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Cover photo: Kevin Maisonave, AbbVie, Certified Histotechnologist
Back cover photo courtesy of AbbVie
INTRODUCTION

This chart pack provides facts and figures about prescription medicines and their role in the health care system. Topics include medicines’ impact on health and quality of life, the drug discovery and development process, health care spending and costs, the challenges of addressing treatment gaps and improving the use of prescribed therapies, and the contributions of the biopharmaceutical sector.

Data and information in this publication were drawn from a wide range of sources, including government agency reports, peer-reviewed journals, and the Pharmaceutical Research and Manufacturers of America’s (PhRMA’s) own research and analysis. PhRMA hopes this publication provides useful context for discussions regarding the role of medicines and the US economy.
Prescription medicines have yielded important advances, helping patients live longer and healthier lives. Over the past 25 years, prescription medicines have transformed the trajectory of many debilitating diseases and conditions, including HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients.

Today, new drugs are targeting the underlying causes of disease in ways never seen before, and diseases previously regarded as deadly are now manageable and even curable. In this new era of medicine, breakthrough science and personalized therapies are transforming the way we treat patients with a broad range of chronic and rare conditions. Looking forward, continued advances in biopharmaceutical innovation will be critical in addressing unmet needs, improving public health, and solving future health care challenges.
Increases in US Life Expectancy

Innovative medicines have played an integral role in improving life expectancy over the last century.¹

*Life expectancies before 1997 and those in and after 1997 were calculated using a slightly different methodology.

Source: CDC¹,²
A Decade of Advances

2006–2016

2006
- First vaccine for the prevention of cervical cancer
- First drug for chronic chest pain in 20 years
- First once-a-day HIV medicine

2007
- New class of medicines to treat high blood pressure
- First treatment for fibromyalgia

2008
- New type of treatment for Crohn’s disease
- First drug for symptoms of Huntington’s disease

2009
- First treatment for peripheral T-cell lymphoma
- First new drug for gout in 40 years

2010
- 2 new multiple sclerosis drugs
- First therapeutic cancer vaccine

2011
- First lupus drug in 50 years
- 2 new personalized medicines

2012
- First drug to target root cause of cystic fibrosis
- First drug to treat Cushing’s disease

2013
- 2 new personalized medicines to treat the most dangerous forms of skin cancer
- New oral treatment for multiple sclerosis

2014
- Oral treatments for hepatitis C provide cure rates of more than 90%
- 17 new drugs to treat patients with rare diseases

2015
- 2 new drugs for difficult-to-treat forms of high cholesterol
- New cystic fibrosis drug for patients with a genetic mutation that is the most common cause of the disease
- First lupus drug in 50 years
- 2 new personalized medicines

2016
- First drug to treat spinal muscular atrophy
- New personalized therapy for chronic lymphocytic leukemia
- First drug to treat all 6 forms of hepatitis C

Source: FDA
Medicines Are Transforming the Treatment of Many Diseases

**Multiple Sclerosis (MS)**
Expanded treatment options in recent years, including more convenient oral medicines, offer patients greater opportunity to better manage MS and slow disease progression.⁴

**Hepatitis C**
Recent advances have doubled cure rates for patients and helped avoid serious disease complications—including cirrhosis, advanced liver disease, liver cancer, and death.⁵

**Cancer**
New therapies have contributed to a 25% decline in cancer death rates since the 1990s. Today, 2 out of 3 people diagnosed with cancer survive at least 5 years.⁶,⁷

**Rheumatoid Arthritis (RA)**
Therapeutic advances have transformed the RA treatment paradigm over the past 20 years, shifting from a focus on managing symptoms to aiming for slowed disease progression and even disease remission.⁸

Sources: PhRMA⁴,⁵; ACS⁶,⁷; Boston Healthcare Associates⁸
Medicines Are Transforming Treatment of Many Rare Diseases

Collectively, rare diseases affect 30 million Americans. Treatments are available for only 5% of rare diseases, but recent advances are providing important new options to many patients for the first time.¹⁹

**Hereditary Angioedema (HAE)**¹⁰
HAE causes life-threatening attacks of edema (swelling) of the hands, feet, face, airways, and gastrointestinal tract. Better understanding of the underlying causes of HAE have led to both preventive and acute treatment options that target the underpinnings of the disease.

**Cystic Fibrosis (CF)**¹⁰
Advances in understanding the biology of this condition, which primarily affects the lungs and digestive system, have led to new medicines targeting the root cause—rather than just the symptoms—of CF, including in patients with a genetic mutation known to be the most common cause of the disease.

**Homozygous Familial Hypercholesterolemia (HoFH)**¹⁰,¹¹
HoFH, a genetic condition resulting in extremely high cholesterol, can lead to heart attacks and death by the age of 30. Until recently, treatments were often insufficient in lowering cholesterol levels. Today there are three treatments that can lower cholesterol levels by as much as 50%.

**Morquio A Syndrome**¹⁰
The first-ever treatment for this metabolic disease, which causes severe skeletal abnormalities in early childhood, was approved in 2014. The medicine replaces the enzyme that patients lack, thus allowing them to break down sugars, and has been shown to improve endurance, mobility, and overall quality of life.

Sources: Global Genes⁹; PhRMA¹⁰; FDA¹¹
Rheumatoid Arthritis: Medicines Are Transforming the Lives of Patients

THEN:
Treatments for rheumatoid arthritis were generally effective at reducing joint inflammation but were limited to treating the symptoms of the disease, allowing for a steady, rapid progression from disease onset to disability.

NOW:
Biologic disease-modifying antirheumatic drugs target the underlying sources of inflammation, which improves physical functioning and prevents irreversible joint damage, making disease remission possible.

Source: Boston Healthcare Associates

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HIV/AIDS: Decline in Death Rates

The number of US AIDS deaths decreased dramatically following the introduction of highly active antiretroviral treatment (HAART). As a result of HAART and all the important medical innovations that followed, it is estimated that more than 862,000 premature deaths have been avoided in the United States alone.

Sources: CDC; Truven Health Analytics
HIV/AIDS: Treatment Advances Build Over Time

Dramatic declines in death rates did not occur with one single breakthrough but rather through a series of advances providing important treatment options for patients over time.\textsuperscript{15,16}

*AZT: Azidothymidine

Sources: Boston Healthcare Associates\textsuperscript{15}, CDC\textsuperscript{16}
Cancers: Decline in Death Rates

Since peaking in the 1990s, cancer death rates have declined 25%. Approximately 73% of survival gains in cancer are attributable to new treatments, including medicines.

“I think some of the treatments that we have developed over the last half century or so are really starting to pay off and, honestly, [it] seems limitless as to what may pay off in the future.”

— William Nelson, MD, PhD, Director, Sidney Kimmel Comprehensive Cancer Center

Percent Change by Decade in US Death Rates From Cancer

Sources: ACS17; Seabury SA et al.18; Dunellari A19; NCI20
Chronic Leukemia: Increased Survival Rates

When the first-in-class drug imatinib was approved in 2001 to treat chronic myeloid leukemia (CML), the transformative impact of this new class of medicines had not been completely realized.21

- After initial approval, continued research revealed that imatinib had a greater impact when initiated earlier in the progression of the disease.
- Further research also revealed that imatinib was effective in combating other types of cancer.
- Additional drugs in this class have since been approved that target mutated forms of CML in patients who have become resistant or intolerant to imatinib.22
- Today, survival rates have improved dramatically, and CML patients are living close to normal life spans.23

Sources: Boston Healthcare Associates21; PhRMA22; Gambacorti-Passerini C et al.23; ACS24; Druker BJ et al.25
Rare Diseases: Drug Approvals for Rare Diseases Have Increased

Rare diseases are those that affect 200,000 or fewer people in the United States.\textsuperscript{26}

![Graph: Number of Drug Approvals for Rare Diseases\textsuperscript{27*}}

Although more than 575 orphan drugs have been approved since the passage of the Orphan Drug Act in 1983, continued innovation is still very much needed.\textsuperscript{27}

*Drug approvals for rare diseases include initial approvals of new medicines and subsequent approvals of existing medicines.

Source: FDA\textsuperscript{26,27}
Cardiovascular Disease: Declining Rates of Death

Tremendous strides have been made in reducing cardiovascular disease morbidity and mortality, thanks in part to new medicines.


Source: CDC28,29
Medicines Are Improving Patients’ Quality of Life

Relative to medical technology available a decade ago, new treatments for complex chronic conditions are better tolerated, more efficacious, and more convenient, thereby improving not only life expectancy, but quality of life for patients.

10-Year Decline in Number of Patients With Complex Chronic Conditions* Experiencing Quality-of-Life Impairment**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage Decline</th>
<th>Change in Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional</td>
<td>-9%</td>
<td>765,500 patients</td>
</tr>
<tr>
<td>Physical</td>
<td>-5%</td>
<td>408,000 patients</td>
</tr>
<tr>
<td>Social</td>
<td>-4%</td>
<td>306,000 patients</td>
</tr>
<tr>
<td>Cognitive</td>
<td>-3%</td>
<td>289,000 patients</td>
</tr>
</tbody>
</table>

*HIV, rheumatoid arthritis, leukemias, non-Hodgkin’s lymphoma, multiple sclerosis, and lupus.
**Chart reflects unweighted estimates reported in study.

Source: Brien MJ et al.20
Hepatitis C: Cure Rates Are Rising

Experts project that hepatitis C (HCV) will become a rare disease by 2036 with today’s curative treatments and increased screening.\(^\text{31}\)

**HCV Genotype 1 Prevalence**

- **2.4 million people have Genotype 1 HCV**

**1st Generation (2001-2010)**
- **41% CURED**
  - Interferon and Ribavarin (IFN-R)
  - 48 week treatment

**2nd Generation (2011-2013)**
- **63-80% CURED**
  - Protease Inhibitors with IFN-R
  - 24 to 48 week treatment

**3rd Generation (2013-2014)**
- **90% CURED**
  - Polymerase Inhibitors with IFN-R
  - 12 week treatment

**4th Generation (2014-2016)**
- **94-100% CURED**
  - Combination Antiviral Therapies
  - 8 to 12 week treatment

**Genotype 1 HCV Cure Rates**

- **94-100% CURED**
- **90% CURED**
- **63-80% CURED**
- **41% CURED**

**Interferon Free**

Sources: Kabiri M et al.\(^\text{31}\); PhRMA\(^\text{32}\); FDA\(^\text{33}\)
Projected Reductions in Hepatitis C–Related Complications

Increased screening and the availability of new treatments for hepatitis C are projected to dramatically reduce complications associated with the disease. Projections suggest that the number of liver-related deaths avoided will total 126,500 by 2050. 

