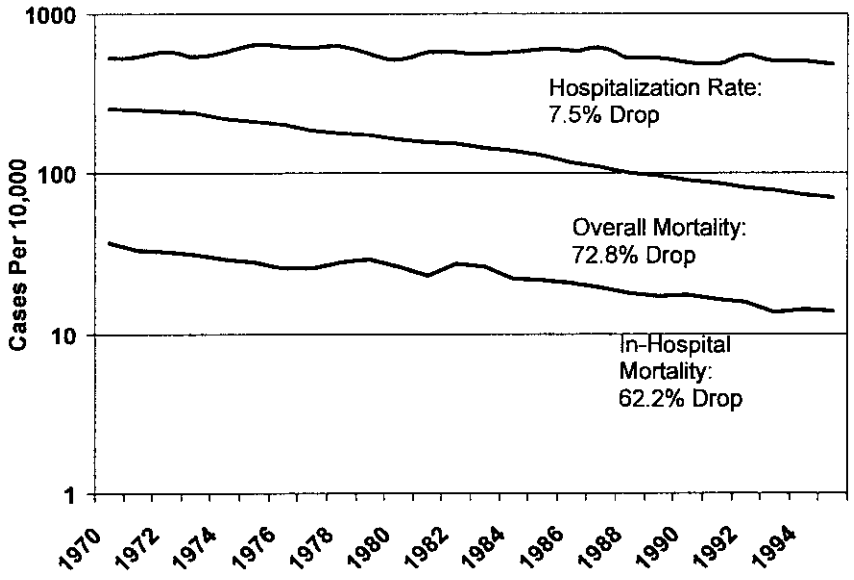
AdvaMed/ACCJ Joint Written Testimony
Chuikyo Industry Hearing
November 12, 2003

AdvaMed and the ACCJ Subcommittee on Medical Devices and Diagnostics thank the members of Chuikyo and the Ministry of Health, Labor and Welfare for giving the Medical Technology industry an opportunity to share our views. To facilitate understanding of our industry's perspective, we respectfully submit this more detailed written statement to augment the oral testimony presented in the time allotted.

As many of you know, medical technology saves and improves lives. Advances in medical technology detect diseases earlier and offer new, more effective treatment options for diseases like cancer and heart failure. Breakthroughs such as coronary stents, implantable defibrillators and minimally invasive bypass surgery have helped reduce the death rate from heart disease in the United States by 72.8% between 1970 and 1995. [1]

US Heart Attack Hospitalizations and Death Rates, 1970-1995



DNA-based tests and other advanced diagnostics are saving thousands of lives in America by detecting cancer and other diseases earlier when they are more treatable. Pap smear testing has played a major role in reducing cervical cancer mortality by over 40% over the last 30 years. New technologies like gene-based tests and computer-based Pap smear analysis are helping save even more lives.

[1] Source: National Heart Lung and Blood Institute, cited in: Morris, C. *Too Much of A Good Thing? Why Health Care Spending Won't Make Us Sick.* Century Foundation, 2000. Table 4.2

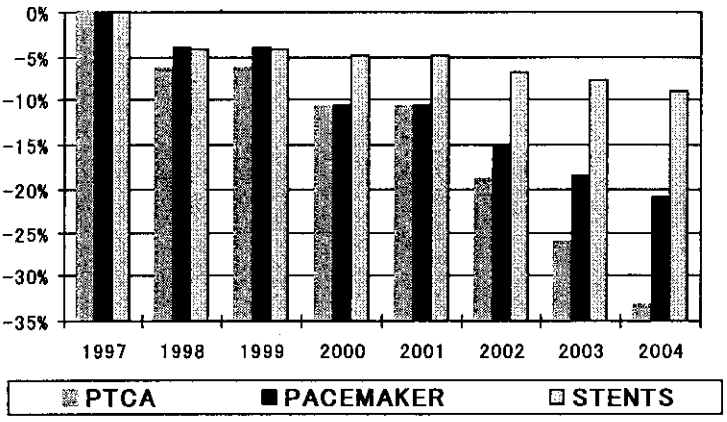
Medical technology is on the cusp of a revolution that will yield even more exciting breakthroughs and enable us to win the fight against many of the costliest and most harmful diseases we face. But for this potential to be realized our firms must be able to continue to invest in the research and development so necessary to produce these innovations.

