Medicines Benefit Patients, the Health Care System and the Economy
Medicines are Transforming the Treatment OF DEVASTATING DISEASES

**HEPATITIS C**
The leading cause of liver transplants and the reason liver cancer is on the rise – is now curable in more than 90 percent of treated patients.*

**CANCER**
New therapies have contributed to a 23% decline in the cancer death rate since its peak in 1991. Today, 2 out of 3 people diagnosed with cancer survive at least 5 years.**

**HIGH CHOLESTEROL**
America’s biopharmaceutical companies are currently developing 190 medicines to treat heart disease, stroke and other cardiovascular diseases. New PCSK9 inhibitors have revolutionized high cholesterol treatment. Between 1991 and 2011, the death rate from heart disease dropped 46%.***

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*Source: U.S. Food and Drug Administration.
**Source: American Cancer Society.
***Source: Pharmaceutical Research and Manufacturers of America (PhRMA) and the Association of Black Cardiologists (ABC), “Medicines in Development for Heart Disease and Stroke,” December 2015.
MORE THAN 7,000 MEDICINES ARE IN DEVELOPMENT

Around the World

MEDICINES IN DEVELOPMENT

Cancers: 1,813
Cardiovascular Disorders: 599
Diabetes: 475
HIV/AIDS: 159

SELECTED DISEASES

Immunological Disorders: 1,120
Infectious Diseases: 1,256
Mental Health Disorders: 511
Neurological Disorders: 1,329

NOTE: Each product is counted exactly once, regardless of the number of indications pursued.

Source: Adis R&D Insight Database.
Developing New Treatments and Cures IS A COMPLEX AND RISKY UNDERTAKING

On average, it takes more than 10 years and $2.6B to research and develop a new medicine.*

![Diagram showing unsuccessful and successful attempts in drug development between 1998 and 2014.](image)

Unsuccessful Attempts

- 123 Alzheimer’s Disease**
- 96 Melanoma***
- 167 Lung Cancer***

Successful Attempts

- 4 Alzheimer’s Disease
- 7 Melanoma
- 10 Lung Cancer

Only 12% of drug candidates that enter clinical testing are approved for use by patients.

*Source: Tufts Center for the Study of Drug Development (CSDD).
Medicines Help Patients
AVOID EXPENSIVE HOSPITAL SERVICES

The U.S. health care system could save $213 billion annually if medicines were used properly*

Adherence to Medicines Lowers Total Health Spending for Chronically Ill Patients**

**Source: Roebuck M.C., et al. “Medication adherence leads to lower health care use and costs despite increased drug spending.” Health Affairs. 2011;30(1):99.”

Prescription Medicines: Costs in Context www.phrma.org/cost
MEDICINES PROVIDE CRITICAL SAVINGS to the U.S. Health Care System

Estimated **10-Year savings** to Medicare from improved adherence to congestive heart failure medications, 2013-2022*

$22.4 billion

$367 billion
Costs avoided by 2050 if we develop a new medicine that delays the onset of Alzheimer’s disease by just five years**


**Source: Alzheimer’s Association.
CASE STUDY
As HIV/AIDS Treatment Improved
SPENDING BECAME SUSTAINABLE

1989

The New York Times
September 15, 1989

AIDS Treatment Costs Put at $5 Billion a Year
“We have got to get our act together now because the medical system is going to be crushed in two years.”
–Daniel Hoth, director of the division of AIDS at the National Institute for Allergy and Infectious Diseases

“If we don’t act now, we will be soon rationing health by queuing.” …

“People will wait longer and longer in the emergency rooms, more people will die, the whole level of care will decrease significantly.” He called it “a downward spiral of effects which we cannot afford.”
–Dr. Douglas Shenson, Montefiore Medical Center

Today

“We USED TO THINK HIV COSTS WOULD OVERWHELM US....BUT WE FIGURED IT OUT AND LET DRUG DEVELOPMENT PROGRESS.”
– Ira Klein, M.D., M.B.A., FACP, Aetna

