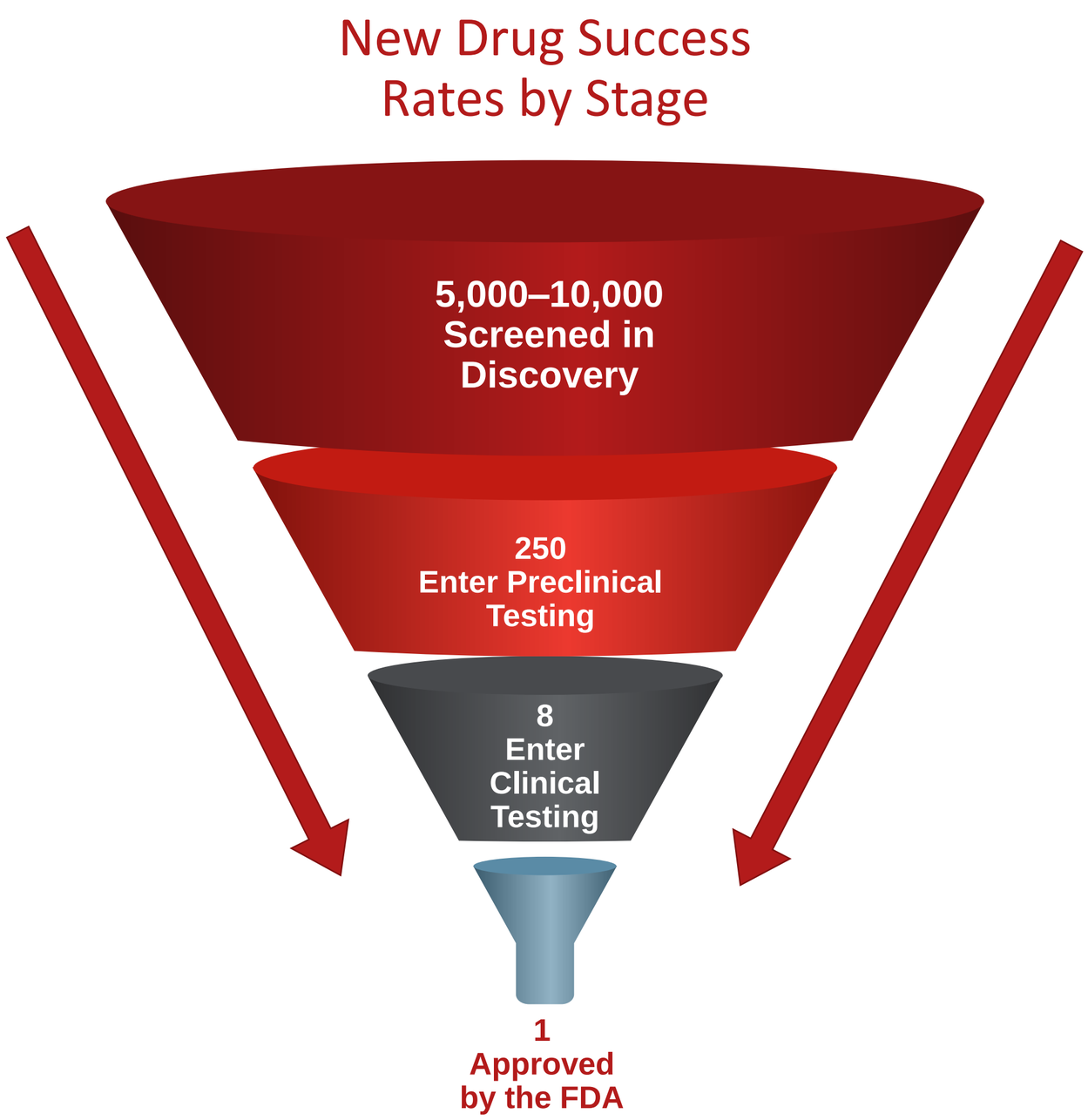
Developing a New Drug is a Long, Uncertain, and Expensive Proposition: Typical Timeline

Drug Development Timeline



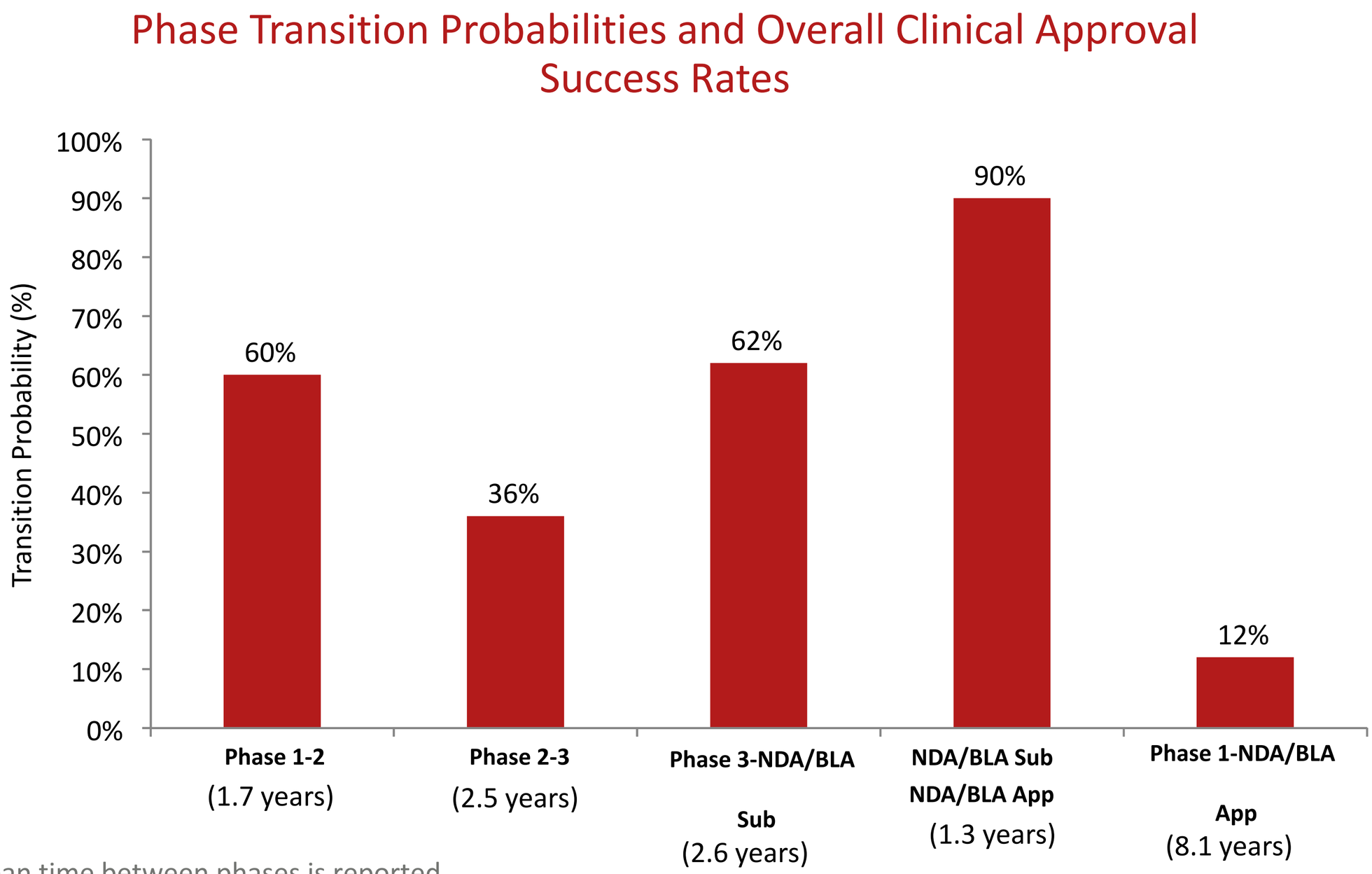
Source: PhRMA Pharmaceutical Industry Profile 2003, Chapter 1: Increased Length and Complexity of the Research and Development Process. DiMasi, JA, Hansen, RW, Grabowski, HG. “The Price of Innovation: new estimates of drug development costs.” *Journal of Health Economics*. 2016.

