



PhRMA DAYS Press Conference

June 1, 2016

Dr. George Scangos, Chairman PhRMA

(Slide #2) – Dr. Scangos picture/bio

Good afternoon and thank you for joining me this afternoon. My name is George Scangos, and I am the CEO of Biogen and the Chairman of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the leading innovative biopharmaceutical research and biotechnology companies in the world, including Japanese companies such as Astellas, Daiichi-Sankyo, Eisai, Otsuka, Shionogi, and Takeda. It is as the Chairman of PhRMA that I speak to you today.

I note that we are celebrating the 20th anniversary of PhRMA Days, which should be viewed as underscore foreign companies' long-standing commitment to the Japanese market.

Over the past two days, I have met with many Japanese leaders in the public and private sectors. We have had wide-ranging and highly productive discussions on everything from how to encourage translational research in Japan -- to how we can ensure that Japan's world-class healthcare system remains sustainable far into the future. These are topics that will continue to shape the healthcare landscape in this country for years to come.

Based on these conversations, three priorities emerged as it relates to the future of healthcare here:

The first is ensuring that Japanese patients continue to have early access to the newest and most innovative medications and therapies.

Secondly that there is a continued focus on the development and implementation of pro-innovation policies to ensure that the pharmaceutical industry can and does positively contribute to the economic growth of Japan, as envisioned by the Abe Administration.

And thirdly, ensuring that foreign pharmaceutical companies continue to positively and properly contribute to the health of the Japanese public and the prosperity of Japan long into the future.

Across the pharma industry globally, we are entering a period with great potential for drug discovery and development. Today, there are more than 7,000 medicines in clinical development around the world – and 70% of these have the potential to be first-in-class therapies. By working together to create novel medicines that benefit individuals and society, we can have a tremendous impact on patients.

In the 1960s, the 5-year survival rate for the most common form of childhood cancer – acute lymphoblastic leukemia – was less than 10 percent. Today it is over 90 percent. When I started my career, many diseases that are reasonably well controlled today, including multiple sclerosis had no treatments at all.

Hepatitis C had not even been identified – it was known as non-A non-B hepatitis. Today it is curable. Most patients with heart disease are now treated effectively. HIV/AIDS is now a chronic disease.

And in neurodegeneration, I believe we are on the cusp of a transformative era where cutting-edge science and technologies may offer important breakthroughs for patients suffering from devastating diseases such as Alzheimer's and Parkinson's disease. Currently, these diseases are putting an increasing strain on countries healthcare budgets – imagine the benefits both to patients and to cost-savings to the system we have just around the corner because of these new, innovative medicines. The rate of scientific and technical advancement is truly stunning. Our understanding of disease biology is increasing dramatically. Our ability to collect and rapidly analyze large and complex data sets is amazing.

I believe the advances we have seen over the last 30 years are *nothing* compared to what we will see over the next 30 years. It is an incredibly exciting time in the pharmaceutical and biotechnology industry. But we need to continue to work with policymakers in Japan and around the world ensure the way is paved to get these new products and technologies to patients in an early timeframe and to provide sufficient reward for innovation so the R&D continues to bring us such breakthroughs.

Specific to Japan, in my discussions this past week, the following important points came up again and again:

First, Japan is vitally important to the global pharmaceutical industry, and in turn, the pharmaceutical industry is a key sector in Japan bringing improved health to patients, driving innovation, fueling economic growth, and employing directly and indirectly hundreds of thousands of Japanese workers.

(Slide #3) - Employment

- Japan boasts a truly innovative and economically powerful domestic pharmaceutical industry, employing half a million Japanese citizens

(Slide #4) – Share of Business R&D (Japan, U.S., EU).

- The pharmaceutical and biotechnology industry is the 3rd largest funder of business R&D in Japan, with a respectable 11% share. Yet, you can see there is tremendous room for growth in Japan.

(Slide #5) – Clinical trials

- Because of Japan's pro-innovation policies, which I will discuss in a moment, Japan has become a hub of clinical trial activities. In 2014, foreign pharmaceutical companies were conducting almost 700 clinical trials at around 12,000 different sites in Japan covering more than 16 therapeutic areas.

Secondly, as a direct result of the Japanese government's pricing reforms and adoption of pro-innovation policies over the last several years, we have seen very significant payoffs for Japan, the Japanese economy and Japanese patients.

- The Japanese government has adopted the promotion of innovation as a core policy.
- In the pharmaceutical sector, the structural reinforcement of the PMDA has steadily improved new drug approval time and measures to promote innovation, including the introduction and perpetuation of the price maintenance scheme, have resulted in a huge change in the environment.

(Slide #6)- Increase in Japanese clinical development pipeline

- The pharmaceutical industry has been increasing its R&D spending in Japan and actively promoting scientific innovation aimed at improving people's health.

(Slide #7) – Drug Lag

The drug lag (which had been preventing Japanese citizens' early access to new innovative drugs) has been significantly reduced from 42 months to under a year.

If Japan continues to make this a priority and maintain its focus on creating a pro-innovation environment, the drug lag is expected to diminish even further in the coming years.

(Slide #8) – Drugs submitted for regulatory approval

- Today the pharmaceutical industry is able to bring the newest and most innovative drugs to Japan quickly;
- More medicines are submitted for regulatory approval in Japan today than ever before, thanks to Japan's pro-innovation policies;
- The PMDA (Pharmaceutical and Medical Devices Agency) is now known as one of the most effective regulatory agencies in the world;
- And there is now a strong presence, in the form of AMED (Agency for Medical Research and Development) in support of basic, clinical and translational research.