The focus of this testimony is on how current pricing and regulatory policies in Japan are hurting the medical technology industry, disproportionately impacting foreign manufacturers, and at the same time impeding access, denying potential benefits to Japanese patients, the healthcare system, and Japan's overall economy.

The Impact of Cost Containment

We have witnessed over the last decade a steady decline in pricing for the innovative technologies we bring to Japan. These cuts have been part of a broad effort to contain Japan's healthcare costs despite the reality of increased demand brought on by an aging population and healthcare delivery with significant inefficiency.

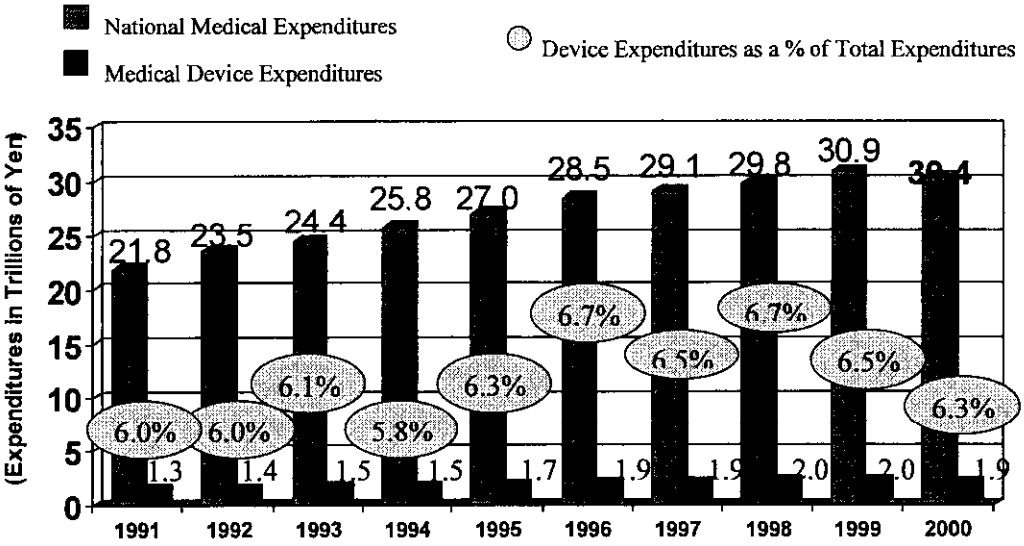
Japan Price Trends for PTCA, Pacemakers, and Stents, 1997-2004[2]



But while Japan's healthcare expenditures have continued to rise, spending on medical technology has been stagnant for the past decade, and even falling in recent years.

[2] Based on NHI official reimbursement prices.

Change in Medical Device Expenditures as a Percentage of Total Healthcare Expenditures in Japan[3]



This result has direct consequences for Japanese patients. All of the stakeholders in the system are jockeying for the limited yen available, but is it really fair to target medical technology in the current environment? Japan has twice the volume of outpatient visits and five times the hospital length of stay as the average among OECD nations. We believe there is substantial savings that could be realized if this excess utilization could be reduced by just a small fraction. At the same time, Japanese patients struggle to obtain the most modern technology. Japan has managed to preserve universal coverage, but patient access to many of the latest technologies is several generations behind.

The patient impact of high market and regulatory costs in Japan.

Let me share with you some examples of technologies that are not available in Japan today, that are being widely used in other industrialized countries. In a recent survey of AdvaMed/ACCJ member firms we have identified the following examples of advanced technologies not available in Japan.[4] Our companies largely attribute this to the pricing and regulatory environment.

- Coronary stents
- Implantable cardioverter defribrillators (ICDs)
- Cardiac resynchronization therapy (CRT)
- Bioabsorbable implants
- Abdominal aortic aneurysm (AAA) stent graft
- Trans-myocardial revascularization (TMR)

[3] "National Medical Expenses" and "Dynamic Statistics of Pharmaceutical Industry Production," MHLW, 2001.

[4] Compiled based on responses provided in response to US industry survey. For a full, detailed list, see attached appendix.

