Costs, Trends, Concerns and Cost Control Options

Specialty Drugs

Goals for Today

DEVELOP AN UNDERSTANDING OF THE SPECIALTY DRUG INDUSTRY AND ITS DIFFERENCE FROM TRADITIONAL PHARMA.

REVIEW PAST PREDICTIONS, CURRENT PERFORMANCE, AND IMPORTANT/EVOLVING TRENDS.

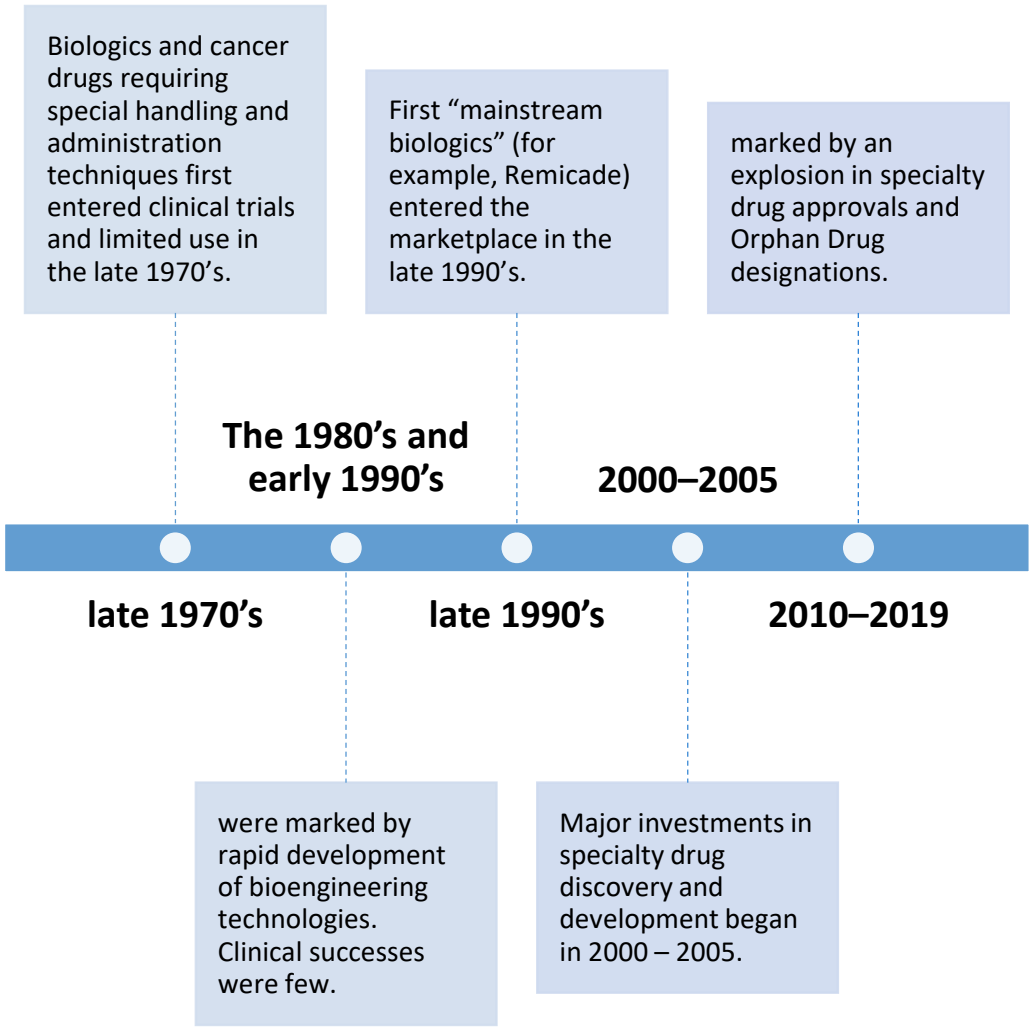
IDENTIFY ETHICAL AND FUNDING ISSUES DRIVING COST AND INFLUENCING THE MARKET.

REVIEW OPTIONS FOR CONTROLLING COST AND TREND AT BOTH THE EMPLOYER GROUP AND NATIONAL LEVELS.

The Basics

History and Definitions

Evolution of an Industry



Specialty Drugs: What are they?