Avoided Cases of Hepatitis C–Related Complications by 2050

- Liver-Related Deaths: 126,500
- Advanced Cirrhosis: 124,200
- Liver Cancer: 78,800
- Liver Transplants: 9,900

Source: Kabiri M et al.\(^\text{34}\)
The development of a new treatment that delays the onset of Alzheimer’s could reduce Medicare and Medicaid spending on patients with Alzheimer’s by $218 billion annually by 2050.*

*Assumes research advances that delay the average age of onset of Alzheimer’s disease by 5 years beginning in 2025
**Projected savings to Medicare and Medicaid assume research breakthroughs that slow the progression of Alzheimer’s disease. This would dramatically reduce spending for comorbid conditions and expensive nursing home care.

Source: Alzheimer’s Association35
Notes and Sources


Notes and Sources


The rapid pace of scientific advances is bringing tremendous hope to patients. The pipeline for new medicines has never been more promising, with about 7,000 medicines in development around the world. Over the past decade, PhRMA member companies have invested more than half a trillion dollars in biopharmaceutical research and development (R&D), accounting for the majority of private biopharmaceutical R&D spending. Development of new medicines is a long and rigorous process, with many setbacks along the way. The process has become more costly and complex over the past decade. As scientific complexities create new challenges in R&D, biopharmaceutical companies are working to create efficiencies and enter new collaborations across the research ecosystem.
About 7,000 Medicines in Development Globally

Biopharmaceutical researchers are working on new medicines* for many diseases, including:

- **Cancers**: 836
- **Alzheimer’s Disease**: 77
- **Diabetes**: 171
- **Rare Diseases**: 566
- **Heart Disease & Stroke**: 190
- **Autoimmune Diseases**: 311
- **Mental Health Disorders**: 135
- **Neurological Disorders**: 420

*Defined as single products that are counted only once regardless of the number of indications pursued

Source: Adis R&D Insight Database¹
Potential First-in-Class Medicines in the Pipeline

An average of 74% of drugs in the clinical pipeline are potential first-in-class medicines.

Percentage of Products in Clinical Development and Regulatory Review That Are Potentially First-in-Class, Selected Therapeutic Areas, 2016

- Alzheimer's Disease: 86%
- Cancer: 79%
- Psychiatry: 75%
- Neurology: 74%
- Cardiovascular: 73%
- Diabetes: 73%
- Immunology: 68%
- HIV/AIDS: 60%

Source: Analysis Group²
Cutting-Edge Research Drives Development of Medicines

Biopharmaceutical researchers are pursuing many novel scientific approaches that are driving therapeutic advances.

**ALZHEIMER’S DISEASE**

- β-secretase inhibitors block the enzyme that causes plaque formation, which could halt progression of the disease.

**CANCER**

- Chimeric antigen receptor (CAR) t-cell immunotherapy involves the personalized modification of immune-boosting T-cells to target and kill blood cancer cells.
- CRISPR/Cas9 technology edits gene sequences in T-cells, reprogramming them to seek and destroy tumor cells.

**MIGRAINE**

- CGRP inhibitors inhibit the signaling pathway that leads to migraine attacks.

**CROHN’S DISEASE**

- SMAD7 blockers stop the production of a protein that, in excess, inhibits normal immune cell activation.

**ZIKA**

- DNA-based vaccines enter immune cells and train them to recognize and attack the virus.

Source: Analysis Group
Harnessing Innovation in Rare Diseases

Since the passage of the Orphan Drug Act in 1983, we have seen tremendous advances in treatments for rare diseases, with the Food and Drug Administration approving more than 575 orphan drugs (compared with fewer than 10 in the decade before passage).

- Rare diseases affect 30 million Americans
- Approved treatments are available for only 5% of all rare diseases
- 7,000 rare diseases exist today
- 80% of rare diseases are genetic in origin
- More than 560 medicines are in development for rare diseases

Source: PhRMA
Biopharmaceutical Companies Are Committed to Advancing Personalized Medicine

In recent years, we have seen remarkable advances in targeted therapy, and the R&D pipeline has never been more promising.

MORE THAN 25% of new medicines approved by the FDA in 2016 were

PERSONALIZED MEDICINES

42% of new medicines in the pipeline have the potential to be

Sources: Personalized Medicine Coalition; Tufts CSDD
The Lengthy, Costly, and Uncertain Biopharmaceutical Research and Development Process

From drug discovery through FDA approval, developing a new medicine on average takes 10 to 15 years and costs $2.6 billion.* Less than 12% of the candidate medicines that make it into phase I clinical trials are approved by the FDA.

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*The average R&D cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Sources: PhRMA adaptation of DiMasi JA et al.; Tufts CSDD; FDA7
Biopharmaceutical Research Companies Play a Pivotal Role in Drug Discovery and Development

The private sector makes the largest R&D contributions in translating basic research findings into therapeutic advances for patients.

Share of Contributions to Key R&D Milestones for the Most Transformative Drugs of the Past 25 Years

- Discovery: 58% Public, 42% Private
- Development: 73% Public, 27% Private
- Manufacturing: 81% Public, 19% Private

Source: Tufts CSDD
Biopharmaceutical Industry Does the Vast Majority of Research to Translate Basic Science Into New Medicines

While basic science is often initiated in government and academia, it is biopharmaceutical firms that provide the necessary critical mass, expertise, and experience needed to develop new medicines.⁹

2015 Biopharmaceutical Industry R&D Investment: $75.3 Billion¹⁰

2015 NIH Research Spending: $29.6 Billion¹⁰

In addition to basic research and biopharmaceutical-related research, NIH supports applied research on medical devices, diagnostics, prevention, and other areas.¹¹

Sources: Tufts CSDD⁹; TEConomy Partners¹⁰; NIH¹¹
Innovative Biopharmaceutical Companies Sit at the Heart of a Dynamic R&D Ecosystem in the United States

The vibrant US biomedical R&D ecosystem is critical in bringing new medicines to patients and maintaining US leadership in biopharmaceutical R&D.
Collaboration Is Key in Researching and Developing New Medicines

The rapid pace of science and technological advances is propelling a new era in biopharmaceutical innovation in the United States. As the science becomes more complex, partnerships are crucial to advancing biomedical progress. Examples of key collaborative efforts across the R&D spectrum include:

**AMP (ACCELERATING MEDICINES PARTNERSHIP)**
- Developing new diagnostics and biological targets for treatments in Alzheimer’s disease, type 2 diabetes, rheumatoid arthritis, and lupus

**BIOMARKERS CONSORTIUM**
- Combining expertise and resources to rapidly identify, develop, and qualify biomarkers, which will then advance new therapies and guide improvements in regulatory and clinical decision making

**LUNG-MAP (LUNG CANCER MASTER PROTOCOL)**
- Using comprehensive genetic screening to identify mutations in lung cancer patients in order to direct them to a specific investigational treatment, while operating under a single clinical trial protocol

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**THE PARTNERS**
- Biopharmaceutical companies, NIH, patient and disease organizations

Sources: NIH, Foundation for NIH, Lung-MAP
Researchers Are Harnessing Collaborations to Accelerate Innovation

In recent years, stakeholders across the biopharmaceutical research ecosystem have shifted to non-asset-based, precompetitive partnership models in order to leverage their strengths in creative ways, create efficiencies, and tackle scientific and technological challenges.

New R&D PARTNERSHIPS
more than doubled

The number of CONSORTIA increased 9x

Early Stage PARTNERSHIPS
more than doubled

Source: Deloitte
PhRMA Member Company R&D Investment

The pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm.”

— Congressional Budget Office (CBO)\(^{17}\)

### PhRMA Member Company R&D Expenditures, 1995-2016\(^{18}\)

Sources: CBO\(^{17}\), PhRMA\(^{18}\)
The Costs of Drug Development Have More Than Doubled Over the Past Decade

Many factors are driving increasing costs of biopharmaceutical R&D, including increased clinical trial complexity, larger clinical trial sizes, greater focus on targeting chronic and degenerative diseases, and higher failure rates for drugs tested in earlier-phase clinical studies.

AVERAGE COST TO DEVELOP ONE NEW APPROVED DRUG—INCLUDING THE COST OF FAILURES (in Constant 2013 Dollars)

<table>
<thead>
<tr>
<th>Decade</th>
<th>Cost (in Constant 2013 Dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970s</td>
<td>$179M</td>
</tr>
<tr>
<td>1980s</td>
<td>$413M</td>
</tr>
<tr>
<td>1990s-Early 2000s</td>
<td>$1.0B</td>
</tr>
<tr>
<td>2000s-Early 2010s</td>
<td>$2.6B</td>
</tr>
</tbody>
</table>

Source: DiMasi JA et al.19
Setbacks in Alzheimer’s Disease Research Provide Stepping Stones for Future Innovation

Since 1998, 123 medicines in development for the treatment of Alzheimer’s disease have not made it through clinical trials, with only 4 gaining FDA approval. These setbacks highlight the complexity of the R&D process. Though disappointing, they provide important knowledge to fuel future research.
Cancer Researchers Build on Knowledge Gained From Setbacks to Inform Future Advances

Developing a new cancer medicine is a complex process, fraught with setbacks, but these so-called “failures” are not wasted efforts. Researchers learn from them to inform future study and direct research efforts.

*The scientific process is thoughtful, deliberate, and sometimes slow, but each advance, while helping patients, now also points toward new research questions and unexplored opportunities.*

— Clifford A. Hudis, MD, FACP

Chief Executive Officer, American Society of Clinical Oncology
Chief, Breast Medicine Service, Memorial Sloan Kettering Cancer Center
Professor, Weill Cornell Medical College

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**MELANOMA**
- 96 unsuccessful attempts
- 7 new drugs

**BRAIN CANCER**
- 75 unsuccessful attempts
- 3 new drugs

**LUNG CANCER**
- 167 unsuccessful attempts
- 10 new drugs

*Setbacks and advances from 1998 to 2014

Sources: Patel JD et al.; PhRMA
Pediatric Clinical Research: Overcoming Challenges

The Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) provide important regulatory requirements and incentives that work in tandem to increase clinical studies in pediatric populations. Together, these laws, made permanent in 2012, spur pediatric research and help researchers overcome unique challenges for this vulnerable population.