Developing a New Drug is a Long, Uncertain, and Expensive Proposition: Success by Stage



Source: PhRMA Pharmaceutical Industry Profile 2003, Chapter 1: Increased Length and Complexity of the Research and Development Process. DiMasi, JA, Hansen, RW, Grabowski, HG. “The Price of Innovation: new estimates of drug development costs.” *Journal of Health Economics*. 2016.

12% of Drugs That Start Phase 1 are Approved, and it Takes an Average of 8 Years (same % with more recent data)



Note: Mean time between phases is reported in (parentheses)

Source: DiMasi et al. 2016.

Drug Development Case Study: Eli Lilly Was Ready to Test Mounjaro in a Phase 3 Type-2 Diabetes Trial in 2019

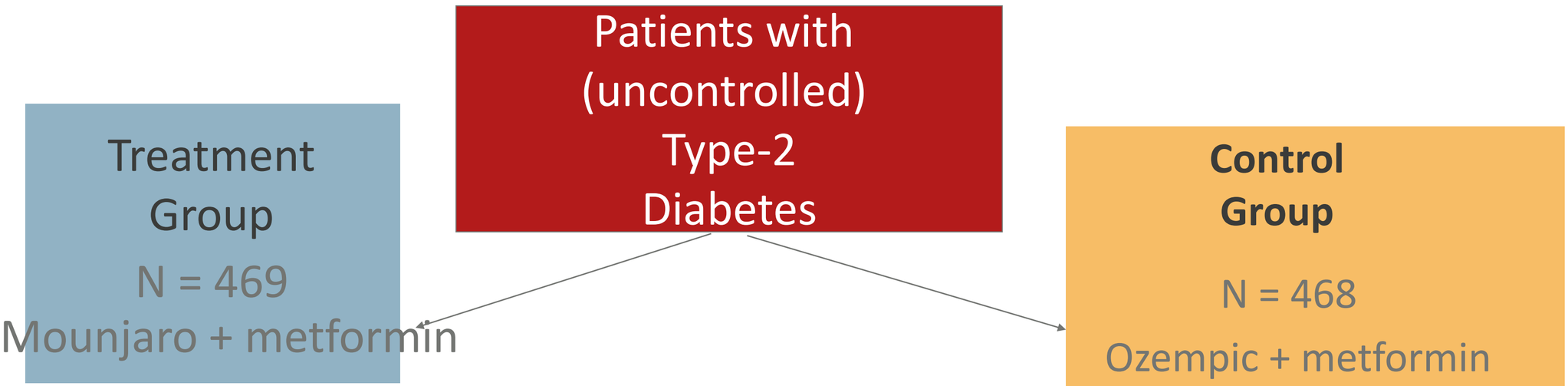
- Most Type-2 diabetes patients take a generic drug, metformin, by itself or in combination with another drug from a different class with a different mechanism of action (+ exercise and healthy diet).

- However, many patients still do not meet the recommended blood sugar level (i.e., an HbA1c lab test level of less than 7.0).

- Mounjaro (brand name) is a GLP-1 receptor agonist that helps revive insulin secretion.

- “Tirzepatide (scientific/generic name) lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes” (from Mounjaro’s FDA-approved label).

Mounjaro's Phase 3 Randomized Controlled Trial (RCT)



Primary Endpoint

Secondary endpoint

Efficacy:		
- Reduction in HbA1c	2.3	1.8
- % patients hitting 7.0	86%	79%
- Pounds lost	28	13
% of patients with:		
- Abdominal pain	5%	4%
- Diarrhea	18%	9%
- Nausea	17%	4%
- Vomiting	9%	2%

In 4 separate trials, Monjaro was compared w/o metformin vs. a placebo; and separately versus 3 insulin drugs.

1) Should the Food and Drug Administration (FDA) approve Mounjaro?

2) What decision rule does the FDA use?

How the FDA Makes Approval Decisions

FDA's decision rule:
Are the health benefits (actual or expected) better than or same as the control group?

If so, do the health benefits outweigh the possible side effects or safety issues?

Phase 4 Studies

The FDA often mandates Phase 4 (post-approval) studies as a condition for approval, to explore whether safety issues in a RCT persist in a broader patient population.

NOT Prices

The FDA does not consider the drug's price. Ditto with European regulatory bodies.

FDA Approves a Drug for an Indication, Not a Drug

INDICATIONS AND USAGE

MOUNJARO® is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. (1)

Limitations of Use:

- Has not been studied in patients with a history of pancreatitis (1, 5.2)
- Is not indicated for use in patients with type 1 diabetes mellitus (1)

Mounjaro's Approved Label

Physicians can use a drug "off-label" once it is approved.

- Mounjaro for Type-1 diabetes, for example
- Mounjaro for weight loss for non-Type-2 diabetes patients, for example

But pharmaceutical firms cannot market off-label, and health insurers are more likely to refuse to pay when a drug is used off-label (or require prior authorization before agreeing to pay).

About 20% of Prescriptions Are for Off-Label Uses, and a Majority for Some Drugs

Off-Label Prescription Efficacy

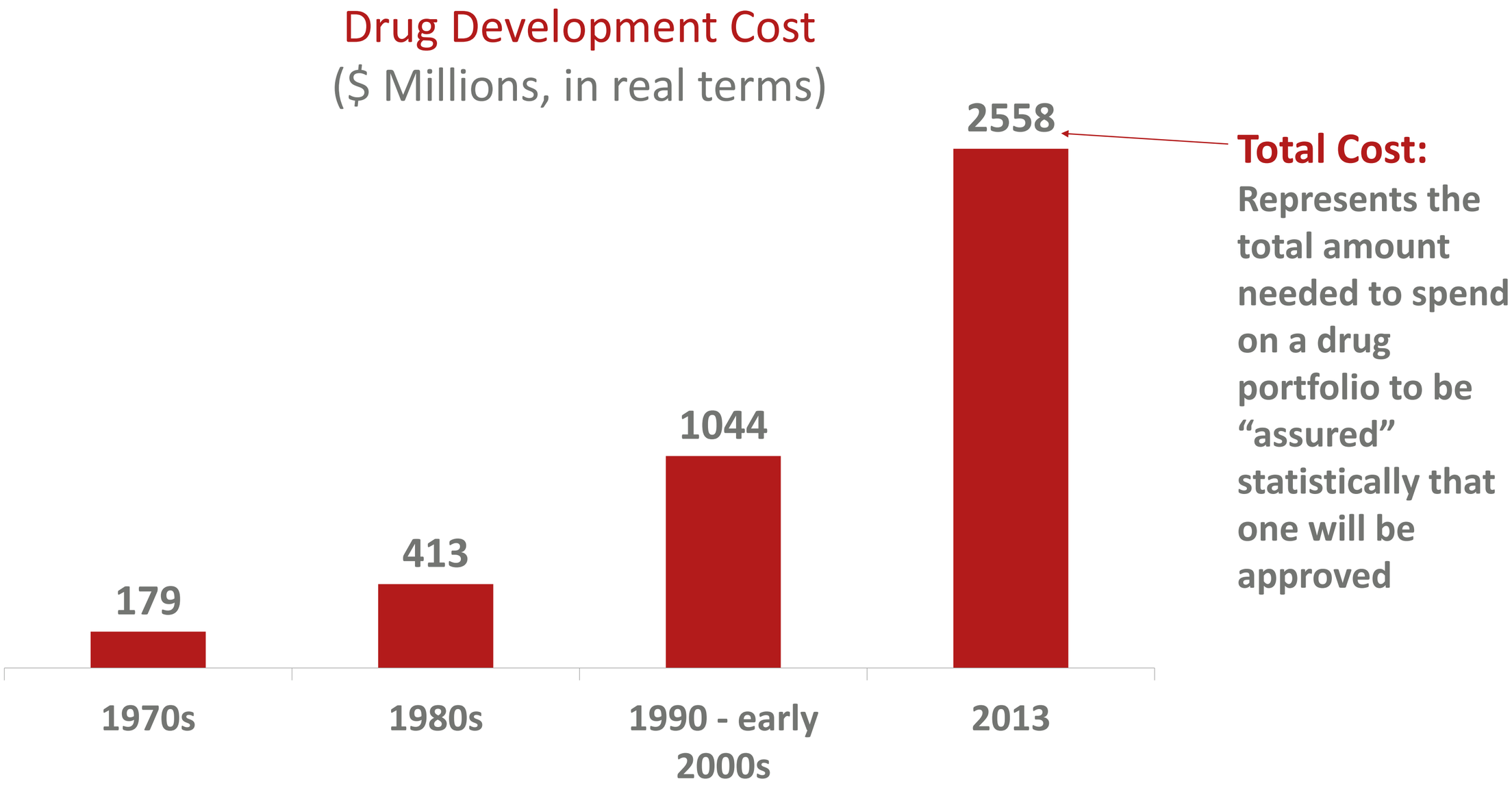
Only 30% of off-label prescriptions were supported by evidence of clinical efficacy (e.g., results from a published study after the drug was approved).