The Short Answer:

It Depends…

The Easy Definition: Cost

CMS: > $670 per month (2019)

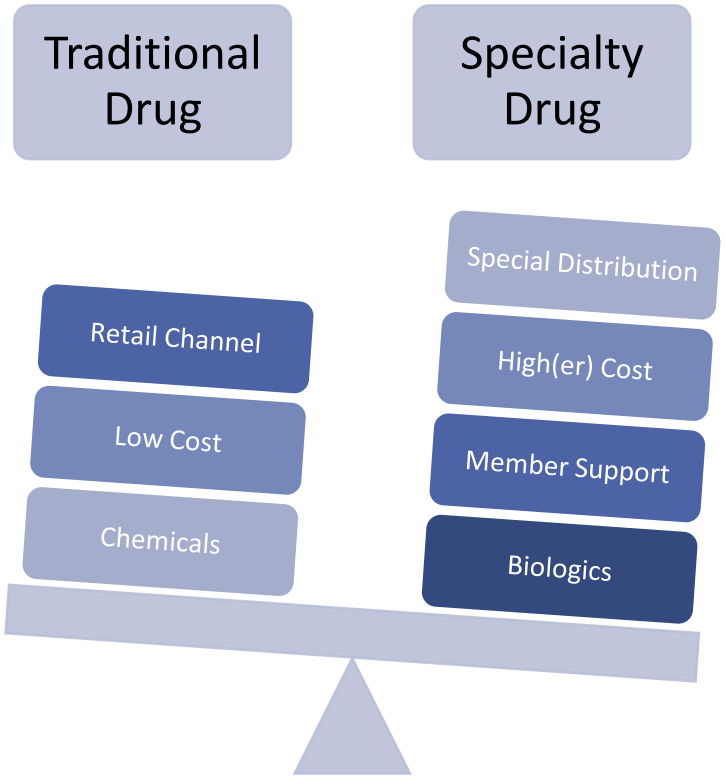
PBM "A" > $750 per dose

Tends to be used by public sector entities.

Use by PBMs decreasing, partly because of formulary and rebate issues.

Can cause confusion/misclassification when lower cost therapeutic equivalents or biosimilars enter the market.

The Better Definition: "Functional"



Used by most PBMs.

Minimizes formulary and rebate issues within a single plan or multiple plan designs from the same carrier, TPA, or PBM.

May create issues with cross-vendor comparisons.

A Special Case: Orphan Drugs

Specialty Drugs or Not?

Economic and Clinical Impact?

Definition

An **orphan drug** is a pharmaceutical agent developed to treat medical conditions which, because they are so rare, would not be profitable to produce without government or other support. These conditions are referred to as **orphan diseases.**

The assignment of orphan status to a disease and to drugs developed to treat it is a matter of public policy in and has yielded medical breakthroughs that might not otherwise have been achieved.

1. About 60% of orphan drugs are biologics; 30% are cancer drugs.
2. Orphan Drug designation has yielded more drugs and medical breakthroughs that might not otherwise have been achieved.
3. Manufacturers are favoring development of drugs eligible for "Orphan" status.

The Orphan Drug Act- Good or Bad?

The Orphan Drug Act (ODA) of January 1983, was/is meant to encourage pharmaceutical companies to develop drugs for diseases that have a small market.

Under the ODA drugs, vaccines, and diagnostic agents qualify for orphan status if intended to treat a disease affecting less than **200,000** American citizens.

Under the ODA orphan drug sponsors qualify for seven-year FDA-administered market **Orphan Drug Exclusivity** (ODE), "tax credits of up to 50% of R&D costs, R&D grants, waived FDA fees, protocol assistance and may get clinical trial tax incentives.

Unintended consequences…

1. More drugs eligible as market evolves.
2. Creates long-term market monopolies without price controls.
3. Costs tend to shift to private payors and under or uninsured
4. No provisions for profit-sharing or repayment of grants and credits.