HIV/AIDS Death Rates

<table>
<thead>
<tr>
<th>Year</th>
<th>Death Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>10.2</td>
</tr>
<tr>
<td>1995</td>
<td>16.2</td>
</tr>
<tr>
<td>2000</td>
<td>5.2</td>
</tr>
<tr>
<td>2005</td>
<td>4.2</td>
</tr>
<tr>
<td>2010</td>
<td>2.7</td>
</tr>
</tbody>
</table>

HAART COMBINATIONS INTRODUCED
The Biopharmaceutical Sector is the SINGLE LARGEST FUNDER OF BUSINESS R&D IN THE UNITED STATES

**Share of Total US Business R&D by Industry, 2013**

- **Pharmaceuticals & Medicines**: 17%
- **Software**: 13%
- **Automobiles**: 5%
- **Aerospace**: 4%
- **Computer Systems Design**: 3%
- **Scientific R&D Services**: 1%

The biopharmaceutical sector accounts for the single largest share of all US business R&D, representing 17% of all domestic R&D funded by US businesses.

**NOTE:** The remaining 57% share of business R&D spending is conducted by other industries, including subsectors of the machinery sector, the electrical equipment sector, and the professional, scientific, and technical services sector.

Source: PhRMA analysis of National Science Foundation data.
The Biopharmaceutical Industry’s
IMPACT ON THE U.S. ECONOMY

Nearly 4.5 Million Jobs

ECONOMIC OUTPUT FROM INDUSTRY

$1.2 Trillion

Nearly $311 Billion paid in wages and benefits

Annual average compensation of $123,108 in direct jobs is more than twice the average annual salary for all other jobs.

Prescription Drug Costs in Perspective
Medicines Account for a Stable Share of Health Care Spending

Health Care Expenditures Attributable to Retail and Non-Retail Prescription Drugs, 2008-2024

Source: Altarum Institute, “A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail,” August 2015.
**Federal Government Projects**

**MEDICINE SPENDING WILL GROW IN LINE WITH HEALTH SPENDING**

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**Spending Growth Rate**

- **Percent Annual Growth Rate**
  - 2008: 2.5%
  - 2009: 4.7%
  - 2010: 0.1%
  - 2011: 2.2%
  - 2012: 0.2%
  - 2013: 2.4%
  - 2014: 12.2%
  - 2015: 8.1%
  - 2016: 8.5%
  - 2017: 6.3%
  - 2018: 6.0%
  - 2019: 6.4%
  - 2020: 6.5%
  - 2021: 6.4%
  - 2022: 6.4%
  - 2023: 6.8%
  - 2024: 6.7%
  - 2025: 6.8%

**NOTE:** Total retail sales including brand medicines and generics

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**Source:** Centers for Medicare & Medicaid Services (CMS).

**Prescription Medicines: Costs in Context** [www.phrma.org/cost](http://www.phrma.org/cost)
GROWTH IN OTHER HEALTH CARE SERVICES WILL BE FIVE TIMES
Total Medicine Spending Growth Through Next Decade

Projected Annual Growth in Spending ($ Billions)

- Other Health Care Services (10-year cumulative increase: $2,044 billion)
- All Prescription Medicines (10-year cumulative increase: $390 billion)

**Source: PhRMA analysis of Altarum Institute, “A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail,” August 2015.
BRAND MEDICINE NET PRICE GROWTH SLOWED IN 2015
as Discounts, Rebates Negotiated by Payers Rose Sharply

Source: IMS Institute for Healthcare Informatics, National Sales Perspectives, March 2016.
Negotiating power is increasingly concentrated among fewer pharmacy benefit managers (PBMs), with the Top Three PBMs accounting for three quarters of the market.

PBM Market Share, by Total Equivalent Prescriptions

- Express Scripts: 25%
- CVS Health (Caremark): 24%
- OptumRx/Catamaran*: 22%
- All Other: 29%

Top 3 Market Share: 75%

NOTE: OptumRx and Catamaran merged in 2015. Their 2014 shares are shown combined.