- Enteral/colonic stenting
- Pacemakers

Altogether, tens of thousands of Japanese patients are not able to access these therapies. Instead, they are treated with care that does not reflect the latest therapy – or in some cases there is no effective therapy available to them at all.

Japanese patients should not be obliged to accept illness and disability that can be avoided if the system allowed access to treatments available abroad. But the problem that is becoming clear is that the number of elderly patients who need intensive care is growing dramatically, and that Japan has to find a way to treat them less expensively, and more effectively.

Reimbursement and regulatory hurdles impact domestic industry the hardest.

Early this year, the Ministry of Health, Labor and Welfare (MHLW) released an excellent document that it called the "Vision" for the medical technology industry. We studied this document carefully and agree with many of its conclusions – particularly the importance of a strong domestic industry in Japan.

The reason the Japanese domestic industry is struggling is because of a regulatory and reimbursement environment that makes it nearly impossible to develop and introduce products in a rapid and timely fashion.

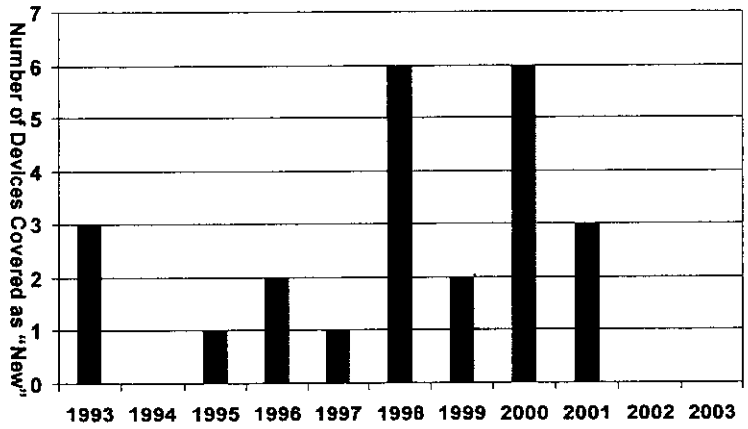
The R-Zone price revision process has brought steady declines in reimbursement levels for existing medical technologies – making many of the products in these price categories less profitable to produce. At the same time, enormous hurdles in receiving a new price for innovative products have decreased incentives to ever bring such products to market.

Over the past 10 years, existing product prices have declined by up to 35%[5] and, in aggregate, only 24, or .1 %, of new products have been awarded new reimbursement categories.[6]

How can Japan build a strong industry of its own in the face of these economic disincentives?

[5] See chart pg. 2.
[6] Calculated based on JFMDA survey results, Summer 2003, and total products introduced during the same time period.

New Product Prices Awarded, 1993-2003[7]



New Product Pricing

A significant barrier is the rare and unpredictable assignment of appropriate new, reimbursement levels to new technologies. This has led manufacturers to utilize the pricing process for existing (B-category) technologies -- even for truly innovative products -- rather than risk delay in market introduction for products with short (18-month average) lifecycles.

But receiving a discounted, old price for a new innovation is a major deterrent to the introduction of the latest technologies – why would an innovator invest in developing a new product if it is assigned the same price as the existing technology? Modification to the FAP price differential multiplier for new products from 2.0 to 1.5 would further reduce the incentive to bring new products to the Japanese market.

The criteria for C1- and C2-category product reimbursement categories must be clarified and listing cycles should be implemented four times per year for C1-category products, and on a rolling basis, but at least within one year for C2-category products.

The October 29 Chuikyo materials indicated that consideration was being given to the separation of technical fees from medical material costs for certain products. We recommend that the Ministry consider an appropriate functional category assignment for all products involved. Any assigned category pricing should reflect the actual results of the pricing survey.

[7] Based on JFMDA survey results, Summer 2003.

Specific FAP Concerns

Foreign average pricing adds to the penalties of doing business in Japan and incorrectly imposes an approach designed for pharmaceuticals.

A newer policy also impacts innovation in the Japanese market by artificially borrowing prices from other, completely different markets – as if there is no difference in selling the product in Japan. The introduction in 2002 of the Foreign Average Price (FAP) policy severely compounds the problems for manufacturers that happen to have overseas markets by targeting products for extreme price cuts, without even considering the local costs of doing business, and the costs of regulatory compliance. There are several fundamental problems with the FAP approach.