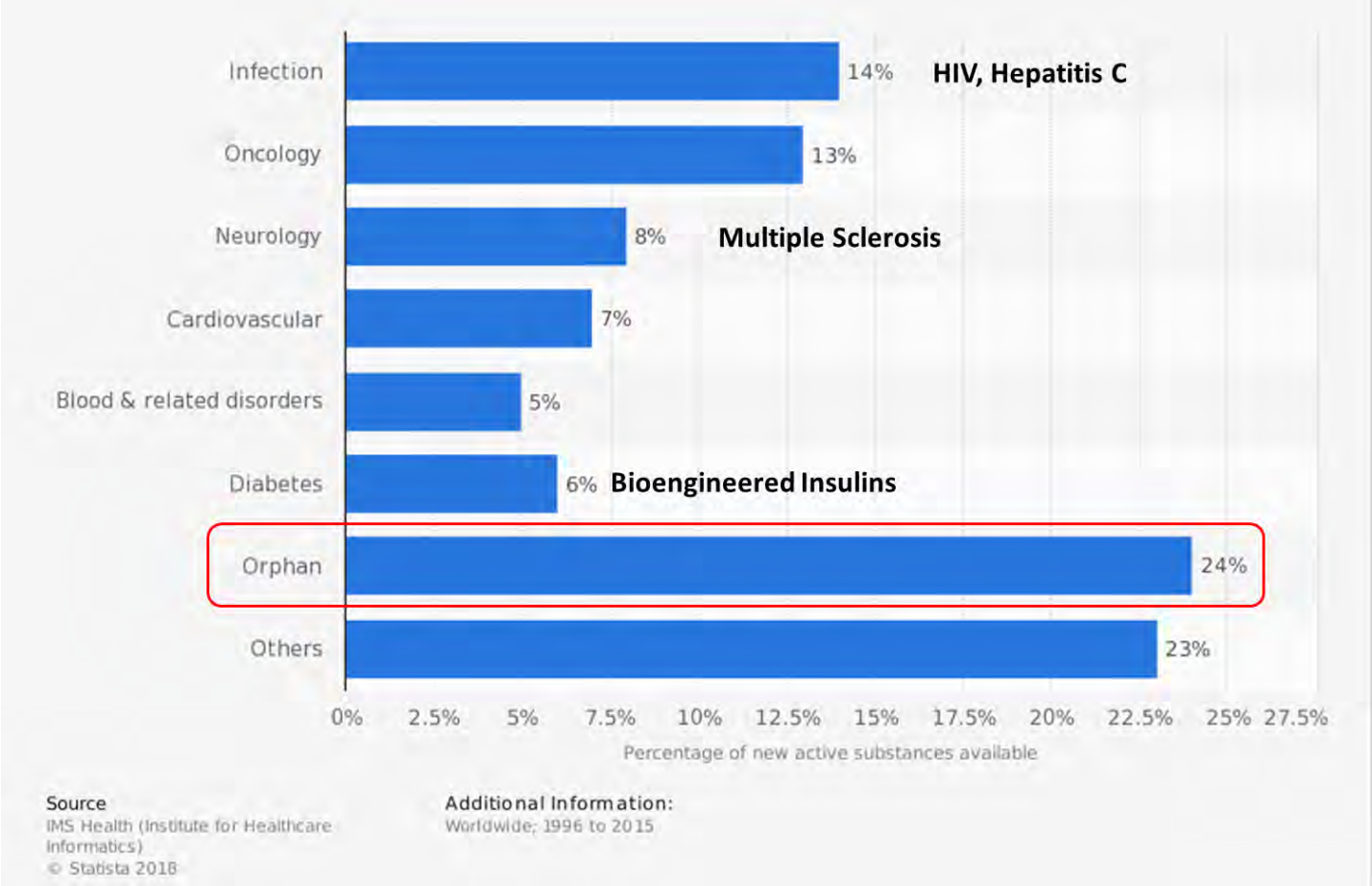
The Basics

Costs, Trends, and Forecasts

U.S. & Global Trends and Market Dynamics

The Past

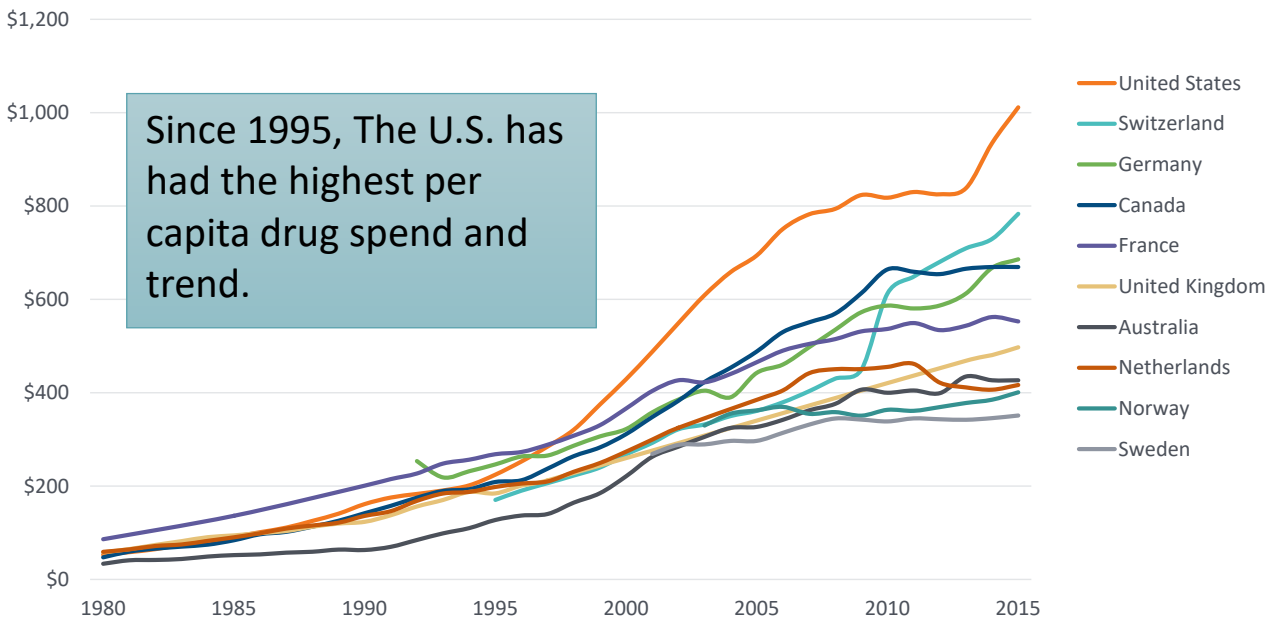
Drug Development 1996 - 2019



Global Cost Comparisons

Exhibit 1

National Trends in Per Capita Pharmaceutical Spending, 1980–2015



Notes: Final expenditure on pharmaceuticals includes wholesale and retail margins and value-added tax. Total pharmaceutical spending refers in most countries to "net" spending, i.e., adjusted for possible rebates payable by manufacturers, wholesalers, or pharmacies. Data from all countries include only the portion spent on