Dr. Ryan

Ryan is a senior research scientist who works to discover potential treatments for autoimmune conditions like lupus. Ryan believes nothing is possible without innovation, which spurs his drive and passion to keep moving forward despite the numerous setbacks researchers in his field commonly face.

Mitra

Mitra is a school counselor living with an autoimmune disease she fights daily. Knowing that an army of researchers is working to develop the next treatment to improve her own and others’ lives serves as a source of optimism for Mitra and helps her maintain the resilience needed to face the challenges caused by her disease.
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**Cover photo:** Dr. Ryan Moslin, Bristol-Myers Squibb researcher; and Mitra, autoimmune disease survivor
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, the contributions of the biopharmaceutical sector, and costs and access in other developed countries.

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.
ADVANCES IN TREATMENT

Medicines’ Impact on Health and Quality of Life

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 heart disease, HIV/AIDS, cancer, and hepatitis C, 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 revolutionizing 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.*

Sources: CDC\(^{1,2}\)
# A Decade of Advances

<table>
<thead>
<tr>
<th>Year</th>
<th>2008</th>
<th>2010</th>
<th>2012</th>
<th>2014</th>
<th>2016</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
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<td>2009</td>
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<td></td>
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<tr>
<td><strong>2008</strong></td>
<td>New type of treatment for Crohn’s disease</td>
<td>First treatment for peripheral T-cell lymphoma</td>
<td>2 new multiple sclerosis drugs</td>
<td>Oral treatments for hepatitis C provide cure rates of more than 90%</td>
<td>First drug to treat spinal muscular atrophy</td>
<td>New drug class to treat HIV in patients who failed other therapies</td>
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<tr>
<td></td>
<td>First drug for symptoms of Huntington’s disease</td>
<td>First drug for gout in 40 years</td>
<td>First therapeutic cancer vaccine</td>
<td>17 new drugs to treat patients with rare diseases</td>
<td>New personalized therapy for chronic lymphocytic leukemia</td>
<td>First new treatment in 10 years to alleviate pain caused by endometriosis</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>3 new drugs to prevent migraines</td>
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<td><strong>2009</strong></td>
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<td><strong>2017</strong></td>
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<tr>
<td><strong>2018</strong></td>
<td></td>
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</tr>
</tbody>
</table>

- First drug for symptoms of Huntington’s disease
- First treatment for peripheral T-cell lymphoma
- First new drug for gout in 40 years
- 2 new multiple sclerosis drugs
- First therapeutic cancer vaccine
- First drug to target root cause of cystic fibrosis
- First drug to treat Cushing’s disease
- Oral treatments for hepatitis C provide cure rates of more than 90%
- 17 new drugs to treat patients with rare diseases
- First drug to treat spinal muscular atrophy
- New personalized therapy for chronic lymphocytic leukemia
- First drug to treat all 6 forms of hepatitis C
- New drug class to treat HIV in patients who failed other therapies
- First new treatment in 10 years to alleviate pain caused by endometriosis
- 3 new drugs to prevent migraines
- Oral treatments for hepatitis C provide cure rates of more than 90%
- 17 new drugs to treat patients with rare diseases
- First drug to target root cause of cystic fibrosis
- First drug to treat Cushing’s disease
- Oral treatments for hepatitis C provide cure rates of more than 90%
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- First drug to treat spinal muscular atrophy
- New personalized therapy for chronic lymphocytic leukemia
- First drug to treat all 6 forms of hepatitis C
- New drug class to treat HIV in patients who failed other therapies
- First new treatment in 10 years to alleviate pain caused by endometriosis
- 3 new drugs to prevent migraines

Source: FDA
Medicines Are Transforming the Treatment of Many Diseases

**Multiple Sclerosis (MS)**
Advances in recent years, including convenient oral medicines and the first-ever treatment for progressive MS, offer patients greater opportunity to better manage MS and slow disease progression.⁴

**Hepatitis C**
Recent therapeutic advances can cure the disease and help patients avoid serious disease complications—including cirrhosis, advanced liver disease, liver cancer, and death.⁵

**Cancer**
New therapies have contributed to a 27% decline in cancer death rates since the 1990s.⁶ The chance a cancer patient will live 5 years or more has increased 41% across all cancers since 1975.⁷

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

Sources: PhRMA⁴,⁵, Siegel RL et al.⁶, ACS⁷, 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.9

**Fabry Disease**10

Fabry disease is a genetic disorder that can cause fat buildup in blood vessels, nerves, and other organs and slowly progress to kidney disease, abnormal heart rhythm, stroke, and early death. The first treatment for adults was approved in 2018 and works by increasing the activity of a deficient enzyme.

**Hereditary Transthyretin-Mediated Amyloidosis (hATTR)**12

hATTR interferes with the normal functioning of nerves, heart, and other organs and can lead to loss of sensation, pain, or immobility in the limbs. The first treatment for this often fatal genetic disease was approved in 2018 and targets the root cause by interfering with abnormal RNA protein production.

**Primary Hemophagocytic Lymphohistiocytosis (HLH)**11

Primary HLH is an inherited and life-threatening immune disorder typically affecting children. The disorder causes damage to various organs, including the liver, brain, and bone marrow. The first treatment specifically for HLH was approved in 2018 for adults and children.

**Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)**13

BPDCN is an aggressive blood cancer affecting multiple organs, including the lymph nodes and skin. The first treatment specifically for BPDCN was approved in 2018 for adults and children. Prior to this treatment, intensive chemotherapy and bone marrow transplant had been the standard of care.

Sources: Global Genes9; FDA10-13
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
AIDS Mortality in the United States

The number of AIDS deaths in the US decreased dramatically following the introduction of highly active antiretroviral therapy (HAART) combinations in 1996. 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.\textsuperscript{15}

**Annual Number of AIDS Deaths in the United States\textsuperscript{16,17}**

Sources: Truven Health Analytics\textsuperscript{15}; CDC\textsuperscript{16,17}
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{18,19}

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1981</td>
<td>AIDS first reported</td>
</tr>
<tr>
<td>1984</td>
<td>HIV identified as the cause of AIDS</td>
</tr>
<tr>
<td>1987</td>
<td>First treatment introduced: AZT* (a nucleoside analog reverse-transcriptase inhibitor)</td>
</tr>
<tr>
<td>1987</td>
<td>AZT labeling expanded for dosing, earlier use, and pediatric use</td>
</tr>
<tr>
<td>1991</td>
<td>First protease inhibitors approved</td>
</tr>
<tr>
<td>1991</td>
<td>First nucleotide analog approved</td>
</tr>
<tr>
<td>1994</td>
<td>AZT found to reduce the risk of transmission from mother to infant</td>
</tr>
<tr>
<td>1994</td>
<td>HAART combinations introduced</td>
</tr>
<tr>
<td>1994</td>
<td>First fusion inhibitors approved</td>
</tr>
<tr>
<td>1995</td>
<td>Rates of transmission from mother to infant dropped to less than 2%</td>
</tr>
<tr>
<td>1995</td>
<td>First one-pill-a-day treatment approved</td>
</tr>
<tr>
<td>1996</td>
<td>First protease inhibitors approved</td>
</tr>
<tr>
<td>2001</td>
<td>First nucleotide analog approved</td>
</tr>
<tr>
<td>2003</td>
<td>First C-C chemokine receptor type 5 agonist approved</td>
</tr>
<tr>
<td>2006</td>
<td>Rates of transmission from mother to infant dropped to less than 2%</td>
</tr>
<tr>
<td>2011</td>
<td>HHS recommended earlier initiation of treatment to control immunologic response</td>
</tr>
<tr>
<td>2012</td>
<td>First approval of a medicine for preexposure prophylaxis (PrEP)</td>
</tr>
<tr>
<td>2017</td>
<td>HIV/AIDS death rate in the US dropped 88% since the introduction of HAART</td>
</tr>
</tbody>
</table>

*AZT: Azidothymidine

Sources: Boston Healthcare Associates\textsuperscript{18}, CDC\textsuperscript{19,20}
Cancers: Decline in Death Rates

Since peaking in the 1990s, cancer death rates have declined 27%.\textsuperscript{21} Approximately 73% of survival gains in cancer are attributable to new treatments, including medicines.\textsuperscript{22}

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\textsuperscript{24}

Sources: Siegel RL et al\textsuperscript{21}; Seabury SA et al\textsuperscript{22}; NCI\textsuperscript{23}; Dunellari A\textsuperscript{24}
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.25

- After initial approval, continued research revealed that imatinib had a greater impact when initiated earlier in the progression of the disease.

