



To contribute to a goal of **Japan as the best place to live and age**

Launch of the Vision of the innovative pharmaceutical industry

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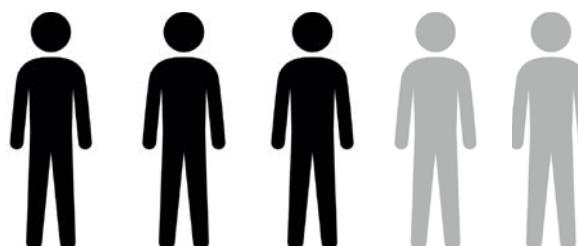
Tokyo, July 10, 2018

Maintaining a pro-innovation policy environment is essential to ensure the sustainability of the Japanese health care system

In an aging society, medicines represent an excellent option to improve healthier lifespans while reducing expensive downstream health-related costs

Incremental innovation allows patients to continue to contribute to society¹

Step by step, we are beating cancer. Today, 3 out of 5 Japanese with cancer survive at least 5 years



81% of cancer patients return to work within 12 months of their initial sick leave

Investment in new innovations that address social cost is needed²

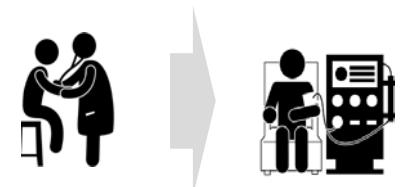
Societal cost of dementia is already huge and will grow as the population ages



50% of care cost borne by families.
100,000 people per year leave work to provide care

Prevention of expensive complications can achieve a high return on investment³

Prevention of diabetic aggravation Dialysis



Number of patients:	2,000,000	100,000
Annual medical cost: (per patient):	¥400,000	¥5,800,000

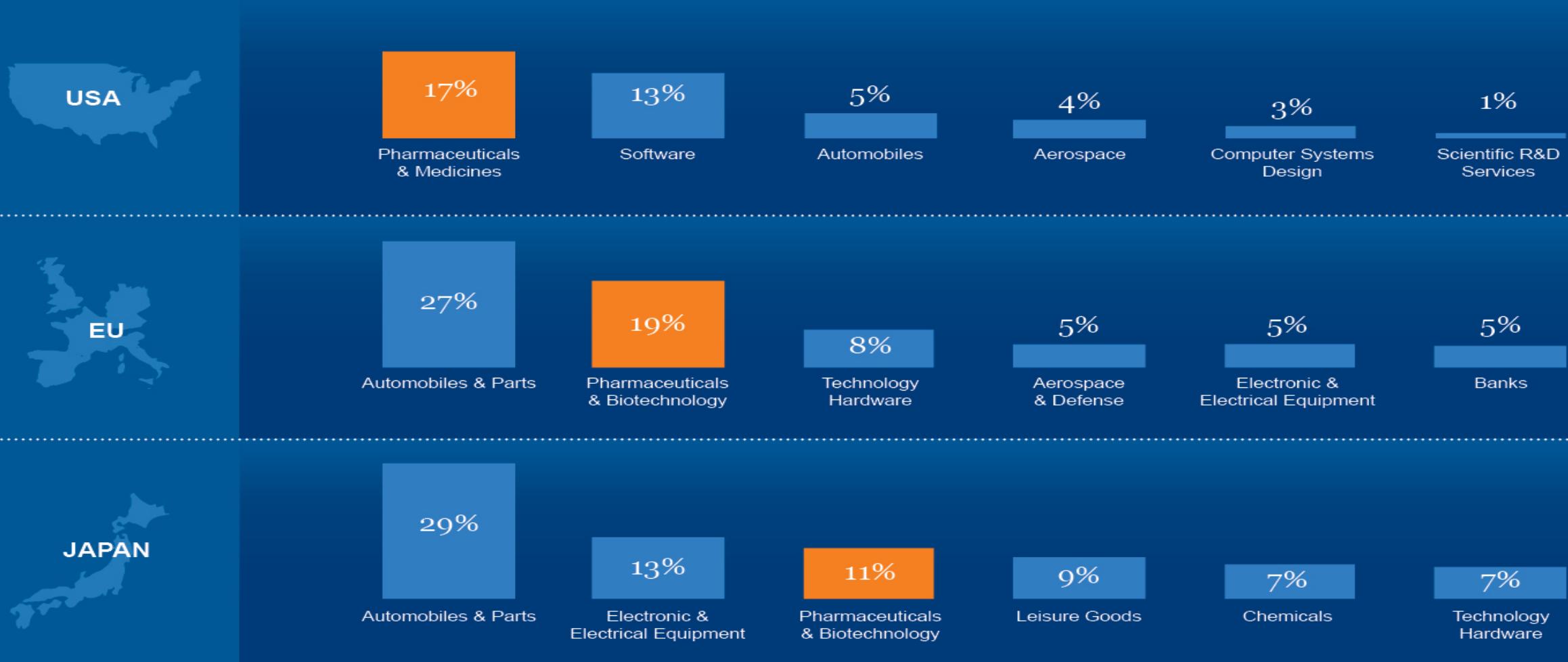
Source: ¹Endo et al., 2015, "Returning to work after sick leave due to cancer: a 365-day cohort study of Japanese cancer survivors," Journal of Cancer Survivorship. Note: Return to work includes full-time and part-time work.