Source: Drug Channels Institute.
CASE STUDY
Critics Proven Wrong on Hepatitis C Medicine Spending

What payers claimed would happen

“[I]t forces payers…to consider whether or not they can even sustain the pharmacy benefit they provide to members.”
– EXPRESS SCRIPTS (OCTOBER 2014)

“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 2014)

“Never before has a drug been priced this high to treat a patient population this large, and the resulting costs will be unsustainable for our country. The burden will fall upon individual patients, state and federal governments, and payers who will have to balance access and affordability in a way they never have had to before.”
– EXPRESS SCRIPTS (APRIL 2014)

What actually happened

“Hepatitis C is the first example where price is lower in the U.S. vs. Western Europe because of our negotiations.”
– EXPRESS SCRIPTS (DECEMBER 2015)

“The price is sufficiently low that we can go to our clients and say that they can treat every patient with hepatitis C.”
– EXPRESS SCRIPTS (JANUARY 2015)

“Our clients will save more than $1 billion this year on hepatitis C medications, and we will financially guarantee that their patients will adhere to their therapy.”
– EXPRESS SCRIPTS (JANUARY 2015)

“After our deal, other payers have begun to follow suit and negotiate their own arrangements with either AbbVie or Gilead. Because of our initial action, these follow-up negotiations will ultimately lower the national spend on hepatitis C drugs by more than $4 billion annually.”
– EXPRESS SCRIPTS (JANUARY 2015)
### Case Study

**Critics Proven Wrong on High Cholesterol Medicine Spending**

<table>
<thead>
<tr>
<th>What payers claimed would happen</th>
<th>What actually happened</th>
</tr>
</thead>
<tbody>
<tr>
<td>“These drugs are not only expensive but they present a financial challenge to the health care industry.”  &lt;br&gt;– Harvard Pilgrim Health Care (September 2015)</td>
<td>“We are in a situation where we can bargain with the drug manufacturers to get a significant discount in return for an exclusive deal.”  &lt;br&gt;– CVS Health (November 2015)</td>
</tr>
<tr>
<td>“While these drugs are being viewed as breakthroughs, they also have the potential to wreck financial havoc on clients who do not proactively manage.”  &lt;br&gt;– Express Scripts (July 2015)</td>
<td>“We were able over the course of tough negotiations to get good economics on both products.”  &lt;br&gt;– Express Scripts (October 2015)</td>
</tr>
<tr>
<td>“Given the number of people potentially eligible for treatment with PCSK9 will number in the millions, the potential overall expenditures by payers are huge.”  &lt;br&gt;– CVS Health (July 2015)</td>
<td>“We feel very confident we can manage this and this won’t mess up our clients’ budgets in 2016.”  &lt;br&gt;– Express Scripts (October 2015)</td>
</tr>
</tbody>
</table>
Insurers’ Data Show
MEDICINES ARE NOT MAIN DRIVER OF PREMIUM INCREASES

Average Dollar Increase in Monthly Premium by Category, 2016 Individual and Small Group Plans

- $0.76 Risk & Profit
- $5.12 Taxes & Fees
- $0.53 Administration
- $0.65 Capitation
- $0.79 Other
- $3.29 Prescription Drugs
- $4.06 Professional
- $10.06 Hospital Inpatient & Outpatient

Total Premium Increase: $25.26

56% of premium increase is due to hospital and professional costs

“Pharmaceutical expenses may be the factor most open to exploitation by health plans searching for a Trojan horse with which to usher in excessively priced insurance rates.”

—Consumers Union in San Francisco

Source: Avalere Health.
Nearly 9 Out of Every 10 U.S. Prescriptions ARE FILLED WITH GENERICS

Generic Share of Prescriptions Filled 1984-2014*

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

$1.68 TRILLION
10-YEAR SAVINGS (2005-2014)**

*Source: IMS Health.
Medical Procedures Become More Expensive Over Time, BUT COST CONTAINMENT IS BUILT INTO MEDICINE LIFE CYCLE

Percutaneous Coronary Angioplasty (PTCA)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>$47,962</td>
</tr>
<tr>
<td>2013</td>
<td>$79,391</td>
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</table>