- Further research 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.26

- Today, survival rates have improved dramatically, and CML patients are living close to normal life spans.27

Sources: Boston Healthcare Associates25; PhRMA26; Gambacorti-Passerini C et al.27; ACS28; Druker BJ et al.29
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{30}

Although more than 750 orphan drugs have been approved since the passage of the Orphan Drug Act in 1983, \textbf{continued innovation is still very much needed.}\textsuperscript{30}

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

Sources: NIH\textsuperscript{30}; FDA\textsuperscript{31}
Cardiovascular Disease: Declining Rates of Death

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

US Death Rates Due to Diseases of the Heart*

Since 2000 alone, the death rate from HEART DISEASE has declined by 36%.


Sources: CDC^32,33
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>Area</th>
<th>Percentage Decline</th>
<th>Number of Fewer Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional</td>
<td>-9%</td>
<td>765,500</td>
</tr>
<tr>
<td>Physical</td>
<td>-5%</td>
<td>408,000</td>
</tr>
<tr>
<td>Social</td>
<td>-4%</td>
<td>306,000</td>
</tr>
<tr>
<td>Cognitive</td>
<td>-3%</td>
<td>289,000</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.34
Hepatitis C: Advances Driving Down Prevalence of Disease

The introduction of direct-acting antivirals (DAAs) and subsequent improvements in cure rates revolutionized the treatment of hepatitis C (HCV), significantly driving down prevalence of disease.

Decreasing Number of HCV-Infected Patients, by Insurance Type, US 2010-2030$^{35*}$

*Cure Rates$^{36,37}$

- 1st Generation DAAs (Protease Inhibitors): 63-80%
- 2nd Generation DAAs (Polymerase Inhibitors): 84-90%
- 3rd Generation DAAs (Combination Antivirals): 93-100%

*Model takes into account launch of DAAs, change in HCV screening policies, and implementation of the Affordable Care Act.

Sources: Chhatwal J et al.$^{35}$; PhRMA$^{36}$; FDA$^{37}$
Hepatitis C Medicines Produce Savings in Medicaid

By 2019, total cumulative costs of HCV treatment since the introduction of highly effective interferon-free DAAs are expected to be fully offset by total cumulative health care costs associated with avoided costly disease complications in Medicaid. By 2020, these total cumulative savings are estimated to reach $12 billion.


Source: Roebuck MC et al.38
Unmet Need: Future Impact of New Treatments for Alzheimer’s Disease

The development of a new treatment that delays the onset of Alzheimer’s disease could reduce Medicare and Medicaid spending on patients by $218 billion annually by 2050.*


<table>
<thead>
<tr>
<th>Year</th>
<th>Current Trajectory</th>
<th>Projected With Delayed Onset Due to Treatment Advances</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>$182</td>
<td>$182</td>
</tr>
<tr>
<td>2030</td>
<td>$310</td>
<td>$262</td>
</tr>
<tr>
<td>2040</td>
<td>$529</td>
<td>$377</td>
</tr>
<tr>
<td>2050</td>
<td>$765</td>
<td>$547</td>
</tr>
</tbody>
</table>

*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 Association
Notes and Sources


Notes and Sources


Notes and Sources


The Process of Drug Discovery and Development

The rapid pace of scientific advances is bringing tremendous hope to patients. The pipeline for new medicines has never been more promising, with more than 8,000 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. 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 8,000 Medicines in Development Globally

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

**ALS (Amyotrophic Lateral Sclerosis)**
Stem cell therapies aim to replace and/or protect damaged motor neurons and slow disease progression.

**GENETIC DISORDERS**
Gene therapies can halt the progression of many diseases by directly altering the genetic mutations that cause them.

**RNAi technology** can prevent disease from occurring by interfering with the expression of genes.

**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.

**HEMOPHILIA**
Adeno-associated viral (AAV) vector-mediated gene therapies enable patients to clot blood and can reduce the need for chronic treatment to prevent bleeding episodes.

Source: Adis R&D Insight Database
**About 4,500 Medicines in Development in the United States**

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

<table>
<thead>
<tr>
<th>Disease</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CANCERS</strong></td>
<td>1,120</td>
</tr>
<tr>
<td><strong>HIV</strong></td>
<td>52</td>
</tr>
<tr>
<td><strong>SKIN DISEASES</strong></td>
<td>328</td>
</tr>
<tr>
<td><strong>RARE DISEASES</strong></td>
<td>566</td>
</tr>
<tr>
<td><strong>HEART DISEASE &amp; STROKE</strong></td>
<td>200</td>
</tr>
<tr>
<td><strong>ASTHMA &amp; ALLERGY</strong></td>
<td>130</td>
</tr>
<tr>
<td><strong>MENTAL DISORDERS</strong></td>
<td>140</td>
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<tr>
<td><strong>NEUROLOGICAL DISORDERS</strong></td>
<td>537</td>
</tr>
</tbody>
</table>

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

Source: Adis R&D Insight Database


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%

Source: Analysis Group\(^3\)
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 more than 770 orphan drug approvals (compared with fewer than 10 in the decade before passage).\textsuperscript{4}

\*Rare diseases are defined as conditions for which there are fewer than 200,000 patients diagnosed in the United States.

Sources: FDA\textsuperscript{4}; Danese E et al.\textsuperscript{5}; PhRMA\textsuperscript{6}
Cell and Gene Therapies Offer to Transform the Treatment of Disease

An exciting field of medicine is emerging, offering the possibility of treating and even curing disease by directly altering genes and cells. At a basic level, these therapies entail genetic manipulation of cells either inside or outside the body so that cellular function is permanently changed within the body. These medicines are revolutionizing the way disease is treated, often offering profound and durable responses after a single dose or administration.

Across multiple fields of science, we stand at an inflection point in medicine—where new technology is creating foundational opportunities to treat and cure disease in ways that weren’t possible just a short time ago…. Over the next several years, we’ll see this approach become a mainstay of treating, and probably curing, a lot of our most devastating and intractable illness.”

— Scott Gottlieb, MD
Commissioner, US Food and Drug Administration

5 diseases currently treated with cell and gene therapy

100+ diseases being explored for potential treatment with cell and gene therapies

289 cell and gene therapies in development

Sources: FDA; PhRMA
The Potential for Digital Health Advances to Enhance Drug Development and Patient Care

Technological advances can increase access to clinical trials, enable efficient information exchange, speed drug development and delivery of new treatments, enhance clinical decision making, and engage patients.

Digital-based care delivery and digital therapeutics have the potential to reduce burden on patients, clinicians, and investigators.

Continuous monitoring provides the ability to predict and detect health conditions.

Artificial intelligence and machine learning have the potential to improve analysis, modeling, and evaluation.

Digital technologies allow increased patient connectivity and empowerment.

Source: Adapted from Avalere Health®
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 42% \(^\text{10}\) of new medicines approved by the FDA in 2018 were PERSONALIZED MEDICINES.

42% \(^\text{11}\) of new medicines IN THE PIPELINE have the potential to be PERSONALIZED MEDICINES.

Sources: Personalized Medicine Coalition\(^\text{10}\); Tufts CSDD\(^\text{11}\)
The R&D Process for New Drugs Is Lengthy and Costly, With High Risk of Failure

From drug discovery through FDA approval, developing a new medicine takes, on average, 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.

*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.

Key: IND=Investigational New Drug Application, NDA=New Drug Application, BLA=Biologics License Application

Sources: PhRMA adaptation of DiMasi JA et al.12; Tufts CSDD13; FDA14
The Private Sector Leads the Translation of Basic Research Findings Into New Medicines

Percentage Contribution of R&D Milestones Achieved by Private and Public Sectors

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

Source: Chakravarthy R et al.
Biopharmaceutical Industry Does the 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 expertise and experience needed to develop new medicines.\textsuperscript{16}

2017 Biopharmaceutical Industry R&D Investment: $97 Billion\textsuperscript{17}

2017 NIH Research Spending: $32.6 Billion\textsuperscript{17}

In addition to basic research and biopharmaceutical-related research, NIH supports applied research on medical devices, diagnostics, prevention, and other areas.\textsuperscript{18}

Sources: Chakravarthy R et al.\textsuperscript{16}; Research!America\textsuperscript{17}; NIH\textsuperscript{18}
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.
Technology Transfer Between Universities and Industry Has Resulted in Economic Growth and Continued Innovation

Enacted in 1980, the Bayh-Dole Act created a uniform framework for the sharing of technology between universities and the private sector that has facilitated timely and effective commercialization of federally funded research.

**POSITIVE IMPACT OF BAYH-DOLE**

Commercialization of federally funded research has increased dramatically.

