US list prices are the only appropriate comparator.

Because of different characteristics of the pharmaceutical business, that industry has a published "Red Book" with list prices. No such publication exists for medical devices, because of the different structures of the markets and wide variety of products.

Market-wide published list prices are only available for the US and Japanese markets; such price data are not available for UK, Germany, or public hospitals in France.

France is the only country among these that does publish a list of prices, under their TIPS system, but it is essential to recognize that these prices are only applicable to private hospitals and, in the case of certain product types, do not represent the majority of the French market. In fact, the most expensive and technologically advanced products are typically only found in France's public hospitals – where the TIPS prices do not apply at all. Finally, the MHLW should know that beginning next year France will likely be replacing the unsuccessful TIPS payment method with a new payment system that resembles the Diagnosis Related Group (DRG) payments in the US.

Unpublished data on a company's European prices belong to the individual company and are highly sensitive proprietary information. Any attempt by AdvaMed to collect these prices for submission to the Government of Japan for sector–specific meetings on future by-function reimbursement prices for the industry could raise US antitrust concerns. The by-function nature of the reimbursement system for medical devices adds a legal complication that does not exist for the by-brand pharmaceutical reimbursement system.

Even if collection of European price data were possible, it is not an "apple-to-apple" comparison. The European Union's regulatory regime for medical technology is one of the most effective and efficient regimes in the world. It is no coincidence that the leading global medical technology firms frequently introduce their new products into the European marketplace long before they do so in Japan or the United States. Price levels are different because cost structures are significantly different. Comparison of prices without comparison of related costs is not reasonable.

We also are concerned that accurate collection and comparisons of European data is not practically possible. We note that European price data shared by the Chuikyo medical devices subcommittee during their discussions on October 29 dates from 1997 – literally years before many of the current technology models were introduced. There are entire generations of products that have been created since 1997 and there is no reasonable comparison of Japan prices today with European prices from that period.

Even if it were possible to collect current prices in Europe, and it were possible to identify comparable products, anecdotal evidence of lower prices at select hospitals in foreign markets do not accurately reflect prices across the whole market and should not be used as the basis for assessing price differentials. Various factors contribute to cost

structures for individual hospitals and a wide variation in sales prices exist in foreign markets, as they do for Japanese hospitals. Factors contributing to a particular hospital's prices are unknown and its prices are therefore not appropriate as a gauge of overall pricing within a market.

US list price data is the only legal, reasonable comparator.

Added regulatory burdens will drive up costs

In addition to product pricing, one of the greatest concerns that we have is that Japan today has a regulatory environment that stifles innovation. This is most obvious when you examine Japan's own domestic medical technology industry, which has become less and less competitive as it tries to survive within an overly-regulated system. The Ministry's recent Vision for the domestic medical technology underscores this declining competitiveness. We believe this decline is a direct result of misguided government policies that do not address the fundamental issues in the healthcare system.

The new regulatory changes under PAL reform will result in even higher costs than are incurred in other markets:

- Introduction of a user fee system encompassing the highest fees in the world on a per product average basis will add additional costs for submission-related consultations, submission reviews, audits, etc.

  Based on industry estimates, approval of a submission for a Class III product requiring clinical data will cost around Y5.8 million total, based on the estimated fees for reviews, audits, etc. A comparable product submission in the US would cost either Y417,600 (510K submission, which account for over 90% of applications) or Y5.3 million (PMA-S, which account for 3% of applications). In Europe, the cost of a Notified Body review for a Class III product would be approximately Y452,952.[18]

- The new MAH licensing system entails additional unique in-country organizational and staffing requirements, including salaries for 3 new directors or "sanyaku." In addition, estimates based on a survey of ACCJ companies with an average of 20 overseas manufacturing sites and 200 approvals per year predict that companies will incur additional costs of around Y448 million per year to comply with new licensing requirements. This includes estimated costs of Y8M for registration and maintenance of all licenses (MAH, Labeling, Manufacturing, and Sales), Y40M for manufacturing site (including sterilization site) visits, and Y400M for maintenance of approvals based on new requirements, respectively.