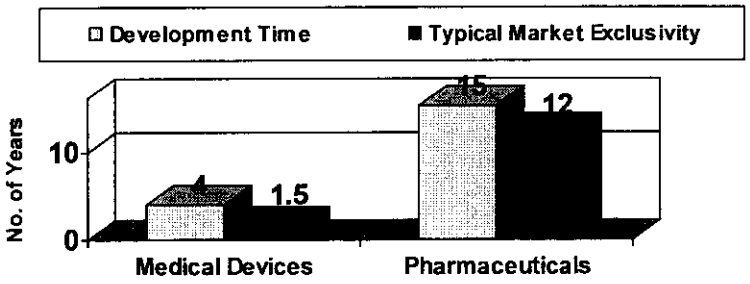
First, the FAP policy sets reimbursement limits based on a multiplier of foreign prices that is borrowed from current policies for pharmaceuticals. Most countries do not apply formulas designed for pharmaceuticals for reimbursement of medical technologies. The US, France and Germany all distinguish between drugs and devices in deriving appropriate prices. Our products are different in nearly all respects from pharmaceuticals:

- generally, medical technology industries have a shorter investment recovery period with lower development costs but higher distribution costs,
- medical technologies require ongoing service and maintenance,
- medical technologies are often integral to clinical procedures, so physician training costs are often much higher,
- medical technologies can change the nature and setting of certain therapies, and
- medical technologies pose less medical risk than pharmaceuticals as they typically involve incremental improvements.

Several of these important differences – high distribution costs, and the need for physician training and product service and maintenance all lead to costs that are highly variable according to the local market and generally do not apply to the same extent to pharmaceuticals.

Another important difference that we mention is the incremental nature of medical device innovation. This means life cycles are far shorter for medical devices than for drugs – typically just 6 months to 4 years. On average, a new technology is only on the market 18 months before the next, iterative change is introduced – meaning that there is an ongoing process of physician expertise that develops feedback with the manufacturer and then further improvement of the technology itself. This stream of improvement cannot really exist if a product is already obsolete by the time it reaches the market in Japan.

Typical Product Development and Market Exclusivity Time Frames[8]



For all of these reasons, it is absolutely essential that the reimbursement price for medical technologies be designed according to factors relevant to our industry. The foreign price ratios that are used for pharmaceuticals are a completely arbitrary solution to pricing for medical technologies, ignoring the unique attributes of these products and the costs of bringing them to this market.

FAP limits are arbitrary and fail to account for the high costs of doing business in Japan.

In addition to the unique properties of medical device technologies, various factors compound the higher additional costs for introducing innovative medical technologies in Japan, relative to other markets. Specific aspects of the Japanese market that drive up prices include:

- Overall costs of management and doing business for our industry remain comparatively high, requiring more investment of resources.
- Japan's regulatory approval process is expensive and time-consuming. These requirements bring higher clinical trial costs, unique Japan requirements, and a burdensome approval process that result in new products taking 80% longer for approval than in the U.S., minimizing return-on-investment period.[9]
- On average, new products are introduced in Japan more than two years after they appear in the United States. Products that are substantially equivalent to an existing technology can take even longer to be introduced in the Japanese market.[10]
- Sales, general and administrative expenses are 42% higher in Japan than in the US.[11]
- Inventory costs are over 20% of Japan sales which can mean costs that are substantially higher than in the US for some manufacturers.[12]

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[8] Sources: AdvaMed, 2002 survey; www.phrma.org.

[9] Based on a Summer 2003 ACCJ survey of products applications submitted between April 1, 2002 – May 30, 2003 revealed that mean processing times are 699.8 days for "new" category products, 495 days for "improved" category products, and 227.1 days for "me-too" category products.

[10] Based on Summer 2003 survey, mean launch dates in Japan were 26 months later than in the US for "new" category products, 23.4 months for "improved" category products, and 28.3 months for "me-too" category products.

[11] Source: *A Japan-US Comparison of Operating Costs for Medical Device Manufacturers*, PwC, 2001

[12] Ibid.

