

PhRMA Days Press Conference



April 12, 2017

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Chairman of the Board, PhRMA

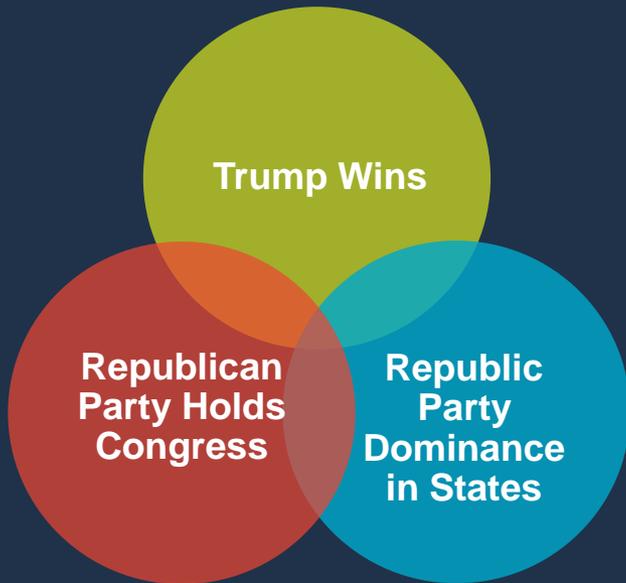
Roadmap

- I. Recent Developments in the United States
- II. Biopharmaceutical Industry's Contribution to Innovation and Economic Growth in Japan

January 31 Meeting with President Trump



PhRMA's Key Messages for the Trump Administration



- The U.S. should continue to lead the world in medical innovation
- Policymakers should seek strong trade agreements that level the playing field
- Government regulations should be modified to enable the private sector to lead the move to a value-driven health care system
- We need to modernize the FDA to bring safe medicines to the market faster, enhance competition and help control overall health care costs

Defend Against Flawed Policy Proposals

FLAWED PROPOSALS

REALITY



Allow Medicare to “negotiate” prices for prescription drugs

Congressional Budget Office directors of both parties have said Medicare would not be able to negotiate further savings



Allow patients to import medicines from other countries

Not a single Department of Health and Human Services Secretary has been able to certify importation will pose no risk to public health and generate cost savings



Transparency of R&D costs for individual medications

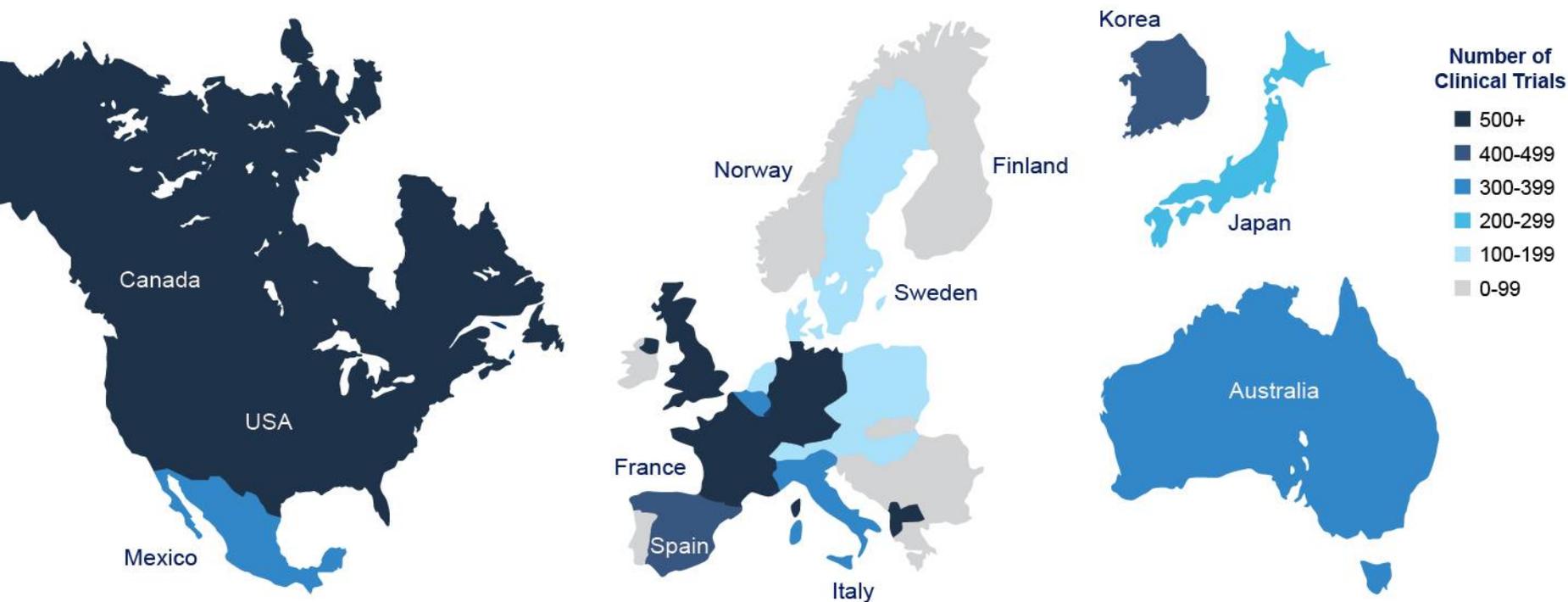
Misleading picture of true R&D costs; fails to give patients the info they want and need