Physician Determination of On- vs Off-Label

In a separate survey of 1,200 physicians, only 55% could correctly determine whether or not a particular use of a drug was on-label (supported by RCT evidence) or off-label.

Source: Pan, *Clinical Pharmacology & Therapeutics*, May 2012.

Why Are Biotech and Pharmaceutical Firms Willing to Spend So Much to Develop a New Drug?

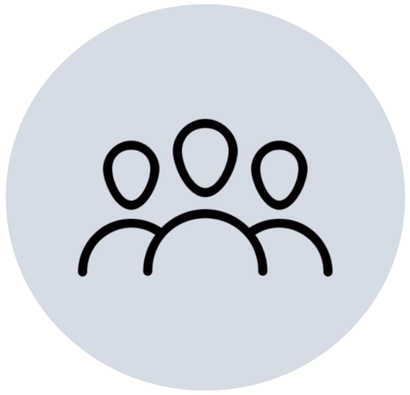


Source: DiMasi et al., 2016, *Journal of Health Economics*.

Patents Allow a Firm to Recover R&D Costs; Expiration Triggers Fierce Competition

Generic Protection

Patents **prevent other firms from producing a generic**, or bioequivalent, copy of a drug for the 20-year life of a patent.



Bioequivalent Competitors

Without patent protection, any firm could take a drug the day it is approved by the FDA and **"reverse-engineer"** it. They could sell a bioequivalent version of the drug **without having invested** millions of dollars developing it.

Competitive Pricing

Multiple firms in competition would **lead to drug prices close to production cost**, meaning research and development (R&D) costs couldn't be recouped.

Patent Pricing

Patents allow a firm to **charge a price above the cost of producing** the drug to make a profit and recoup R&D costs.

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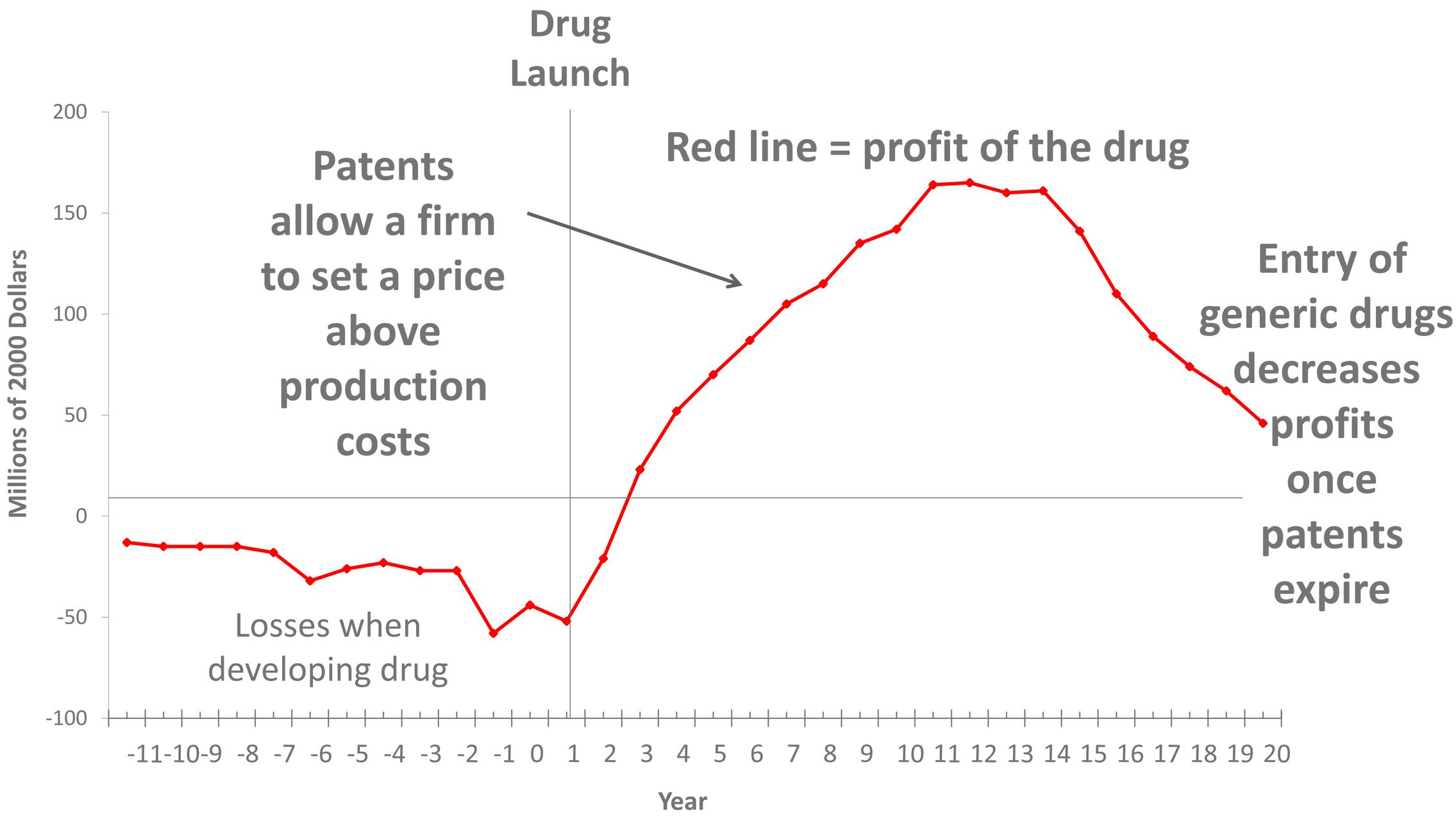
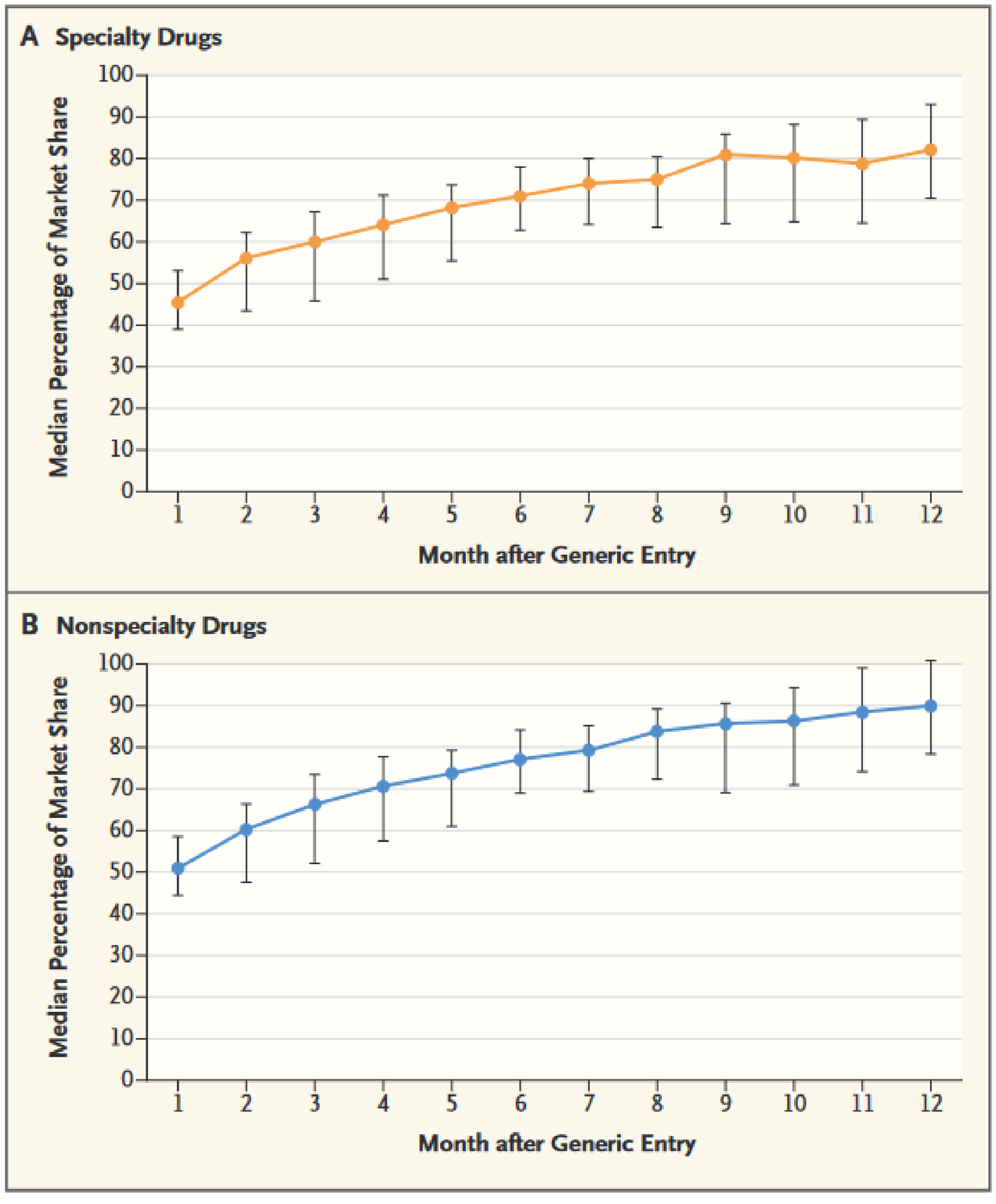
https://www.iconfinder.com/iconsets/security-double-colour-blue-black-vol-3