[18] Source: AdvaMed/Eucomed survey of orthopedic product manufacturers, September 2003. Based on company-reported numbers on average notified body fees for a Class III product review.

- New PMS "contributions" will put increased financial burdens on companies. Industry estimates that a company with Y1.7 billion in mixed sales of Class I-IV products would incur Y9.11million in additional expenses per year.

- Other costs include new unique traceability and periodic infection report requirements for biologics, QS audit requirements, and implantable device patient card requirements, etc.

Until these structural issues are addressed, price differentials are unavoidable, and maybe even necessary to maintain operational viability. The multiplier for both existing medical technology functional categories and for new products should be substantially higher than presently in the FAP rule.

What's Really At Stake – Japan's Health Care Costs and the Health of Japanese Patients

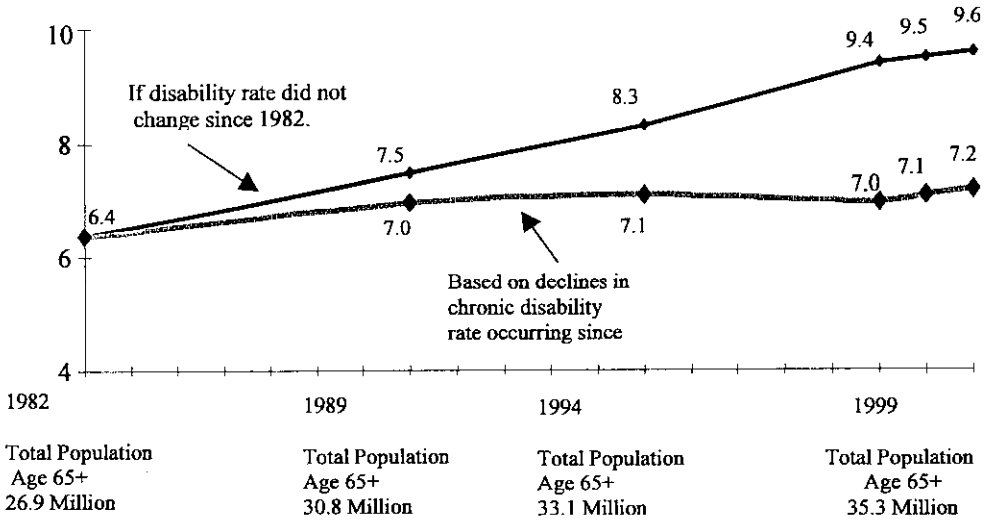
Device products are among the tools that Japan needs going forward to reform its health care system. Increased efficiency and productivity are the only answer to Japan's growing health care expenses. But Japan's current policies are destroying innovation, freezing the advancement of medical care with outdated, costly and invasive procedures.

The potential for balancing Japan's budget and achieving better health outcomes is not just a theory – it is supported by the experience of other countries that have trimmed excessive lengths of stay and patient visits to focus on the elements of health care that truly add value to patients. In the U.S., we save approximately $19 billion each year in reduced costs for caring for fewer elderly disabled patients – because the rates of disability have dropped dramatically in the past 20 years.[19] We too have a greater number of older patients – but they are healthier than ever before. This is the contribution of medical technologies at work – helping patients stay on their feet without the need for expensive long term care and the support of caretakers.

19 Manton KG, Gu X. ,,Changes in the prevalence of chronic disability in the United States black and nonblack population above age 65 from 1982 to 1999 ,, Proc Natl Acad Sci U S A. 2001 May 22; 98(11):6354-9.

Projected Versus Actual Disabled Elderly[20]

Number of Chronically Disabled Americans Age 65 and Over



Japan must seek ways to get more return on the money it spends on health care – and this can only occur by using technologies to treat patients in less costly settings, help them recover faster and with better outcomes.