Atorvastatin 10mg

<table>
<thead>
<tr>
<th>Year</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>$2.13</td>
</tr>
<tr>
<td>2013</td>
<td>$0.18</td>
</tr>
<tr>
<td>2014</td>
<td>$0.15</td>
</tr>
</tbody>
</table>

Source: Average hospital charges for Atorvastatin 10mg data adapted from HCUP Hospital Charge database 2005 and 2013. IMS National Sales Perspective (NSP) Invoice Price in 2005 (branded Lipitor), 2013 (generic) and 2014 (generic).
**Example**

**THEN & NOW**

How Prescription Drug Prices Fall Significantly Over Time

<table>
<thead>
<tr>
<th>MEDICINE</th>
<th>BRAND NAME THEN</th>
<th>VS</th>
<th>GENERIC NOW</th>
<th>% CHANGE</th>
</tr>
</thead>
</table>
| **DIOVAN HCT**
  Hypertension             | $87             |    | $13         | -85%     |
| **LIPITOR**
  Cholesterol             | $85             |    | $4          | -95%     |
| **PLAVIX**
  Blood Thinner           | $166            |    | $5          | -97%     |
| **SEROQUEL**
  Schizophrenia           | $87             |    | $3          | -97%     |
| **ZYPREXA**
  Schizophrenia & Bipolar Disorder | $393 |     | $8          | -98%     |

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

NOTE: Figures represent the average annual price for 30 pills of the most commonly dispensed form and strength. “Then” price represents the average price in the year prior to generic entry. “Now” price represents the average price in CY 2014.

Source: IMS analysis for PhRMA, May 2015.
$93 BILLION OF U.S. BRAND SALES are Projected to Face Generic Competition

Brand Spending Facing Generic Competition, 2016-2020

Projections exclude biologics, which will face competition from biosimilars entering the market.

Notes: Pre-expiry sales of products are calculated for products losing exclusivity (LOE) in each year, the sales in the prior year for each product are aggregated to represent the collective industry exposure to LOE. Loss of exclusivity does not indicate generic market entry. Small molecule losses of exclusivity only.

Source: IMS Institute for Healthcare Informatics, "Global Medicines Use in 2020: Outlook and Implications."
Changes in the Prescription Medicine Marketplace: Challenges and Opportunities
Economics of Medicines Have
CHANGED MARKEDLY IN RECENT YEARS

THE SCIENCE IS HARDER AND MORE COSTLY

Researchers targeting more complex diseases

Rise of personalized medicine

Higher regulatory hurdles

Longer, more complex clinical trials

Genomics/molecular medicine are complex new frontiers

Increased cost of R&D

THE MARKET IS TOUGHER

Slow uptake of new medicines/rapid adoption of generics

Eroding intellectual property (IP) protections

Increased patient cost-sharing and coverage restrictions

Providers increasingly accountable for cost of care

Increase in required government rebates

BIOPHARMACEUTICAL INNOVATION
Cost to Develop a New Medicine
MORE THAN DOUBLED OVER PAST DECADE

Average Cost to Develop an Approved Medicine – Including Setbacks

- **1970's**: $179 Million
- **1980's**: $413 Million
- **1990's-Early 2000's**: $1.0 Billion
- **2000's-Early 2010's**: $2.6 Billion

KEY DRIVERS INCLUDE:
- Increased trial complexity and regulatory burdens
- Increased focus on areas where science is difficult and failure risks high
- Expanded research burden to meet payer demands

NOTE: In constant 2013 dollars.

Source: Tufts Center for the Study of Drug Development (CSDD).
INCREASING INTELLECTUAL PROPERTY THREATS

*Cause Uncertainties and Costs for Biopharmaceutical Companies*

Intensified efforts to invalidate patents

Continued efforts to reduce or eliminate data and market exclusivity

Generic challenges to patents happening earlier and more frequently reducing patent life for innovator drugs

*THE WALL STREET JOURNAL.*

June 10, 2015

‘Patent Death Squads’ vs. Innovation

The Patent Trial and Appeal Board was supposed to make the system better. It hasn’t. — By Peter J. Pitts
COMPANIES RACE TO BE FIRST TO MARKET
with a New Medicine

Competing brands generally launch within two years.