- Write-offs and spoilage are over 30% of Japan sales for some types of products.[13]
- On average, customers in the U.S. purchase 10 times greater volumes of products than customers in Japan, allowing for substantially more efficient distribution.[14]
- Dealer discounts account for 20-30% of the price in Japan.[15]
- Uniquely burdensome post-market surveillance requirements yield higher compliance costs.
- Sudden changes in the rules are disruptive to the stability of our business in Japan and prevent our companies from being able to plan their investment in the market.

What is most perplexing about the FAP price revisions is that they cannot ever produce substantial savings for Japan's overall healthcare budget; the products targeted in 2002 constitute only .44% of the medical device budget, which is only about 7.6% of total healthcare expenditures.[16] As we've mentioned, far more significant targets for cost containment could be found in well-documented excesses such as the long lengths of hospital stays and other inefficiencies in the system. The Ministry has never released a savings target that it wishes to achieve through FAP price revisions. We are concerned that as a result of these factors the FAP price cuts disproportionately target product manufacturers overseas and provide no real benefit to the healthcare budget or to Japanese patients.

Regional challenges in the Japanese market also drive up costs of doing business that are not recognized by the FAP approach.

Where the nature of our business leads to national variation between the market costs between countries, it also leads to local variation within Japan. Again, these factors are far less expensive for pharmaceutical producers.

Because many of our technologies depend on the expertise of clinical specialists, it can be very expensive and difficult to deliver care and technologies in prefectures where there are few qualified physicians.

Similarly, because of the very large number of Japanese hospitals, the concentration of specialized care can be very diffuse, and some hospitals conduct only a few procedures per year. This places an increased financial responsibility on industry to provide personnel, training, and education. In addition, efficiency of care and lengths of stay may be driven by inefficient hospitals.

To give you a sense of this difference, the United States has 5,800 hospitals to serve a population of 281 million. In Japan, you have approximately 9,000 hospitals serving 126 million citizens.[17] The ratios of Japanese physicians per patient and hospital beds per

[13] Ibid.
[14] Ibid.
[15] Ibid.
[16] Ibid, p. 9, based on data from *R&D, Medical Device Market 2001*, PWC Analysis.
[17] Source: World Bank compilation of health statistics; inpatient LOS data are from Health Affairs, May 2003, p. 97.

patient are well documented by the MHLW, and these show sources of market inefficiency that dramatically increase our costs of bringing technologies to Japan.

Comparison of Characteristics of US and Japanese Healthcare

	US	Japan
Number of Hospitals	~5,800	~9,000
Population Size (2003)	281 million	126 million
Hospital Beds per 1,000 population (1999)	3.6	16.4
Outpatient visits per capita per year (1996)	5.8	16
Average acute hospital length of stay (2000)	5.9 days	30.4 days

Current price differentials have largely been eliminated..

Price data demonstrate that previous repricing and FAP price revisions have lowered price gaps to minimal levels – even for the most criticized products – given the higher costs unique to Japan. AdvaMed has done a survey of current US list prices compared with Japan's reimbursement levels for the products considered for FAP cuts in 2002 and after the final FAP cuts are applied in January 2004 and have found that:

- The average price differential (Japan reimbursement to US list for the main 4 US manufacturers) for the most widely utilized PTCA catheter category: **2.24**
- The average price differential (Japan to US list for main 3 US manufacturers) for the most widely utilized pacemaker category: **1.54**
- The average price differential (Japan to US list for the main 4 US manufacturers) for stents in functional category 135(3): **1.77**
- The average price differential (Japan to US list for the main 3 US manufacturers) for orthopedic implants and parts: **.92**

Moreover, because of the drastic price cuts imposed on PTCA catheters and pacemakers in the last repricing revision, they should be exempt from further FAP price recalculations in 2004 according to the rules adopted by Chuikyo less than two years ago. For many of the companies experiencing severe FAP cuts in 2002, the products affected represent a major portion of their businesses here in Japan. Changing the rules capriciously to allow for further drastic price cuts is unfair and unwarranted.

The so-called "15% rule" reflects the need for a predictable and rational business environment. Changing this rule arbitrarily, even before the impact of the previous revisions can be assessed, reinforces the apparent discriminatory and arbitrary aspects of the FAP policy.