²Ministry of Health, Labour and Welfare, 2015, Study on the Economic Impact of Dementia in Japan, Health Labour Sciences Research Grant.

³Source: Ministry of Economy, Trade and Industry (accessed April 2018) http://www.meti.go.jp/policy/mono_info_service/healthcare/downloadfiles/2017healthcare_presentation_v2.pdf.

The Biopharmaceutical Sector in Japan Has the Potential to Become the Largest Funder of Business R&D

Share of Business R&D by Industry^{1,2}



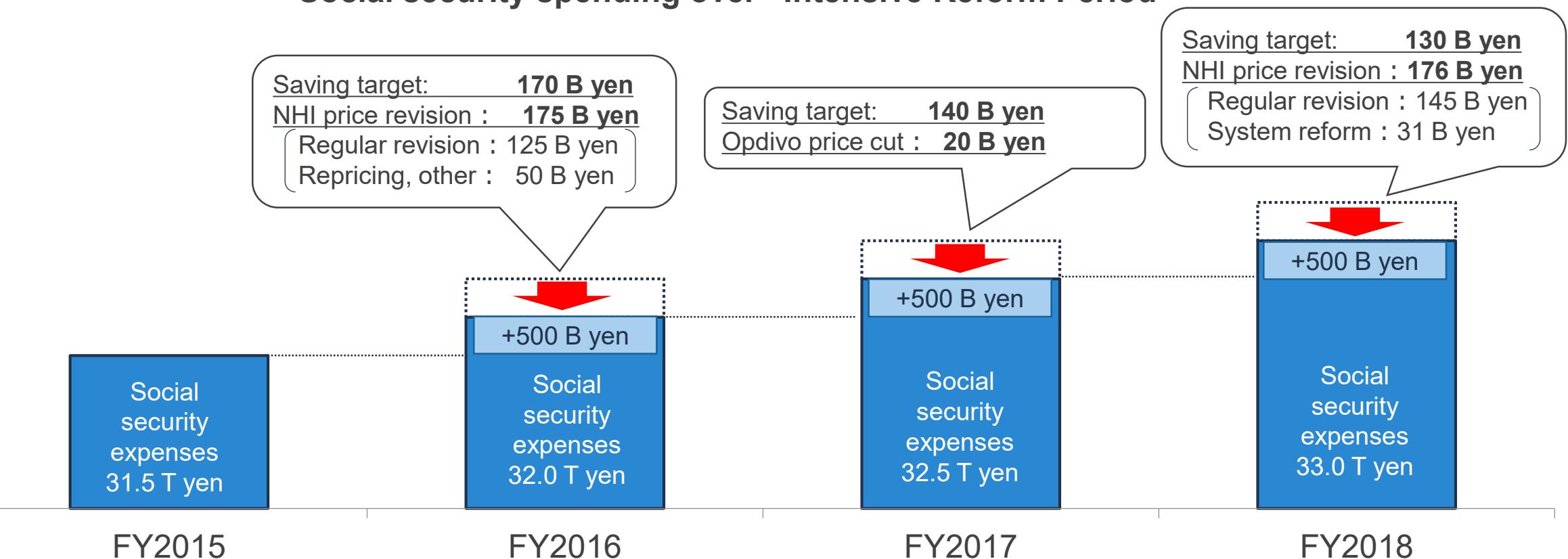
Note: The remaining share of business R&D spending is conducted by other industries, including subsectors of the machinery sector, the electrical equipment sector, and the professional, scientific, and technical services sector.

Source: ¹PhRMA analysis of National Science Foundation, National Center for Science and Engineering Statistics, data. Funds spent for business R&D performed in the United States, by source of funds and selected industry: 2013; ²European Commission, 2016, The 2016 EU industrial R&D investment scoreboard.

Social security spending control that strongly depends on NHI price revision is not sustainable and lacks balance

- 3 years total saving target to manage annual social security spending growth within 500 B yen was **440 B yen**
- 3 years total saving generated by NHI price revision was **371 B yen** (more than 80% of total saving over 3 years)

Social security spending over “Intensive Reform Period”



Japan's Direction Away from Pro-Innovation Policies C癩ides with China's Efforts to Create a Business Environment that is More Predictable and Rewards Innovation

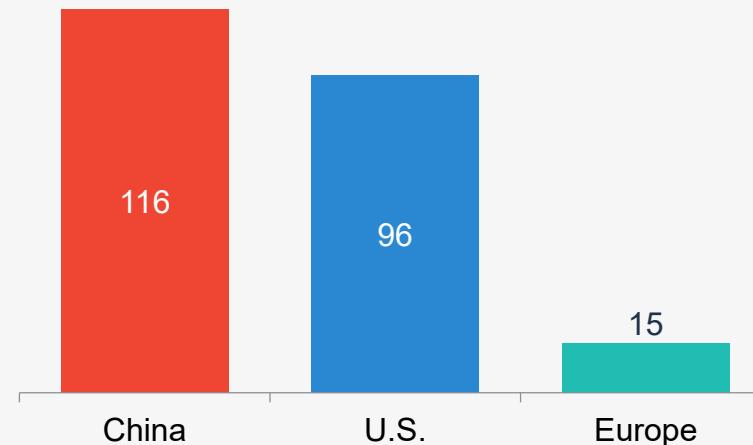
China has implemented a number of regulatory reforms to facilitate its participation in simultaneous global development and product introduction as well as proposed significant intellectual property improvements