Roadmap

- I. Recent Developments in the United States
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Industry-Sponsored Clinical Trials Contribute Significant Value to the Countries in Which They Are Located

In 2015, the biopharmaceutical industry sponsored 9,059 clinical trials around the world



Industry Has Continued to Increase Investment in Clinical Development across Japan

Number of PhRMA Japan and EFPIA Japan Member Company Sponsored Clinical Trials, 2015

In 2015, PhRMA Japan and EFPIA Japan member companies sponsored



of medicines in Japan, supporting tangible economic activity in the prefectures in which they are located¹



18,095 Sites

+55% since 2013



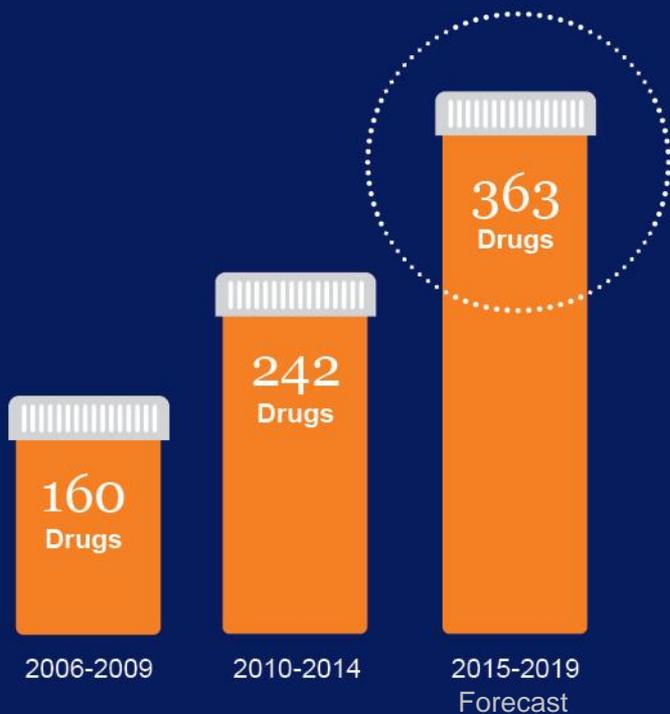
16+ Therapeutic Areas

- Allergy
- Cardiology
- CNS
- Dermatology
- Endocrine Metabolic Disease
- Gastroenterology
- Hematology
- Immunology
- Infectious Disease
- Musculoskeletal Disease
- Oncology
- Ophthalmology
- Respiratory Disease
- Urology
- Rare Diseases
- Others

