Maryland Prescription Drug Affordability Board Meeting

March 22, 2021

PhRMA
RESEARCH • PROGRESS • HOPE

Historical Overview

Founded in
1958

Headquartered in
Washington, DC

With offices in…

Albany, NY
Atlanta, GA
Baton Rouge, LA
Cincinnati, OH
Chicago, IL
Denver, CO
Foxborough, MA
Olympia, WA
Richmond, VA
Sacramento, CA
St. Paul, MN
Tallahassee, FL
Tokyo, Japan
Dubai, UAE

Governed by a
33 member board of directors.

PhRMA members invested an estimated
$83 billion in 2019
in discovering and developing new medicines.

PhRMA's membership is currently composed of
33 biopharmaceutical companies
with operations in the United States that are engaged in research, manufacturing and commercialization of innovative brand name finished dosage prescription medicines.

Over a quarter century, the biopharmaceutical industry has evolved, with five major trends characterizing the changes:

1. increased complexity of the research and development process;
2. continued investment in R&D;
3. increased use of medicines in health care;
4. increased value for today's patients; and
5. continued importance of patent incentives for innovative medicines.

Impact of Upper Payment Limits

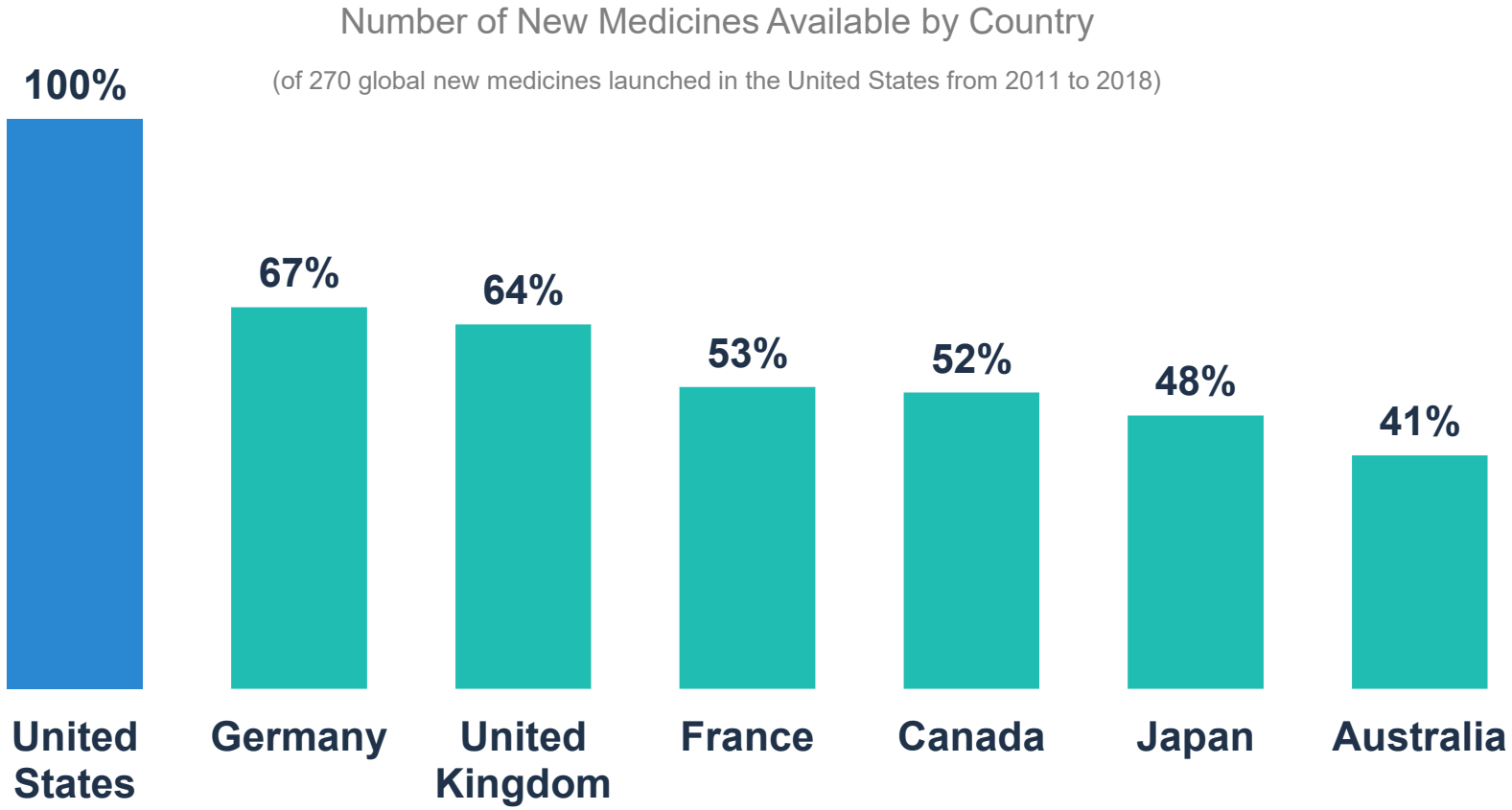
- Barriers to Access
- Innovation & Investment in Research and Development
- Fail to Address Supply Chain
- Legal Concerns

Barriers to Access

- Products that cannot be purchased at state-price may be unavailable

- Arbitrary price setting, cost review analysis, and potential for discrimination

Long-term Impact on Access



Source: PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Agency, Health Canada and Australia Therapeutic Goods Administration data.
Note: New active substances approved by the above regulatory agencies and launched in the United States and other countries from January 1, 2011 to December 31, 2018.

We are in a new era of medicine where breakthrough science is transforming care with innovative treatment approaches...