In 2017:

- **MORE THAN 1,000** startup companies were formed
- **NEARLY 800** commercial products stemming from university research were introduced

From 1996 to 2015, licensing activity spurred by Bayh-Dole included:

- **Close to $591 BILLION** contributed to US GDP
- **ABOUT 4.2 MILLION** US jobs supported across all industries

Sources: Association of University Technology Managers; Pressman L et al.
Collaboration Is Key in Researching and Developing New Medicines

The rapid pace of scientific 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:

- **Developing new diagnostics and biological targets for treatments in Alzheimer’s disease, type 2 diabetes, rheumatoid arthritis, Parkinson’s disease, and lupus**

- **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**

- **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**

- **Bolstering research to improve prevention and treatment for opioid misuse and addiction and enhancing pain management by developing new biomarkers and a data sharing collaborative**

**Sources:** NIH\(^21\); FNIH\(^22\); Lung-MAP\(^23\); NIH\(^24\)
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.

Source: Deloitte
PhRMA Member Company R&D Investment

PhRMA Member Company R&D Expenditures, 1995-2018

Expenditures (in Billions)

Source: PhRMA26
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)

- 1970s: $179M
- 1980s: $413M
- 1990s-Early 2000s: $1.0B
- 2000s-Early 2010s: $2.6B

Source: DiMasi JA et al.27
The Complexity of Clinical Trials Has Increased

During the past decade, clinical trial designs and procedures have become much more complex, reducing trial participation and retention rates.

<table>
<thead>
<tr>
<th>Clinical Trial Complexity</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 et al.28
Setbacks in Alzheimer’s Disease Research Provide Stepping Stones for Future Innovation

Since 1998, 146 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.

Unsuccessful Investigational Drugs for Alzheimer’s Disease, 1998-2017

146 Total Unsuccessful Drugs | 4 Total Approved Medicines

Source: PhRMA29
Cancer Researchers Build on Knowledge Gained From Setbacks to Inform Future Advances

Developing a new cancer medicine is a complex process and can take, on average, 1.5 years longer than the development of other medicines. Although the process is fraught with setbacks, some “failures” can inform future study and help guide 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

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.30; PhRMA31
Pediatric Clinical Research: Overcoming Challenges

The Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) establish requirements and provide important incentives that help increase the number of clinical studies in pediatric populations. These laws spur pediatric research for this vulnerable population.

**BPCA/PREA Success**

- Since 1998, more than 770 pediatric labeling changes
- Since 2007, more than 680 pediatric studies have been completed

**Unique Challenges in PEDIATRIC RESEARCH**

- Small patient populations
- Distinct dosage and formulation requirements
- Unique ethical, scientific, and medical considerations
- Difficult to enroll patients in trials

Before 1997

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

By 2012

That number had been reduced to nearly 50%

Sources: FDA; ACS
Enhancing the Drug Discovery, Development, and Review Process

The 21st Century Cures Act and Prescription Drug User Fee Act help ensure the FDA has the tools and resources needed to better manage the significant emerging science and innovation of today to meet the challenges of tomorrow.

INTEGRATING PATIENT PERSPECTIVE
Advance patient-focused drug development at the FDA and throughout the clinical trials process through appropriate incorporation of patient input, patient-reported outcomes, and increased patient engagement.

ADVANCING USE OF REAL-WORLD EVIDENCE
Keep pace with latest technological advances by enabling use of real-world evidence and real-world data in regulatory decision making.

INCREASING ACCEPTANCE OF INNOVATIVE CLINICAL TRIAL DESIGNS
Create efficiencies in drug development through use of adaptive clinical trial designs and pragmatic clinical trials as well as increased use of advanced data analytics.

ACCELERATING QUALIFICATION AND USE OF BIOMARKERS
Adapt biomarker qualification development and other regulatory pathways to support the development of emerging cell and gene therapies, personalized medicines, and companion diagnostics.
Learning From Patients to Develop Better Treatments

As important stakeholders in the drug development process, patients, family members, and caregivers can provide unique and valuable perspectives on the disease and available treatment options. These perspectives can inform evaluation of a medicine’s benefits and risks and provide the context for FDA regulatory decision making.

WHO CAN PROVIDE PATIENT PERSPECTIVES?

- Patients
- Family Members
- Caregivers

BENEFITS OF PATIENT PERSPECTIVES

- **RESEARCHERS**
  include patient perspective throughout drug development process.

- **THE FDA**
  incorporates patient perspective into its regulatory decision making.

- **NEW MEDICINES**
  reflect patient and caregiver needs.

Source: PhRMA\textsuperscript{18}
Notes and Sources

Notes and Sources


Notes and Sources

27. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: new estimates of R&D costs. *J Health Econ.* 2016;47:20-33. Previous research by DiMasi and Grabowski estimated the average R&D costs in the early 2000s at $1.2 billion in constant 2000 dollars (see DiMasi JA, Grabowski HG. The cost of biopharmaceutical R&D: is biotech different? *MDE Manage Decis Econ.* 2007;28:469-479). That estimate is based on the same underlying survey as estimates for the 1990s to early 2000s reported here ($800 million in constant 2000 dollars) but is updated for changes in the cost of capital.


MARKET DYNAMICS

The Economics of Drug Development and the Market Forces That Shape Spending on Medicines

Competition is a hallmark of the US prescription medicines market. Negotiating power is concentrated among a few pharmacy benefit managers (PBMs), which forces new medicines to compete for coverage and increases the likelihood of excluding medicines from coverage altogether. The built-in cost containment of the prescription drug lifecycle remains unique in health care, where new medicines eventually lead to lower-cost generics—and soon many biosimilars—that bring long-term value to patients.

Ongoing investment in research and development (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. Average returns on R&D investments have been declining. Accounting for uncertainty and risk, biopharmaceutical industry profits are in the middle range among all industries.

The market is rapidly evolving, increasingly linking payment to results and affecting how drugs are prescribed. Value-based contracts and other market-based arrangements show promise for improving outcomes and reducing costs.
Illustrative Pharmaceutical Lifecycle

New pharmaceutical medicines typically face competition after a relatively short time on the market, first from brand competitors, and eventually from generics.

<table>
<thead>
<tr>
<th>DRUG DEVELOPMENT</th>
<th>BRAND DRUG LIFESPAN*</th>
<th>GENERICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average time to develop a new medicine:</td>
<td>Average time on market before generic entry:</td>
<td>Generics remain in use for many years at a small fraction of the original brand’s cost.</td>
</tr>
<tr>
<td>At least 10-15 years³</td>
<td>12.5 years⁴**</td>
<td>**</td>
</tr>
</tbody>
</table>

Most brands already have at least one brand competitor when they enter the market or get one within 2 years.²

³Brand drug market share generally declines rapidly after generic entry.

²For brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed.

Sources: PhRMA¹; DiMasi JA et al.²,³; Grabowski H et al.⁴
Medicines Offer Built-in Cost Containment, Which Is Unique in Health Care

The price of a medicine commonly used to prevent cardiovascular disease dropped 90% between 2005 and 2015, while the average charge for a surgical procedure to treat it increased 92% over the same period.

Sources: PhRMA analysis of HCUP Hospital Charge data; IQVIA
Powerful Purchasers Negotiate on Behalf of Payers

Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs), each purchasing medicines for more people than the populations of entire European countries.

Top 3 PBMs’ Market Share 76%

- OptumRx (UnitedHealthGroup): 30%
- CVS Health (Caremark): 24%
- Express Scripts: 23%
- All Other: 23%

PBMs and insurers determine:

- **FORMULARY**: if a medicine is covered
- **TIER PLACEMENT**: patient cost sharing
- **ACCESSIBILITY**: utilization management through prior authorization or fail first
- **PROVIDER INCENTIVES**: preferred treatment guidelines and pathways

Source: Drug Channels Institute
Number of Brand Medicines Excluded From PBM Formularies Has Increased Over Time

When a medicine is excluded from a pharmacy benefit manager’s (PBM’s) formulary, patients cannot access it without paying the list price. This can interrupt the continuity of a patient’s treatment as well as their doctor’s ability to make prescribing decisions that best meet their patients’ needs.\(^8\)

Sources: Tufts CSDD\(^8\); Drug Channels Institute\(^9\)
Case Study in Manufacturer-Payer Negotiations: Hepatitis C Medicines

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.10

<table>
<thead>
<tr>
<th>What Payers Claimed Would Happen</th>
<th>What Actually Happened</th>
</tr>
</thead>
<tbody>
<tr>
<td>“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.” — Express Scripts, April 201411</td>
<td>“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 201513</td>
</tr>
<tr>
<td>“This pricing, which Gilead attempts to justify as the cost of medical advancement, will have a tsunami effect across our entire health care system.” — America’s Health Insurance Plans, July 201412</td>
<td>“We are receiving market-leading rates from both companies. Neither company wanted to be left off the formulary.” — Prime Therapeutics, January 201514</td>
</tr>
<tr>
<td>“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 201515</td>
<td></td>
</tr>
</tbody>
</table>

Sources: LaMattina J10; Cortez MF11; Ignagni K12; Silverman E13; Langreth R14; New York Times Editorial Board15
Brand-to-Brand Competition Drives Savings in US Market-Based System

Payers leverage purchasing power and competition among brand medicines to negotiate substantial discounts on medicines.