retail prescription medications, except for the Netherlands and the United Kingdom, where spending on pharmaceuticals includes prescribed medicines, over-the-counter medications, and other medical nondurable goods. Pharmaceuticals consumed in hospitals and other health care settings are excluded.

Data: Organisation for Economic Co-operation and Development, 2017. Data for Australia and Canada from 2014.

The Commonwealth Fund

Source: D. O. Sarnak, D. Squires, and G. Kuzmak, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?* The Commonwealth Fund, October 2017.

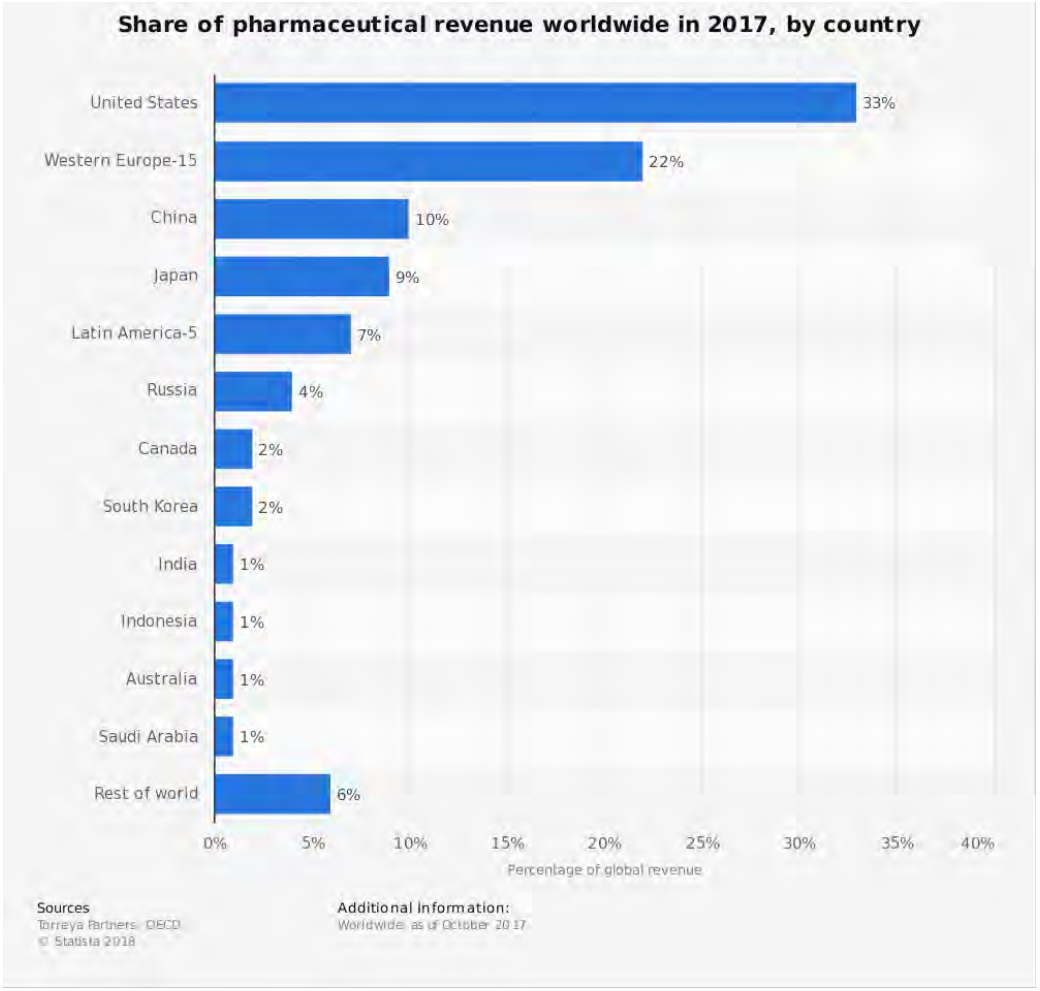
Why is the U.S. an Outlier?