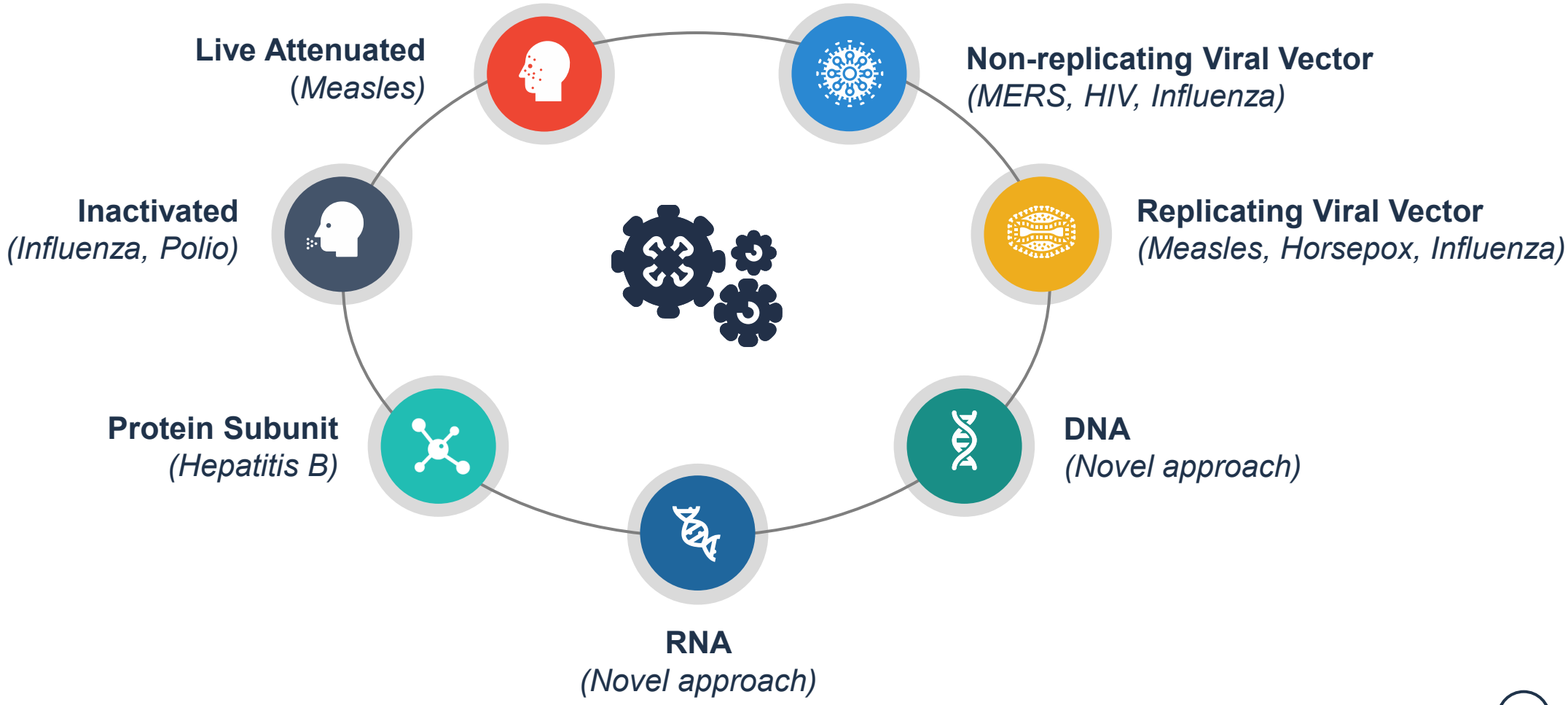
Then

- Medicines made of chemical compounds
- Medicines treat broad diseases
- Radiation and chemotherapy to treat cancer

Now

- Medicines made from living cells
- Medicines targeted to specific patient based on genetic makeup
- Immunotherapy that harnesses body's own immune system to fight disease
- CAR T-cell therapy
- CRISPR

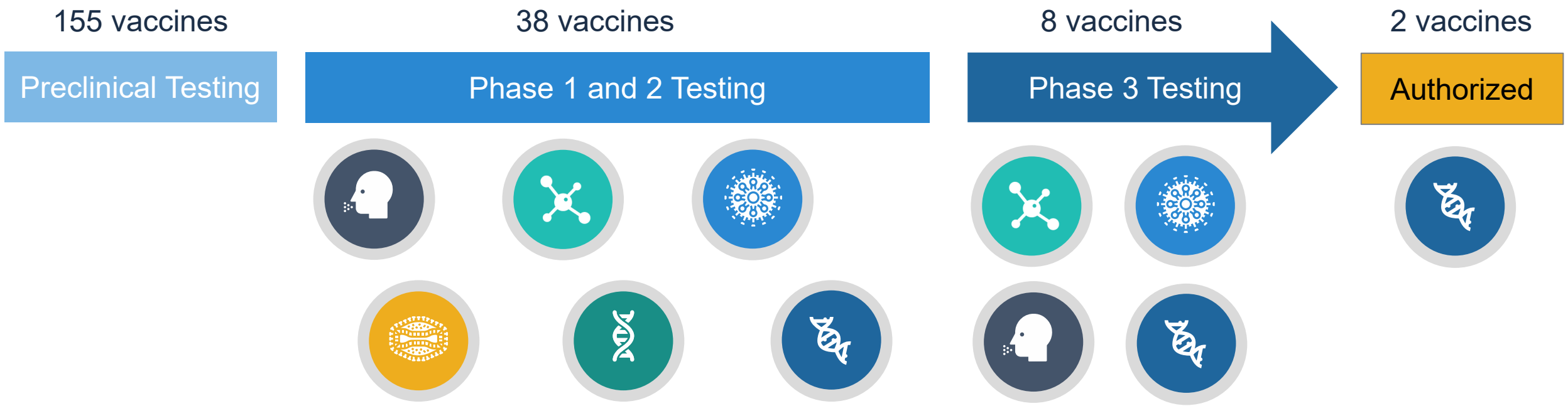
Using Many Approaches to Develop Vaccines



Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Developing and Testing Vaccines to Prevent COVID-19

COVID-19 vaccines currently under investigation include over **200 unique "shots on goal"**