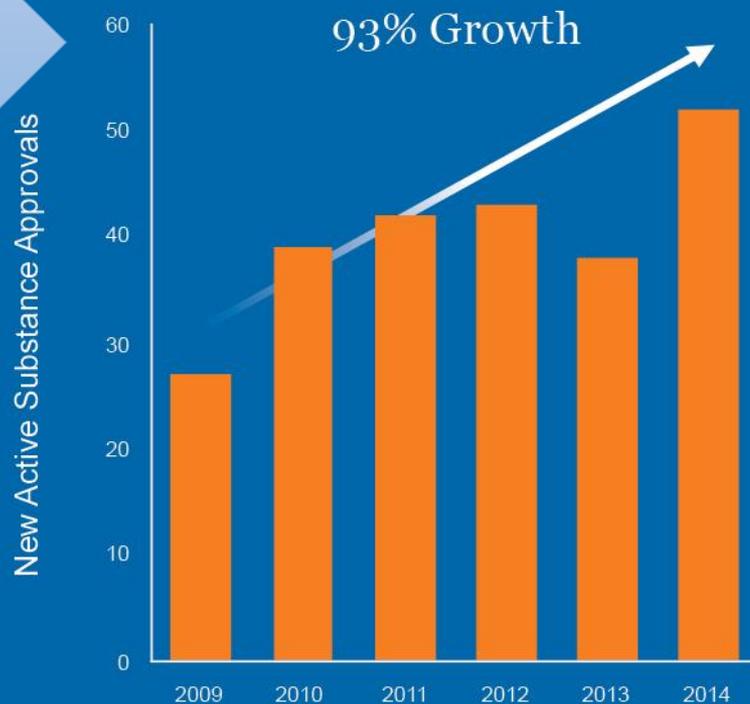


Favorable Policies and Reductions in Approval Times Have Led to Significant Increases in Available Innovative Therapies

Since the introduction of several favorable policies, the number of drugs submitted for regulatory approval has increased sharply¹...



...driving increases in the number of approved innovative therapies in Japan²



Medicines Are Transforming the Treatment of Many Difficult Chronic Diseases



Cardiovascular Disease

Between 2000 and 2012, the death rate from cardiovascular disease dropped 27% in Japan.² New PCSK9 inhibitors continue to revolutionize therapy for high cholesterol.

Drugs In Development
in Japan^{1*}

42



Diabetes

Between 2000 and 2012, new therapies contributed to a 20% decline in the diabetes death rate in Japan.²

28



Rheumatoid Arthritis

The recent introduction of disease-modifying therapies has dramatically improved the lives of patients and caregivers by slowing and sometimes even reversing negative physical symptoms of the disease.³

35



Death rates for
non-communicable diseases

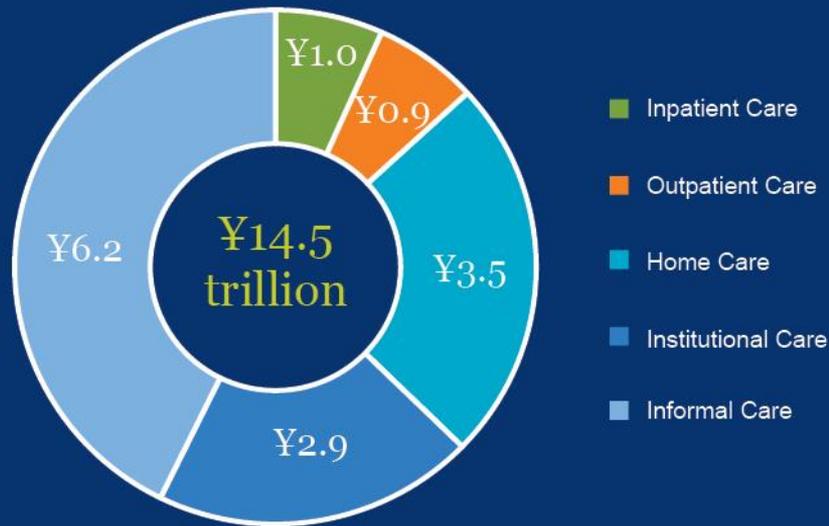
declined by

18%

in Japan from 2000 to 2012²

Without Investment in New Medicines the Cost of Disease Could Bankrupt the Japanese Health Care System