U.S.-based manufacturers fund a disproportionate share (50%) of global drug development costs. These costs are "passed through" to U.S. employers and PBMs largely due to price controls in other countries (see below)

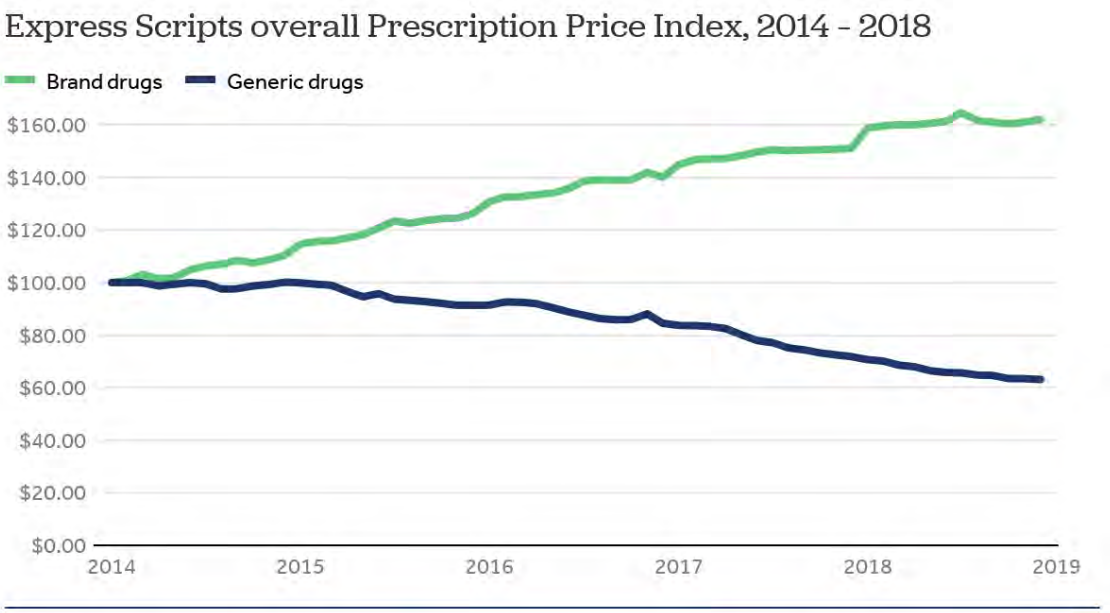
Other countries have artificially low *per capita* costs due to external reference pricing and other cost and price controls.

The lower prices in these other countries reflected their more centralized processes for procuring pharmaceuticals and determining coverage.

