



2018 PhRMA Days Press Conference

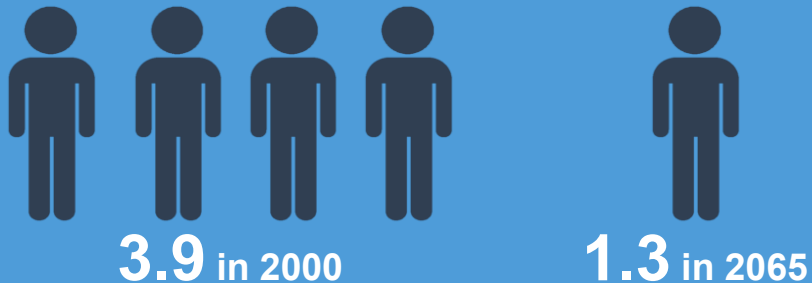
Robert A. Bradway, Chairman of the Board, PhRMA

The Aging Population in Japan Is Leading to Greater Demand for Health Care

Aging Population



Working Population to Support One Elderly Person



National Medical Care Expenditure



■ 0-14 years ■ 15-64 years ■ 65+ years

59.3% of medical care costs were
spent on the elderly in FY2015

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 using living cells



Medicines targeted to specific patient based on genetic makeup



Immunotherapy that harnesses the body's own immune system to fight disease



CAR T-cell therapy



CRISPR

A Decade of Advances Globally: 2006-2016

2006

Cervical cancer
Chronic chest pain
HIV

2007

High blood pressure
Fibromyalgia

2008

Crohn's disease
Huntington's disease

2009

Peripheral T-cell lymphoma
Gout

2013

Skin cancer
Multiple sclerosis

2012

Cystic fibrosis
Cushing's disease

2011

Lupus
Personalized medicine

2010

Multiple sclerosis
Therapeutic cancer vaccine

2014

Hepatitis C
Rare diseases

2015

High cholesterol
Cystic fibrosis

2016

Spinal muscular atrophy
Chronic lymphocytic leukemia
Hepatitis C

Innovative Therapies Allow Patients to Continue Contributing to Society...



Cancer survivors

globally are 1.4 times more likely to be unemployed than healthy individuals¹, however...



...4 out of 5 cancer patients

around the world today are returning to work following diagnosis due to innovative therapies.²