Afforded the right environment, medical technologies can contribute to:

- Improved Quality of Life: Medical technologies improve patient QOL by reducing hospitalizations and helping patients avoid or recover from surgery faster.
- Reduced Disease and Complications: Advances in medical technology can help diagnose disease earlier, minimize treatment needs, and reduce complications.
- Improved Mortality and Morbidity: Innovations in medical technologies lower mortality and morbidity rates.
- Reduced Healthcare Spending: Greater efficiency in treatment and care through the use of medical technologies reduce overall healthcare expenditures.
- Increased Worker Productivity: Improved health of workers and disability rates raise productivity levels.
- Stronger Economic Growth: Increased worker productivity and investment in innovation stimulate economic growth.

Data in the following chart show that medical technologies have direct benefits that contribute to reduced healthcare costs, including:

[20] Ibid.

- Reduced procedure times, reduced length of stay, and reduced recovery times. PTCAs are criticized for their high costs, but their cost is significantly outweighed by the total savings they generate. Estimates are that Japan saves Y2.26 million per patient by treating with PTCA rather than bypass surgery. With a patient pool that numbers around 120,000, utilization of PTCAs yields tremendous cost savings.

Advances in the Treatment of Heart Disease[21]

	Cardiac Bypass Surgery*	Angioplasty with Stent
Procedure Time	120-300 minutes	30-120 minutes
Length of Hospital Stay	9.1 days	3.8 days
Recovery Time	4-6 weeks	1 week

* Only a subset of bypass surgery patients are candidates for angioplasty procedures.

- Reduced disability. This is particularly important for Japan, given its aging population. An aging population maybe inevitable, but disability is not. Japan's challenge is to minimize disease and disability so that people can lead healthy, productive lives, without becoming burdens on their families, society, and the healthcare system.
- Reduced treatment costs through early detection and more accurate diagnosis.

Aging of the population and rising healthcare costs are inevitable. However…

- Disability and treatment costs can be minimized through the use of medical technologies.
- Long-term returns on investment in medical technologies can greatly outweigh the initial cost of the technology.
- Japan could better allocate its resources to maximize the benefits from medical technologies.

Further cuts in medical technology expenditures would ignore these significant benefits and put them at risk.

Partnership Is the Only Solution

We are grateful for the opportunity to share the industry's views and we appreciate your consideration of our concerns. We urge the Chuikyo and policymakers at MHLW to partner with industry to try to find solutions to the Japanese healthcare crisis that truly leverage the advantages that our technologies have to offer. We are eager to work with you to try to find solutions to the Japanese healthcare challenges. However, the solutions

[21] Health United States, 2000. National Center for Health Statistics, Table 92.

must not unfairly single out foreign products, to the detriment of Japan's healthcare system.

We seek to cooperate in seeking solutions to Japan's healthcare challenge. We hope to do this not just by developing and providing innovative technologies for Japanese patients, but by being an active participant in Japan's healthcare debate, including:

- Providing what we hope to be informative presentations to MHLW, Chuikyo, and other health policy decision makers on industry's perspective on policies and the implications of policies based on global experience.
- Interacting regularly with regulatory officials to provide reference materials and industry views on pre- and post-market regulations that ensure product and patient safety without adopting unnecessary burdensome requirements that delay and impede patient access.
- Working with pricing officials to achieve budgetary goals in ways that will not stifle and eliminate incentives to develop and introduce life-enhancing and life-saving innovations that can contribute to cost savings for the healthcare system.
- Enhancing awareness of the value of technology through public fora, and through publications, such as our industry's paper on "Investing in Japanese Patients, Health Care, and Growth: Innovative Medical Technologies for a Healthy Future," which was released by AdvaMed and ACCJ last month.

We look forward to future opportunities for continued dialogue.