**BPCA/PREA Success**

Since 1998, more than 670 pediatric labeling changes

Since 2007, more than 600 pediatric studies have been completed, involving more than 178,000 patients

**Unique Challenges in PEDIATRIC RESEARCH**

- Small patient populations
- Distinct dosage and formulation requirements
- Unique ethical, scientific, and medical considerations

**BEFORE BPCA/PREA**

>80% of medicines used to treat children did not have pediatric dosing information

**AFTER BPCA/PREA**

That number has been reduced to 50%

Sources: FDA, Yao L, American Cancer Society
The Complexity of Clinical Trials Has Increased

During the past decade, clinical trial designs and procedures have become much more complex, demanding more staff time and effort and discouraging patient enrollment and retention.

### THEN & NOW

**Clinical Trial Complexity**

<table>
<thead>
<tr>
<th>Typical Phase III Protocol (Mean of Total Numbers)</th>
<th>2001–2005 THEN</th>
<th>2011–2015 NOW</th>
<th>Increase in COMPLEXITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endpoints</td>
<td>7</td>
<td>13</td>
<td>+86%</td>
</tr>
<tr>
<td>Procedures</td>
<td>110</td>
<td>187</td>
<td>+70%</td>
</tr>
<tr>
<td>Eligibility Criteria</td>
<td>31</td>
<td>50</td>
<td>+61%</td>
</tr>
<tr>
<td>Investigative Sites</td>
<td>40</td>
<td>65</td>
<td>+63%</td>
</tr>
<tr>
<td>Data Points Collected</td>
<td>494,236</td>
<td>929,203</td>
<td>+88%</td>
</tr>
</tbody>
</table>

Source: Getz KA, Campo RA
Innovative Biopharmaceutical Companies Seek to Improve R&D Efficiency

Biopharmaceutical companies are using new approaches to increase R&D efficiency and effectiveness.

**EXAMPLES INCLUDE:**

- **Improving target validation methods** to allow for greater accuracy in identifying and selecting the most promising drug candidates

- **Enhancing IT infrastructure** to improve efficiencies in translating drug discovery and preclinical data into clinical research activity

- **Using adaptive trial designs** to improve late-stage success rates and optimize clinical trial performance and data quality

> [Biopharmaceutical] companies are using a wide variety of innovative approaches to adapt the R&D and manufacturing process to the changing scientific landscape. These innovative approaches to drug discovery, development, and manufacturing shed light on a resilient enterprise making progress in improving the quality, performance, and efficiency of R&D and manufacturing.”

— Tufts Center for the Study of Drug Development

Source: Tufts CSDD
User Fee Agreements Are Critical to Modernizing the Drug Discovery and Development Process

The use of novel drug development tools will enable researchers to follow the trajectory of the science, which is creating new avenues of research, exploration, and discovery.

**Integrating patient perspective**
Advance patient-centered drug development at the FDA and throughout clinical trials process through appropriate incorporation of patient input and increased patient engagement.

**Advancing use of real-world evidence**
Keep pace with latest technological advances by enabling use of both safety and efficacy data in regulatory decision making.

**Increasing acceptance of innovative clinical trial designs**
Create efficiencies in drug development through use of adaptive clinical trial designs as well as increased use of advanced data analytics.

**Accelerating qualification and use of biomarkers**
Speed drug development timelines by creating efficiencies in review of biomarkers in order to advance personalized medicines and companion diagnostics.


Notes and Sources


Biopharmaceutical competition begins in the research and development (R&D) process, well before a medicine ever reaches a patient. Companies “race” to bring the first medicine in a therapeutic class to market, and once a medicine is approved, it typically faces swift competition from other brands in its class. The US prescription drug lifecycle promotes innovation while providing built-in cost containment because brands eventually lead to lower-cost generics—and soon many biosimilars—that bring long-term value to patients.

Ongoing investment in R&D depends on the commercial success of a few products that must make up for all the rest, including those that never reach the market. Recent research has found that average lifetime revenues from new drug launches have declined. Health plans have powerful tools, such as tiered formularies and step therapy, to manage the use of medicines, and negotiating power is increasingly concentrated among fewer pharmacy benefit managers, driving large rebates that reduce overall drug spending. Meanwhile, the market is rapidly evolving, increasingly linking payment to quality and value.
New pharmaceutical medicines face competition after a relatively short period on the market.

**Illustrative Pharmaceutical Lifecycle**

Average time to develop a new medicine:  
At least 10 years

Average time on market before generic entry:  
12.5 years

*For brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed

**Brand drug market share generally declines rapidly after generic entry.

Sources: PhRMA; Tufts CSDD; Grabowski H et al.
Nine Out of Every 10 US Prescriptions Are Filled With Generics

Generic Share of Prescriptions Filled, 1984-2016*

1984: 19%
1990: 33%
1996: 43%
2002: 52%
2008: 72%
2014: 88%
2016: 90%

*Generic share includes generics and branded generics. “Other” category from IMS National Prescription Audit™ not included in calculation.

Source: PhRMA analysis of IMS Health data
A "medicine" is defined as a novel active substance (i.e., a molecular or biologic entity or combination product in which at least one element had not been previously approved by the FDA). Sales are global sales net of rebates and discounts.

Few Approved Medicines Are Commercially Successful

Only about 1 in 5 FDA-approved medicines produce revenues that exceed the average cost of R&D.\textsuperscript{5}

Ongoing investment in R&D depends on the commercial success of a few products that must make up for all the rest, including those that never reach the market.

Present Value of Lifetime Sales of Medicines Introduced, 1991-2009\textsuperscript{6}

A "medicine" is defined as a novel active substance (i.e., a molecular or biologic entity or combination product in which at least one element had not been previously approved by the FDA). Sales are global sales net of rebates and discounts. Sources: Vernon JA et al.\textsuperscript{5}; Berndt ER et al.\textsuperscript{6}
The US Prescription Drug Lifecycle Promotes Innovation and Affordability

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Brand Name Then</th>
<th>Brand Name vs. Generic Now</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DIOVAN HCT</strong> Hypertension</td>
<td>$87</td>
<td>$13</td>
<td>-85%</td>
</tr>
<tr>
<td><strong>LIPITOR</strong> Cholesterol</td>
<td>$85</td>
<td>$4</td>
<td>-95%</td>
</tr>
<tr>
<td><strong>PLAVIX</strong> Blood Thinner</td>
<td>$166</td>
<td>$5</td>
<td>-97%</td>
</tr>
<tr>
<td><strong>SEROQUEL</strong> Schizophrenia</td>
<td>$87</td>
<td>$3</td>
<td>-97%</td>
</tr>
<tr>
<td><strong>ZYPREXA</strong> Schizophrenia &amp; Bipolar Disorder</td>
<td>$393</td>
<td>$8</td>
<td>-98%</td>
</tr>
</tbody>
</table>

Biopharmaceutical companies invest in pioneering research to bring new medicines to patients, and over time those medicines become available as lower-cost generic copies.

Each price represents the average annual price for 30 pills of the most commonly dispensed form and strength. “Then” price represents the average price in the year prior to generic entry. “Now” price represents the average price in CY 2014. Source: IMS Health
Medicines Offer Built-in Cost Containment, Which Is Unique in Health Care

The price of a medicine commonly used to prevent cardiovascular disease dropped 92% between 2005 and 2013, while the average charge for a surgical procedure to treat it increased 66% over the same period.

Source: PhRMA analysis of Healthcare Cost and Utilization Project Hospital Charge data®
Savings From the Prescription Drug Lifecycle
Reduce Treatment Costs for the Most Common Conditions

Incredible advances by innovative pharmaceutical companies, resulting from pioneering scientific work and large-scale investments, eventually lead to lower-cost generics that bring long-term value to consumers.

*Ten therapeutic classes most commonly used by Part D enrollees in 2006 were lipid regulators, angiotensin-converting enzyme inhibitors, calcium channel blockers, beta blockers, proton pump inhibitors, thyroid hormone, angiotensin II, codeine and combination products, antidepressants, and seizure disorder medications.

Source: Kleinrock M®
In the US Health Care System, Health Plans Have Powerful Tools to Reduce Spending on Medicines

- **Tiered Copays**: Higher cost to patients for brands than for generics and preferred brands.
- **Formularies**: List of covered drugs.
- **Prior Authorization**: Requirement to justify a medicine’s use before it is covered.
- **Concentrated Purchasing Power**: Individual pharmacy benefit managers buy medicines for more people than the populations of entire European countries.
- **Step Therapy**: Patients must try and fail on alternatives before certain medicines are covered.
- **Financial Incentives**: Payments to physicians and/or pharmacies for generic prescribing or switching patients to preferred brands.

Plans drive nearly all use of medicines to generics and “preferred” brands.

Source: IMS Health
Powerful Purchasers Negotiate on Behalf of Payers

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs), with the top 3 PBMs accounting for 70% of the market.

Total Equivalent Prescription Claims Managed, 2016

- OptumRx (UnitedHealth Group): 30%
- CVS Health (Caremark): 24%
- Express Scripts: 24%
- All Other: 22%

Source: Pembroke Consulting/Drug Channels Institute

Top 3 PBMs' Market Share 70%
Leveraging increased competition in the hepatitis C market, payers negotiated deep discounts off list prices for new medicines with manufacturers, reducing prices below those in many Western European countries.\textsuperscript{12}

### Case Study in Manufacturer-Payer Negotiations: Hepatitis C Medicines

<table>
<thead>
<tr>
<th>What Payers Claimed Would Happen</th>
<th>What Actually Happened</th>
</tr>
</thead>
</table>
| What they have done with this particular drug will break the country.... It will make pharmacy benefits no longer sustainable. Companies just aren’t going to be able to handle paying for this drug.” | The price is sufficiently low that we can go to our clients and say that they can treat every patient with hepatitis C.”  
  — Express Scripts, January 2015\textsuperscript{15} |
| This pricing, which Gilead attempts to justify as the cost of medical advancement, will have a tsunami effect across our entire health care system.” | We are receiving market-leading rates from both companies. Neither company wanted to be left off the formulary.”  
  — Prime Therapeutics, January 2015\textsuperscript{16} |
| Competitive market forces and hard-nosed bargaining make “tremendously effective” new hepatitis C medicines not just more accessible to ailing patients—but also offer good value to the U.S. health care system.” |  
  — The New York Times Editorial Board, September 2015\textsuperscript{17} |

Sources: LaMattina J\textsuperscript{12}; Cortez MF\textsuperscript{13}; Ignagni K\textsuperscript{14}; Silverman E\textsuperscript{15}; Langreth R\textsuperscript{16}; New York Times Editorial Board\textsuperscript{17}
Use of Generic Medicines Is Highest in the United States

Payers in the United States drive rapid and widespread adoption of generic medicines, allowing them to devote more resources toward newer innovative medicines.