NETHERLANDS

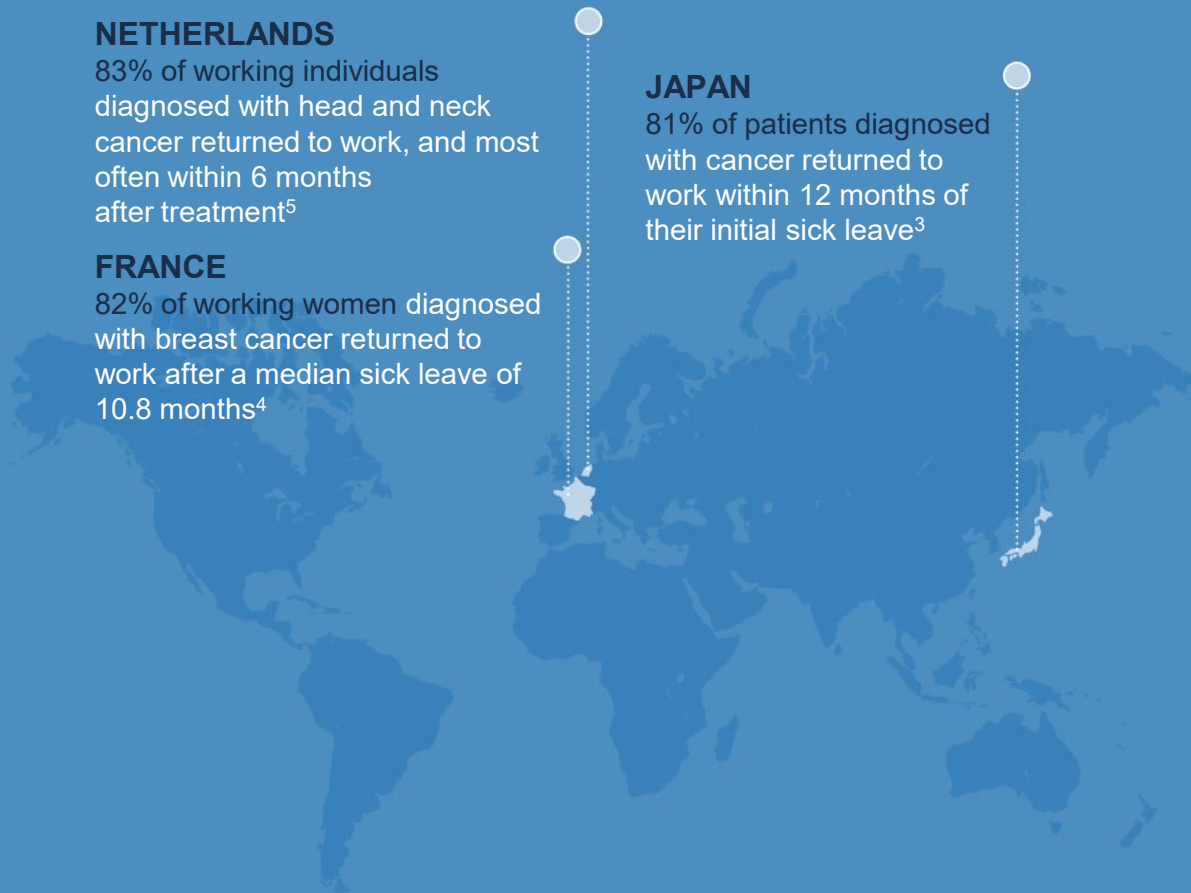
83% of working individuals diagnosed with head and neck cancer returned to work, and most often within 6 months after treatment⁵

FRANCE

82% of working women diagnosed with breast cancer returned to work after a median sick leave of 10.8 months⁴

JAPAN

81% of patients diagnosed with cancer returned to work within 12 months of their initial sick leave³

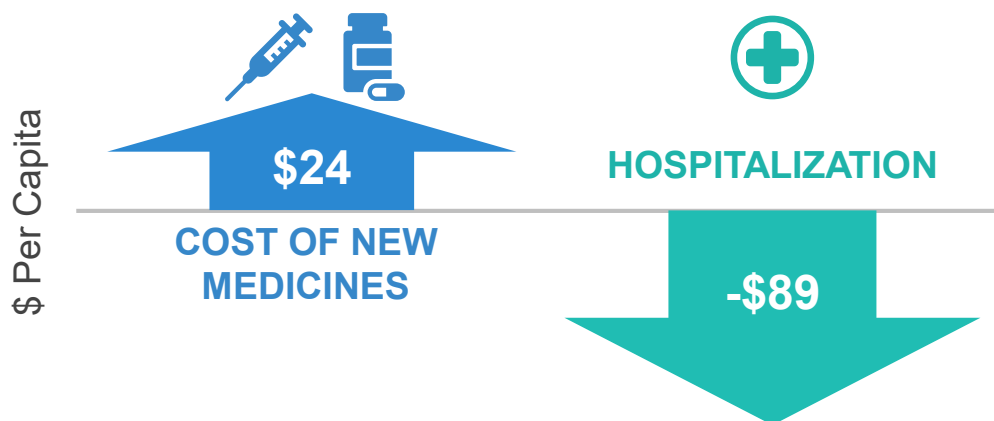


Note: In all three studies, return to work included full-time and part-time work.

Source: ¹de Boer, 2009, "Cancer survivors and unemployment: a meta-analysis and meta-regression," Journal of the American Medical Association; ²Amir and Brocky, 2009, "Cancer survivorship and employment: epidemiology," Occupational Medicine; ³Endo 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; ⁴Fantoni, 2010, "Factors related to return to work by women with breast cancer in Northern France," Journal of Occupational Rehabilitation; ⁵Verdonck-de Leeuw, 2010, "Employment and return to work in head and neck cancer survivors," Oral Oncology.