To sustain the positive momentum that Japan has attained over the years, Japan must make a conscious choice to continue on its pro-innovation path.

- Japan has the world's most rapidly aging society. This has a direct correlation to the associated costs of continuing the national healthcare system.
- From the outside, it appears that Japan stands at a cross-road the easy path would be to simply focus on cutting prices on innovative medicines.
- While that approach may seem beneficial in the short term, that is not a long-term strategy that will benefit Japanese patients, Japanese healthcare companies or the Japanese economy.
- Simply continuing to focus on cutting the price of so-called "expensive" drugs cannot and will not ensure that the Japanese health care system is sustainable into the future.

- We understand there are a number of new price-cutting mechanisms that are in various stages of consideration within the Japanese government, including a possible out-of-cycle drug pricing survey in conjunction with the increase in the consumption tax, a move to annual re-pricing and ad hoc price cuts when new indications are approved. Some are proposing additional review of prices for the most successful new and innovative medicines.
- However, the adoption of such new anti-innovation policies could undermine the predictability and stability of the system and have some serious repercussions for Japanese patients, the Japanese pharmaceutical industry, and the Japanese economy.

(Slide #9) – Contraction of the Japanese drug market

- If an annual drug price revision were to be introduced, we expect that would lead to a major contraction of the Japanese drug market.

(Slide #10) – Japan's share of the global market

- In addition, Japan's position in the global pharmaceutical market would contract further, with the 12% share in 2012 expected to fall to just 5% in 2020.

(Slide #11) – R&D costs versus Sales

- The pharmaceutical industry is a high-risk/high-return business requiring massive investment over a long period of time with an extremely low probability of success. The cost to successfully bring one product to market is today around \$1.6 billion USD. The cost of R&D has increased rapidly in recent years, while at the same time, the average (peak) sales per new drug has plunged.

(Slide #12) – Return of the Drug Lag

- The prospects for earning a return on investment as well as predictability of the marketplace are crucial factors in any company's decision on where to put their future investments. This goes for foreign and domestic pharmaceutical companies alike.
- Were annual drug price revisions to or other new price cutting mechanisms be introduced, this would make it more difficult for companies to recoup their investment costs, and our fear is that this would negatively impact future investment decisions and Japan would be excluded from the group of countries included in multinational clinical trials – thus cutting it out of global simultaneous development.
- The consequences of this would be severe and dramatic. The drug lag would return and much of the hard-won progress that Japan has made over the last several years may be lost.

- At PhRMA, we have specific views as to how this can be avoided:
 - Maintaining pro-growth, pro-innovation policies must be a priority. In particular, Japan should make the price premium scheme a permanent part of the pricing system.
 - Cost containment measures that discourage innovation and undermine progress must be avoided.
 - And pricing structures that discourage heavy investment in R&D must be repealed.

(Slide #13) – Generic penetration

- A pro-innovation agenda is critical to our ability to bring important new medicines to patients. At the same time, we are fully aware of the importance of working together to find ways to ensure the long-term sustainability of Japan's health care system. As one example, we support the generic drug promotion measures of the Japanese Government.

(Slide #14) – Savings from use of generics

- Some of the greatest savings to the healthcare system can come from increasing use of generic drugs. The same is true in the United States and countries around the world. By increasing access to high quality, low cost generics and biosimilar products, we can benefit patients and healthcare economies.

Finally, we know that innovative pharmaceuticals offer great hope – to patients, and also to countries.

- Japan has one of the most rapidly aging societies in the world, which will bring new challenges as Japan works to ensure its healthcare system is sustainable.

(Slide #15) – Cost of Disease

- Alzheimer's disease one example of this.
- Without a therapy for this debilitating form of dementia, the estimated societal cost is projected to grow to over 24 trillion yen by 2060.
- Right now, biopharmaceutical research companies are studying 77 potential new treatments for Alzheimer's in clinical trials.

- We are working on finding ways to significantly slow the onset of Alzheimer's. If we are successful, this will have tremendous implications in terms of the potential benefits to society.
- But in order to continue this level of R&D into medicines that can achieve this and other key health care goals, those pharmaceutical companies pursuing innovation needs to be able to continue to invest. More simply stated, we need to ensure that there is adequate reward for innovation now, so we can invest that into the cures of the future.

CONCLUSION

- Every day, pharmaceutical companies are working to provide a way to cure today's most difficult diseases and healthcare challenges. We want to actively engage with the Japanese government and others to offer solutions to the difficult problems Japan, and other countries around the world, are facing.
- This will require a transparent and comprehensive and transparent dialogue with all stakeholders in the system and a look at the healthcare system more holistically.
- PhRMA and its member companies fully support Japan's goals to maintain its comprehensive social welfare system as vibrant and sustainable far into the future.
- The Japanese government must not waiver on its commitment to innovation. Cost-cutting measures that sacrifice long-term innovation in order to achieve short-term financial windfalls for the healthcare system will likely result in huge society and economic costs in the mid-to-long term. There is too much at stake – for Japanese patients, the healthcare industry and the economy – to go down this path.
- Instead, Japanese policymakers must return to a more predictable policy environment and a renewed emphasis on innovation. This will, in turn, encourage foreign and domestic innovation and investment in Japan, further growth of this sector, to the benefit of the Japanese economy, and of course, further progress in getting the most innovative medicines to Japanese patients in the shortest time possible.
- This is an important and exciting time for the Japanese healthcare industry. We look forward to engaging in this dialogue with Japanese policymakers moving forward, and ensuring that the Japanese healthcare system remains sustainable and continues work for Japanese citizens.