50% of Development Costs, But…



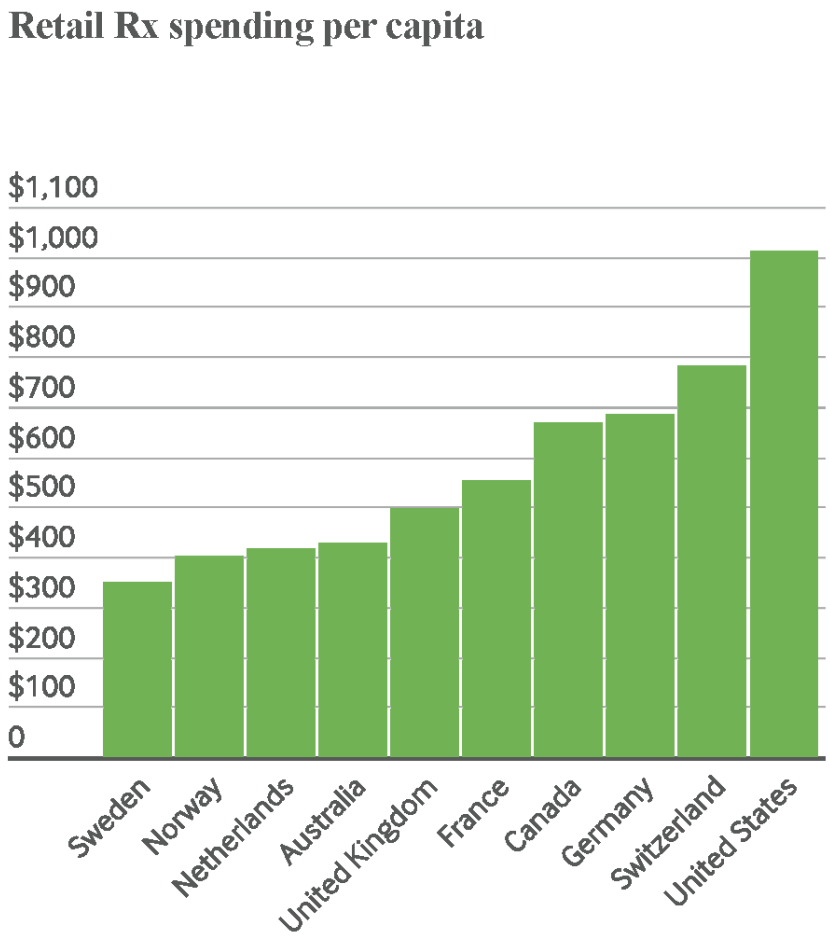
U.S. Brand and Generic Trend



U.S. & Global Trends and Market Dynamics

The Present

Bad News: Global U.S. Cost Comparisons



1. On a drug-by-drug basis, U.S. retail unit drug costs are 5% to 117% higher than in other countries.
2. Drug utilization rates are similar to those seen in other countries.

Other Important Issues: Hidden Costs

- Nearly half of specialty drug costs are adjudicated through medical claims ("Non-PBM Drugs"). These drugs are administered in an outpatient facility setting and are 2X – 3X more expensive than the same drugs purchased through a PBM and administered in a free-standing infusion center or at home.
- Some states are passing legislation prohibiting mark-ups of professional services and supplies in outpatient facility settings. These regulations could also impact Non-PBM Drug Pricing.

Other Important Issues: Fixed Costs

- The overwhelming majority of specialty drugs are prescribed to control serious chronic conditions. With few exceptions, these drugs do not have curative potential.
- These drug costs become a fixed operating expense for the plan and have resulted in increased numbers of Large Claimants.
- Although these costs are predictable, their “persistence” is causing issues with stop-loss and fully-insured quotes and renewals.

Other Important Issues: Value

- The Health Care industry in the U.S. is beginning to experiment with value-based pricing for specialty drugs (already in place in Germany).
- This trend raises important practical and ethical issues:
  - How will “value” be measured?
  - What will be the “value” threshold for drug approval or coverage?
  - What financial model will be used?

Other Important Issues

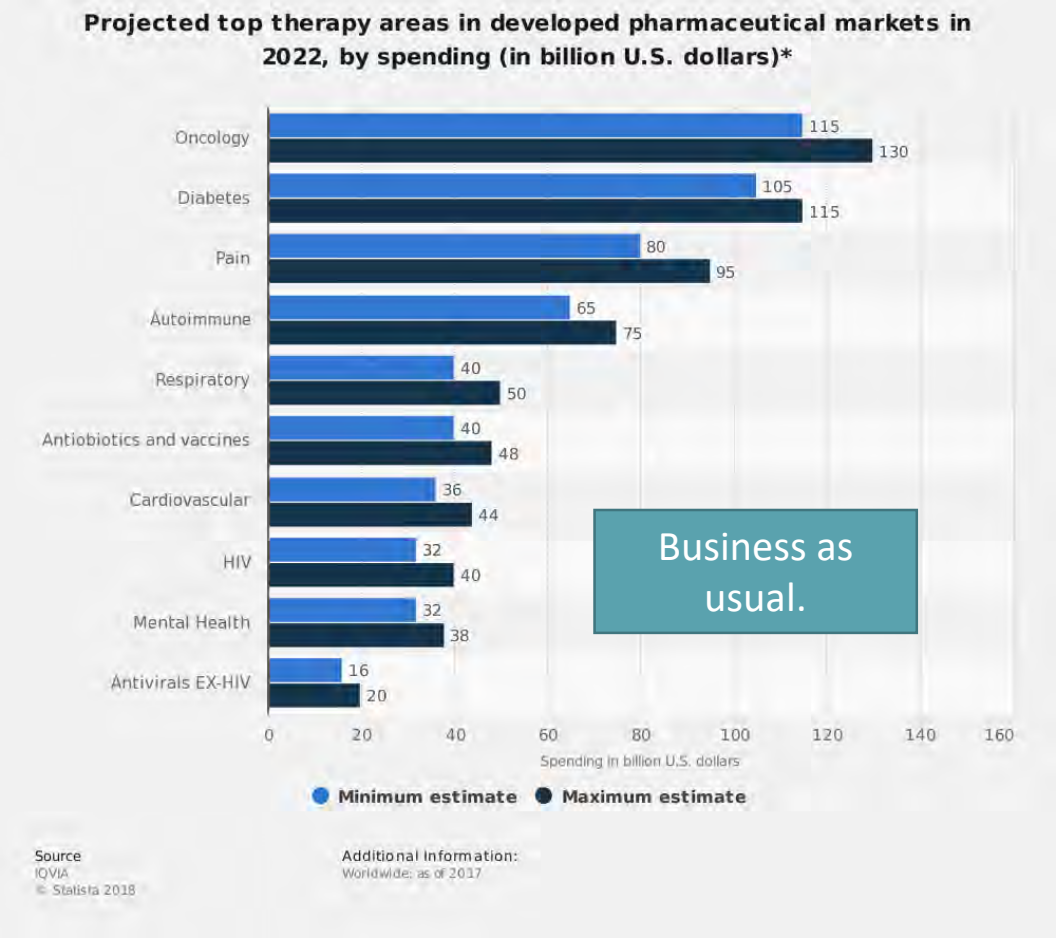
There are early indications that biologics may:

- Be used to treat much more common conditions outside of the current complex disease model. An example is the use of antibodies to treat osteoarthritis pain.
- Be replaced by genetic re-engineering of the immune system (Examples: CAR-T treatment for lymphoma/leukemia and Immune system "restart" ,rather than chronic specialty drug treatment, with stem cell transplant in MS).
- These therapies were not "expected" or predicted a few years ago.

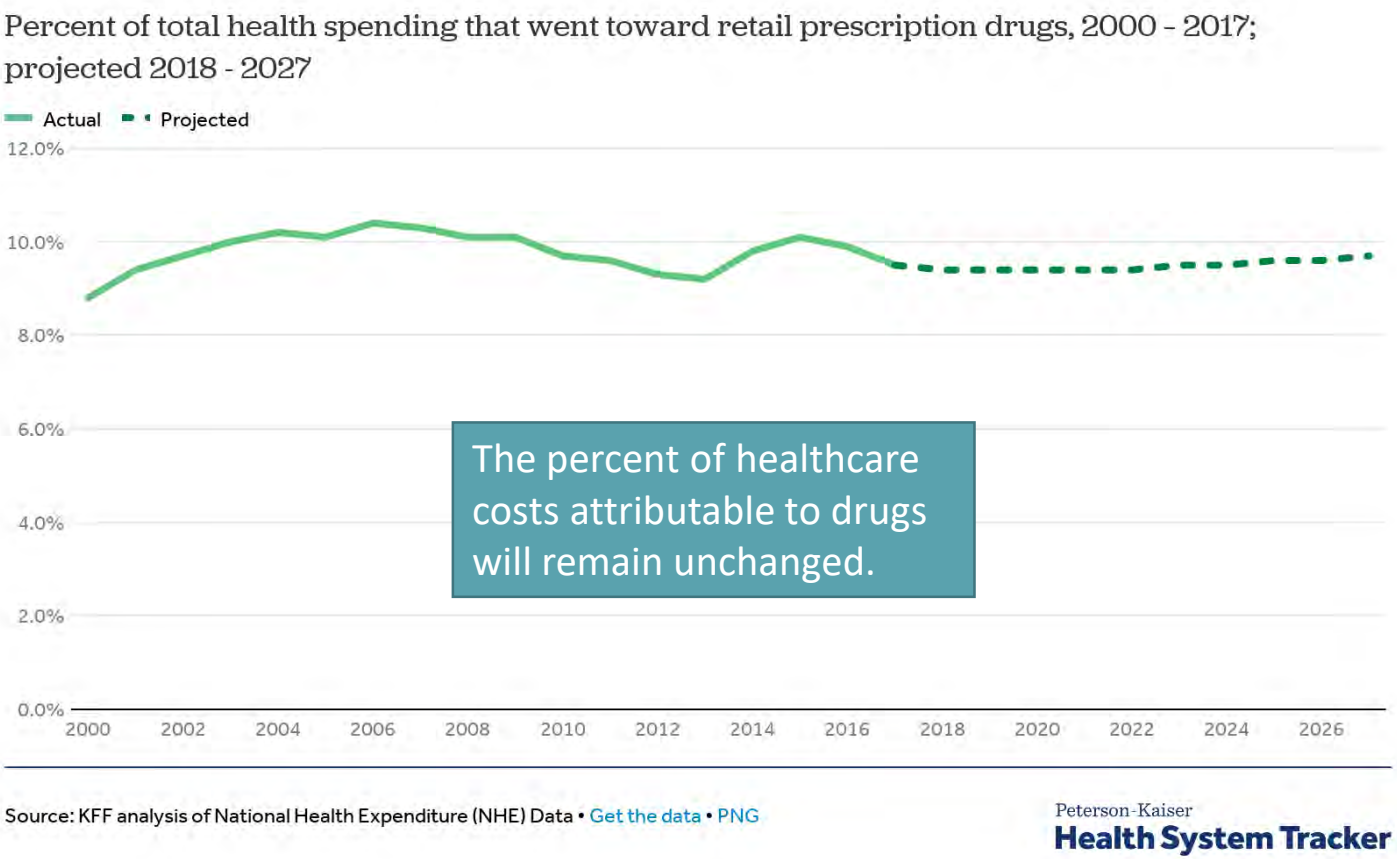
Cost Projections and Drug Development

The Future

Development Pipeline (3 Year Horizon)