Product Life Cycle: Revenue Grows Steadily Over an Extended Time, Then Falls Precipitously



Source: DiMasi and Grabowski, 2012.

Once Patents Expire Generic Versions Enter and 97% of Patients Eventually Shift From the Branded to a Generic Product



Generic Market Share in Medicare Part D by Month after Generic Entry for Specialty and Nonspecialty Drugs, 2014–2019.

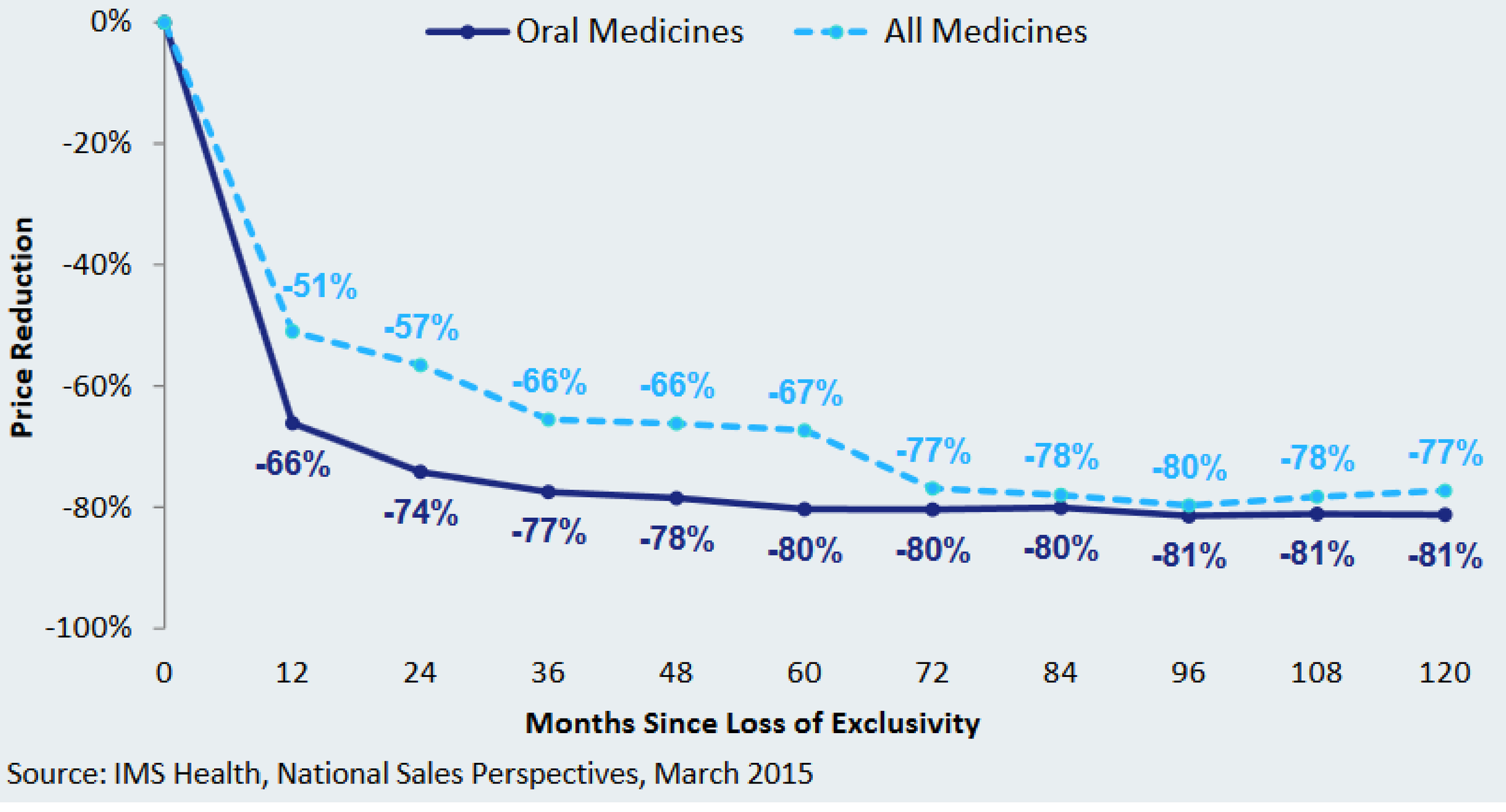
Loss Drivers for <u>Branded Drug</u>

- Automatic substitution at pharmacy
- Health insurers set lower co-pays for generic versus branded drugs

