Press Conference – June 3 2015

Speech of PhRMA Chairman – Kenneth C. Frazier

Good afternoon. I am Ken Frazier, Chairman and CEO of Merck. Today I am here in my capacity as Chairman of PhRMA, the Pharmaceutical Research and Manufacturers of America, representing the major biopharmaceutical companies in the world, including a number of Japanese companies – Takeda, Astellas, Daiichi-Sankyo, Eisai, Shionogi, Otsuka, and Sumitomo Dainippon.

Before I share some of the highlights of my discussions with policymakers and key healthcare stakeholders here in Japan, I'd like to take a step back and remind us all of the purpose of our industry: patients. The patients we serve remain the central focus of our industry; the long-term health of every patient who may benefit from our medicines and vaccines is central to ensuring that both in Japan and abroad, healthcare systems are sustainable and value-driven.

It was 65 years ago that George W. Merck, one of my company's founders and early CEOs, in speaking to a group of aspiring healthcare professionals reminded them that nothing is more important than serving those with unmet medical needs. He left them with a simple charge: "… to remember that medicine is for the patient… it is not for the profits."

To this day, I believe the wisdom of these words still hold true. Over the years, this imperative of inventing and innovating with the patient in mind has come to define not just the company I lead, but the industry I'm honored to represent in this role.

For more than five-and- a-half decades, PhRMA has brought together the world's leading biopharmaceutical and discovery companies – companies with a shared goal to help people live longer, healthier, and more productive lives.

From the mass-production of antibiotics that revolutionized medical science, to the development of vaccines that save 2.5 million lives each year – these breakthroughs have changed the world.

Today, the biopharmaceutical industry is poised to translate the most promising scientific breakthroughs into meaningful treatments capable of tackling the most urgent and vexing medical challenges of our times. This commitment to discovery, invention and innovation, always keeping the patient first and foremost, is what has come to embody our industry at its finest.

Patients, in Japan and throughout the world, are waiting for the next breakthrough medicines that will help them live longer, healthier, and more productive lives. Our mission as an industry is to deliver what they need – promptly and safely.

Our member companies invested $51 billion in research and development on new innovative treatments and cures last year. In that same year, a record number of new therapies – 51 – were approved by the U.S. FDA.

Our unshakable commitment to translating cutting-edge science into meaningful treatments – and potentially cures – is driving progress for patients today – and hope for tomorrow.

For example, currently:

- These companies collectively have more than 7,000 medicines in development globally, including 1,800 drugs to attack and prevent cancer, 475 for diabetes, 1,100 for immunological disorders, and 1,300 for neurological disorders.

- Over 900 of these drugs are biologics. And 70 percent of drugs under development are potential first-in-class medicines.

- We're also developing 80 different medicines to help patients ameliorate and, hopefully, prevent Alzheimer's disease – a tragedy expected to touch as many as 115 million patients, a countless number of caregivers, and cost society in excess of one trillion dollars by 2050.

Hence, we've come together at an extraordinary time: A time of rapid scientific advancement, but also a time of great challenge – where some obstacles to affordability and access have been removed – and others have risen up and must still be overcome.

We must work together with all stakeholders in the healthcare ecosystem and beyond, to create the broad access that is necessary for people to benefit from medicines and vaccines that can improve and extend their lives. And we must create a policy environment that is conducive to building sustainable, value-driven healthcare systems that serve all of us.

Here in Japan, much progress has been made over the past two decades…

Five years ago, the so-called drug lag in Japan meant that there was a four- to- six year gap between the time a drug was approved in the U.S or Europe and its approval in Japan. This lag has been almost completely eliminated through important regulatory and pricing policy reforms.

Japan went many years without approving new vaccines while the world was moving ahead, reaping the significant health benefits of science and development in this area. During the past half-dozen years, new approval processes and legal changes have led to the introduction of a number of new vaccines that are protecting Japan's young and adult populations.