- **Hepatitis C**
  - First in class*
  - Direct-acting antivirals

- **Type 2 Diabetes**
  - First in class*
  - SGLT2 inhibitors

- **Cholesterol**
  - First in class*
  - PCSK9 inhibitors

*Indicates launch year of the first drug in this pharmacologic class.

Source: PhRMA analysis of SSR health data16
Few Approved Medicines Are Commercially Successful

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.

*"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.

Source: Berndt ER et al. 17
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>Number of 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 1 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>25%</td>
<td>60%</td>
<td>94%</td>
<td></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.18
Biopharmaceutical Profits Are in Line With Those of Other Industries

Adjusted for the significant risk and capital investments required to develop medicines, biopharmaceutical industry profits are average among industries.

*Economic profits are accounting profits minus capital expenses.

**Represents the weighted average of pharmaceuticals (8.2%) and biotechnology (2.2%), which are listed as separate industries in the source data.

Source: Adapted from Bates White19
Increasingly Complex Science and Challenging Markets Have Led to Diminishing Returns on Research Investments

Despite headlines about large revenues from new drug launches, biopharmaceutical companies have faced declining financial returns on their R&D investments.

Projected Internal Rate of Return for R&D Investments, 2010-2018

Source: Deloitte
Pharmacy benefit managers (PBMs) do not take possession of the medicines they manage, keeping their spending on fixed assets and other expenses very low. Their resulting profits are even higher than manufacturers’ profits, despite bearing very little risk.

Share of Gross Profit Converted to EBITDA, 2016-2017*

- **Pharmacies**: 29%
- **Insurers**: 31%
- **Manufacturers**: 44%
- **Distributors**: 46%
- **PBMs**: 85%

*Calculated as EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortization) margin divided by gross margin

Analysts at Bernstein tried to get a better picture of how profitable these [supply chain] companies are by excluding the cost of the drugs that are included in their revenue... By this analysis, pharmacy-benefit managers are exceptionally profitable.”

--- Charley Grant, *Wall Street Journal*

Sources: Bernstein Research\(^{21}\); NDP Analytics\(^{22}\); Grant C\(^{23}\)
Fees Paid to PBMs Have Increased Significantly

While pharmacy benefit managers (PBMs) have retained a smaller share of total rebates, they have offset lost profit from rebates with increased fees. In 2016, PBM revenue surpassed $22 billion, nearly twice the 2012 PBM revenue of $11.6 billion. Fees paid to PBMs quadrupled between 2014 and 2016 alone.

PBM Revenue by Source (in Billions), 2012-2016

Source: Pew Charitable Trusts

$0 $5 $10 $15 $20 $25

Part D Fees to PBM
Commercial Health Plan Fees to PBM
Manufacturer Fees to PBM
PBM Supply Chain Margin From Pharmacy
Retained Manufacturer Rebates

Total Fees $11B

Source: Pew Charitable Trusts
Accounting Treatment of R&D Overstates Biopharmaceutical Profits

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 Studies25

[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 Office26

Sources: Scherer FM25; CBO26
Hospitals Mark Up Medicines in the Outpatient Setting, Driving Up Costs to Patients and the Health System

Hospitals mark up medicine prices, on average, nearly 500%. The amount hospitals receive after negotiations with commercial payers is, on average, more than 250% what they paid to acquire the medicine.  

On a medicine with an ASP** of $150, this could result in a charge of $1,050 or more.  

Nearly 1 out of every 5 hospitals marks up medicines to 700% or more of their acquisition costs.  

*Percentages in chart may not add up to 100% due to rounding.  
**ASP: Average Sales Price
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 1,564 consumers, 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 International
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
Biopharmaceutical Company Marketing and Promotion Spending in Context

Use of inflated estimates of marketing and promotion spending has created the false impression that the biopharmaceutical industry spends more on marketing than on R&D. More precise estimates show the opposite to be true.

Select US Biopharmaceutical Industry Expenses, 2016

<table>
<thead>
<tr>
<th></th>
<th>$90.5B</th>
<th>$28.1B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and Development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketing and Promotion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**INCLUDES:**
- Advertising to Consumers
- Advertising to Health Care Professionals
- Sales Representatives

**EXCLUDES:**
- Freight Costs
- Other Unrelated G&A Expenses*

*Indicates general and administrative (G&A) expenses unrelated to marketing and promotion, such as finance and office staffs, rent, utilities, and supplies. Some have inaccurately used sales and G&A expenses as a proxy for industry marketing and promotion expenses.

Sources: Schwartz L et al.31; Research!America32
Increasing Provider Accountability for Cost of Care and Pathway Implementation Is Influencing Prescribing Decisions

<table>
<thead>
<tr>
<th>Health plan clinical pathway programs fully implemented with network oncologists&lt;sup&gt;33&lt;/sup&gt;</th>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>34%</td>
<td>57%</td>
</tr>
<tr>
<td>(Year)</td>
<td>2015</td>
<td>2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital participation in accountable care organizations responsible for cost of care&lt;sup&gt;34,35&lt;/sup&gt;</th>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6%</td>
<td>42%</td>
</tr>
<tr>
<td>(Year)</td>
<td>2011</td>
<td>2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicare payments tied to alternative payment models, which include cost or quality incentives&lt;sup&gt;36,37&lt;/sup&gt;</th>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0%</td>
<td>38%*</td>
</tr>
<tr>
<td>(Year)</td>
<td>2009</td>
<td>2017</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commercial market payments in which provider is at risk for cost of care&lt;sup&gt;37,38&lt;/sup&gt;</th>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6%</td>
<td>28%</td>
</tr>
<tr>
<td>(Year)</td>
<td>2013</td>
<td>2017</td>
</tr>
</tbody>
</table>

*Only represents fee-for-service and is a conservative estimate

Sources: Health Strategies Insights by EVERSANA<sup>33</sup>; American Hospital Association<sup>34,35</sup>; HHS<sup>36</sup>; HCP LAN<sup>37</sup>; Catalyst for Payment Reform<sup>38</sup>
Value-Based Contracts Deliver Results for Patients

Value-based contracts have the potential to benefit patients and the health care system by improving patient outcomes, reducing medical costs, and reducing the costs of medicines.

"We’ve been able to get the best of both worlds. The insurer gets competitive guaranteed discounts on prescriptions, and the manufacturer is aligned and accountable when something doesn’t work."

— Chris Bradbury, Cigna

Outcomes-Based Contracts are associated with

28% lower patient copayments.

Value-Based Contracts could generate more than

$12 Billion if they reduced the diabetes burden in the United States by only 5%.

Sources: PhRMA, Hopkins JS et al.
Innovative Market-Based Arrangements That Link Payment for Medicines to Outcomes Are on the Rise

The number of publicly announced outcomes-based contracts is expected to more than double by 2022.

New US Publicly Announced Outcomes-Based Contracts and Projected Future Increase

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>3</td>
<td>27</td>
</tr>
<tr>
<td>Neuromuscular Disorder</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Metabolic Disorder</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>All Others</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: IQVIA Institute®
Notes and Sources


Notes and Sources


19. Adapted by PhRMA from Bates White. Economic profitability of the biopharmaceutical industry. Report for PhRMA, June 2018. Updated data tables April 2019. Economic profit for each industry is calculated as: (net operating profit less adjusted taxes) - (invested capital x weighted average cost of capital).


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 medicines 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 medicines may limit patients’ access to needed treatments, reduce adherence, and lead to poor health outcomes. Manufacturer cost sharing assistance can help patients afford their medicines and lower abandonment rates.
Insurance Covers a Lower Share of Prescription Drug Costs Than Hospital Care Costs

On average, patients pay out of pocket 12% of their prescription drug costs compared with 4% of costs for hospital care. Meanwhile, hospital care as a percentage of US health care expenditures is significantly larger than outlays on medicines.

Average Share of Health Care Costs Patients Pay Out of Pocket, All Ages\(^1\)

<table>
<thead>
<tr>
<th>Service</th>
<th>Out-of-Pocket Cost Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Inpatient</td>
<td>2%</td>
</tr>
<tr>
<td>Hospital Outpatient</td>
<td>6%</td>
</tr>
<tr>
<td>Hospital Emergency Room</td>
<td>9%</td>
</tr>
<tr>
<td>Prescription Drugs</td>
<td>12%</td>
</tr>
</tbody>
</table>

32% of US Health Care Expenditures\(^2\)

10% of US Health Care Expenditures\(^2\)

Average, All Hospital (4%)

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. Prescription drug spending includes spending on brand and generic drugs, pharmacy, and distribution costs for retail prescriptions. Note: Prescription drug out-of-pocket costs are based on gross medicine price, not the net price after rebates.