Source: Dusetzina et al., 2023

Generics Cut the Price Substantially Once They Enter

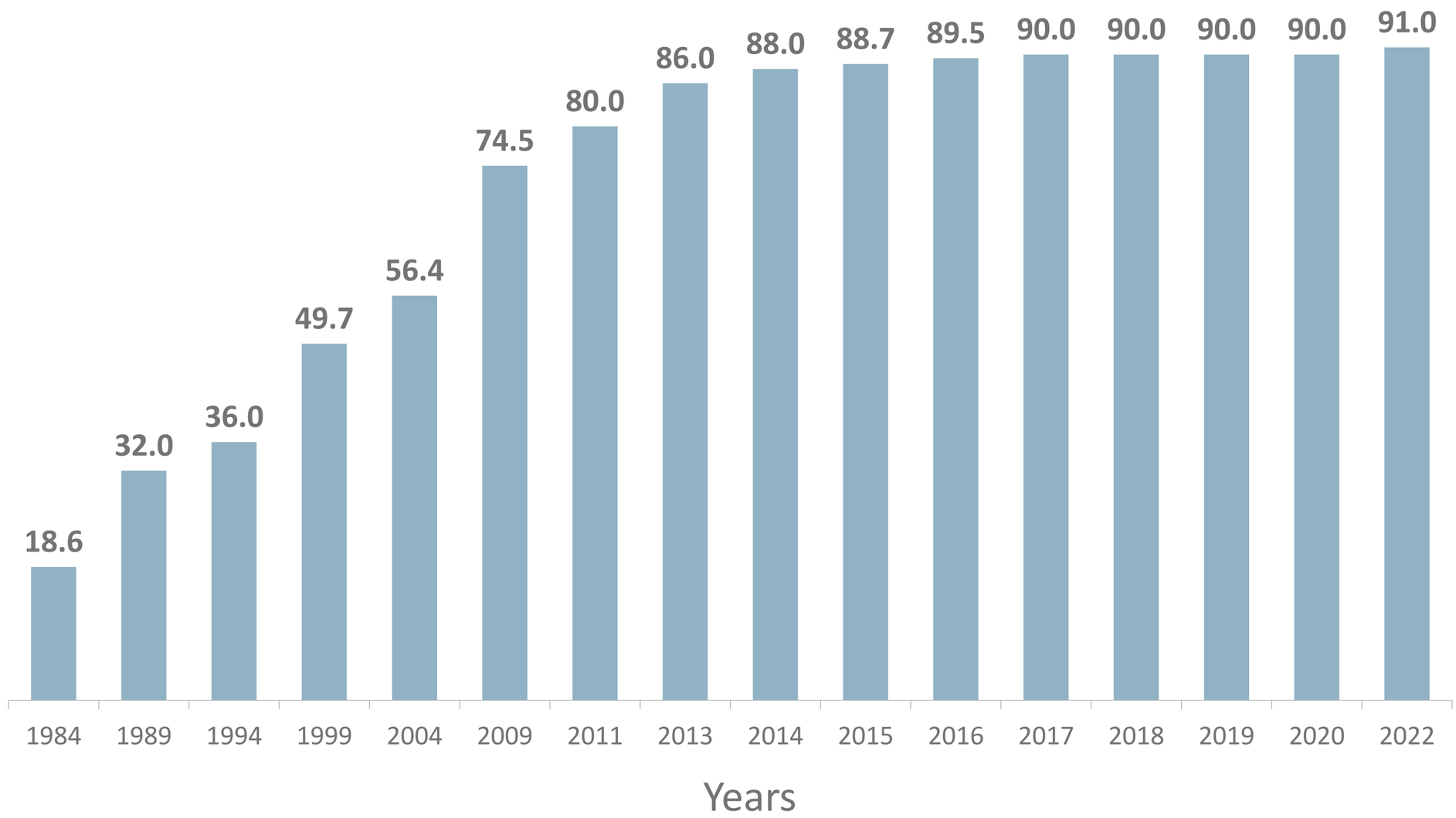
Monthly Price Reductions after Loss of Exclusivity



Source: IMS Health, National Sales Perspectives, March 2015

Generic Drugs Now Account for 91% of Prescriptions Filled (but a Much Smaller % of Pharma Spending)

Generic Share of Total Prescriptions, 1984-2022



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Sources: For 1984-2004, IMS Health National Prescription Audit archives; for 2005-2009, IMS Health National Sales Perspectives; 2010-2012, IMS; GPHA, 2015; for 2018, IQVIA Medicine Use and Spending in the U.S., May 2019.

Patents Do Not Provide “Perfect” Monopolies

Patents provide a (temporary) monopoly on a compound, not a monopoly on treating a health condition

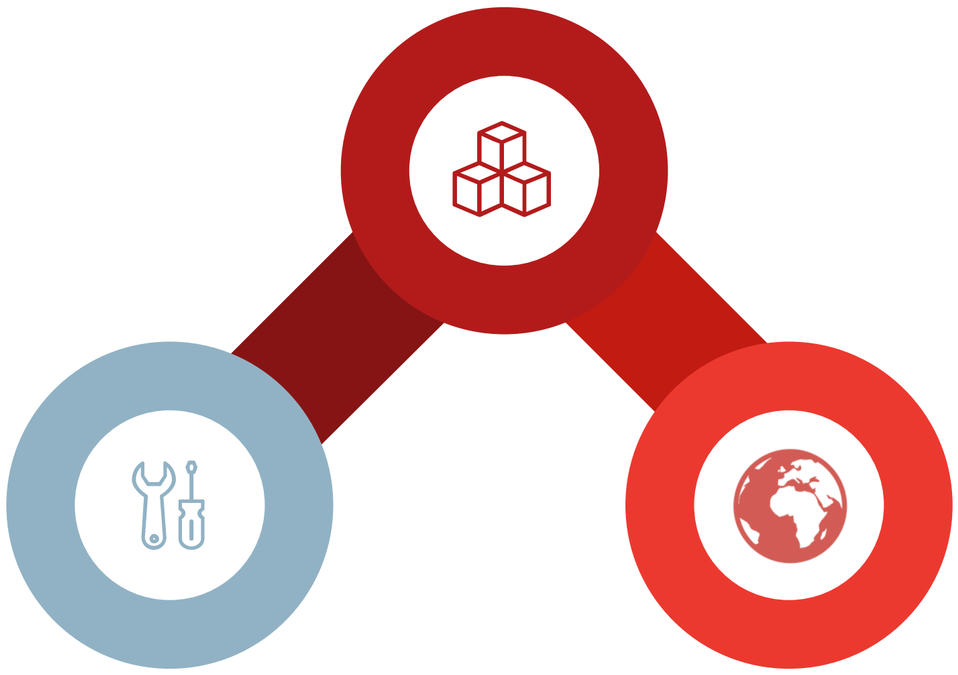
Same-Disease Competition

A company with a patent usually competes against other molecules that treat the same disease:

- Other patent-protected molecules
- Some molecules that are now generic

Alternative Treatment Choices

Some people with a health condition may decide not to be treated, or to be treated without pharmaceuticals