Generic Share of Total Prescriptions Filled, 2015

<table>
<thead>
<tr>
<th>Country</th>
<th>Generic Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>89%</td>
</tr>
<tr>
<td>UK</td>
<td>79%</td>
</tr>
<tr>
<td>Korea</td>
<td>77%</td>
</tr>
<tr>
<td>Australia</td>
<td>75%</td>
</tr>
<tr>
<td>Mexico</td>
<td>74%</td>
</tr>
<tr>
<td>Germany</td>
<td>74%</td>
</tr>
<tr>
<td>Canada</td>
<td>72%</td>
</tr>
<tr>
<td>Turkey</td>
<td>63%</td>
</tr>
<tr>
<td>France</td>
<td>62%</td>
</tr>
<tr>
<td>Japan</td>
<td>55%</td>
</tr>
</tbody>
</table>

Source: PhRMA analysis of QuintilesIMS Institute data18
US Patients Have Access to Cancer Medicines on Average 2 Years Earlier Than Patients in Other Developed Countries

Other developed countries use centralized government price setting and coverage decisions to manage drug spending, resulting in significantly slower patient access to medicines than in the United States.

Delays in Oncology Medicine Approval and Reimbursement in Other Countries Following US Approval, 2010-2014

<table>
<thead>
<tr>
<th>Country</th>
<th>Delay Between US Approval and Country Approval</th>
<th>Delay Between Country Approval and Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>4 months</td>
<td>10 months</td>
</tr>
<tr>
<td>France</td>
<td>7 months</td>
<td>10 months</td>
</tr>
<tr>
<td>UK</td>
<td>13 months</td>
<td>10 months</td>
</tr>
<tr>
<td>Italy</td>
<td>15 months</td>
<td>10 months</td>
</tr>
<tr>
<td>Spain</td>
<td>17 months</td>
<td>10 months</td>
</tr>
<tr>
<td>Australia</td>
<td>17 months</td>
<td>15 months</td>
</tr>
</tbody>
</table>

Source: IMS Consulting Group19
US Patients Have Greater Access to New Cancer Medicines

Other developed countries use centralized government price setting and coverage decisions to manage drug spending, resulting in less patient access to medicines than in the United States.

Availability and Reimbursement Status by 2015 of 49 Cancer Medicines Launched Globally 2010-2014

<table>
<thead>
<tr>
<th>Country</th>
<th>Available and Reimbursed</th>
<th>Not Available or Not Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>41</td>
<td>37</td>
</tr>
<tr>
<td>Germany</td>
<td>32</td>
<td>27</td>
</tr>
<tr>
<td>France</td>
<td>25</td>
<td>27</td>
</tr>
<tr>
<td>Italy</td>
<td>23</td>
<td>26</td>
</tr>
<tr>
<td>Canada</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>Spain</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>UK</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>Scotland</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>Sweden</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>Australia</td>
<td>11</td>
<td>38</td>
</tr>
</tbody>
</table>

In the UK and Scotland, only drugs reimbursed through the National Institute for Health and Care Excellence and the Scottish Medicines Consortium were included among reimbursed drugs. Any additional medicines reimbursed through the Cancer Drugs Fund were not included due to the uncertainty of the continuation of this fund.

Source: IMS Institute for Healthcare Informatics
Clinical Factors Are the Biggest Driver of Physicians’ Prescribing Decisions

Factors Influencing Physicians’ Prescribing Decisions in the United States, 2013

<table>
<thead>
<tr>
<th>Factor</th>
<th>A great deal</th>
<th>Some</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical knowledge and experience</td>
<td>91%</td>
<td>8%</td>
</tr>
<tr>
<td>Patient's particular situation, including drug interactions, side effects, and contraindications</td>
<td>89%</td>
<td>9%</td>
</tr>
<tr>
<td>Articles in peer-reviewed medical journals</td>
<td>50%</td>
<td>42%</td>
</tr>
<tr>
<td>Clinical practice guidelines</td>
<td>48%</td>
<td>44%</td>
</tr>
<tr>
<td>Patient's insurance coverage and formulary</td>
<td>39%</td>
<td>44%</td>
</tr>
<tr>
<td>Information from colleagues and peers</td>
<td>38%</td>
<td>54%</td>
</tr>
<tr>
<td>Pharmaceutical company–sponsored educational programs featuring physician speakers, not Continuing Medical Education</td>
<td>11%</td>
<td>47%</td>
</tr>
<tr>
<td>Information from pharmaceutical company representatives</td>
<td>10%</td>
<td>53%</td>
</tr>
<tr>
<td>Information from insurance and prescription benefits manager representatives</td>
<td>10%</td>
<td>35%</td>
</tr>
</tbody>
</table>

Source: KRC Research

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3 • Market Dynamics—Fundamentals
Direct-to-Consumer Advertising Encourages Patient Engagement and Appropriate Use of Medicines

Advertising has promoted the appropriate use of oral breast cancer therapies consistent with medical practice guidelines.*

*Study measured the effect of DTCA on patients and doctors regarding the use of aromatase inhibitors (AIs) consistent with medical practice guidelines. The study found that DTCA spending on AIs was associated with an overall new AI prescription increase of 0.18% after 3 months (approximately 118 new AI prescriptions per million dollars spent). There was "no significant change associated with DTCA spending for AIs for those aged 40 years or less at any time from 0 to 6 months."

Source: Abel GA et al.22
Direct-to-Consumer Advertising Increases Awareness of Conditions and Treatments

A recent survey of consumers demonstrated the positive contribution of direct-to-consumer (DTC) advertising to patients’ knowledge.

How strongly do you agree or disagree with each statement?
Percentage who AGREE with each statement
(Survey of consumers, n=1564, April 2017)

- ...tell people about new treatments: 88%
- ...alert people to symptoms that are related to a medical condition they may have: 81%
- ...allow people to be more involved in their health care: 79%

Source: Princeton Survey Research Associates International23
Correctly accounting for R&D as a long-lived investment tends to reduce substantially, if not to eliminate altogether, the inference that pharmaceutical companies are on average achieving supranormal profit returns.”

— Frederic Scherer, AEI-Brookings Joint Center for Regulatory Studies

“[T]he standard accounting measure of profits overstates true returns to R&D-intensive industries, such as pharmaceuticals, and makes it difficult to meaningfully compare profit levels among industries. Accounting measures treat most R&D spending (except for capital equipment) as a deductible business expense rather than as a capitalized investment. But the intangible assets that research and development generate—such as accumulated knowledge, new research capabilities, and patents—increase the value of a company’s asset base. Not accounting for that value overstates a firm’s true return on its assets.”

— Congressional Budget Office

“Usual profit figures greatly overstate the industry’s economic profit rate.”

— Joseph Newhouse, Harvard University

Sources: Scherer FM, CBO, Newhouse JP
Biopharmaceutical Profits Are in Line With Those of Other Industries

The most relevant measures of profitability are those that drive actual investment, such as return on equity. Such measures show that the biopharmaceutical industry’s profits are in line with profits in many other industries.

Average Return on Equity for Selected Industries, 2014-2016

<table>
<thead>
<tr>
<th>Industry</th>
<th>Return on Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer Services</td>
<td>31.6%</td>
</tr>
<tr>
<td>Beverages (Soft)</td>
<td>27.4%</td>
</tr>
<tr>
<td>Aerospace/Defense</td>
<td>23.0%</td>
</tr>
<tr>
<td>Trucking</td>
<td>19.1%</td>
</tr>
<tr>
<td>Drugs (Pharma &amp; Biotech)*</td>
<td>16.2%</td>
</tr>
<tr>
<td>Software (System &amp; Application)</td>
<td>15.2%</td>
</tr>
<tr>
<td>Construction Supplies</td>
<td>14.9%</td>
</tr>
<tr>
<td>Health Care Support Services</td>
<td>14.4%</td>
</tr>
<tr>
<td>Farming/Agriculture</td>
<td>11.9%</td>
</tr>
<tr>
<td>Utility (General)</td>
<td>9.9%</td>
</tr>
<tr>
<td>Environmental &amp; Waste Services</td>
<td>7.9%</td>
</tr>
<tr>
<td>Engineering/Construction</td>
<td>3.0%</td>
</tr>
<tr>
<td>Telecom (Wireless)</td>
<td>-3.9%</td>
</tr>
<tr>
<td>Steel</td>
<td>-15.2%</td>
</tr>
</tbody>
</table>

*Represents the unweighted mean for pharmaceuticals (15.4%) and biotechnology (17.0%), which are listed as separate industries in the source data.

Source: PhRMA analysis of data from Damodaran A27
The Economics of Biopharmaceuticals Has Changed Markedly in Recent Years

**THE SCIENCE IS MORE COMPLEX AND MORE COSTLY**
- Researchers targeting more complex diseases
- Higher regulatory hurdles
- Longer, more complex clinical trials
- Genomics/molecular medicine are complex new frontiers
- Increased cost of R&D

**THE MARKET IS MORE CHALLENGING**
- Slow uptake of new medicines/rapid adoption of generics
- Unprecedented scale of patent expiries and patent challenges
- Increased payer demand for evidence
- Providers increasingly accountable for cost of care
- Increased patient cost sharing and access restrictions

Source: PhRMA

3 • Market Dynamics—Recent Trends
Average Lifetime Returns From Newly Introduced Medicines Have Declined in Recent Years

The R&D investments required to bring medicines to patients in the future rely on revenues from existing approved innovative medicines. Continued declines in average lifetime revenues from new medicines could reduce the ability of biopharmaceutical companies to maintain their historically high levels of innovation.

A "medicine" is defined as a novel active substance (ie, a molecular or biologic entity or combination product in which at least one element had not been previously approved by the FDA). Sales are global sales net of rebates and discounts.

Source: Berndt ER et al.29
Competition Has Increased Within Classes of Medicines

The time a medicine is the only drug available in its pharmacological class declined from a median of more than 10 years in the 1970s to close to 2 years from 2005 to 2011.