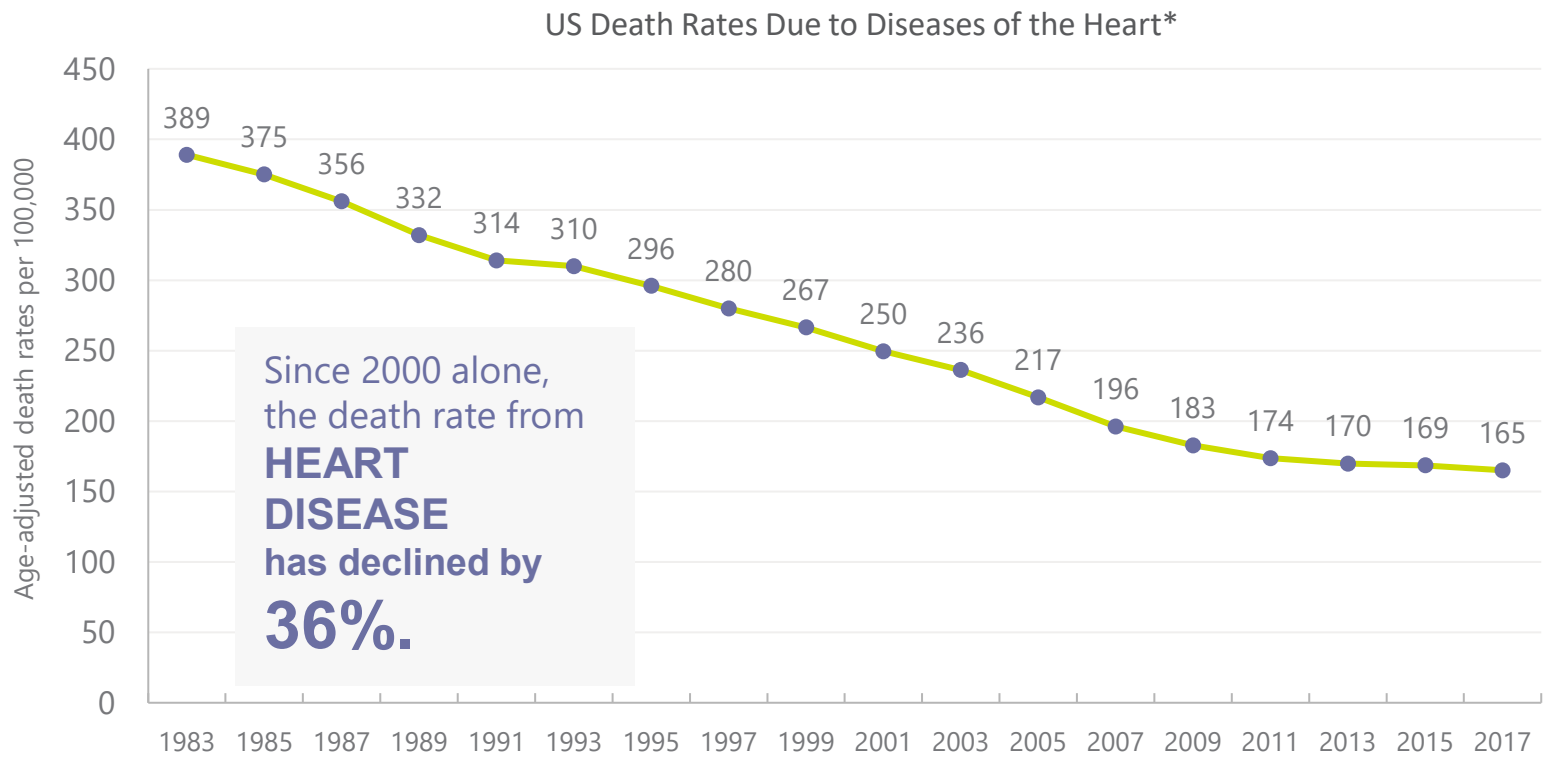


Data as of 11/06/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Cardiovascular Disease: Declining Rates of Death