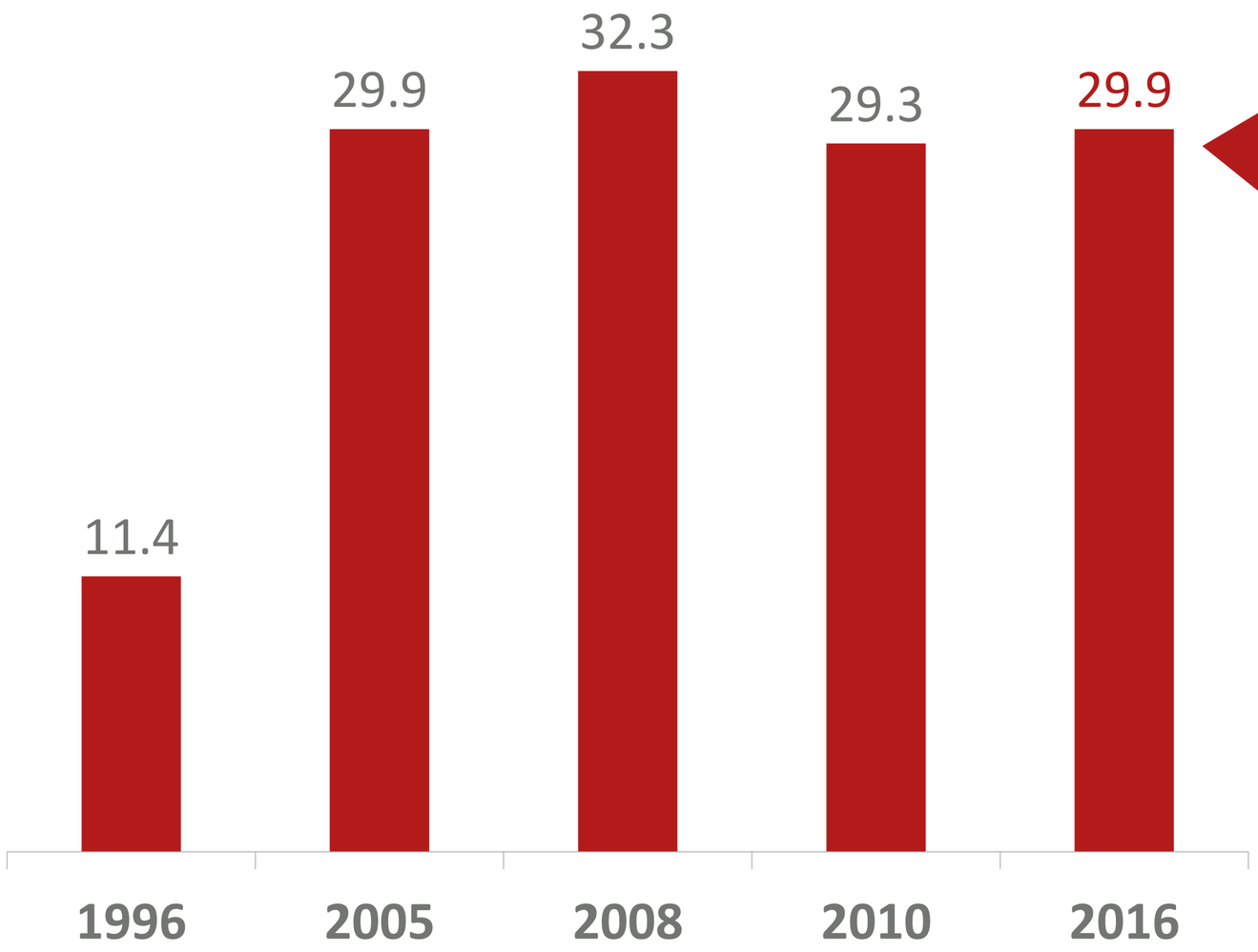


International Enforcement

U.S. patents are not always enforced abroad

Marketing Spending Has Declined in Past Decade But Is Still Focused on Physicians, Not Patients

Industry Spending, $ Billions



	$ Billions
Detailing	$5.6
Samples	$13.5
MD Meetings	$1.0
Direct-to-consumer advertising	$9.6
Other	$0.2
Total	**$29.9**

Source: SK&A, 2012 U.S. Pharmaceutical Promotion Spending; Schwartz and Woloshin, JAMA, 2019.

What is Detailing?

John Oliver’s Take

Why Do Pharmaceutical Firms Spend $30 Billion Per Year on Marketing/Advertising?

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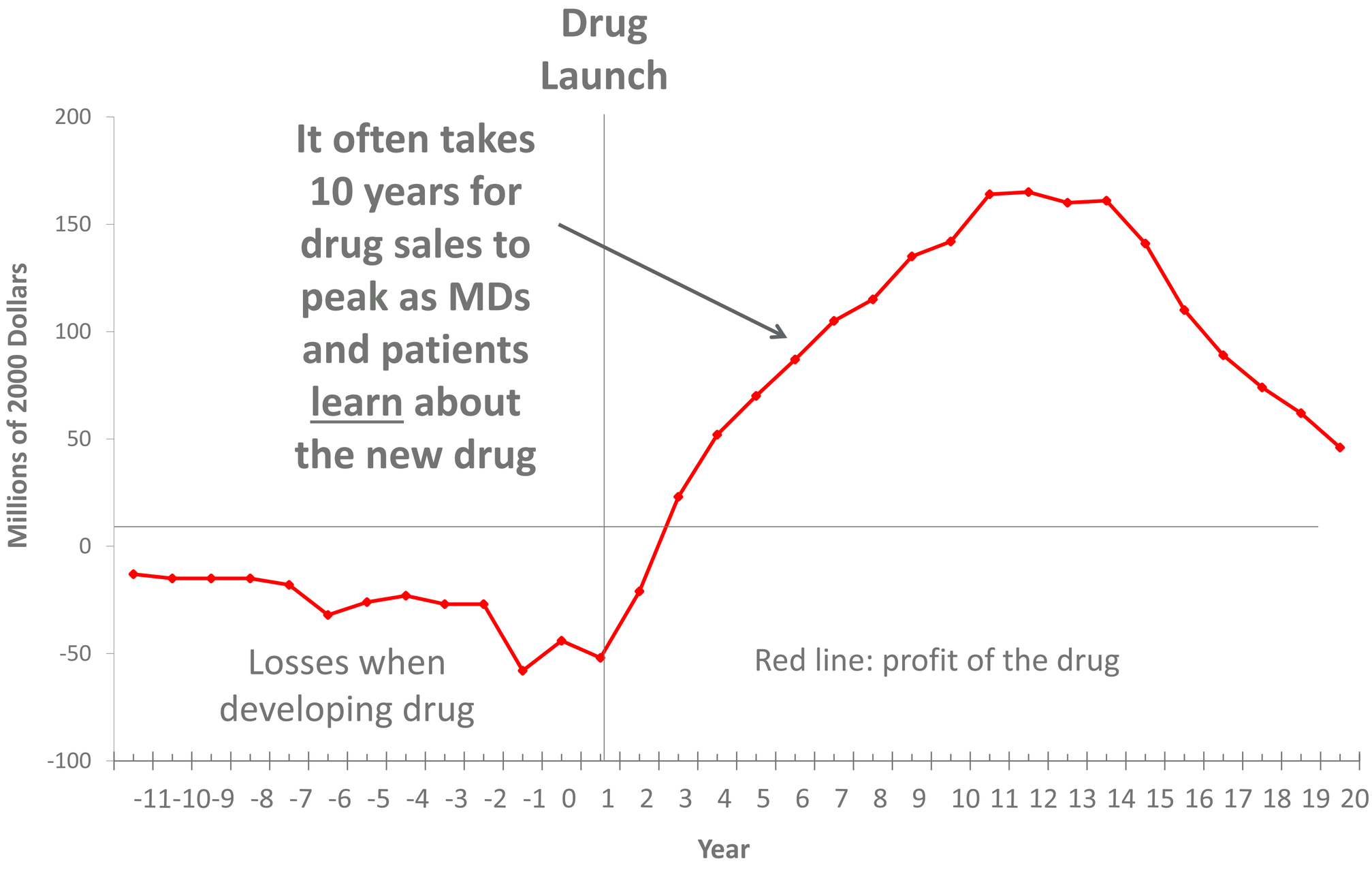
Product Life Cycle: Revenue Grows Steadily Over an Extended Time, Then Falls Precipitously



Source: DiMasi and Grabowski, 2012.

The Slow Uptake

Experience Goods: Pharmaceutical drugs are experience goods; physicians and patients need to try the product in order to determine whether it's valuable to them.

Companies that make experience goods tend to market heavily in order to provide information about the value of their product. (But does marketing also persuade people?)

Source: Berndt, *Health Affairs*, 2001.