In 2014, the societal cost of dementia was ¥14.5 trillion, nearly 3% of Japan's GDP¹



100,000

The number of people quitting their jobs each year to care for sick family members¹

~50%

The percentage of the societal care cost for dementia that is borne by families¹

30 months

The amount of time spent in nursing home care per patient that could be delayed if currently available medicines were used for at least 9 months²

By 2060, the projected societal costs of dementia are estimated to be

¥24.3 trillion

More Than 7,000 Medicines Are in Development Around the World

Medicines in Development



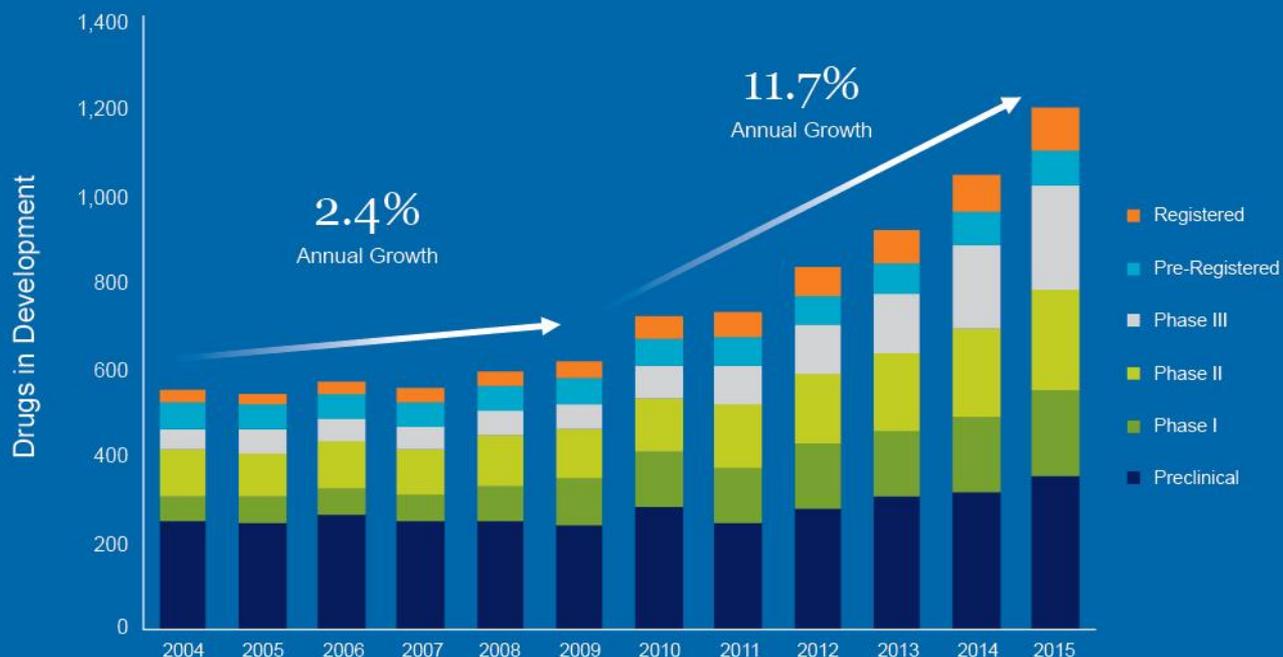
Development of Innovative Medicines Has Accelerated, Providing Hope for New Therapies and Creating Economic Activity