Japan's Neighbors are Raising the Standards for Pharmaceutical IP

- China has announced plans to establish a patent linkage system and extend regulatory data protection for biopharmaceuticals to 10 years
- Taiwan recently passed legislation to establish a patent linkage system as well as extend 3 years of regulatory data protection for additional indications
- Meanwhile, Japan has no robust system for patent linkage: it only offers 4 years of regulatory data protection for additional indications, and 8 years of regulatory data protection for biopharmaceuticals

China Emerging as a World Leader in Cell Therapies

Number of Car-T clinical trials in China now exceeds the US and Europe



Historic Reforms in China Endorsed by Senior Leaders

19th Party Congress reinforces "Healthy China 2030" aspiration

- Deepen health care system reform
- Encourage drug and medical device innovation
- Improve primary care and GP system

Our Vision is built on three key pillars

**INNOVATION
PILLAR**

**SUSTAINABILITY
PILLAR**

**EVIDENCE
PILLAR**

INNOVATION PILLAR

Research & Regulation



Advancing innovation with a world leading regulatory environment to deliver drugs to patients in a safe and timely manner

Promoting innovative pharmaceutical discovery and translation into medical innovation in Japan.

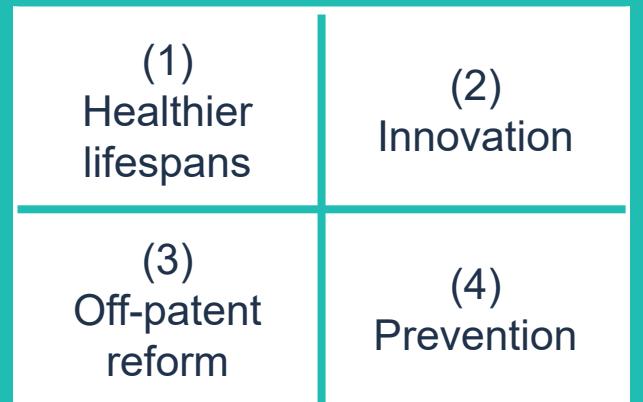
1. Strengthen translational research
2. Harmonizing to global clinical trial guidelines

Improving the competitiveness of Japan as a regional and global leader through regulatory excellence.

3. More flexible use of expedited approval pathways
4. Use data infrastructure to streamline pharmacovigilance

SUSTAINABILITY PILLAR

Investment & Savings



Securing timely and affordable patient access to new innovation in a sustainable universal health care system

Delivering innovation that contributes to an extension of healthy lifespans under a rebalanced NHI that secures timely and affordable patient access to innovation.

5. Innovation as an investment in healthier lifespans
6. Maintain Japan as a priority destination for innovation

Optimizing expenditure through an increase in efficiency of the off-patent sector and investment in primary and secondary prevention.

7. Re-invest savings available through off-patent reforms
8. Encourage primary and secondary prevention

EVIDENCE PILLAR

Quality information

(1) Data infrastructure

(2) Value assessment

(3) Stakeholder involvement



Ensuring policy decisions are evidence-based and incorporate a broad stakeholder voice

Prioritizing establishment of data infrastructure as a key driver for further optimization of the health care system and resources.

9. Create a comprehensive electronic medical record system

Building a world-leading value assessment framework to ensure predictability and provide a sound process to assess the value of innovation.

10. Develop a patient-centered value assessment mechanism

11. Include broad stakeholder input into decision-making

What can the vision deliver to Japan if implemented

For patients

- Will help to ensure the continued improvement in health outcomes and the expectation of healthier lifespans.
- Will help avoid risk of delay in patient access to cutting-edge innovation.
- Will strengthen the inclusion of patient views, preferences and experiences into their health care.

For the health system

- Through re-balancing price reform, sustainable investment in innovation will be possible.
- Increased focus on primary and secondary prevention will also significantly reduce total NHI expenditures.
- Implementation of data infrastructure and value assessment should support efficiencies in the broader system.

For the economy

- Will help strengthen domestic efforts to discover and commercialize new medicines for global health.
- Will help maintain Japan as a preferred destination for foreign direct investment in the face of rising competition.
- Pro-innovation policy leads to a healthier population thus improves overall productivity and economic growth.

The Biopharmaceutical Industry:

Committed to working as a true partner of Japan to achieve the best possible health for its citizens

1. We have developed our vision of how the innovative industry can contribute to a goal of making Japan the best place to live and age
2. Our vision has identified three key areas where we can meaningfully contribute: innovation, sustainability and evidence
3. Our vision provides recommendations on how the government can remove barriers and establish new policies that would enable us to deliver better patient outcomes and economic gains