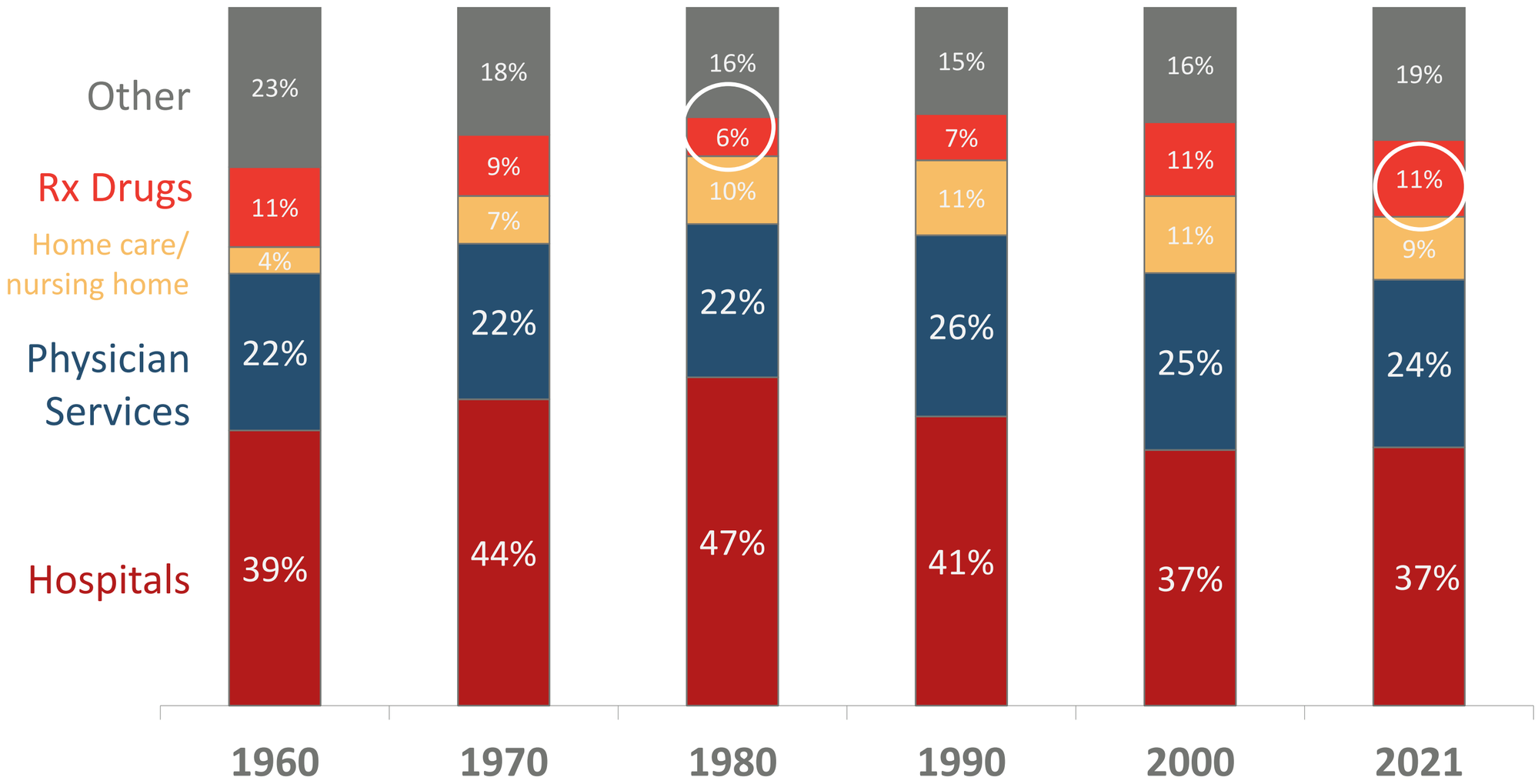
Image Source: https://www.iconfinder.com/rasulh

Conclusions, Part 1 of Pharma

- Developing a drug takes a long time, is expensive, and is not guaranteed to work.
- Patents allow pharmaceutical firms that successfully launch a new drug to make $ on it, thus providing incentives for them to incur the uncertainty and large expenditures involved.
- Generic drugs, which have relatively low prices, now account for 91% of all prescriptions.
- Firms market to physicians and patients to convey information about the drugs, so they will try them (experience goods).
- Marketing is especially important because once the patent expires, generic companies will take over the market.
- The government closely regulates the drug development, manufacturing, and marketing processes.

Pharmaceutical Expenditure Share Has Almost Doubled Over the Past 40 Years

Percentage of Personal Health Care Spending by Type of Service



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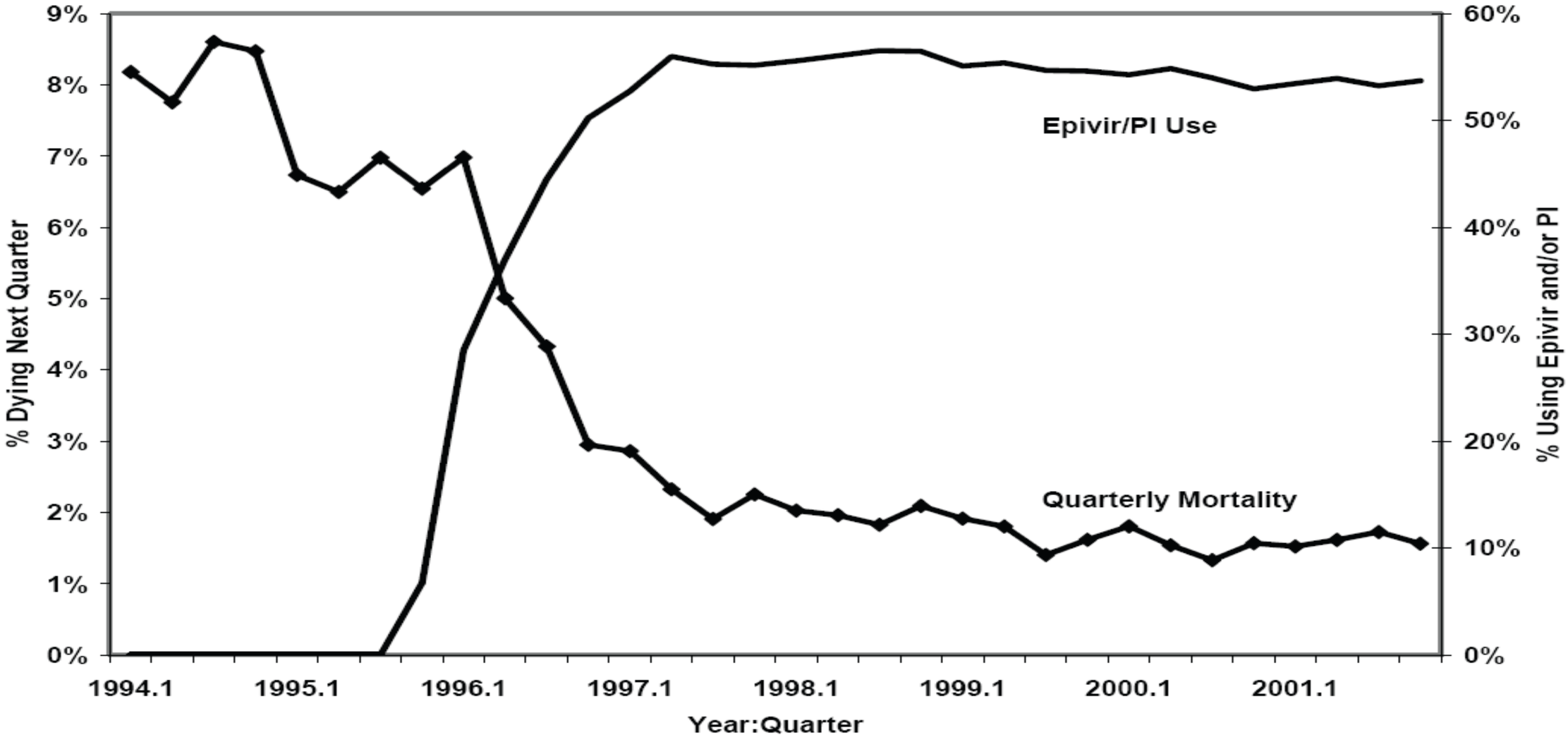
Source: CMS and Hartman et al., 2023.