Time Between Approval of First and Second Medicines in a Pharmacological Class

Half of second medicines in a class were approved within 2.3 years of the first medicine’s approval. One-quarter were approved within just 4 months.

Source: Tufts CSDD

3 • Market Dynamics—Recent Trends
Earlier and More Frequent Patent Challenges by Generic Companies

As early as 4 years after brand launch, a generic company may file a Paragraph IV certification with the FDA to challenge patents associated with the brand medicine, often allowing generic market entry before the patent expiration date.

**Patent challenges are occurring earlier...**

*Average Time From Brand Launch to Paragraph IV Patent Challenge*

<table>
<thead>
<tr>
<th>Year</th>
<th>1995</th>
<th>2005</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years</td>
<td>14.3</td>
<td>8.5</td>
<td>5.2</td>
</tr>
</tbody>
</table>

...and are more common

*Share of Brand Products Experiencing at Least One Paragraph IV Patent Challenge Prior to Generic Entry*

<table>
<thead>
<tr>
<th>Year</th>
<th>1995</th>
<th>2005</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent</td>
<td>25%</td>
<td>60%</td>
<td>94%</td>
</tr>
</tbody>
</table>

All numbers are 3-year moving averages for brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed.

Source: Grabowski H et al.\(^{31}\)
Newly Introduced Generics Are Adopted Rapidly

When a generic version of a medicine becomes available for the first time, it captures an average of three-quarters of the market within 3 months. Some generics capture as much as 90% in that time.

Average Generic Share of Total Use Following Launch of a Brand Medicine’s First Generic*

*Average monthly generic share of total standardized units of a unique molecule/form combination

Sources: Grabowski H et al.; Express Scripts
Market for Medicines Is Changing Rapidly

- Value-Based Insurance Design
- Accountable Care Organizations
- Clinical Pathways
- Providers at Risk for Rx Costs
- Bundled Payments
- Value Assessment Frameworks
- Outcome-Based Arrangements
## Increasing Provider Accountability for Cost of Care and Pathway Compliance Is Influencing Prescribing Decisions

<table>
<thead>
<tr>
<th></th>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients in health plans that incentivize providers to prescribe certain treatments</td>
<td>37% 2014&lt;sup&gt;34&lt;/sup&gt;</td>
<td>90% 2017 (Projected)&lt;sup&gt;35&lt;/sup&gt;</td>
</tr>
<tr>
<td>Hospital participation in accountable care organizations responsible for cost of care&lt;sup&gt;36&lt;/sup&gt;</td>
<td>6% 2011</td>
<td>25% 2014</td>
</tr>
<tr>
<td>Medicare payments tied to alternative payment models, which include cost or quality incentives&lt;sup&gt;37&lt;/sup&gt;</td>
<td>0% 2009</td>
<td>30% 2016</td>
</tr>
<tr>
<td>Commercial market payments in which provider is at risk for cost of care&lt;sup&gt;38&lt;/sup&gt;</td>
<td>6% 2013</td>
<td>21% 2014</td>
</tr>
</tbody>
</table>

Sources: EMD Serono<sup>34,35</sup>; American Hospital Association<sup>36</sup>; HHS<sup>37</sup>; Catalyst for Payment Reform<sup>38</sup>
Innovative Market-Based Arrangements That Link Payment for Medicines to Outcomes Are on the Rise

Number of US Private-Sector Performance-Based Risk-Sharing Agreements for Prescription Medicines, 1997-2016

While the number of risk-sharing contracts has increased, reducing legal, regulatory, and operational barriers could significantly expand the number and scale of innovative contracting agreements.”

— Survey of PhRMA Member Companies

Sources: University of Washington School of Pharmacy, PhRMA
Pragmatic Solutions Can Address Cost Concerns

**MODERNIZE THE DRUG DISCOVERY AND DEVELOPMENT PROCESS**
Modernize the FDA to enable it to keep pace with scientific discovery and increase the efficiency of generic approvals.

**PROMOTE VALUE-DRIVEN HEALTH CARE**
Address barriers to paying for value, develop patient-centered value assessment tools, and support appropriate use of medicines.

**ENGAGE AND EMPOWER CONSUMERS**
Make information about quality and patient costs public to aid in decisions and enforce common-sense rules that prevent discrimination against vulnerable patients.

**ADDRESS MARKET DISTORTIONS**
Reform market-distorting programs such as the 340B Drug Pricing Program.

Source: PhRMA®
Notes and Sources


7. IMS Health analysis for PhRMA. May 2015.


Notes and Sources


Notes and Sources


COST SHARING TRENDS

Evaluating the Impact of Insurance Benefit Design on Patients

Insurers are increasingly using high deductibles, coinsurance, and multiple cost sharing tiers, which push more costs to some patients. Out-of-pocket spending for prescription medications can represent a disproportionate share of total health care costs borne directly by patients, especially those who are low income or chronically ill. High cost sharing for medications may limit patients’ access to needed treatments, reduce adherence, and lead to poor health outcomes.
Insurance Often Covers a Lower Share of Prescription Drug Costs Than the Costs of Other Medical Services

On average, patients pay out-of-pocket 13% of their prescription drug costs compared with 3% of costs for hospital care.

Average Share of Health Care Costs Patients Pay Out of Pocket, All Ages

- Hospital Care: 3%
- Prescription Drugs: 13%

Average, All Health Care (12%)

Source: Avalere analysis of Medical Expenditure Panel Survey, 2014

Prescription drug spending includes spending on brand and generic drugs, pharmacy, and distribution costs for retail prescriptions. Hospital care includes inpatient and outpatient.
Share of Commercial Health Plans With a Prescription Drug Deductible Is Increasing

Percentage of Plans With Deductibles for Prescription Drugs

- **2012**: 23%
- **2015**: 46% (+100%)

Cost sharing for patients is shifting from copayments to less predictable coinsurance.

Source: IMS Institute for Healthcare Informatics²
Patient Cost Sharing Rising as Plans Push More Costs to Patients Through Deductibles and Coinsurance, While Copayments Decrease

Trends in health plan design—toward higher deductibles, coinsurance, and decreased copayments—have shifted costs to patients at a higher rate than overall health plan costs.

Change Among Large Employer Health Plans, 2004-2014

- Patient Deductible Payments: 256%
- Patient Coinsurance Payments: 107%
- Patient Copayments: -26%
- Total Health Plan Payments: 58%

Source: Kaiser Family Foundation³
Subjecting Prescription Drugs to a Combined Deductible Results in Disproportionately High Patient Cost Sharing

When drug coverage is subjected to a large combined (medical and drug) deductible, on average, patients pay a higher share of their drug costs compared with their other health care services costs.

Average Share of Costs Paid by the Plan Among Silver Plans With a Combined Medical/Drug Deductible, 2014*

- Pharmacy: 54%
- Hospital: 72%
- Professional/Other: 71%

*Silver plans accounted for a majority of Health Insurance Exchange enrollment, and combined deductibles were the most common type of deductible arrangement among these plans. A deductible is the amount patients must pay annually with their own money (out of pocket) before a health plan will pay for any expenses. The figure shows the actuarial value for each service category listed (ie, the percentage of covered costs paid by the plan).

Source: Milliman, Inc. 4
Plains Increasingly Subject Certain Medicines to Higher Cost Sharing

Increased use of 4 or more tiers by plans means that more patients are subject to what is commonly higher cost sharing on the specialty tier. Medicines on the specialty tier are also more likely to be subject to coinsurance than products placed on lower cost sharing tiers. 

The use of 4 or more cost sharing tiers is...

*Silver plans account for a majority of Health Insurance Exchange enrollment. "Tiers" refer to the different levels of cost sharing that plans require patients to pay for different groupings of medicines.

Sources: KFF; Avalere Health PlanScape®; KFF/Health Research & Educational Trust
Cost Sharing Is Based on the Undiscounted List Price When Patients Pay for Brand Drugs With Coinsurance or in a Deductible

Cost sharing for nearly 1 in 5 brand prescriptions is based on list price.

More than half of commercially insured patients’ out-of-pocket spending for brand medicines is based on list price.

Source: PhRMA®
Insurers May Be Discouraging Enrollment Through Drug Benefit Design

By placing all drugs to treat certain high-cost conditions on the highest drug formulary cost sharing tier, a practice known as adverse tiering, some insurers may be trying to discourage patients with certain conditions from enrolling in their plans.

Cystic fibrosis and PCSK9 products were excluded because each group contains only two drugs.

Other classes not appearing in this chart had rates below 1% in 2016.

Source: Avalere Health PlanScape®
RAND researchers found that doubling copays reduced patients’ adherence to prescribed medicines by 25% to 45% and increased emergency room visits and hospitalizations.

Source: Goldman DP et al.10
Patients Facing High Cost Sharing Commonly Do Not Initiate Treatment

Chronic myeloid leukemia patients facing high out-of-pocket costs for medicines on a specialty tier are less likely to initiate drug therapy than patients receiving a cost sharing subsidy and take twice as long to initiate treatment.

Percentage of Chronic Myeloid Leukemia Patients Initiating Treatment

- **Patients facing high cost sharing**
  - 1 month: 21%
  - 3 months: 36%
  - 6 months: 45%

- **Patients facing minimal cost sharing**
  - 1 month: 53%
  - 3 months: 65%
  - 6 months: 67%

Time Following Diagnosis

Source: Doshi JA et al.\(^{11}\)
Formulary Restrictions Can Lead to Greater Medical Spending

Nonelderly Medicaid patients facing formulary restrictions* for antipsychotic medications were 7% to 13% more likely to be hospitalized and had higher medical costs than patients in states without formulary restrictions.

*Restrictions examined: prior authorization, step therapy, and quantity limits

Source: Seabury SA et al.12
Patient Assistance Programs Help Patients Access Needed Medicines

Despite more Americans having insurance, many are facing high cost sharing that puts their ability to stay on a needed therapy at risk. Patient assistance programs sponsored by US biopharmaceutical companies are one option to help patients maintain access to needed medicines.

Since 2005, the Partnership for Prescription Assistance (PPA) has helped connect NEARLY 10 MILLION uninsured or underinsured patients to assistance programs that may provide medicines they need for free or nearly free.