Sources: Avalere analysis of Medical Expenditure Panel Survey, 2016\(^1\); CMS\(^2\)
Patient Spending Rises as Plans Use More Deductibles and Coinsurance

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

Change Among Large Employer Health Plans, 2006-2016

*Patient out-of-pocket costs are growing faster than overall costs of benefits.

Source: Kaiser Family Foundation
Share of Employer-Sponsored Health Plans With a Prescription Drug Deductible Is Increasing

The percentage of employer-sponsored plans requiring deductibles for pharmacy benefits continues to increase.

Percentage of Plans With Deductibles for Prescription Drugs

- 2012: 23%
- 2017: 52%

Source: PwC
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 becoming more common in employer plans.

Share of Workers in Plans With 4 or More Tiers

<table>
<thead>
<tr>
<th>Year</th>
<th>3%</th>
<th>5%</th>
<th>7%</th>
<th>13%</th>
<th>14%</th>
<th>20%</th>
<th>23%</th>
<th>32%</th>
<th>44%</th>
<th>51%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2010</td>
<td>7%</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>13%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>14%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>20%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>23%</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>32%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>44%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*52% of plans with coinsurance for the fourth tier have a maximum amount.

Sources: Kaiser Family Foundation
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 these patients take twice as long to initiate treatment.

Percentage of Chronic Myeloid Leukemia Patients Initiating Treatment

<table>
<thead>
<tr>
<th>Time Following Diagnosis</th>
<th>Patients facing high cost sharing</th>
<th>Patients facing minimal cost sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>21%</td>
<td>53%</td>
</tr>
<tr>
<td>3 months</td>
<td>36%</td>
<td>65%</td>
</tr>
<tr>
<td>6 months</td>
<td>45%</td>
<td>67%</td>
</tr>
</tbody>
</table>

Source: Doshi JA et al.7
High Cost Sharing Reduces Adherence

RAND researchers found that doubling copays reduced patients’ adherence to prescribed medicines by 25%-45% and increased emergency room visits and hospitalizations.

Percentage Change in Adherence From Doubling Medicine Copays, by Drug Class

Source: Goldman DP et al.²
Cost Sharing Is Based on the Undiscounted List Price When Patients Pay for Brand Drugs With Coinsurance or in a Deductible

In 2017, more than half of commercially insured patients’ out-of-pocket spending for brand medicines was based on list price.

*Percentages may not add up to 100% due to rounding.

Source: IQVIA®
Cost Exposure for Brand Medicines Is Becoming More Prevalent Over Time

In 2017, 7% of claims for brand medicines had cost sharing of $125 or more, and these claims now represent more than half of total patient cost exposure.

Source: IQVIA
As Cost Sharing Rises, Patients Are More Likely to Abandon Their New Medicines

New Patient Abandonment by Final Out-of-Pocket Cohort*
(Commercial Claims; PayCo® Brands; 2017)

*Sample is limited to new patient approvals across top brands, which span over 25 traditional and specialty therapeutic areas.

Source: IQVIA

---

*Cost Sharing Trends*
Patients Who Abandon Prescriptions Often Do Not Initiate Another Therapy

Most patients who abandon a brand drug do not fill another drug prescription within 90 days, indicating that they may not be receiving any treatment for their condition.

New Patient Abandonment, Subsequent Fill (Brands, 2014)

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Fill within 90 days</th>
<th>Fill within 60 days</th>
<th>Fill other product</th>
<th>Fill nothing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-Acting Insulin</td>
<td>78%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPP-4</td>
<td>80%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLP-1</td>
<td>79%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary Combination</td>
<td>81%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: IMS Institute for Healthcare Informatics
Manufacturer Cost Sharing Assistance Cards Can Help Offset Patient Abandonment

Patient abandonment rates increase with out-of-pocket costs, but manufacturer cost sharing assistance, like copay cards, reduces patient out-of-pocket costs, which lowers abandonment rates.

New Patient Abandonment Trend Comparing Current and Adjusted Copay Card for Patients (Commercial Claims; PayCo® Brands)

Source: IQVIA
Without Coupons, Patients Would Face Higher Average Out-of-Pocket Costs per Prescription

Each January, patients in the commercial market with deductibles face steep increases in out-of-pocket costs for brand drugs.

Average Primary Cost Exposure, 2014-2017*
(Commercial Copay Card Claims; All Brands)

*Averages are calculated among paid claims where a copay card is used as the secondary payer and normalized to 30 days.

Source: IQVIA

Cost Sharing Trends
Manufacturer Cost Sharing Assistance Can Help Ease Patients’ Out-of-Pocket Costs

In 2017, just 0.4% of commercial claims were filled with a coupon for a brand medicine that had a generic equivalent.

Programs that do not count manufacturer cost sharing assistance toward a patient’s deductible or out-of-pocket maximum hurt the sickest patients, leaving them vulnerable to unexpected out-of-pocket costs as high as several thousands of dollars to continue taking their medicine.

Source: IQVIA
Despite more Americans having insurance, many are facing high cost sharing that puts their ability to stay on a needed therapy at risk. Because of this, biopharmaceutical companies provide patient assistance in a variety of ways.

Building off the work of the Partnership for Prescription Assistance, PhRMA built the **Medicine Assistance Tool (MAT)** in 2019 to provide patients, caregivers, and providers with a streamlined point of access for information that can help them make more informed health care decisions.

**MAT INCLUDES:**

- A search engine to connect patients with medicine-specific financial assistance programs
- Resources to help patients navigate their insurance coverage
- Links to websites providing cost information referenced in PhRMA member company direct-to-consumer television advertising

Source: PhRMA\(^\text{16}\)
Notes and Sources


Notes and Sources


SPENDING ON MEDICINES

Understanding Medicine Costs in Context

Prescription medicines represent a small share of national health spending, and government estimates project that medicines will remain a stable share of health spending through the next decade. In 7 of the past 10 years, spending on retail prescription medicines grew more slowly than total health care costs and is projected to grow just 3 percent to 6 percent annually over the next decade, in line with total health care spending. Rebates, discounts, and fees paid by brand manufacturers to the government, private payers, and supply chain entities increased to $166 billion in 2018. Brand medicine net price growth, which reflects these rebates and discounts, was less than inflation for the second year in a row.
In 7 of the Last 10 Years, Retail Prescription Medicine Costs Grew More Slowly Than Total Health Care Costs

Government actuaries project prescription medicine spending growth to remain between 3% and 6% annually through 2027, in line with overall health care spending growth.¹

2014 saw 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.³,⁴

*Total net retail sales including brand medicines and generics

Sources: PhRMA analysis of CMS data¹²; RAND Corporation³; FDA⁴
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 in a physician’s office 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.

<table>
<thead>
<tr>
<th>Healthcare Category</th>
<th>US Health Care Spending 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Govt and Private Health Insurance Admin.</td>
<td>8%</td>
</tr>
<tr>
<td>Hospital Care</td>
<td>31%</td>
</tr>
<tr>
<td>Physician and Clinical Services</td>
<td>18%</td>
</tr>
<tr>
<td>Dental Services</td>
<td>4%</td>
</tr>
<tr>
<td>Other†</td>
<td>13%</td>
</tr>
<tr>
<td>Nursing Home, Home Health, and Related</td>
<td>12%</td>
</tr>
<tr>
<td>PRESCRIPTION MEDICINES*</td>
<td></td>
</tr>
<tr>
<td>Brand Manufacturers</td>
<td>7%</td>
</tr>
<tr>
<td>Generic Manufacturers</td>
<td>3%</td>
</tr>
<tr>
<td>Supply Chain Entities†</td>
<td>4%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>14%</td>
</tr>
</tbody>
</table>

*Breakout of prescription medicine spending based on analysis of 2015 data.
†Supply chain entities include wholesalers, pharmacies, pharmacy benefit managers, and health care providers.
‡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 data; Altarum Institute; Berkeley Research Group
Prescription Medicine Spending Contributed Less Than One-Tenth of Total Health Care Spending Growth in the Past Decade

Cumulative Spending Growth Over 10 Years (in Billions), 2009-2018

*Total National Health Expenditures amount does not reflect listed categories. Not all categories are shown.

Sources: PhRMA analysis of CMS data
Prescription Medicines Are Expected to Account for a Stable Share of Total Health Care Expenditures Through the Next Decade

US Health Care Expenditures Attributable to Retail and Nonretail Prescription Medicines, 2010-2027*

*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.

Sources: Altarum Institute^{10,11}
Cumulative Spending Growth for Other Health Care Will Be More Than Five Times That of Medicines Through the Next Decade

Projected Cumulative Growth in Spending (in Billions), 2018-2027

- Other Health Care: 10-year cumulative increase: $2,101 billion
- Prescription Medicines (Retail and Nonretail): 10-year cumulative increase: $370 billion

Sources: PhRMA analysis of CMS data; PhRMA analysis of Altarum Institute data
Actuaries at the Centers for Medicare and Medicaid Services (CMS) annually publish estimates of retail prescription medicine spending for the next 10 years. Looking back at projections made since 2000, estimates made 1 year prior to the publication of actual spending amounts overestimated retail medicine spending two-thirds of the time.

