

## **“Innovation and Reward Contributing to a Healthy Economy”**

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The issues that were brought up in Japan’s healthcare reform package present enormous challenges. Meanwhile, technological advances (in genome research, medicines, anticancer drugs, etc.) offer many opportunities. Yet the Japanese economy has not performed well since the burst of the speculative bubble. Moreover the US economic slowdown and the uncertainty of the nature of the US economy’s landing, compounded with slow growth in Europe will exacerbate this problem. On top of all of this, the Japanese government faces budget constraints due to its slowing economy and aging population. With this as background, we should not lose sight of the principal theme: how do you get patients rapid access to the latest medicines.

The technical competitiveness of Japanese pharmaceutical firms is comparable to those in the US and Europe when measured by the number of patents exported by Japan. In fact in terms of efficiency the UK and Japan are leaders in patents produced per dollar spent. Yet 95% of British products are global, while 80% of Japanese products are not global. Why?

Japan’s regulatory environment is too constrictive. PhRMA, as well as experts in the field such as Professor Tokita of Hitotsubashi, recommends deregulation and the establishment of market based pricing.

There are much more pharmaceutical companies in Japan than there are in the US or Europe, but they are smaller and don’t have the same R&D critical mass in absolute terms. The challenges in risk and investment for research in this industry are immense. If the final product price is controlled, as it is in Japan, one cannot be sure that the risk will be rewarded. Japan’s millennium project offers a good chance for Japan to catch up with the US.

European companies have grown smaller and fewer in number. The US is a more preferable destination for capital in biotechnology. Countries like Italy and Sweden, which are highly regulated and have price controls, have been seeing their competitiveness fall.

A healthy pharmaceutical industry offers benefits to the national economy such as benefiting patients, providing returns to shareholders, and wages and salaries to employees. Pharmaceutical R&D is most productive in those countries with free or relatively free market systems such as the US, UK, Switzerland, and Germany. Meanwhile, the least productive R&D occurs in highly regulated markets such as France, Sweden, and Italy.

The Japanese economy faces a number of challenges: negative GDP growth, public finances problems, capital investment, non-performing loans, and balance sheet restructuring. How can Japan stimulate an innovative culture to bring about commercial and economic success? And how does a strictly regulated environment need to change?

Private capital and risk venture capital are needed to stimulate economic growth. Japan has to reward innovation; currently, innovation is sometimes penalized because of the pricing system in place.

The pricing system in Japan has unintended consequences. Because of special price reductions, some innovative products with documented, superior therapeutic value are punished. The new product comparator price method leads to innovation not being recognized. The compound effect of drug price regulations serves as a disincentive to invest.

Biennial downward NHI price revisions reduce the return on investment and adversely affect the introductory new product prices. The foreign price may be inadequate to compensate for the depressed introductory price. Therefore, a small price premium for therapeutic value cannot compensate for the impact of comparator price revisions.

PhRMA's proposals are the following: Eliminate distortions in the system. Encourage investment in the research and development of innovative new drugs. Strengthen the international competitiveness and reinforce the R&D capacity of the pharmaceutical industry in Japan. PhRMA wishes to play a constructive role by offering incremental reforms that expand support for biomedical innovation, discovery, and patient access.

Our guiding principles are the following: a transparent pricing structure that supports innovation; competition and actual transaction price reimbursement; and a more efficient drug use and transparent medical fee structure. Japan should work toward market-based principles.

The beneficiaries of our proposal would include patients, physicians, the healthcare system, the economy, and the drug industry.

### **Question & Answer**

***Q: The US government has given \$10 billion to universities and the NIH. Do you see this as a benefit?***

**Antony Butler**

I cannot confirm that figure, but it is important money. Cooperation between these institutions and government has been successful.

***Q: Actually the number is closer to \$20 billion to public research. Industries benefit indirectly. The NIH makes grants for public health, not for promoting business.***

**Antony Butler**

Culturally it is more difficult in Japan to develop small groups of individuals, specializing in biotechnology, to break up and re-form as they do in the US. The Japanese like stability.

***Q: Another challenge for biotechnology is the hype of the genome. To look at genes, scientists will run into the problem of public genetic information as an issue. In the US, there is no federal regulation on this.***

**Antony Butler**

It poses all kinds of ethical problems. Insurance companies want genetic information to decide whom to insure. The EU and US are against this idea. Public reaction is strong. It is not our place to decide the answers to these ethical questions; it is society that will answer these questions. What we need is a public debate from both sides—scientists need to be more vocal.

***Q: Can you comment on why deregulation will reduce costs?***

**Antony Butler**

The costs are high, but Japan's prices are not higher compared to other markets. Products are priced within a narrow band. This pricing encourages the use of older and lower quality drugs.

***Q: What are Japanese firms saying? Are they an obstacle to your proposal? Why doesn't the Japanese government wake up to the US's NIH strategy?***

**Antony Butler**

Actually, we work closely with EBC, JPMA (Japan Pharmaceutical Manufacturers Association), and FPMAJ (Federation of Pharmaceutical Manufacturers Association of Japan). We agree with their members on the need to reward innovation. Some Japanese companies have a larger portfolio of older drugs, so they are reluctant to see the prices of these drugs reduced.

***Q: Some of these companies would prefer to have the protection removed.***

***Q: Is Japan a competitor, partner, or just a market for you?***

**Antony Butler**

It is a competitor and a partner.

***Q: We are talking about healthcare here. Patients are the ultimate customers. We are not talking about, say, the steel industry.***

***Q: What is your strategy for the future?***

**Antony Butler**

We are not lone players; we are not outsiders in Japan. We can't simply push for US industries. Getting consensus among our Japanese partners would be desirable.

*-The RIETI editorial department is responsible for this article.*