**WHAT PPA OFFERS**

- Single point of access to information on more than 475 public and private patient assistance programs—including nearly 200 programs offered by biopharmaceutical companies

- A database of nearly 10,000 free or low-cost health care clinics across the country
Notes and Sources

1. Avalere Health analysis of the US Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, 2014. https://meps.ahrq.gov/mepsweb. Accessed May 2017. Analysis includes individuals with any source of health care coverage, public or private; this includes individuals who had health coverage without coverage for prescription drugs, which can be expected to account for less than 2% of those with health coverage.


6. Avalere Health PlanScape®, a proprietary analysis of exchange plan features, December 2015.


9. Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC (MMIT). Coverage is weighted according to unique plan-state combinations. Sample includes all silver plans offered in 50 states and the District of Columbia. MMIT uses universal tier status rather than raw tier numbers to facilitate comparisons across plans and markets. Avalere Health uses universal tier status for tiering analyses and raw tier status for cost-sharing analyses.
Notes and Sources


Prescription medicines represent a small share of national health spending, and government estimates project medicines to remain a stable share of health spending through the next decade. Multiple sources confirm a significant slowdown in net prescription medicine spending growth over the past 2 years. Brand medicine net prices continue to grow at low single-digit rates, reflecting the rebates and discounts paid by brand manufacturers. Rebates, discounts, and fees paid by brand manufacturers increased to $106 billion in 2015, with more than one-third of gross spending rebated back to payers or retained by the supply chain.
Prescription Medicine Spending Growth: 2008-2025*

Government actuaries project prescription drug spending growth to remain between 6% and 8% through 2025, in line with overall health care spending growth.¹

2014 saw a record 41 medicines approved by the FDA—including a number of transformative medicines for debilitating diseases—as well as 15.7 million Americans gaining coverage through the Affordable Care Act.²³

*Total retail sales including brand medicines and generics

Sources: PhRMA analysis of CMS data¹; RAND Corporation²; FDA³
Prescription Medicines Are Expected to Account for a Stable Share of Total Health Care Expenditures Through 2025

US Health Care Expenditures Attributable to Retail and Nonretail Prescription Medicines, 2008-2025*

*Retail prescription medicines are those filled at retail pharmacies or through mail service. Nonretail prescription medicines are those purchased through physicians’ offices, clinics, and hospitals and are typically administered to the patient by the provider.

Source: Altarum Institute
Spending on All Prescription Medicines Is a Small Share of Total US Health Care Spending

Prescription medicines, whether picked up at a retail pharmacy or administered by a physician or hospital, account for about 14% of total annual health care spending. Half of this total goes to brand manufacturers, with the rest going to generic manufacturers and the supply chain.

*Supply chain entities include wholesalers, pharmacies, pharmacy benefit managers, and health care provider locations.

**Other includes expenditures for Other Professional Services, Nondurable Medical Products, Durable Medical Equipment, Public Health Activity, Research, Structures, and Equipment.

Sources: PhRMA analysis of CMS data⁵; Altarum Institute⁶; Berkeley Research Group⁷
Multiple Data Sources Confirm Dramatic Slowdown in Prescription Medicine Spending Growth

Government actuaries reported a slowing of net prescription drug spending growth in 2015, and numerous sources showed a further slowing in 2016.

**Annual Growth in Net Prescription Medicine Spending**

<table>
<thead>
<tr>
<th>Source</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altarum Institute*</td>
<td>6.6%</td>
<td>4%</td>
</tr>
<tr>
<td>CVS Health</td>
<td>5.0%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Express Scripts</td>
<td>5.2%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Quintiles IMS</td>
<td>8.5%</td>
<td>4.8%</td>
</tr>
</tbody>
</table>

*Altarum estimates represent growth in spending from December of prior year to December of year listed. All other estimates represent average annual growth from previous year.

Sources: CMS; Altarum Institute; CVS Health; Express Scripts; IMS Institute for Healthcare Informatics
$140 Billion of US Brand Sales Are Projected to Face Generic or Biosimilar Competition From 2017 to 2021

The savings from new generics and biosimilars in the coming years are expected to match the large-scale savings observed in recent years.

Pre-LOE* Value of Small Molecule and Biologic Products at Risk (in Billions), 2012-2021

- **2012-2016:** $94 Billion
- **2017-2021:** $140 Billion**

*Pre-loss of exclusivity (LOE) sales of products are calculated for products facing LOE in each year; the sales in the prior year for each product are aggregated to represent the collective industry exposure to LOE. LOE does not indicate generic or biosimilar market entry.

**Figures may not sum due to rounding.

Source: QuintilesIMS Institute**

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87x416

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**Figures may not sum due to rounding.

Source: QuintilesIMS Institute**
Cumulative Spending Growth for Other Health Care Services Will Be 5 Times That of Medicines Through Next Decade

Projected Cumulative Growth in Spending (in Millions), 2016-2025

- Other Health Care Services
  - 10-year cumulative increase: $2,044 billion
- Prescription Drugs (Retail and Nonretail)
  - 10-year cumulative increase: $390 billion

Sources: CMS14; PhRMA analysis of Altarum Institute data15
Spending on Cancer Medicines Represents About 1% of Overall Health Care Spending

Cancer Medicines as a Portion of Total US Health Care Spending, 2016

*2016 CMS total national health expenditures is a projection.
**Cancer drug invoice spending does not include discounts.

Sources: QuintilesIMS Institute\textsuperscript{16}; CMS\textsuperscript{17}
Medicines Account for a Small Share of Health Spending Differences Between the United States and Other Countries

Per Capita Health Care Spending in the United States, Canada, and Germany, 2014

Other health care services, such as hospitalizations and physician visits, drive the large majority of the spending differences between OECD* countries.

- **United States**: $9,024
  - **Rx Medicines**: $5,119
  - **All Other Health Care**: $3,905
- **Canada**: $4,492
  - **Rx Medicines**: $1,886
  - **All Other Health Care**: $2,606
- **Germany**: $5,119
  - **Rx Medicines**: $2,092
  - **All Other Health Care**: $3,033

*Organisation for Economic Co-operation and Development (OECD)

Source: PhRMA analysis of OECD data

---

5 • Drug Spending Trends
Growth in Prescription Medicine Prices Has Been in Line With Other Health Care Prices

Average Price Levels, Selected Goods and Services, 2007-2016

Source: PhRMA analysis of Bureau of Labor Statistics data
Rebates and Other Discounts Reduced Average Price Growth for Brand Medicines by Nearly Two-Thirds in 2016

Commonly reported invoice (or list) prices are higher than what payers ultimately pay for medicines.

Average Price Growth for Brand Medicines, 2011-2016*

*Includes protected brand medicines only (ie, brand medicines without generic versions available in the year indicated).

**Net price growth reflects impact of off-invoice rebates and discounts provided by manufacturers.

Source: QuintilesIMS Institute

5 • Drug Spending Trends
More Than One-Third of Gross Spending for Brand Medicines Is Rebated Back to Payers or Retained by the Supply Chain

Manufacturers received less than $63 for every $100 of gross spending on brand medicines in 2015.

<table>
<thead>
<tr>
<th>Gross Brand Rx Spending*</th>
<th>$100.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market Access Rebates &amp; Discounts</td>
<td>-$18.50</td>
</tr>
<tr>
<td>Statutory Rebates &amp; Fees</td>
<td>-$12.00</td>
</tr>
<tr>
<td>Other Supply Chain Entities**</td>
<td>-$6.90</td>
</tr>
<tr>
<td><strong>Net Payment to Manufacturer</strong></td>
<td>$62.60</td>
</tr>
</tbody>
</table>

*Gross brand prescription spending represents the initial payment made to pharmacies prior to any off-invoice rebates and discounts. This is the measure typically seen in public reports.

**Other supply chain entities include pharmacies, providers, wholesalers, and group purchasing organizations.

Total US rebates, discounts, and fees paid by brand manufacturers increased from $67 billion in 2013 to $106 billion in 2015.

Source: Berkeley Research Group
Notes and Sources


Notes and Sources


Outcomes and Savings

Overcoming Gaps in Treatment, Improving Outcomes, and Reducing Costs Through Better Use of Medicines

Undertreatment of complex and chronic conditions as well as suboptimal use of prescribed medicines are significant public health problems, costing the US economy hundreds of billions of dollars each year. Medicines help patients live healthier lives and reduce the need for costly health care services such as emergency department visits, hospital stays, surgeries, and long-term care. An ever-growing body of evidence demonstrates that improved use of prescribed medicines can result in better health outcomes, lower costs for other health care services, and increased worker productivity.
The Human and Economic Costs of Chronic Disease

More than 1 million lives could be saved annually through better treatment and prevention of chronic disease.

- **Mean annual cost per person in the US**: $8,600
- **AMERICANS**: 191 million have at least one, 75 million have multiple chronic diseases.

**Costs of CHRONIC DISEASE in 2015**
- **Annual costs**: $2.8 trillion in medical costs and lost productivity
- **5% of the population** accounts for **50% of US health care spending**

Sources: IHS¹; Agency for Healthcare Research and Quality²
Diabetes: An Example of Underdiagnosis and Undertreatment

Uncontrolled diabetes can lead to kidney failure, amputation, blindness, and stroke.

PREVALENCE

30 million Americans have DIABETES

DIAGNOSIS

23 million are DIAGNOSED

TREATMENT*

19 million are TREATED

CONTROL

8 million have CONTROLLED DIABETES

4 million are TREATED

8 million have UNCONTROLLED DIABETES

7 million are UNDIAGNOSED

11 million are UNSUCCESSFULLY TREATED

*Treatment includes blood sugar control (medicines, diet, and exercise) and testing to prevent complications. Data rounded to whole numbers.

Source: IHS Life Sciences analysis of CDC data

6 • Outcomes and Savings
Potential Savings From Better Use of Medicines

Better use of medicines could eliminate up to $213 billion in US health care costs annually, which represents 8% of the nation’s health care spending.

Avoidable Annual US Health Care Costs, 2012 (in Billions)

- Nonadherence: $105
- Medication Errors*: $21
- Suboptimal Prescribing**: $87
- Total Avoidable Costs: $213

*Category includes medication errors ($20 billion) and mismanaged polypharmacy ($1 billion)
**Category includes untimely medicine use ($40 billion), inappropriate antibiotic use ($35 billion), and suboptimal generic use ($12 billion)

Source: IMS Institute for Healthcare Informatics
Failure to Prescribe the Indicated Treatment Is the Most Common Prescribing Quality Problem

RAND researchers report that failure to prescribe an indicated treatment is a far more common quality problem than inappropriate medicine use.