Sources: PhRMA analysis of CMS data

14,15
Pharmacy Benefit Managers (PBMs) and Government Actuaries Report Slowing Growth in Medicine Spending

Annual Growth in Net Retail Prescription Medicine Spending

<table>
<thead>
<tr>
<th>Year</th>
<th>CVS Health</th>
<th>Express Scripts</th>
<th>National Health Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>5.0%</td>
<td>5.3%</td>
<td>8.9%</td>
</tr>
<tr>
<td>2018</td>
<td>3.3%</td>
<td>0.4%</td>
<td>3.3%*</td>
</tr>
</tbody>
</table>

*Projected

Sources: CVS Health\(^{16,17}\); Express Scripts\(^{18,19}\); CMS\(^{20,21}\)
Competition From Generics and Biosimilars Is Expected to Reduce US Brand Sales by $105 Billion From 2019 to 2023

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

Lower Brand Invoice Spending Due to Loss of Exclusivity (in Billions), 2014-2023

- 2014: -$12
- 2015: -$15
- 2016: -$14
- 2017: -$17
- 2018: -$16
- 2019: -$14
- 2020: -$22
- 2021: -$16
- 2022: -$20
- 2023: -$33

2014-2018: $72 Billion*

2019-2023: $105 Billion

*Figures may not sum due to rounding.
One-Third of Gross Spending for Medicines Is Rebated Back to Payers or Retained by the Supply Chain

Manufacturers received $66 for every $100 of gross spending on medicines in 2018.

<table>
<thead>
<tr>
<th>Medicine List Price</th>
<th>$100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rebates to Payers &amp; Government</td>
<td>-$23</td>
</tr>
<tr>
<td>Supply Chain Entities*</td>
<td>-$5</td>
</tr>
<tr>
<td>Patient Assistance &amp; Non-rebate Payments to Government**</td>
<td>-$6</td>
</tr>
</tbody>
</table>

Net Payment to Manufacturer $66

*Supply chain entities include pharmacies, providers, wholesalers, and group purchasing organizations.
**Includes FDA user fees, coverage gap discounts, 340B program discounts, and patient assistance.

Source: PhRMA analysis of Nephron Research data
Manufacturers’ Gross-to-Net Reductions Have More Than Doubled Since 2012

Rebates and discounts provided by manufacturers to government, private payers, and distributors totaled over $166 billion in 2018.

Total Value of Pharmaceutical Manufacturers’ Gross-to-Net Reductions (in Billions), 2012-2018

<table>
<thead>
<tr>
<th>Year</th>
<th>reductions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>$74</td>
</tr>
<tr>
<td>2013</td>
<td>$83</td>
</tr>
<tr>
<td>2014</td>
<td>$102</td>
</tr>
<tr>
<td>2015</td>
<td>$124</td>
</tr>
<tr>
<td>2016</td>
<td>$139</td>
</tr>
<tr>
<td>2017</td>
<td>$153</td>
</tr>
<tr>
<td>2018</td>
<td>$166</td>
</tr>
</tbody>
</table>

GROSS-TO-NET REDUCTIONS are defined as “rebates, off-invoice discounts, copay assistance, price concessions, and other reductions like distribution fees, product returns, the 340B Drug Pricing Program, and more.”

Source: Drug Channels Institute

24
Patients Often Do Not Directly Benefit From Negotiated Rebates and Discounts Paid by Manufacturers

Prices paid by wholesalers, pharmacies, pharmacy benefit managers (PBMs), and health plan sponsors all vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power.

**Flow of Payment for a $400 Insulin Prescription** *(Patient is in Deductible Phase)*

- **Manufacturer**
  - Retains $88
  - $400 purchase price
  - $18 fee

- **Wholesaler**
  - Retains $2
  - $384 purchase price
  - $294 rebates/fees

- **Pharmacy**
  - Retains $25.25
  - $294 rebates/fees
  - $1.50 dispensing fee
  - $0.25 fee

- **PBM**
  - Retains $53.75
  - $408 purchase price
  - $240 rebates/fees
  - $1 admin fee

- **Health Plan/Plan Sponsor**
  - Retains $239

- **Scott**
  - SPENDS $408
  - Scott pays above the original purchase price of $400 (because he is still in the deductible phase within his health plan).

This graphic is illustrative of a hypothetical product with a wholesale acquisition cost (WAC) of $400 and an average wholesale price (AWP) of $480. It is not intended to represent every financial relationship in the marketplace. The payment amounts do not add up to $400 due to markups and discounts along the supply chain.

Source: PhRMA25
Growth in Prescription Medicine Prices Has Been in Line With Other Health Care Prices

Average Price Levels, Selected Goods and Services, 2000-2018

Hospital and Related Services
Medical Care Prescription Medicines
Consumer Price Index—Urban, All Items

Source: PhRMA analysis of Bureau of Labor Statistics data

Spending on Medicines
Rebates and Other Discounts Offset Virtually All Growth in Medicine Prices in 2018

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

Average Price Growth for Brand Medicines, 2011-2018*

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

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

Source: IQVIA Institute
Nine out of Every Ten US Prescriptions Are Filled With Generics

Generic Share of Prescriptions Filled, 1984-2018*

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

Sources: IQVIA Institute²⁸; Drug Channels Institute²⁹
The US Prescription Medicine Lifecycle Promotes Innovation and Affordability

<table>
<thead>
<tr>
<th>MEDICINE*</th>
<th>BRAND NAME THEN</th>
<th>VS. GENERIC NOW</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIOVAN HCT</td>
<td>2010 $87</td>
<td>$7</td>
<td>-92%</td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIPITOR</td>
<td>2010 $85</td>
<td>$6</td>
<td>-93%</td>
</tr>
<tr>
<td>Cholesterol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLAVIX</td>
<td>2011 $166</td>
<td>$4</td>
<td>-98%</td>
</tr>
<tr>
<td>Blood Thinner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEROQUEL</td>
<td>2010 $87</td>
<td>$2</td>
<td>-98%</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZYPREXA</td>
<td>2010 $393</td>
<td>$17</td>
<td>-96%</td>
</tr>
<tr>
<td>Schizophrenia &amp; Bipolar Disorder</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

THEN & NOW

How Prescription Medicine Prices Fall Significantly Over Time

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 December 2017.

Source: IQVIA Institute
Spending on Cancer Medicines Represents Less Than 2% of Overall Health Care Spending

Cancer Medicines as a Portion of Total US Health Care Spending, 2018

Cancer Medicines $58.4 Billion

TOTAL Health Care Spending $3.6 Trillion

* Cancer medicine spending reflects invoice spending, which does not account for rebates and discounts.
**Projected

Sources: IQVIA Institute; CMS
Notes and Sources


23. Nephron Research. Presentation at the Operationalizing a World Without Rebates Forum; March 21, 2019; Washington, DC.
Notes and Sources


30. IQVIA Institute for Human Data Science analysis for PhRMA. May 2018.


6 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.

- **$8,600** mean annual cost per person in the US
- **$42 trillion** estimated cost 2016-2030

**Costs of CHRONIC DISEASE**

- **AMERICANS**
  - 191 million have at least one
  - 75 million have multiple

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. Care for people with diagnosed diabetes accounts for 1 in 4 health care dollars in the United States.³

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

Sources: American Diabetes Association³; IHS Life Sciences analysis of CDC data⁴
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.

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

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

*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
Lowering Cost Sharing for Seniors at the Pharmacy Counter Can Generate Medicare Savings

Sharing a portion of negotiated manufacturer rebates directly with patients could improve medicine adherence and result in savings for seniors and Medicare in Part D.

**BENEFITS OF SHARING NEGOTIATED REBATES:**

- Lower beneficiary out-of-pocket spend by **$350 per year**
- Save Medicare nearly **$1,000 per year** for every senior taking diabetes medicine
- Reduce total health care spending by approximately **$20B over 10 years**

Source: IHS Markit
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.8

MEDICAID

Increased use of medicines is associated with reductions in Medicaid expenditures from avoided use of inpatient and outpatient services.9,10

Sources: CBO; Roebuck MC; Roebuck MC et al
Improved Medicine Use Can Lead to Savings in Medicare

Between 20% and 40% of Medicare beneficiaries with common chronic diseases are not adherent to their medicines. Billions of dollars in cost savings from avoided hospital stays can result from improved adherence.