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

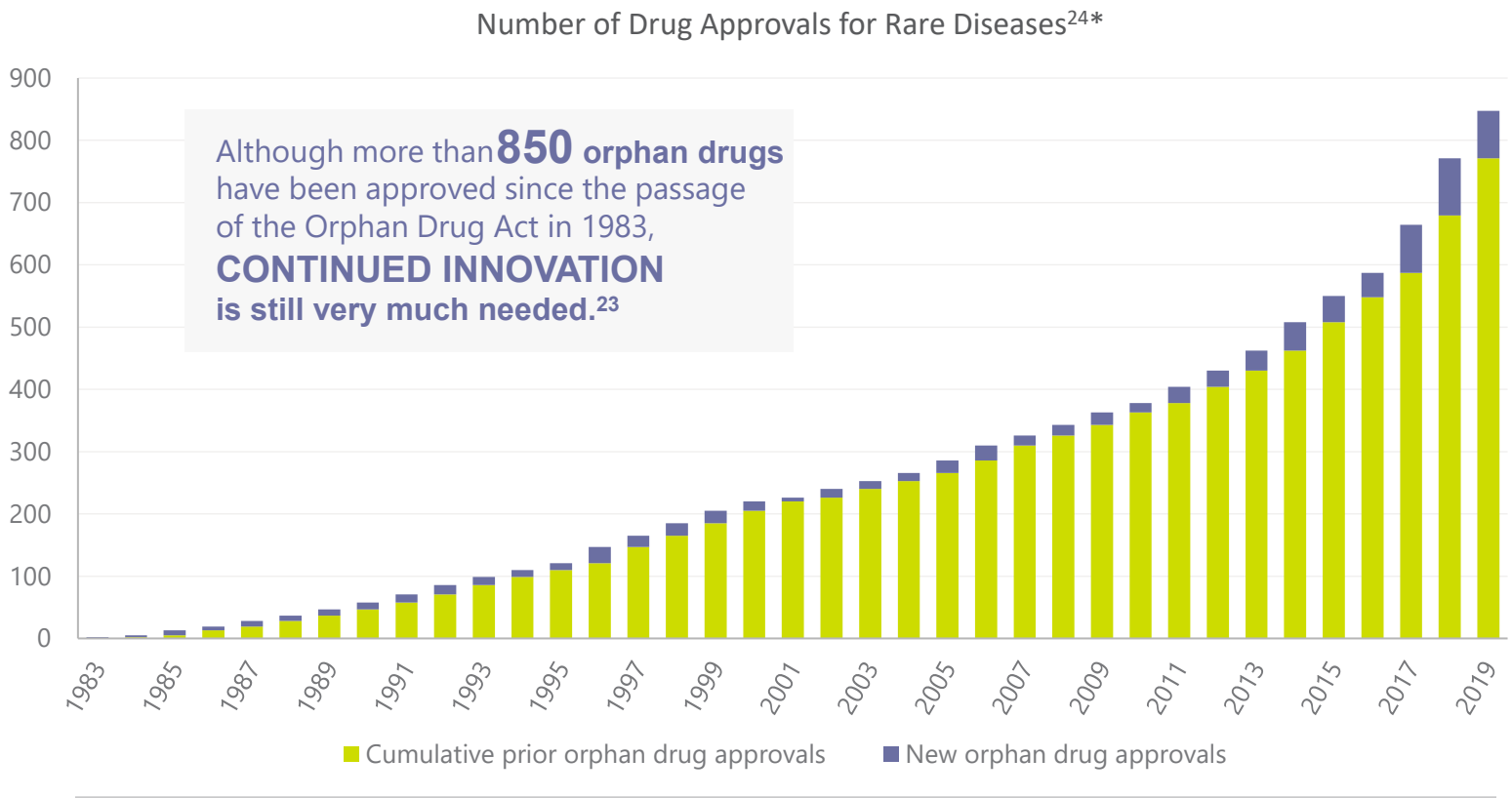


*Age-adjusted death rates based on year 2000 US standard population. 1980-1998 causes of death are classified by the International Classification of Diseases, Ninth Revision (ICD-9). Beginning in 1999, causes of death have been classified by the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10).

Sources: CDC[25,26]

Rare Diseases: Drug Approvals Meet Unmet Needs

Rare diseases are those that affect 200,000 or fewer people in the United States.[23]

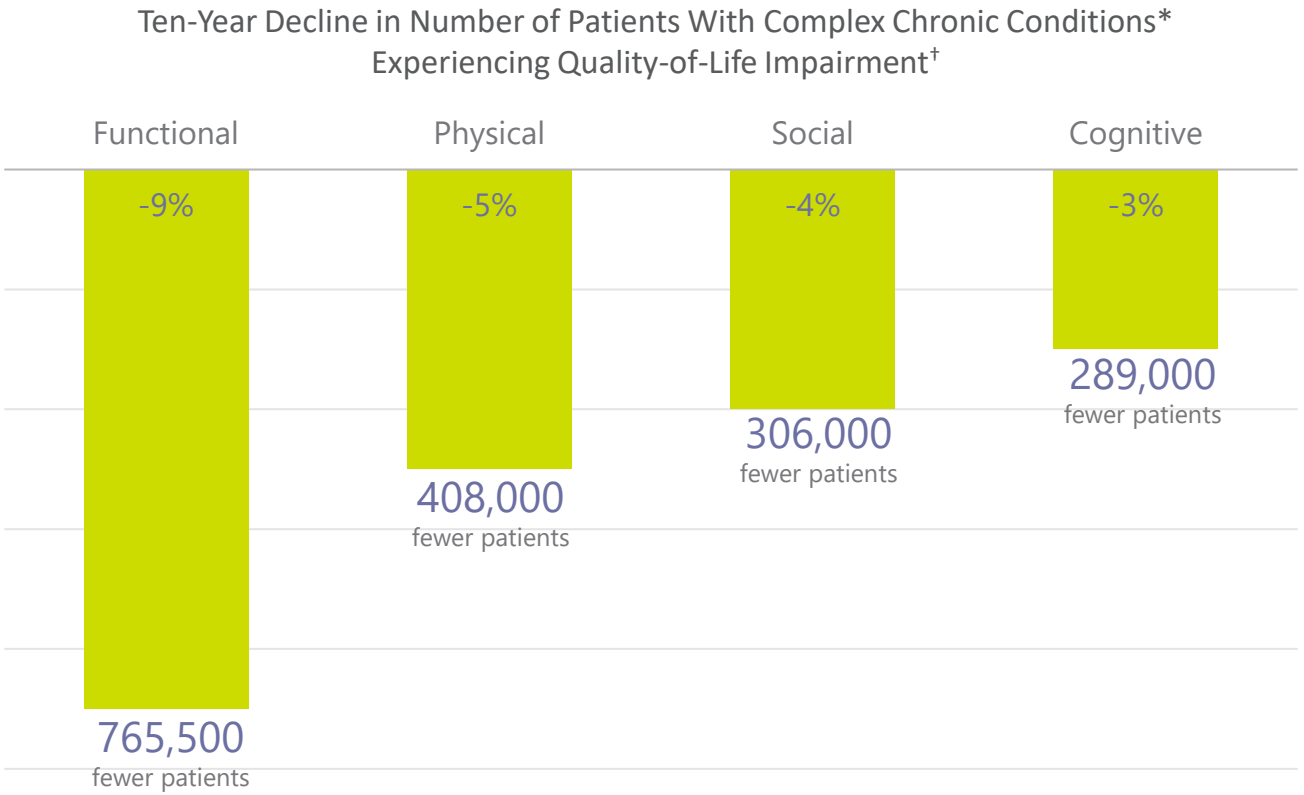


*Drug approvals for rare diseases include initial approvals of new medicines and approvals for new indications of existing medicines.

Sources: NIH[23]; FDA[24]

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.