![Quality Problems Among Vulnerable Older Patients](chart)

*Quality indicators were developed and implemented based on systematic literature reviews and multiple layers of expert judgment.

Source: RAND Health
Better Use of Medicines Yields Significant Health Gains by Avoiding the Need for Other Medical Services

Due to a growing body of evidence, in 2012 the Congressional Budget Office (CBO) began recognizing reductions in other medical expenditures associated with an increased use of prescription medicines in Medicare.

Pharmaceuticals have the effect of improving or maintaining an individual’s health... adhering to a drug regimen for a chronic condition such as diabetes or high blood pressure may prevent complications... taking the medication may also avert hospital admissions and thus reduce the use of medical services.”

— CBO

Since the CBO announcement, the evidence has continued to develop, broadening the potential for cost offsets in the health care system.

**CHRONIC DISEASES**

Medicare savings due to better use of medicines may be 3 to 6 times greater than estimated by the CBO for seniors with common chronic conditions, including heart failure, diabetes, and hypertension.

**MEDICAID**

Increased use of medicines is associated with reductions in Medicaid expenditures from avoided use of inpatient and outpatient services.

Sources: CBO; Roebuck MC; Roebuck MC et al.
Mounting Evidence Demonstrates the Potential for Savings and Improved Outcomes

**HYPERTENSION**
Better treatment and adherence to antihypertensive medicines could save nearly 200,000 lives and avert more than 1 million hospitalizations.⁹

**DIABETES**
Improved medication adherence among diabetes patients could result in more than 1 million avoided emergency department visits and hospitalizations annually, for potential savings of $8.3 billion each year.¹⁰

**MENTAL HEALTH**
Better management of and adherence to treatment for mental health can save $22.8 billion annually.¹¹

**CONGESTIVE HEART FAILURE**
Improving adherence to congestive heart failure medicines could result in federal savings of $22.4 billion over 10 years.¹²

Nonadherence has also been linked to excess hospitalizations for conditions such as osteoporosis,¹³ chronic obstructive pulmonary disease,¹⁴,¹⁵ and other chronic conditions¹⁴-¹⁸ with costs of more than $200 billion per year.¹⁹

Sources: Cutler DM et al.⁹; Dall TM et al.¹⁰; IHS Markit¹¹; Jiang Y, Ni W¹²; Modi A et al.¹³; Stuart BC et al.¹⁴; van Boven JF et al.¹⁵; Roebuck MC et al.¹⁶; Stuart B et al.¹⁷; Stuart BC et al.¹⁸; IMS Institute for Healthcare Informatics¹⁹
Recent Studies Show Significant Value From Better Use of Medicines

Patients with less common diseases are able to offset health care spending by exercising better adherence.

**PARKINSON’S DISEASE**
Health care savings of **up to $6,300** in less than 2 years can be achieved among patients with Parkinson’s who continually stay on therapy.\(^{20}\)

**MULTIPLE SCLEROSIS**
Improved persistence to medications reduces the likelihood of a patient’s hospital admission by **up to 50%**.\(^{21}\)

**CYSTIC FIBROSIS**
Among children with cystic fibrosis, poor medication adherence is associated with more hospitalizations and emergency department visits and an increase of **more than $14,000** in same-year medical costs compared with children who are highly adherent.\(^{22}\)

**LUPUS**
Nonadherence among children on Medicaid who are diagnosed with lupus is associated with a **55%** increased rate of emergency department use and a nearly **40%** increased rate of hospitalizations.\(^{23}\)

Sources: Wei YJ et al.\(^{20}\); Thomas NP et al.\(^{21}\); Quittner AL et al.\(^{22}\); Feldman CH et al.\(^{23}\)
Improving Adherence Increases Worker Productivity

For workers with asthma/chronic obstructive pulmonary disease (COPD), better medication adherence results in more than $3,100 in savings on average per worker annually.

Difference in Absenteeism and Short-Term Disability for Adherent Patients Compared With Nonadherent Patients

Source: Carls GS et al.24
Gaining Drug Coverage Reduced Other Medical Spending

The Medicare prescription drug benefit increased access to medicines for those previously without drug coverage, resulting in reduced nondrug medical spending\(^{25}\) and an overall savings of $13.4 billion in 2007, the first full year of the benefit.\(^{26}\)

**Average Reduction in Nondrug Medical Spending in 2006 and 2007 for Beneficiaries Who Gained Drug Coverage Through Medicare Part D\(^{25}\)**

<table>
<thead>
<tr>
<th>Part A</th>
<th>Part B</th>
<th>Other Nondrug*</th>
<th>Total Nondrug Medical Spending</th>
<th>Average Total Spending Reduction per Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td></td>
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<tr>
<td>-$200</td>
<td>-$200</td>
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<td>-$400</td>
<td>-$400</td>
<td>-$400</td>
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<td>-$600</td>
<td>-$600</td>
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<td>-$800</td>
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<tr>
<td>-$1,000</td>
<td>-$1,000</td>
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<tr>
<td>-$1,200</td>
<td>-$1,200</td>
<td>-$1,200</td>
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<tr>
<td>-$1,400</td>
<td>-$1,400</td>
<td>-$1,400</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Average

\(-$816\)

\(-$268\)

\(-$140\)

\(-$1,224\)

\*Home health, durable medical equipment, hospice, and outpatient institutional services

**PART D**

Since the implementation of Part D in 2006, nearly 200,000 Medicare beneficiaries have lived at least 1 year longer, with an average increase in longevity of 3.3 years.\(^{27}\)

Sources: McWilliams JM et al.\(^{25}\), Afendulis CC, Chernew ME\(^{26}\), Semilla AP et al.\(^{27}\)
Notes and Sources


Notes and Sources


Notes and Sources


27. Semilla AP, Chen F, Dall TM. Reductions in mortality among Medicare beneficiaries following the implementation of Medicare Part D. Am J Managed Care. 2015;21:S165-S172.
Sustaining and Growing State and Local Economies

America’s biopharmaceutical industry is the foundation for one of the country’s most dynamic innovation and business ecosystems. The industry is among the most research and development (R&D) intensive in the United States, accounting for 1 out of every 6 dollars spent on domestic R&D by US businesses. The industry’s large-scale research and manufacturing supply chain supports high-quality jobs in communities across the United States. More biopharmaceutical venture capital is invested in startups in the United States than anywhere else in the world, providing an ongoing source of highly skilled jobs aimed at making advances in biopharmaceutical science. However, US leadership in innovation is facing increasing challenges from emerging global competitors seeking to attract and grow a biopharmaceutical presence in their own countries.
The Biopharmaceutical Industry Is the Single Largest Funder of Business R&D in the United States

The biopharmaceutical industry accounts for the single largest share of all self-funded R&D, representing 1 out of every 6 dollars (17%) spent on domestic R&D by US businesses. Furthermore, US industry is also the largest global funder of biopharmaceutical R&D, accounting for about half of all R&D investments worldwide.

*The remaining 57% share of business R&D spending is conducted by other industries, including subsectors of the machinery sector, the computer and electronic products sector, and the electrical equipment, appliance, and components sector.

Source: PhRMA analysis of National Science Foundation data
The US Biopharmaceutical Sector Invests More in R&D Relative to Sales Than Other Manufacturing Industries

The biopharmaceutical sector invests more in R&D relative to sales than any other manufacturing industry, investing more than 6 times the average for all manufacturing industries.

R&D as a Percentage of Sales by Industry, 2000-2013

- Pharmaceuticals & Medicines: 19.9%
- Semiconductor: 17.5%
- Computer & Electronic: 13.4%
- Medical Equipment & Supplies: 7.9%
- Chemical: 6.7%
- Aerospace: 5.8%
- Transportation: 3.7%
- All Manufacturing: 3.1%
- Petroleum & Coal: 0.3%

Source: NDP Analytics^2
The Biopharmaceutical Industry Invests More R&D Dollars per Employee Than Any Other Industry

According to a 2015 Brookings Institution study on advanced industries, the biopharmaceutical industry has the highest R&D intensity in the US economy. A more recent analysis found similar results, with biopharmaceutical companies investing more than 12 times the amount of R&D per employee as manufacturing industries overall.

R&D Expenditures per Employee by Manufacturing Sector and Industry, 2000-2013

<table>
<thead>
<tr>
<th>Industry</th>
<th>R&amp;D Expenditures per Employee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals &amp; Medicines</td>
<td>$147,281</td>
</tr>
<tr>
<td>Semiconductor</td>
<td>$57,755</td>
</tr>
<tr>
<td>Chemical</td>
<td>$55,717</td>
</tr>
<tr>
<td>Computer &amp; Electronic</td>
<td>$47,084</td>
</tr>
<tr>
<td>Aerospace</td>
<td>$23,231</td>
</tr>
<tr>
<td>Medical Equipment</td>
<td>$20,098</td>
</tr>
<tr>
<td>Transportation Equipment</td>
<td>$16,986</td>
</tr>
<tr>
<td>All Manufacturing Industries</td>
<td>$11,844</td>
</tr>
<tr>
<td>Petroleum &amp; Coal</td>
<td>$10,994</td>
</tr>
<tr>
<td>Machinery</td>
<td>$8,485</td>
</tr>
<tr>
<td>Electrical Equipment</td>
<td>$7,365</td>
</tr>
<tr>
<td>Misc Nonmedical Equipment</td>
<td>$4,622</td>
</tr>
</tbody>
</table>

Sources: Brookings Institution; NDP Analytics
The Biopharmaceutical Industry Employs the Largest Share of R&D Workers Across All Manufacturing Industries

One out of every 8 R&D workers in the nation’s manufacturing industries is employed by the biopharmaceutical industry.

Selected Manufacturing Industries’ Share of Total R&D Workers, 2013*

*All other manufacturing sectors account for the remaining 52% of the R&D workforce.

Source: PhRMA analysis of National Science Foundation data5
R&D Is a Driver of Economic Growth

Recognizing that R&D is a key contributor to economic growth, the Bureau of Economic Analysis in 2013 started measuring R&D in Gross Domestic Product (GDP) calculations. Over the past quarter century, biopharmaceutical R&D assets grew more than 1200%—fastest among all industries (which are up 200% on average)—and now account for more than one-third (36%) of all R&D assets in the United States.

*Current-cost net stock of intellectual property

Source: Bureau of Economic Analysis
The Economic Reach of the US Biopharmaceutical Industry

Every biopharmaceutical sector job supports nearly 5 additional jobs outside the industry.