### Annual Savings per Person From Better Adherence

<table>
<thead>
<tr>
<th>Disease</th>
<th>Savings ($)</th>
<th>Avoidable Hospital Inpatient Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>$5,170</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>$1,847</td>
<td></td>
</tr>
<tr>
<td>Heart Failure</td>
<td>$7,893</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>$5,824</td>
<td></td>
</tr>
</tbody>
</table>

### Outcomes With Improved Adherence

- **Diabetes**: $4.5B cost savings
  - 2.9M avoidable hospital inpatient days
- **Hyperlipidemia**: $5.1B cost savings
  - 5.2M avoidable hospital inpatient days
- **Heart Failure**: $5.6B cost savings
  - 4.2M avoidable hospital inpatient days
- **Hypertension**: $13.7B cost savings
  - 7.3M avoidable hospital inpatient days

Source: Lloyd JT et al.¹¹
Better Adherence Generates Savings in Medicaid

Optimal adherence to medicines for a range of chronic conditions leads to reductions in hospitalizations for many patients enrolled in Medicaid.

Reductions in Hospitalizations Due to Medication Adherence*

- Congestive Heart Failure: 26%
- Schizophrenia/Bipolar Disorder: 26%
- Hypertension: 25%
- Diabetes: 12%
- Asthma/COPD: 9%

Economic impact of nonadherence on Medicaid hospital spending was $8 BILLION in 2017.

*Results apply to Medicaid populations that are not blind or disabled.

Source: Roebuck MC et al.
Improving Access to Treatment Could Reduce the Clinical and Economic Impact of Addiction

The economic impact of the opioid crisis in the United States was estimated to be $504 billion in 2015. Medication-assisted treatment (MAT) is an evidence-based approach for the treatment of opioid use disorder that pairs behavioral therapy with medicines that block the effects of opioids and/or mitigate the symptoms of opioid withdrawal.

Doubling access to MAT in the commercial market alone over the next 15 years could:

- Prevent up to 6.1M overdoses
- Save as many as 805K lives
- Save the health care system as much as $645B

Sources: Hagemeier, NE; IHS Markit
Recent Studies Show Significant Value From Better Use of Medicines

Patients with a range of diseases could offset health care spending by exercising better adherence.

**PARKINSON’S DISEASE**
Health care savings of up to $6,300 in fewer than 2 years can be achieved among patients with Parkinson’s who continually stay on therapy.\(^{15}\)

**MULTIPLE SCLEROSIS**
Initiation of therapy is associated with reductions of up to $5,700 in medical costs, driven by decreased use of outpatient services and inpatient hospital stays.\(^{16}\)

**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.\(^{17}\)

**LUPUS**
Nonadherence among children on Medicaid who are diagnosed with lupus is associated with a 55% increase in emergency department use and a nearly 40% increase in hospitalizations.\(^{18}\)

Sources: Wei YJ et al.\(^{15}\); Nicholas J et al.\(^{16}\); Quittner AL et al.\(^{17}\); Feldman CH et al.\(^{18}\)
Innovative Medicines Improve Patients’ Ability to Work

New drugs increase worker productivity by 4.8 million work days and add $221 billion in wages per year.

Percent Increase in Worker Productivity Due to Innovative Medicines

- Musculoskeletal: 27%
- Gastrointestinal: 15%
- Infectious: 43%
- Hepatitis C: 167%
- Average Increase, all Diseases: 30%

Disease Areas With Innovative Medicines

Source: Chen AJ et al.19
Notes and Sources


7 ECONOMIC IMPACT

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 footprint, along with its attendant 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 (18%) 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.

Share of Total US Business R&D by Industry, 2016*

*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 data¹
The US Biopharmaceutical Sector Is Among the Biggest Investors in R&D Relative to Sales

Biopharmaceutical investments in R&D, as a percentage of sales, are more than 6 times the average for all manufacturing industries, making the sector one of the most R&D-intensive industries.

R&D as a Percentage of Sales by Industry, 2001-2015

- Communications Equipment: 25.3%
- Pharmaceuticals & Medicines: 21.5%
- Semiconductor: 20.5%
- Computer & Electronic: 15.2%
- Medical Equipment & Supplies: 8.5%
- Chemical: 7.1%
- Aerospace: 6.7%
- Transportation: 3.9%
- All Manufacturing: 3.3%
- Petroleum & Coal: 0.2%

Source: NDP Analytics²
The Biopharmaceutical Industry Invests More R&D Dollars per Employee Than Any Other Industry

On a per employee basis, biopharmaceutical companies invest 12 times more in R&D than the average for manufacturing industries overall.

R&D Expenditures per Employee by Manufacturing Sector and Industry, 2001-2015

- Pharmaceuticals & Medicines: $165,844
- Communications Equipment: $100,661
- Semiconductor: $68,158
- Chemical: $62,325
- Computer & Electronic: $54,088
- Aerospace: $29,923
- Medical Equipment: $23,109
- Transportation Equipment: $19,457
- All Manufacturing Industries: $13,312
- Petroleum & Coal: $9,838
- Machinery: $9,194
- Electrical Equipment: $8,194
- Misc. Nonmedical Equipment: $5,471

Source: NDP Analytics
The Biopharmaceutical Industry Employs the Largest Share of All Manufacturing R&D Workers

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

Selected Manufacturing Industries’ Share of Total R&D Workers, 2015*

*All other manufacturing sectors account for the remaining 50% of the R&D workforce.

Source: PhRMA analysis of National Science Foundation data
The Economic Reach of the US Biopharmaceutical Industry

Every biopharmaceutical sector job supports a total of five jobs across the economy.

- **811,000** direct jobs (Innovative Biopharmaceutical Industry)
- **1,422,000** indirect jobs (Vendors and Suppliers)
- **1,806,000** induced jobs (Additional Private Economic Activity)

**4,039,000** TOTAL JOBS

The biopharmaceutical industry supported more than 4 million jobs across the US economy in 2017.

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

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

Percentage of Jobs in Sector by Occupation, 2017*

<table>
<thead>
<tr>
<th>Private Sector Overall</th>
<th>Biopharmaceutical Industry</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Life, Physical, &amp; Social Sciences†</td>
</tr>
<tr>
<td></td>
<td>Production</td>
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<tr>
<td></td>
<td>Office &amp; Administrative Support</td>
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<tr>
<td></td>
<td>Management</td>
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<tr>
<td></td>
<td>Business &amp; Financial Operations</td>
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<tr>
<td></td>
<td>Architecture &amp; Engineering†</td>
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<tr>
<td></td>
<td>Sales &amp; Related (eg, wholesalers)</td>
</tr>
<tr>
<td></td>
<td>Computer &amp; Mathematical†</td>
</tr>
<tr>
<td></td>
<td>Transportation &amp; Material Moving</td>
</tr>
<tr>
<td></td>
<td>All Other‡</td>
</tr>
<tr>
<td>45%</td>
<td>16%</td>
</tr>
<tr>
<td>15%</td>
<td>15%</td>
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<tr>
<td>10%</td>
<td>8%</td>
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<td>6%</td>
<td>13%</td>
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<td>5%</td>
<td>12%</td>
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<td>5%</td>
<td>9%</td>
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<tr>
<td>3%</td>
<td>8%</td>
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<td>2%</td>
<td>8%</td>
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<td>1%</td>
<td>6%</td>
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<td>5%</td>
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<tr>
<td>6%</td>
<td>9%</td>
</tr>
<tr>
<td>7%</td>
<td>5%</td>
</tr>
</tbody>
</table>

*Column percentages may not add up to 100% due to rounding.
†Indicates a STEM occupation.
‡Other occupations include health care practitioners/techs (2.8% of biopharma industry jobs); installation/maintenance/repair (2.5%); arts/design/entertainment/sports/media (0.9%); building & grounds cleaning/maint (0.6%); legal (0.4%); health care support (0.4%); construction/extraction (0.3%); educ/training/library science (0.3%); protective services (0.2%); community/social services (0.2%); personal care & service (0.1%); farming/fishing/forestry (0.1%); and food prep/serving (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 in 2018.

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

— International Trade Administration

Sources: ITA; PhRMA analysis of US Census Bureau data
The Biopharmaceutical Sector’s Extensive US Manufacturing Footprint

Approximately 1,100 manufacturing plants involved in the production of human-use medicines are located in 45 US states and Puerto Rico. Biopharmaceutical companies are building the plants to make cutting-edge therapies of the future in the United States.

Biopharmaceutical Manufacturing Facilities by State/Territory (January 2019)^9,10

Sources: NDP Analytics^9; Hargreaves B^10
Industry-Sponsored Clinical Trials Contribute Significant Value to the Communities in Which They Are Located

In 2017, the biopharmaceutical industry sponsored more than 4,500 clinical trials of medicines in the United States, involving 920,000 participants and supporting $42 billion in economic activity across all 50 states, the District of Columbia, and Puerto Rico.*

*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.
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 Partners\(^\text{12}\)
The United States Leads in Biopharmaceutical Intellectual Property

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

US Patents Granted in Pharmaceuticals by Region/Country of Inventor, 2016*

- United States, 56.9%
- European Union, 19.5%
- All Others, 9.1%
- Asia, ** 6.7%
- Japan, 5.2%
- China, 2.6%

*Percentages may not add up to 100% due to rounding.
**Asia includes India, Malaysia, South Korea, and others.