In past years, the environment in Japan has become more supportive of pharmaceutical innovation. Patients with unmet needs have increased access to medicines that can help them, and government policies now encourage innovation. The Japan Agency for Medical Research and Development, known as "AMED," has also just begun to operate here. AMED provides opportunities to address some of the challenges in translational research.

It's with this progress in mind that I met with many of the critical stakeholders who collaborate across Japan's healthcare ecosystem – government health ministers and senior officials, non-governmental healthcare leaders, and leaders within our industry.

My goal was to convey our industry's commitment to Japanese patients, to improving healthcare in Japan, and to contributing to Japan's economic growth today and into the future. In doing so, I emphasized the following important themes:

- **The pharmaceutical industry is the world's most research-intensive industry sector, investing more of our revenues into R&D than any other.** We are a key national and global driver of economic growth, creating new jobs, stimulating the R&D environment, and raising both the health and productivity of the workforce. You might be surprised to hear that the foreign pharmaceutical industry employs 40,000 people in Japan, and the Japanese pharmaceutical industry employs another 125,000. And we are all expanding our clinical development throughout the nation.

- **Healthcare is an investment in people, in the economy, and in the future – not just another line in the budget.** And so despite the serious budget challenges that Japan is facing, especially with an aging population and an aging workforce, funding for healthcare brings higher worker productivity, a longer healthy life-span, and a better quality of life. Budget issues can be managed by replacing the patent-expired products with their generic versions.

- **Drug expenditures are an investment in society and the nation, and should not be treated as a cost.** A recent study by IMS projected that drug spending in Japan between 2013 and 2025 would increase by only 0.13 percent per year as a result of Japan's bold policies to promote both generic drug growth and innovative drug development.

- **The introduction of a new drug pricing system five years ago that encourages and promotes innovation was an important development in improving healthcare and growing the economy in Japan**. In part because of this price premium, we are bringing our pipelines to Japan quickly so we can develop and introduce drugs into Japan at the same time as in the U.S. and Europe. The impact is elimination of the drug lag, increased innovation and investment, and providing patients with prompt access to

the world's newest, safest, and best medicines. Also, under this premium reform, our companies are bringing dozens of unapproved drugs and indications to Japan in response to the requests from MHLW and other key stakeholders.

I also discussed some of the potential barriers and challenges to our continued progress.

- **Recent proposals to revise drug prices based on a drug price survey at the time of the planned increase in the consumption tax in April 2017 would have the same impact as an annual drug revision – a proposal that the government wisely decided last year not to pursue because of the negative effects it could have on the drug lag, investment, jobs, and healthcare.** In recent years, a drug pricing system rewarding innovation and a high level of predictability in pharmaceutical administrative policies have had many positive effects resulting in a higher number of new approved drugs, increased foreign direct investment in Japan, and the elimination of the drug lag. It is important that we must not risk reversing these impressive and important gains.

- **We need consistent and predictable long-term policies.** As you know, it takes 10 to15 years and over $2 billion to bring a drug to market. We appreciate the renewal of the premium price system for the current two-year period, but think it is vital that the premium become a regular part of the pricing system, ending the uncertainty of a renewal every two years, and that no other changes be made in the program.

- **Current restrictions requiring that prescriptions for new drugs be limited to only 14 days places a large and unnecessary burden on patients and physicians, in some cases seriously delaying the use of new medicines.** We continue to request that the rule be significantly modified.

- **We appreciate the many improvements to the regulatory process that the government has made in recent years.** Our industry's dialogue with PMDA is excellent and continues to deepen. PMDA Chief Executive Dr. Kondo has made

impressive changes in how the agency operates, especially in speeding up drug reviews, and I want to recognize him for that.

- **We are committed to ensuring the safety of our drugs.** We appreciate the opportunities we have had to work closely with PMDA and MHLW on the implementation of an improved risk management system.