Time Between Approval of First and Second Medicines in a Pharmacologic Class Has Declined Dramatically

10.2 years
1970’s

2.3 years
2005-2011

BRAND COMPETITION HELPS CONTROL COSTS

Source: Tufts Center for the Study of Drug Development (CSDD).
RAPID CHANGE IN THE MARKET
for Medicines

VALUE-BASED INSURANCE DESIGN

CLINICAL PATHWAYS

ACCOUNTABLE CARE ORGANIZATIONS

PROVIDERS AT RISK FOR MEDICINE COSTS

BUNDLED PAYMENTS

VALUE ASSESSMENT FRAMEWORKS

OUTCOME-BASED ARRANGEMENTS
**Increasing Provider Accountability for Cost of Care and Pathway Compliance is INFLUENCING PRESCRIBING DECISIONS**

<table>
<thead>
<tr>
<th></th>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients in health plans that incentivize providers to prescribe certain treatments*</td>
<td>37%</td>
<td>88% (Projected)</td>
</tr>
<tr>
<td></td>
<td>2014</td>
<td>2016</td>
</tr>
<tr>
<td>Hospital participation in accountable care organizations responsible for cost of care**</td>
<td>6%</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>2014</td>
</tr>
<tr>
<td>Medicare payments tied to alternative payment models which include cost or quality incentives***</td>
<td>0%</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td>2009</td>
<td>2014</td>
</tr>
<tr>
<td>Commercial market payments where provider is at-risk for cost of care****</td>
<td>6%</td>
<td>21%</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td>2014</td>
</tr>
</tbody>
</table>

---

***Source: U.S. Department of Health & Human Services. HHS reaches goal of tying 30 percent of Medicare payments to quality ahead of schedule.
****Source: Catalyst for Payment Reform. 2013 / 2104 National Scorecard on Payment Reform.”
Medicines are Increasingly Put in the HIGHEST-COST TIER BY INSURANCE COMPANIES

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

Share of Silver Plans by Number of Tiers*
- 3 or Fewer Tiers
- 5 or More Tiers

Share of Employees in Plans with 4 or More Tiers**

Beyond high cost sharing, barriers to access include insurer practices like prior authorization and step therapy.

NOTE: Silver plans account for a majority of health insurance exchange enrollment. *Tiers* refer to the different levels of cost sharing that plans require patients to pay for different groupings of medicines.

*Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, December 2015.
**Source: Kaiser Family Foundation/Health Research & Educational Trust, Employer Health Benefits: 2015 Annual Survey.
Share of Commercial Plans with a PRESCRIPTION DRUG DEDUCTIBLE IS INCREASING

PERCENT OF PLANS WITH DEDUCTIBLES ON PRESCRIPTION DRUGS*

2012: 23%
2015: 46%

+100%

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

*Source: IMS Health, Emergence and Impact of Pharmacy Deductibles, September 2015.
Patient Assistance Programs Can Play an Important Role in MAINTAINING PATIENT ACCESS TO MEDICINES

Since 2005, PPA has helped
NEARLY 10 MILLION PATIENTS GET ACCESS
to public and private assistance programs.

Despite more Americans having insurance, many are facing high cost sharing that puts their ability to stay on a needed therapy at risk.

WHAT PPA OFFERS

- Single point of access to information on more than 475 public and private patient assistance programs. Programs offer access to more than 2,500 prescription medicines, including a wide range of generics.
- An interactive map and directions to nearly 10,000 free health care clinics throughout the United States.
- Visit www.pparx.org to learn more.
PRAGMATIC SOLUTIONS
to Address Cost Concerns

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

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

ENGAGE AND EMPOWER CONSUMERS
• Make quality and cost information public to aid in decisions and enforce common-sense rules that prevent discrimination against vulnerable patients

ADDRESS MARKET DISTORTIONS
• Improve risk adjustment models and reform market distorting programs like the 340B Drug Pricing program