Total Retail Pharmacy Spend



Coping with costs

Market Reform- The Big Fix

The “Big Fix” for Specialty Drug Costs

This is an international macroeconomic problem that will not be solved by imposing price controls on our domestic manufacturers, nor will it be solved quickly.

An effective permanent solution will require international agreements providing for:

1. Fair Distribution of R & D Costs; and,
2. Equitable transparent international drug pricing.

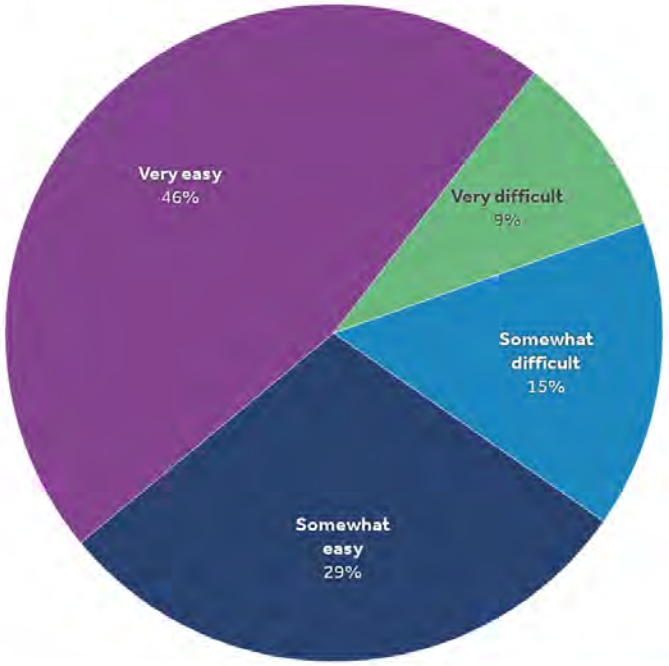
An intermediate step could be to set up a national multipayor or single payor risk pool for members with “unusually” high specialty drug costs.

In the Meantime…

Employer Options

What won't Work: Members Pay More

Among adults who currently take any prescription medicine, percent who report ease or difficulty affording to pay the cost of their prescription medicine



Source: KFF Health Tracking Poll (conducted Feb 14 – 24, 2019) • Get the data • PNG

Peterson-Kaiser Health System Tracker

1. Fortunately, About half of adults taking prescription medications have little or no difficulty paying for them.
2. However, 24% have difficulty affording their drugs at all, and are less compliant.
3. This problem is particularly important for members on specialty drugs.

Mandatory Specialty Pharmacy

Mandating that all specialty drugs must be purchased through the PBM (rather than a facility-based provider can result in significant savings.

Downsides:

1. Member disruption;
2. Provider complaints; and,
3. Increased administrative costs.

Five Tier Formulary Design

EXHIBIT 1

Five-Tier Formulary Design

Tier 1	**Generic drugs:** Typically the most affordable and are equal to their brand-name counterparts in quality, performance characteristics, and intended use.
Tier 2	**Preferred brand-name drugs:** Proven to be safe, effective, and favorably priced compared to nonpreferred brands.
Tier 3	**Nonpreferred brand-name drugs:** These drugs have either a generic or preferred brand available; therefore, patients' cost share will be higher.
Tier 4	**Preferred specialty drugs:** Proven to be safe, effective, and favorably priced compared to nonpreferred specialty drugs.
Tier 5	**Nonpreferred specialty drugs:** These drugs typically have a preferred brand available; therefore, patients' cost share will be higher.

SOURCE BlueCross BlueShield Federal Employee Program (adapted).

Five tiers can produce significant savings when blended with a preferred formulary design. Members can avoid higher out of pocket costs by working with their provider to select preferred specialty drugs.

Summary

1. U.S. Drug Prices are higher than those in other industrialized countries. Significant barriers to "unilateral" price reduction exist.
2. Specialty Drug development continues; Orphan Drugs figure prominently.
3. High drug trend prior to 2016 has abated. Forecasts for future costs are much more favorable than those released several years ago.
4. Despite the difficulty of implementing the "big fix", there are actions that employers can take to mitigate forward cost risk.