Over 1,000 medicines

are in development in Japan today, providing hope for patients in need of new medicines and supporting tangible economic activity in terms of R&D employees and clinical trials

Japanese Clinical Development Pipeline



Global Challenges Loom that Threaten Continued Innovation and Patient Access to Medicines

Global Biopharmaceutical Innovation

Innovation is harder and more costly

Longer, more complex clinical trials

Higher regulatory hurdles

Increased costs of R&D

Investment in innovation is increasingly risky

Ad-hoc fiscal austerity measures

Greater cost-sharing and coverage restrictions

Eroding intellectual property protections

Increased reference pricing and parallel trade

Payers mandating off-label use to reduce costs

Challenges exist impeding patient access

Complex HTA processes delaying patient access

Lack of formalized path for personalized medicines and orphan drugs

Restrictive clinical guidelines and cost-effectiveness requirements limiting access to the best care

Contracting and tendering limiting therapeutic options

In Japan, Uncertainty and Unpredictability Threaten Progress Made Over the Past Decade



Japan Biopharmaceutical Innovation

Innovation is harder and more costly

- Per-patient clinical trial costs in Japan are two to six times higher than anywhere else in the world¹

Investments in innovation are increasingly risky given the unpredictability of the Japanese market

- The Price Maintenance Premium is now subject to a zero-based review.
- Further reduction of drug prices will make R&D investment and drug launch in Japan less attractive³
- The stagnant Japanese economy is a risk to future investments in health care

Challenges exist impeding patient access

- “Optimal Use Guidelines” are introducing uncertainty in the new product adoption process
- HTA that imposes cost-effectiveness thresholds threatens to undermine innovation and reverse progress on patient access to innovative medicines⁴

Putting Spending on Prescription Medicines in Perspective across Key Developed Markets

								
	USA	Japan	Germany	France	UK	Italy	Canada	Spain
Total Spending on Hospital Care, 2014	\$1,786B	\$271B	\$191B	\$124B	\$117B	\$92B	\$70B	\$73B
Total Spending on Prescription Medicines, 2014	\$277B	\$82B	\$49B	\$34B	\$29B	\$29B	\$22B	\$16B
Ratio (Hospital Care / Prescription Medicines)	6.4	3.3	3.9	3.6	4.0	3.2	3.2	4.6



SPENDING ON
Prescription Medicines



SPENDING ON
Hospital Care

Expenditure on hospital care across countries is
3-6 times the total spending
on prescription medicines

Medicines Are Part of the Solution and More Can Be Done Together

Governments, Providers, and Payers

● Improve Efficiency

Look at all health care costs, reduce administrative costs and waste, and improve efficiency

● Pay for Value

Support evidence-based care and empowered patients and providers, backed by sound research and quality measures

● Find Solutions

Avoid blanket policies that chill investment, and collaborate to find new approaches

Biopharmaceutical Companies



Continue developing innovative therapies, promote medication adherence, and maintain efforts to support broad patient access

Industry Engaging as a Responsible Partner in Healthcare

Basic Principle:

- The benefits a pro-innovation agenda brings to patients and Japanese economic growth must be considered, instead of focusing solely on cost-cutting

Our Conclusion:

- Further efficiencies to our sector can bring cost-savings while allowing continued support of pro-innovative policies to help alleviate health burdens for patients and also to stimulate economic growth

Industry Engaging as a Responsible Partner in Healthcare

To support these, PhRMA's members have:

- Created a new “Vision” for the Japanese healthcare system
- Developed a set of technical proposals for each element of the reform plan

Activities:

- Strong collaboration with industry partners to develop proposals addressing stated concerns of the Japanese government
- Frequent meetings with MHLW and other government officials to exchange views and deliver possible solutions
- Engagement with other Japanese stakeholders to increase their understanding of industry positions and proposed solutions

PhRMA's Vision: Making Japan the best place to live and age