New Medicines Reduce Spending on Hospitalizations and Other Services

New Cardiovascular Medicines Led to Direct Savings on Hospitalizations in 20 OECD Countries*, 1995-2004



Per capita expenditure on cardiovascular hospitalizations would have been **\$89 (70%) higher** in 2004 had new cardiovascular medicines not been introduced in the period 1995–2004

2018 Pricing Reform Package Has Serious Implications for the Future

Balance between “sustainability of NHI” and “promotion of innovation” has not been achieved

1

Price Maintenance Premium

- **Limits the scope by narrowly defining innovation**
(number of eligible products reduced by 40%)

2

Cost Effectiveness Assessment

- Price for 7 pilot drugs to be **adjusted in April 2018**
- **Development of “full-scale” HTA system to be completed by end of FY 2018**

3

Annual Price Survey and Revision

- Based on the results of price revision for all products during 2018-2020, **scope of off-year revision will be decided in 2020**

Rushed Decisions Regarding Price Maintenance Premium Yielded Negative Outcome for Innovation

Innovation inappropriately defined as speed to market

Best-selling innovative pharmaceutical product in the world deemed “not innovative” under the new PMP system because it was not introduced within 3 years of the first-in-class therapy.

Company criteria fails to appropriately evaluate new methods of discovery

Leading new cancer product with over 650 global clinical trials underway and expected to be effective in up to 30+ cancer types globally is only counted as “1” product under the PMP company eligibility criteria.

Company criteria favors large companies over small

Companies ranked in 3 tiers. Tier 2 and 3 company products can never achieve full innovation premium.
Over 50% of PhRMA Japan members informed that they are not innovative enough to qualify for Tier 1.

What Message Does This Send to Inventors and Investors in Japan?

Japan's Direction on Health Technology Assessment Raises Concern for Innovators and Patients

The CEA pilots and international experiences offer important lessons to ensure that any HTA system promotes innovation and patient access to new treatments

Lack of Transparency

The pilots have raised serious questions about the fairness, transparency and predictability of the Japanese market.

The CEA pilot process:

- Lacked clarity in company requirements and timelines
- Provided inadequate consultation with industry, patients and providers

Key Deficiencies in Model

Narrow focus on cost-per-QALY threshold undervalues innovative medicines to patients, providers and the health care system.

The CEA pilot model:

- Puts a low price on life
- Minimizes social and ethical factors in determining value
- Targets the most innovative medicines for price cuts

Poor Outcomes Abroad

No country has implemented CEA without stifling innovation and delaying patient access to new medicines.

The UK has experienced:

- Delay and denial of access
- Reduced choice for providers
- Lower rates of cancer survival
- Political backlash

Strong Pro-Innovation Policies Vital for Continued Investment in Japan and Patient Access to Innovative Medicines

Summary of Reform

Industry Asks

Price Maintenance Premium (PMP)

PMP reduced by 40%

Address deficiencies in the PMP

Cost Effectiveness Assessment

Possible outcome on HTA will force significant additional price cuts and potential rationing of medicines

Develop an HTA system in an open and transparent manner, based on learnings from other countries, that does not impede patient access

Annual Repricing with 2019 Consumption Tax

Certain stakeholders advocating for annual repricing including on innovative products. Japan already the only developed country with a domestic industry that reprices drugs every 2 years

Maintain biennial price revision system for innovative products

Drug Pricing Reform Process

Key decisions made without taking into account comments and suggestions from industry and other key stakeholders

Ensure an open and interactive process that allows for meaningful input from all stakeholders before decisions are made

Adding Life to Years

Medicines Are Part of the Solution to the Challenges of an Aging Society and More Can Be Done Together

Government, 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 backed by sound research and quality measures

● Find solutions

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

Pharmaceutical Companies

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



Going Boldly Together To Achieve **Healthy Aging in Japan**



The Innovative Biopharmaceutical Industry remains committed to working with the Japanese government and other stakeholders as a **true partner to promote pro-growth, pro-innovation policies for the benefit of Japanese patients, Japanese workers, and the economy.**



THANK YOU!