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

Source: Brien MJ et al[27]

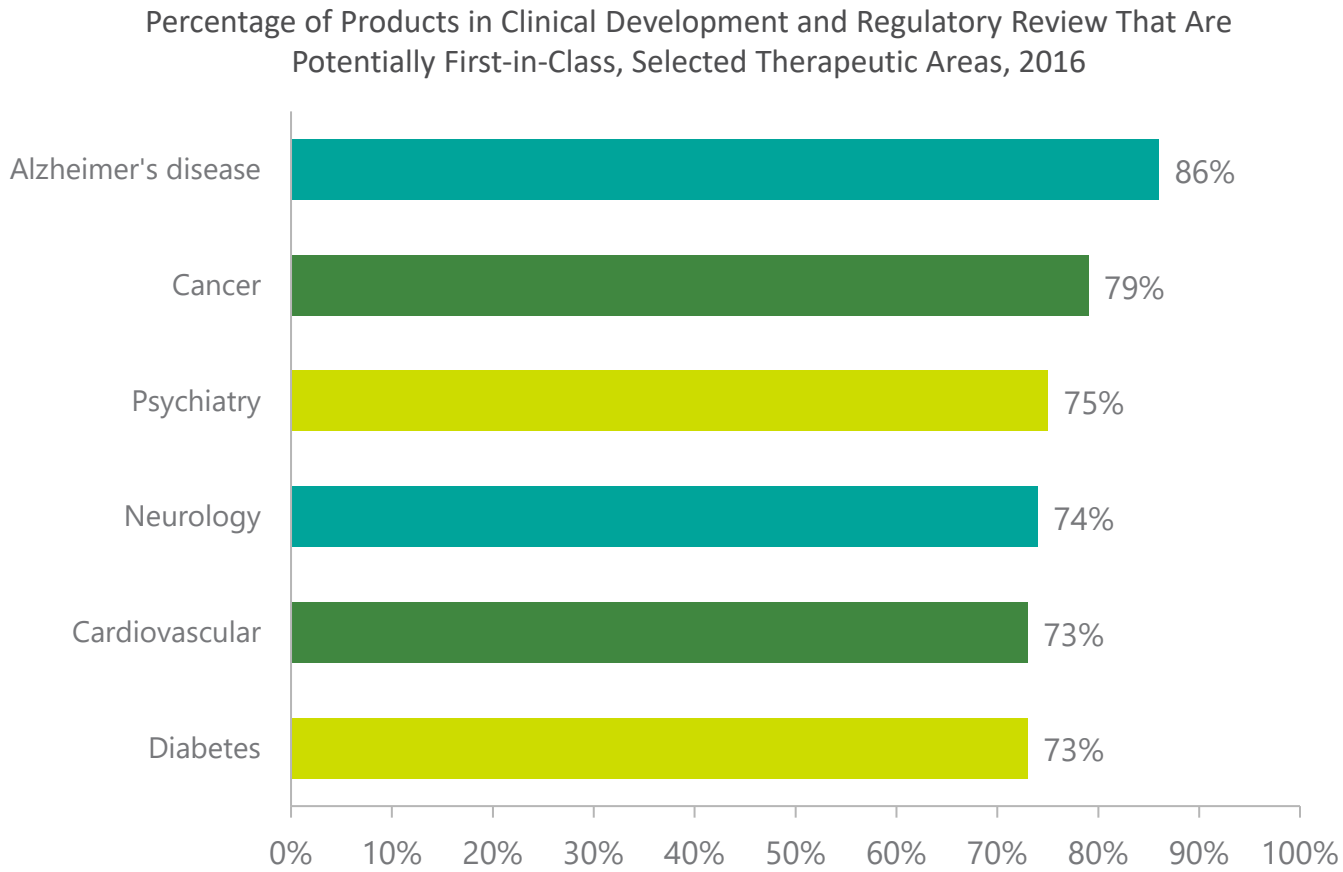
About 4,500 Medicines in Development in the United States

Biopharmaceutical researchers are working on new medicines* for many diseases and on select prevention and treatment approaches.

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

Source: PhRMA analysis of Adis R&D Insight database[2]

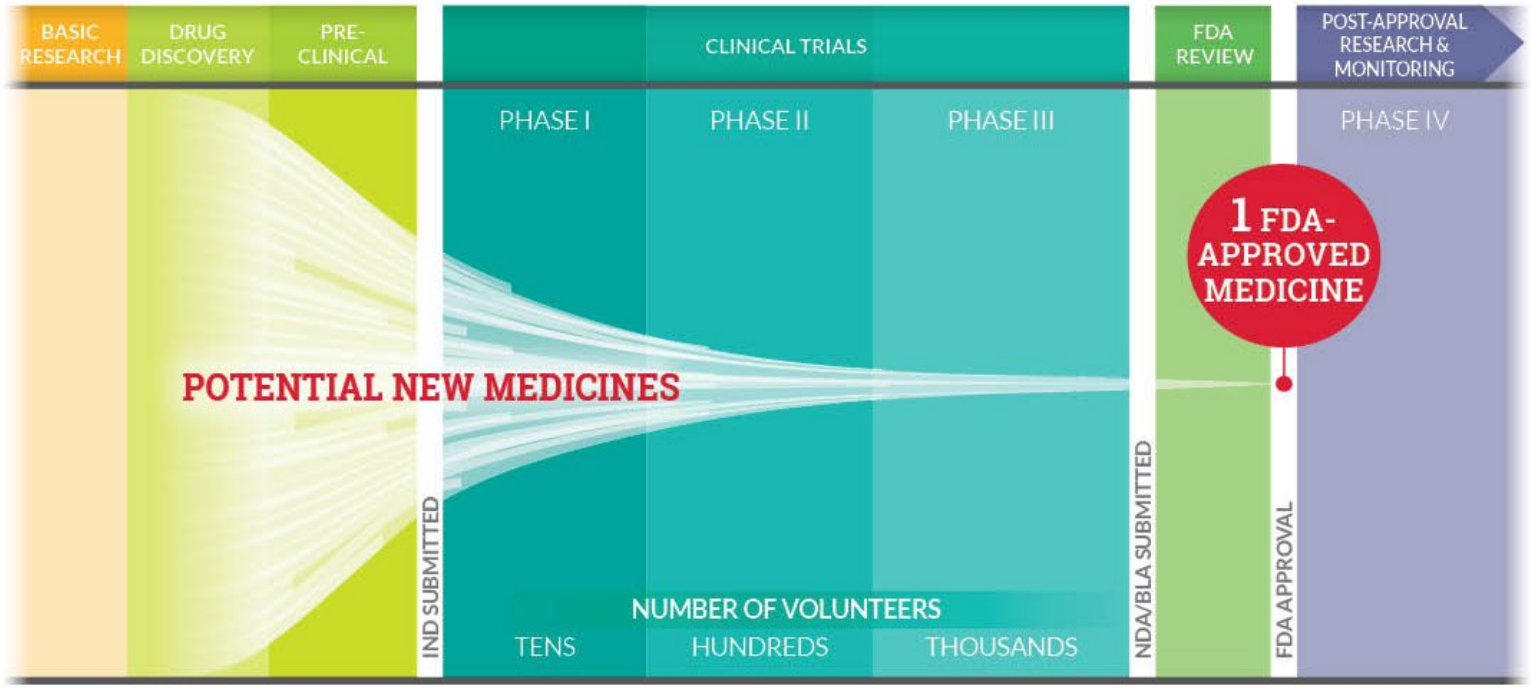
Potential First-in-Class Medicines in the Pipeline



Source: Analysis Group[3]

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.