Source: PhRMA analysis of National Science Foundation data
The United States Leads in Biopharmaceutical Venture Capital Investment

Almost three-quarters of worldwide venture capital investments in biopharmaceutical startups are made in the United States.

Biopharmaceutical Venture Capital Investment by Region/Country, 2018*

- United States, 72.1%
- Europe, 13.4%
- China, 11.1%
- All Others, 3.5%

*Percentages may not add up to 100% due to rounding.

Source: TEConomy analysis for PhRMA
Biopharmaceutical Venture Capital Provides Tremendous Resources for Startup Company Financing

Between 2000 and 2017, venture capitalists invested over $95 billion in more than 8,000 deals helping to start up over 3,300 biopharmaceutical companies across the United States.

Source: PhRMA analysis of PitchBook Venture Investment database
The Biopharmaceutical Industry Supports a Broader Ecosystem Through Corporate Venture Capital

Corporate venture capital (CVC) from biopharmaceutical companies and others plays an increasingly important role in financing emerging biopharmaceutical companies, now accounting for over half of VC investment in the sector.

US CVC Investment in Biopharmaceutical Startups, 2008-2018

Source: 4Q 2018 Pitchbook-NVCA Venture Monitor
The Biopharmaceutical Industry Is Reducing Its Impact on the Environment

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
- Setting limits on wastewater discharges to reduce environmental impact of manufacturing discharges

Sources: Deloitte; IFPMA
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:

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

Source: Battelle Technology Partnership Practice 19
Other Nations Are Challenging US Leadership in Biopharmaceutical Innovation

Emerging economies are exceeding US performance on key measures related to a robust biopharmaceutical environment.

"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

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

Sources: TEConomy Partners
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:

1. **Strong INTELLECTUAL PROPERTY protections, including patent and regulatory data protection**

2. **A well-functioning, science-based REGULATORY SYSTEM**

3. **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, PhRMA22; Deloitte23
Notes and Sources


9. NDP Analytics; for PhRMA. Analysis of the US Food and Drug Administration’s Drug Establishments Current Registration Site. April 2019.


12. TEConomy Partners; for PhRMA. *Driving Innovation and Economic Growth for the 21st Century: State Efforts to Attract and Grow the Biopharmaceutical Industry*. Columbus, OH: TEConomy Partners; December 2016.
Notes and Sources


Of the new medicines launched globally each year, far more are available in the United States than in other developed countries. As a result, US patients have better outcomes for conditions where new medicines are most critical.

Spending on prescription medicines is a similarly small percentage of total health care spending in the United States as in other developed countries. Consequently, medicines account for a small share of the overall difference in per capita health spending between the US and these other countries.

US market-based prices for new medicines incentivize the large and uncertain investments required to bring new medicines to market. While the US system makes efficient use of cost saving generics and competition among brand medicines, other wealthy countries use a variety of government mandates or controls to set artificially low prices for new medicines. Emulating those practices in the United States would lead to reduced R&D and innovation, harming patients with unmet medical needs.
More Medicines Are Available to US Patients

Nearly 90% of newly launched medicines from 2011 to 2018 were available in the United States, compared to just two-thirds in Germany, half in France, and even less in Canada and Australia.

Number of New Medicines Available by Country*
(of 307 drugs launched 2011-2018)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of New Medicines</th>
<th>Available Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>270</td>
<td>88%</td>
</tr>
<tr>
<td>Germany</td>
<td>198</td>
<td>64%</td>
</tr>
<tr>
<td>UK</td>
<td>182</td>
<td>59%</td>
</tr>
<tr>
<td>Italy</td>
<td>166</td>
<td>54%</td>
</tr>
<tr>
<td>Japan</td>
<td>156</td>
<td>51%</td>
</tr>
<tr>
<td>France</td>
<td>152</td>
<td>50%</td>
</tr>
<tr>
<td>Canada</td>
<td>140</td>
<td>46%</td>
</tr>
<tr>
<td>South Korea</td>
<td>109</td>
<td>36%</td>
</tr>
<tr>
<td>Australia</td>
<td>109</td>
<td>36%</td>
</tr>
<tr>
<td>New Zealand</td>
<td>63</td>
<td>21%</td>
</tr>
<tr>
<td>China</td>
<td>41</td>
<td>13%</td>
</tr>
</tbody>
</table>

*New Molecular Entities (NMEs) approved by the FDA, European Medicines Agency (EMA), and/or Japan’s Pharmaceuticals and Medical Devices Agency (PMDA), and launched in any country between 2011 and 2018.

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA, and PMDA data^1

For example, of the 16 new diabetes medicines launched over the period, only three were available in France.
US Patients Have Significantly Greater Access to New Cancer Medicines

Other developed countries use centralized government price setting and coverage decisions to manage drug spending. As a result, patients in those countries have fewer cancer medicines available to them than US patients.

International Approval and Coverage Decisions of 45 Oncology Drugs Approved in the US and Covered by Medicare, 2009-2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Approved and Covered</th>
<th>Approved and Not Covered</th>
<th>Not Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>15</td>
<td>4</td>
<td>26</td>
</tr>
<tr>
<td>France</td>
<td>15</td>
<td>11</td>
<td>19</td>
</tr>
<tr>
<td>Australia</td>
<td>21</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Canada</td>
<td>21</td>
<td>11</td>
<td>13</td>
</tr>
</tbody>
</table>

Source: Zhang Y et al.²
US Patients Have Access to Cancer Medicines on Average 2 Years Earlier

To the extent that patients in other developed countries have access to cancer medicines, they have to wait longer to access those medicines compared to patients in the United States.

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

Source: IMS Consulting Group
US Patients Have Better Outcomes for Conditions Where New Drugs Are Most Critical

Cancer death rates are lower in the United States, where patients have greater and more timely access to cancer medicines than in other developed countries.

*2013 is the latest year for which data are available for all listed countries.

Source: PhRMA analysis of WHO data

Age-Standardized Cancer Death Rates, 2013*

Deaths per 100,000

US: 115.2
Italy: 119.7
France: 120.5
Germany: 122.8
UK: 128.9
Lung Cancer Patients Experience Better Survival Under the Market Access Policies in the United States

American patients diagnosed with locally advanced and metastatic non-small cell lung cancer (NSCLC) gained an estimated 201,700 life-years in total due to innovative medicines being made available with little to no delay after regulatory approval. Half of these survival gains would have been lost if the United States had adopted health technology assessment frameworks like those used by foreign governments to determine access to care.

*US NSCLC patients diagnosed between 2006 and 2017

Source: IHS Markit
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 covering and reimbursing innovative medicines than payers in other developed countries.

**Generic Share of Total Prescriptions Filled, 2017**

<table>
<thead>
<tr>
<th>Country</th>
<th>Generic Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>86%</td>
</tr>
<tr>
<td>Germany</td>
<td>81%</td>
</tr>
<tr>
<td>New Zealand</td>
<td>79%</td>
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<tr>
<td>Canada</td>
<td>78%</td>
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<tr>
<td>UK</td>
<td>74%</td>
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<tr>
<td>South Korea</td>
<td>71%</td>
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<tr>
<td>France</td>
<td>66%</td>
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<tr>
<td>Australia</td>
<td>64%</td>
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<tr>
<td>Japan</td>
<td>60%</td>
</tr>
<tr>
<td>Italy</td>
<td>53%</td>
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</tbody>
</table>

Source: PhRMA analysis of IQVIA MIDAS® data
Spending on Prescription Medicines Is a Small Percentage of Total Health Care Spending Around the World

Prescription Medicines as a Percentage of Total Health Care Spending,* 2015

*Total health care spending includes hospital care, physician and clinical services, home health and nursing home care, government administration and net cost of private health insurance, dental and other professional services, as well as durable medical equipment.

Source: Altarum Institute
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, 2017

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

*Organisation for Economic Co-operation and Development

Source: PhRMA analysis of OECD data
If Governments of Other Wealthy Countries Valued Medicines Fairly, Patients Globally Would Benefit

If prices for medicines in other OECD countries were just 20% higher, the resulting increase in R&D would benefit patients around the world, including those in the United States.

A shift toward market-based drug prices in other wealthy countries would result in:

- **1.1 years** of increased life expectancy for an American who is 15 years old today
- **9% more** new treatments available annually by 2030—equivalent to 8 more new drugs launched in 2030 alone
- **Welfare gains of $10 trillion** for Americans and **$7 trillion** in other OECD countries over the next 50 years

Sources: Schwartz TT et al.; USC Schaeffer Center
Notes and Sources

3. IMS Consulting Group report for PhRMA. Patient access to innovative oncology medicines across developed markets. June 2016.