- **We encourage further harmonization with international standards for all regulatory areas.** PMDA has been increasingly active in collaborating with foreign regulatory agencies. PhRMA hopes MHLW and PMDA will be increasingly flexible in the approval and regulatory process in promoting simultaneous global development, including Multiregional Clinical Trials (MRCT), long-term studies, and CMC requirements.

- **We are interested in the new "Sakigake" policy of promoting first global approval of drugs in Japan.** Our companies are now bringing their pipelines to Japan much earlier in the development phase, and we look forward to being part of this process.

- **We need to do much more in early monitoring, early diagnosis, and, especially, early intervention to prevent disease and to ameliorate the effects of disease.** Three-quarters of all healthcare expenditures in our two countries, Japan and the United States, are going to the treatment of chronic disease today. Looking ahead, with the aging of the population, that percentage is likely to only to increase. This makes it absolutely critical to focus on prevention to improve overall public health and in manage long-term budget challenges.

And on the topic of vaccines, which have long been recognized at the most cost-effective way to improve individual and public health:

- **I am encouraged by the Japanese government's commitment and by legal changes that are taking place and resulting in new vaccines being added to the**

list of recommended vaccines for children and for adults. Medical science continues to open new avenues to caring for patients. The development of preventive vaccines, and looking ahead to therapeutic vaccines, for chronic diseases, including cancer, offers unprecedented opportunities to improve public health. Japan ought to be at the forefront of promoting and using these vaccines.

- **We recognize that awareness of the safety, health impact, and value of vaccines by physicians and the public is critical.** PhRMA has held symposia and published studies to help raise this awareness in Japan. This is one of our top priorities.

- **We hope the process for the inclusion of vaccines into the National Immunization Program will be made transparent and timely.** This would include increasing the frequency of review committee meetings, a clearer timeline for approval and inclusion, and more transparency in the preparation and content of fact sheets used in the evaluation process.

- **It is critical that the government's evaluation and decision-making in the approval process for new vaccines and in the monitoring and managing of adverse events be science-based and not subject to non-science-based pressures from the public, media, or politicians.** Worldwide health authorities, most particularly the World Health Organization's Global Advisory Committee on Vaccine Safety, have noted damaging public health effects when decisions on vaccines are not based on science, and I encourage the government to ensure that such a science-based process is in place in Japan.

- **Translational science, moving the seeds of research out of the laboratory and into the development process and commercialization, is the key to providing patients with the best and most innovative medicines.** Here in Japan, it is crucial that you take advantage of the great discoveries being made in Japanese research institutions, and ensuring Japan has a world-class pharmaceutical industry. I want to

congratulate the government on creating AMED – the Agency for Medical Research and Development.

We at PhRMA have created several programs that support translational science in Japan. These include an annual visit by young Japanese medical researchers to the U. S. to learn about the successes and challenges in translational science and an annual symposium in Tokyo to promote awareness among young researchers of the importance of working in this area. We are looking for additional ways to support Japan's efforts, including working with AMED.

Let me conclude by reminding us all that innovation, or as I prefer to say, invention, remains the cornerstone and foundation upon which a sustainable, value-driven healthcare system can thrive. Our industry is on the cusp of some of the greatest medical breakthroughs in decades; breakthroughs that were unimaginable only a few years ago; breakthroughs that will transform not only patients' lives, but that have the potential to help transform the economic productivity of nations around the world. It is critical that policy and regulatory approaches keep pace with this new era of rapid scientific advancement.

Together, I'm confident that we'll continue to create and maintain the right conditions to ensure that our industry can bring the newest and most innovative medicines to Japanese patients and citizens, that we can draw on the incredible science that exists in Japan in the biopharmaceutical area, and that we can work with Japanese colleagues to help make the industry in Japan world-class.

We must never lose sight of the purpose for which our medicines and vaccines are intended – to improve the lives and livelihoods of the millions of people here in Japan and around the globe who are counting on us to succeed.

Thank you for your attention. I am happy to answer your questions.