Appendix: **Select Examples of Product Availability Gaps**

Technology	Situation in Japan	Lost Benefits
Coronary Stents for Treatment of Heart Disease	Companies report that coronary stents used in Japan are 2 generations behind those used in other countries, due to delays in regulatory and reimbursement decisions.	Use of more innovative models reduces the incidence of restenosis and thus the need for follow-up procedures or coronary by-pass surgery. Consequently, 120,000 patients (2002 statistics) in Japan are denied **QOL benefits** and the healthcare system is denied significant **cost savings** that could be derived from minimizing surgery through the use of more advanced stents.
Implantable Cardioverter Defibrillators (ICDs) to treat heart disease and prevent Sudden Cardiac Death (SDC)	Companies indicate that ICD versions available in Japan are 4 generations and about 3 years behind those used in other countries, due to regulatory and reimbursement issues.	ICD patients in Japan are denied this **life-saving and life-enhancing technology** and the healthcare system is denied significant **cost savings** that could be derived from minimizing surgery through the use of more advanced ICD technologies.
Cardiac Resynchronization Therapy (CRT) to treat heart failure	CRT innovations are not available to Japanese patients.	Studies have shown that use of CRT can reduce the number of hospitalizations due to heart failure, reduce the average treatment cost per patient. This contributes to **improved QOL**, as well as **reduced patient disability and healthcare costs.**
Bioabsorbable Implants for ACL repairs, rotator cuff repairs, etc.	Companies report that product changes to alter product color from white to make products used around joints more visible has not been marketed in Japan because MHLW requires clinical trials for the approved in Japan without clinical trials, even though no trials were required in other countries because the colorant had been approved for use in other products.	While these products have been on the market in other countries since 1997, helping contribute to **safer and faster procedures** and **reduced complications**, Japanese doctors and patients are denied this product. This has implications for **patient QOL and disability,** as well as **healthcare costs.** Separate production lines are maintained currently to continue to manufacture the product only for the Japanese market. However, companies indicate that the cost-effectiveness of continuing to do so is diminishing. **Patients may soon be denied this technology and its benefits entirely.**
Abdominal Aortic Aneurysm (AAA) Stent Graft to treat and prevent rupture of the abdominal aorta	Clinical trials and approval of the technology is still pending in Japan, although it has been on the market for years in other countries.	The technology replaces traditional, invasive surgical approaches and thus **reduces burdens on AAA patients, hospitalization and recovery times, and treatment costs.** Japanese patients do not benefit from this technology.
Trans-myocardial Revascularization (TMR) to improve blood flow in treating cardiac	Approval of the technology is still awaiting completion of clinical trials and approval in Japan, although the technology	Japanese cardiac ischemia patients are denied the benefits of TMR, including **reduced post-surgery chest pain, improving recovery times, patient QOL,**

ischemia (usually used in conjunction with Coronary Artery By-pass Graft (CABG)	has been available in Western markets for years. A next generation technology has been approved overseas, and approval of the obsolete technology may no longer be pursued.	**and treatment costs**.
Enteral/Colonic Stenting to treat intestinal tumors	Approval of the technology in Japan is awaiting completion of clinical trials and regulatory approval, although it has been widely used in foreign markets for years. Japanese patients do not have access to this technology	Japanese patients suffering from intestinal tumors are denied the **QOL benefits** of this technology.
Pacemakers to treat heart disease	Latest models available in US and Europe are not available in Japan, due to regulatory delays.	Pacemaker innovations **improve the health and QOL** of patients and contribute to **reduced healthcare costs**.
PET/CT and **3TMRI** imaging technologies for detection and diagnosis of disease	Most advanced imaging technologies are not available in Japan due to regulatory delays and low reimbursement levels.	Advances in imaging technologies allow earlier detection and treatment of patients, which **reduces the need for more invasive treatments and treatment costs** and **enhances patient QOL**. Japanese patients are denied the enhance benefits derived from these products.