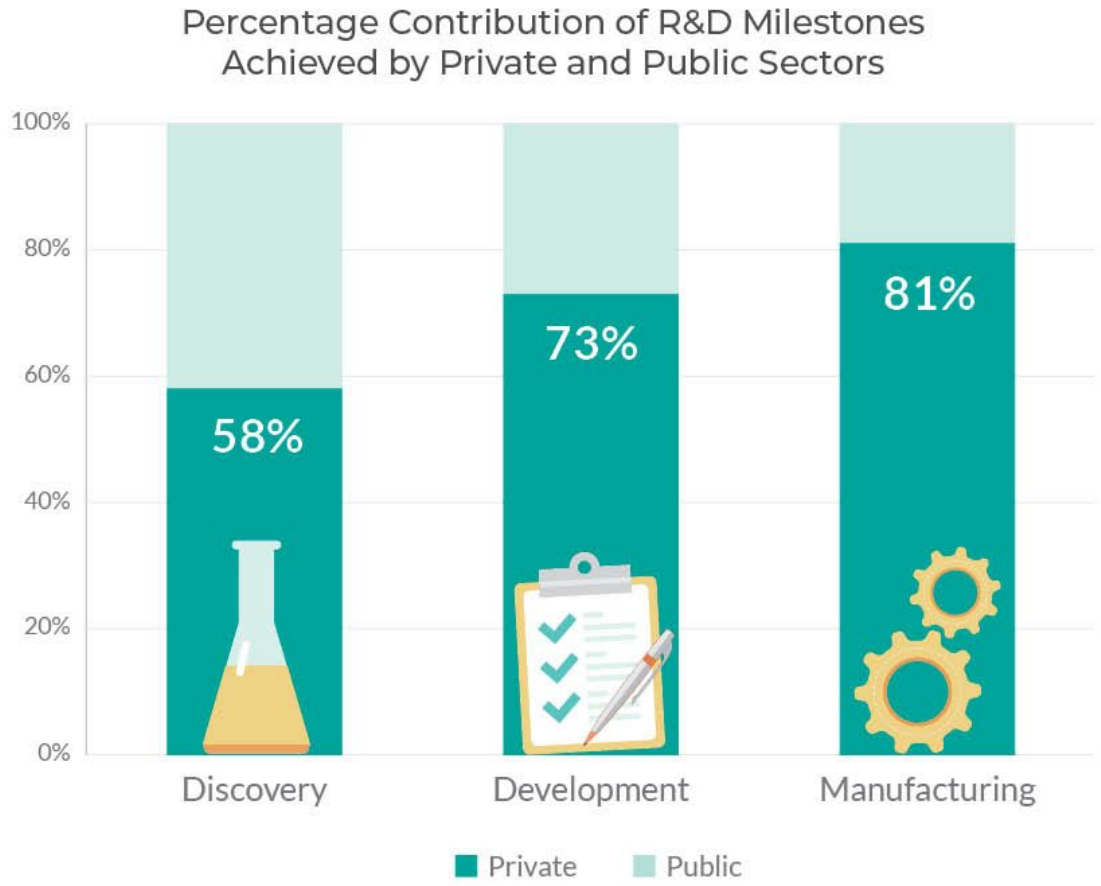


Key: IND=Investigational new drug application, NDA=New drug application, BLA=Biologics license application

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

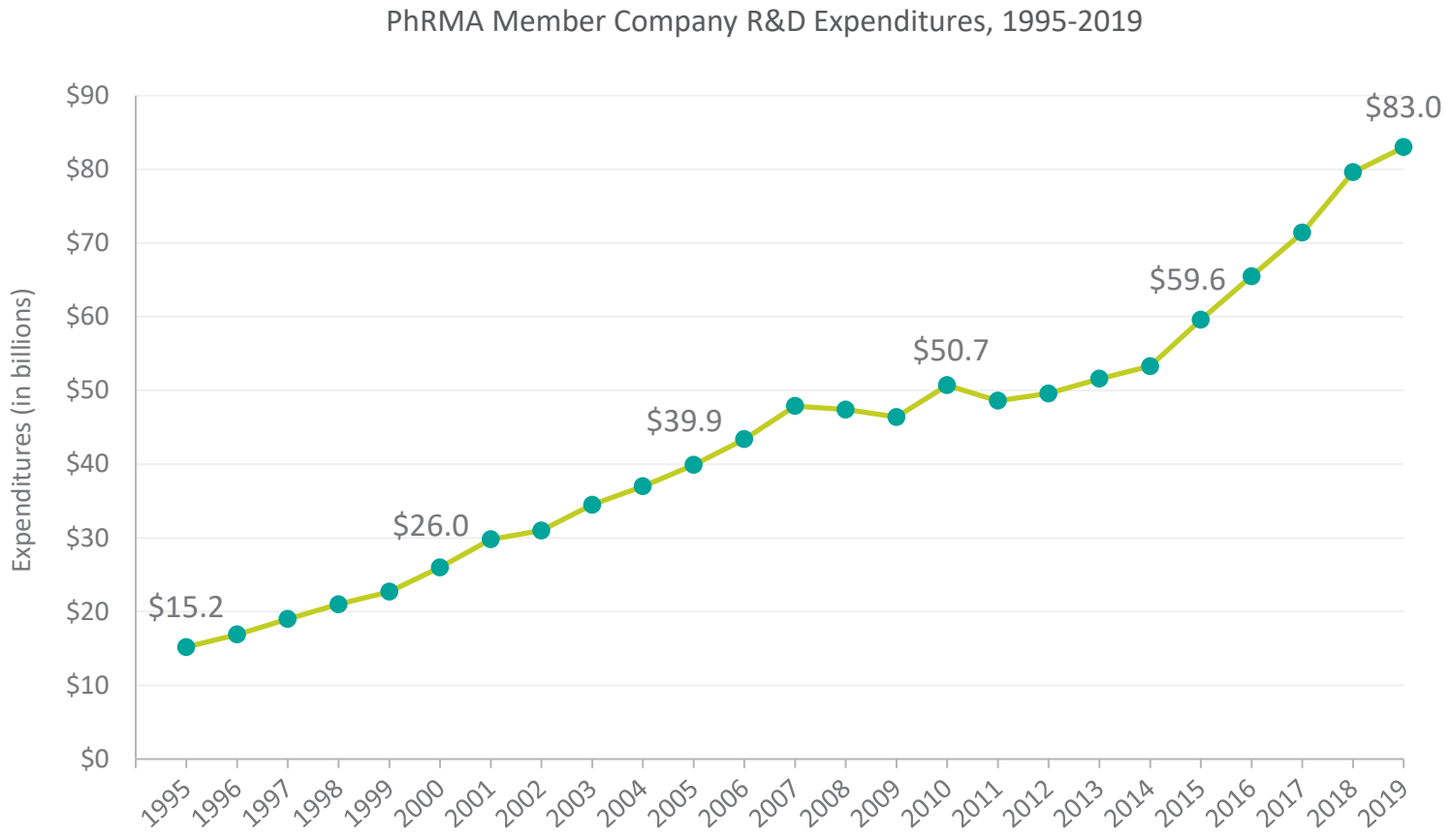
Sources: PhRMA adaptation of DiMasi JA et al[12]; Tufts CSDD[13]; FDA[14]