Some of the Increased Use of Prescription Drugs Has Clearly Improved Health

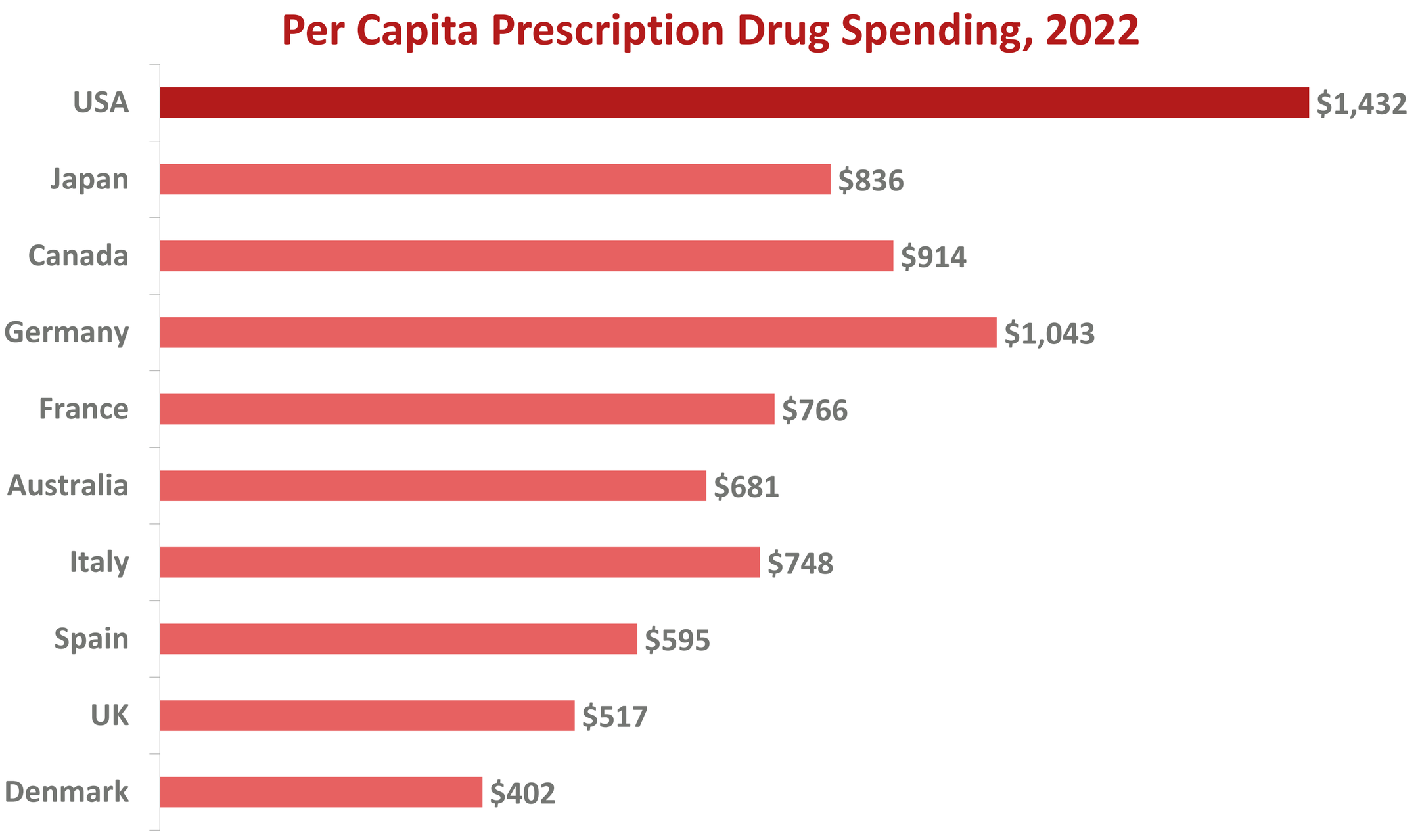
Protease Inhibitor Cocktails Reduced HIV Mortality Sharply

Figure 5: Quarterly Mortality Rate and Use of PI/Epivir



Covid vaccines are another good example

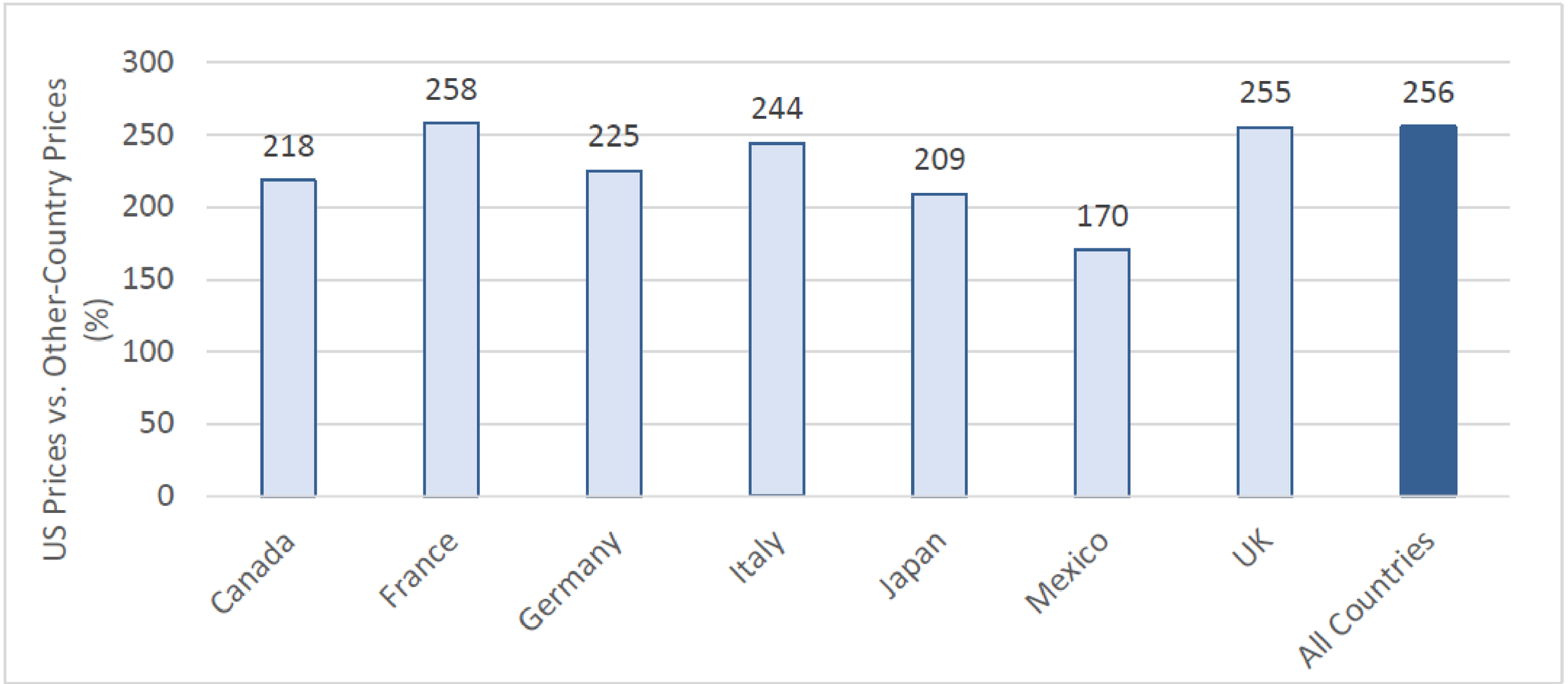
Other High-Income Countries Spend Much Less Than the U.S. on Prescription Drugs, Largely Due to Lower Prices



Source: Organization for Economic Cooperation and Development, OECD, 2023.

U.S. Pays Much Higher Prices for Drugs Than Other Countries

Figure S.1. U.S. Prescription Drug Prices as a Percentage of Prices in Selected Other Countries, All Drugs, 2018



SOURCE: Author analysis of IQVIA MIDAS sales and volume data for calendar year 2018 (run date October 28, 2019).

Drug prices in the U.S. are much higher than in peer countries, 2018.

Source: Mulcahy et al., 2021.

Why are drug prices so much lower in Europe, Japan, and Canada than the United States?

What would happen if the U.S. government regulated prices like Europe and Japan do, or if we had a single payer system?

Higher U.S. Drug Spending Driven by Higher Prices and Greater Use of New/Expensive Drugs but Not a Greater Quantity of Prescriptions

Prices Set in Market

U.S. drug prices are set in the market by pharmaceutical firms, who negotiate with hundreds of private health insurers (but not the U.S. government, by law, until 2026).

Internationally, Firms Negotiate with One Entity

A major reason prescription drug prices are about 60% lower in other developed countries is that pharma firms negotiate with one entity (the government), which gives the government negotiating power via a take-it-or-leave-it threat.

Japan and EU Policies

EU and Japan also have policies that favor the use of older less expensive drugs, which creates additional negotiating power for a single entity.

Image Source: https://www.iconfinder.com/Makoto_msk