803,000 direct jobs

1,817,000 indirect jobs

2,146,000 induced jobs

4,766,000 TOTAL JOBS

The biopharmaceutical industry supported more than 4.7 million jobs across the US economy in 2015.

Source: TEConomy Partners
The US Biopharmaceutical Sector Produces High-Quality Jobs in an Array of Fields

One-third of the jobs in the biopharmaceutical sector are in key STEM (Science, Technology, Engineering, and Math) occupations, a far higher share than in the private sector as a whole.

### Percentage of Jobs in Sector by Occupation, 2015*

<table>
<thead>
<tr>
<th>Private Sector Overall</th>
<th>Biopharmaceutical Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td>7%</td>
<td>14%</td>
</tr>
<tr>
<td>5%</td>
<td>12%</td>
</tr>
<tr>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>10%</td>
<td>8%</td>
</tr>
<tr>
<td>2%</td>
<td>8%</td>
</tr>
<tr>
<td>3%</td>
<td>7%</td>
</tr>
<tr>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>45%</td>
<td>9%</td>
</tr>
</tbody>
</table>

*Figures may not sum due to rounding.

**Indicates a STEM occupation

***Other occupations include health care practitioners/techs (3.2% of biopharma industry jobs); installation/maintenance/repair (2.4%); arts/design/entertainment/sports/media (1.0%); building & grounds cleaning/maint (0.6%); legal (0.4%); health care support (0.4%); protective services (0.3%); community/social services (0.3%); educ/training/library science (0.3%); construction/extraction (0.2%); personal care & service (0.1%); food prep/serving (0.1%); and farming/fishing/forestry (0.1%).

Source: TEConomy Partners®
US Biopharmaceutical Exports Have Grown

Biopharmaceutical exports have nearly tripled since 2002, accounting for about 4% of all US exports by 2016.

"Pharmaceuticals rank as one the top exporting sectors for IP-intensive industries in the United States."

— International Trade Administration

Sources: ITA; PhRMA analysis of USITC data
Industry-Sponsored Clinical Trials Contribute Significant Value to the Communities in Which They Are Located

In 2013, the biopharmaceutical industry sponsored 6,199 clinical trials of medicines in the United States, involving a total of 1.1 million volunteer participants and supporting a total of $25 billion in economic activity across all 50 states and the District of Columbia.*

Estimated Economic Impact From Industry-Sponsored Clinical Trial Sites Across the United States, 2013

*Estimates reflect only those activities occurring at clinical trial sites and exclude more centralized cross-site functions such as coordination and data analysis. Also excluded are nonclinical R&D activities such as basic and preclinical research and the significant economic contribution from non-R&D activities of the industry such as manufacturing and distribution. Source: Battelle Technology Partnership Practice11
States Are Increasingly Targeting the Biopharmaceutical Industry in Their Economic Development Plans

Recognizing the broad economic impact of the biopharmaceutical industry, states across the country are adopting a range of policies and programs to attract and grow the industry within their borders.

Common policies and programs that states are pursuing include:

- Adopting comprehensive, targeted strategies for life science industry development
- Building research capacity and infrastructure
- Building advanced manufacturing capabilities
- Advancing the STEM talent pipeline
- Accelerating innovation through entrepreneurial development programs
- Increasing the availability of financial capital for life science development
- Establishing economic incentives for life science innovation

Source: TEConomy Partners12
The United States Leads in Biopharmaceutical Intellectual Property

The intellectual property related to more than half of new medicines was created in the United States.

US Patents Granted in Pharmaceutical Technology by Region/Country of Inventor, 2014*

- United States, 55.2%
- European Union, 21.6%
- Japan, 6.4%
- Asia**, 5.4%
- China, 1.8%
- All Others, 9.5%

*Figures may not sum due to rounding.
**Asia includes India, Malaysia, Singapore, South Korea, and others.

Source: PhRMA analysis of National Science Foundation data

7 • Economic Impact
Two-thirds of worldwide venture capital investments in high-growth biopharmaceutical startups are made in the United States.

Biopharmaceutical Venture Capital Investment by Region/Country, 2016

- United States: 67%
- Europe: 19%
- China: 9%
- All Others: 5%

Source: NDP Analytics
The Biopharmaceutical Industry Supports a Broader Ecosystem Through Corporate Venture Capital

The corporate venture arms of established biopharmaceutical companies have helped fuel the next generation of medical innovations by investing more than $6 billion in startups in the US over the past decade. Much of this investment (90%) has been directed toward early-stage innovation and support for the formation of new startups.

US Biopharmaceutical Corporate Venture Capital Investment, 2006-2016

Source: NDP Analytics
Domestic giving made up the largest portion of total corporate giving across all sectors surveyed. Domestic giving made up 78% of total giving in 2013.* Ninety percent of these contributions were in the form of in-kind product donations.

### Biopharmaceutical Companies Lead Corporate Giving

Biopharmaceutical companies led worldwide corporate giving in 2013.* Ninety percent of these contributions were in the form of in-kind product donations.

<table>
<thead>
<tr>
<th>Average Corporate Giving by Sector</th>
<th>Total Giving as % of Pretax Profit</th>
<th>Total Giving per Employee</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Companies</td>
<td>1.0%</td>
<td>$644</td>
</tr>
<tr>
<td>Biopharmaceuticals</td>
<td>19.4%</td>
<td>$24,453</td>
</tr>
<tr>
<td>Energy</td>
<td>0.8%</td>
<td>$2,912</td>
</tr>
<tr>
<td>Utilities</td>
<td>1.2%</td>
<td>$1,092</td>
</tr>
<tr>
<td>Information Technology</td>
<td>1.1%</td>
<td>$666</td>
</tr>
<tr>
<td>Consumer Staples</td>
<td>1.1%</td>
<td>$608</td>
</tr>
<tr>
<td>Industrials</td>
<td>0.8%</td>
<td>$244</td>
</tr>
</tbody>
</table>

*Domestic giving made up the largest portion of total corporate giving across all sectors surveyed. Domestic giving made up 78% of total giving in 2013.

Source: CECP*16
The Biopharmaceutical Industry Is Advancing STEM Education in the United States

The STEM workforce accounts for more than 50% of the nation's sustained economic growth. From 2008 to 2012, PhRMA member companies and their foundations supported more than 90 STEM education programs across the United States, impacting more than 1.6 million students and 17,500 teachers.

PhRMA member company and foundation contributions to STEM education in the United States include:

- **4,500** Number of employee volunteers
- **27,000** Number of employee hours volunteered
- **600** Number of individual STEM-related grants awarded
- **$100M** Total STEM education program funding provided
- **85%** Percentage of industry-sponsored STEM programs focused on K-12

Source: Battelle Technology Partnership Practice
Other Nations Are Challenging US Leadership in Biopharmaceutical Innovation

"Today, a more intensive and globalized competition for the biopharmaceutical industry is taking root, with the developing world joining European competitors in seeking to challenge the U.S. global leadership in innovation. The United States is now facing increasing competition to attract and grow a biopharmaceutical presence not just from developed countries, but also from emerging nations such as Brazil, China, and Singapore that are laying the groundwork for future growth."

— TEConomy Partners

Key Measures for a Robust Biopharma Environment

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>China 0.47%</td>
<td>China 118%</td>
<td>China 580</td>
</tr>
<tr>
<td>Singapore 0.13%</td>
<td>Singapore 92.9%</td>
<td>Singapore 551</td>
</tr>
<tr>
<td>Brazil 0.11%</td>
<td>Brazil 44.2%</td>
<td>US 497</td>
</tr>
<tr>
<td>US -0.05%</td>
<td>US 37.6%</td>
<td></td>
</tr>
</tbody>
</table>

Source: TEConomy Partners
The Biopharmaceutical Industry Is Increasingly Focused on Environmental Sustainability

Biopharmaceutical companies are pioneers in green chemistry and are committed to finding creative and innovative ways, including the following, to reduce waste, conserve energy, and adopt other more environmentally friendly processes.

- Implementing manufacturing methods that replace many solvents with safer alternatives
- Constructing facilities that are LEED-certified (Leadership in Energy and Environmental Design)
- Expanding use of biocatalyzed processes, which are shorter, produce less waste, and reduce environmental impact
- Adopting new manufacturing processes to reduce emissions and energy use
- Adapting single-use production systems to minimize environmental impact
- Expanding focus on setting and achieving environmental goals to reduce environmental impact at the company level

Source: Deloitte
Fostering Growth of the US Biopharmaceutical Industry Depends on Policies That Support R&D Investment

Industry analysts have consistently identified 3 policy areas as critical for the US biopharmaceutical industry to remain an engine of economic growth and innovation:

- Strong INTELLECTUAL PROPERTY protections, including patent and data protection
- A well-functioning, science-based REGULATORY SYSTEM
- COVERAGE AND PAYMENT policies that support and encourage medical innovation

“The capability to innovate is fast becoming the most important determinant of economic growth and a nation’s ability to compete and prosper in the 21st century global knowledge-based economy.”

— Battelle Technology Partnership Practice

Sources: Battelle Technology Partnership Practice, PhRMA; Deloitte

7 • Economic Impact
Notes and Sources


6. US Department of Commerce, Bureau of Economic Analysis. National data. Table 2.1. Current-cost net stock of private fixed assets, equipment, structures, and intellectual property products by type. [https://bea.gov/iTable/iTable.cfm?ReqID=10&step=1#reqid=10&step=3&isuri=1&1003=18. Click on Section 2, then Table 2.1. Last revised September 7, 2016. Accessed May 2017.](https://bea.gov/iTable/iTable.cfm?ReqID=10&step=1#reqid=10&step=3&isuri=1&1003=18. Click on Section 2, then Table 2.1. Last revised September 7, 2016. Accessed May 2017.)

7. TEConomy Partners; for PhRMA. *The Economic Impact of the US Biopharmaceutical Industry.* Columbus, OH: TEConomy Partners; July 2017.

8. TEConomy Partners; for PhRMA. *The Economic Impact of the US Biopharmaceutical Industry.* Columbus, OH: TEConomy Partners; July 2017.


Notes and Sources


14. NDP Analytics; for PhRMA. Analysis of Thomson Reuters venture capital data. NDP Analytics; for PhRMA. Analysis of Thomson Reuters venture capital data.

15. NDP Analytics; for PhRMA. Analysis of Thomson Reuters ventur... data.