Private Sector Scientific and Industrial Expertise Is Required to Develop and Manufacture New Medicines



Source: Chakravarthy R et al[15]

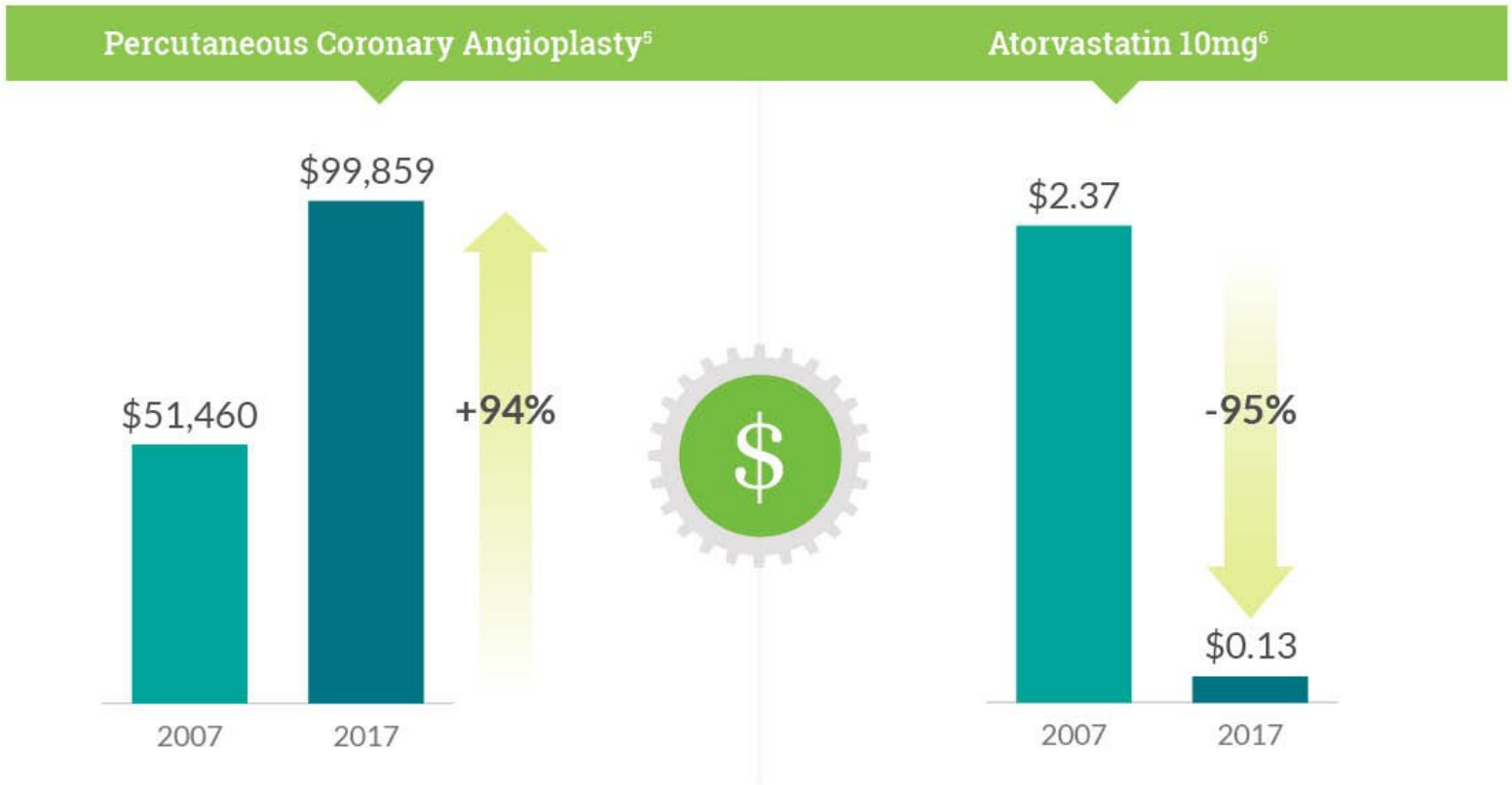
PhRMA Member Company R&D Investment



Source: PhRMA[32]

Medicines Offer Built-in Cost Containment, Which Is Unique in Health Care

The price of a medicine commonly used to prevent cardiovascular disease dropped 95% between 2007 and 2017, while the average charge for a surgical procedure to treat it increased 94% over the same period.



Sources: Xcenda analysis of HCUP hospital charge data[5]; IQVIA[6]

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 vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power.

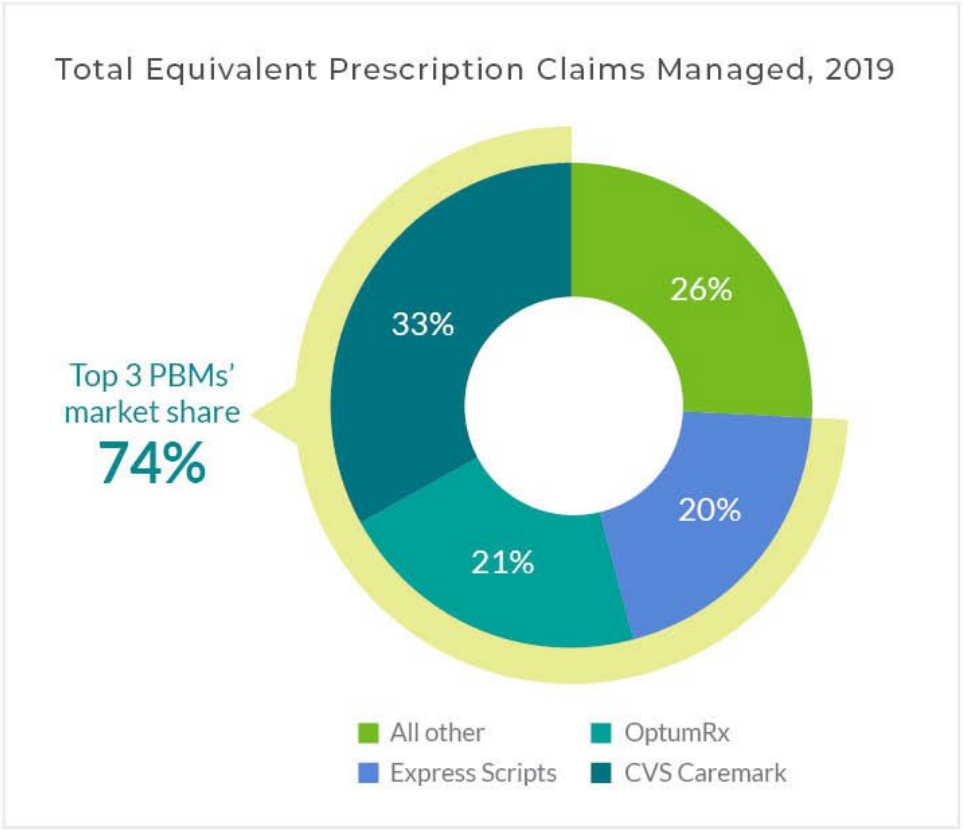
Flow of Payment for a $400 Insulin Prescription for a Patient in the Deductible Phase

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: PhRMA[25]

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.



PBMs and insurers determine:

FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

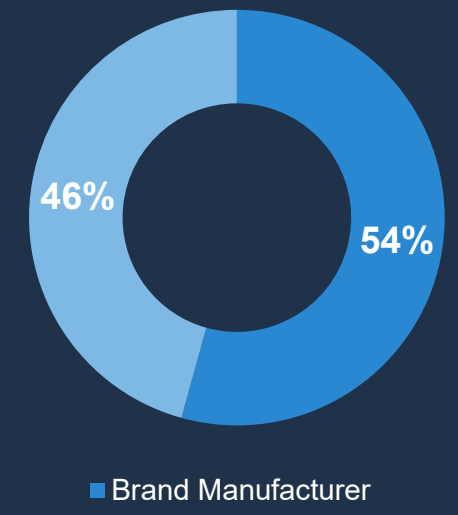
ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

Source: Drug Channels Institute[7]

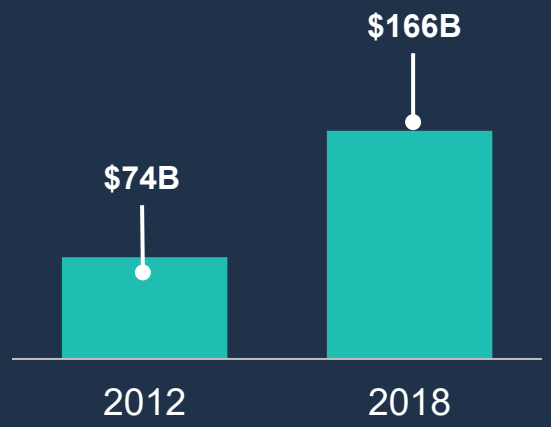
Nearly half of spending on brand medicines goes to entities other than the manufacturers who developed them.

Percent of Total Spending on Brand Medicines Received by Manufacturers and Other Entities, 2018



Source: Berkeley Research Group, 2020.

Rebates, discounts, fees and other price concessions have more than doubled since 2012



Source: Drug Channels Institute, 2019.

Impact of Upper Payment Limits

- Barriers to Access
- Innovation & Investment in Research and Development
- Fail to Address Supply Chain
- Legal Concerns

Market-based Reforms

MODERNIZE THE DRUG DISCOVERY AND DEVELOPMENT PROCESS

- Modernize the FDA to keep pace with scientific discovery and increase efficiency of generic approvals
- Promote and incentivize generic competition.

PROMOTE VALUE-DRIVEN HEALTH CARE

- Remove barriers restricting information companies can share with insurers.
- Reform regulations discouraging companies from offering discounts tied to outcomes.
- Modify Medicaid best price requirements.

EMPOWER CONSUMERS AND LOWER OUT-OF-POCKET COSTS

- Provide patients with access to negotiated rebates.
- Address affordability challenges in the deductible.
- Make more information on health care out-of-pocket costs and quality available to patients.

ADDRESS MARKET DISTORTIONS

- Address burdensome regulations that distort programs like the 340B Drug Pricing program.

IMPROVE TRADE AGREEMENTS

- Enforce existing trade agreements.
- Ensure new trade agreements recognize value of innovative medicines.

Contact Information

Kristin Parde
Deputy Vice President, State Policy
PhRMA
Kparde@phrma.org