

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org



AdvaMed
Advanced Medical Technology Association

**SENATE FOREIGN RELATIONS
SUBCOMMITTEE ON EAST ASIAN AND PACIFIC AFFAIRS
HEARING ON
U.S.-JAPAN RELATIONS**

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**STATEMENT BY
STEPHEN P MACMILLAN,
PRESIDENT AND CHIEF EXECUTIVE OFFICER,
STRYKER CORPORATION**

**ON BEHALF OF
THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)**

AdvaMed and its member companies would like to thank the Chairman, Ranking Member, and Members of the Committee for holding this timely and important hearing today. Japan is our industry's largest overseas market, second only to the United States. We applaud the Committee for recognizing Japan's continued importance in the global economy, world trade, and U.S. foreign trade. We also greatly appreciate the work Executive Branch agencies have done on our industry's behalf.

The Medical Technology Industry

AdvaMed represents over 1300 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. AdvaMed is proud to represent an industry that brings new hope to patients around the world, and U.S. companies are still benchmark manufacturing leaders in terms of total production, innovation and highest quality products. Our member companies manufacture nearly 90% of the \$94 billion U.S. health care technology market, and nearly 50% of the \$220 billion of medical technology products that are purchased globally each year. In 2004, U.S. exports in medical devices and diagnostics totaled over \$24 billion. The medical technology industry directly employs about 350,000 workers in the U.S.

Our industry is fueled by intensive competition and the innovative energy, driving very rapid innovation cycles that in many cases can lead to new product iterations every 18 months. About 70% of AdvaMed's membership is comprised of small and medium sized enterprises. Accordingly, our industry is most successful in fair, transparent, global markets where products can be adopted in a timely fashion and on their merits.

Innovative medical technology saves and enhances peoples' lives. Our products enrich patients' productivity and quality of life, thereby improving living standards and benefiting society overall.

Medical technology also contributes substantially to economic growth. Our products increase productivity by allowing workers to recover from illness faster, remain longer in the workforce, and thrive without expensive long-term care. Studies show that funds invested in health care yield far greater benefits than costs to a nation's economy over the long term.

The use of medical technology will become even more important as a nation's population ages. According to the 2002 Commission on Global Aging, medical advances will bring "longer, healthier, more productive lives with declining rates of disability for the elderly." Innovative medical technologies offer an important solution for nations that face the challenges of balancing serious budget constraints and the demands of serving aging populations.

To deliver this value to patients, our industry invests heavily in research and development (R&D). Today, our industry leads global medical technology R&D, both in terms of innovation as well as investment. The level of R&D spending in the medical devices and diagnostic industry, as a percent of sales, more than doubled during the 1990s – increasing from 5.4% in 1990 to 8.4% in 1995 and over 11% last year. In absolute terms, R&D spending has increased 20% on a cumulative annual basis since 1990. Our industry's level of spending on R&D is more than three times the overall U.S. average.

Global Challenges

Despite the great advances the medical technology industry has made in improving patient quality of life and delivering considerable value for its innovations, patient access to critical medical technology advances can be hindered by onerous government policies. Patients and health care systems experience much less benefit from our industry's R&D investment when regulatory procedures are complex, non-transparent, or overly burdensome – all of which can significantly delay patient access and drive up costs. In the future, patients will be further disadvantaged if reimbursement systems fail to provide appropriate payments for innovative products – which will subsequently affect the availability of R&D funds and the stream of new technologies.

The medical technology industry is facing these challenges around the world as governments enact more regulations. While we support those regulations that ensure product safety and efficacy, many others are being imposed without scientific justification, and in non-transparent processes, which only adds to costs and delays without improving patient outcomes.

As governments prioritize difficult budget decisions, they sometimes look to short-term decreases in health care expenditures without accurately assessing the long-term implications. In most cases, governments do not effectively measure the contributions medical technology makes in enhancing patient outcomes and productivity as well as expanding economic growth, which would more than offset the costs of providing these products. Instead, governments often inappropriately include reduced reimbursement rates as part of overall budget cuts.

The Challenge in Japan

This is the situation we are facing in Japan, and it is getting more difficult every year. Japan's system for approving use of new medical technologies is the slowest and most costly in the developed world. Although Japan is one of the wealthiest countries in the world – the second largest economy in the world – its spending on health care is among the lowest of major developed countries. On a *per capita* basis, Japan's spending of 7.8% of GDP is lower than 17 other Organization of Economic Cooperation and Development (OECD) member countries.

Japan is compounding the problem by imposing more burdensome and costlier regulations, thereby penalizing the U.S. medical technology industry. Japan's latest regulations are expected to cost our industry over \$1.5 billion just to achieve compliance to 2010. ¹

At the same time, Japan has made significant reimbursement reductions for medical technologies that impact the medical device industry in many ways, including limiting the availability of funds that could be devoted to R&D of new and innovative products. Inventing products that save and enhance lives requires large investments. Deep cuts for medical technologies in Japan have put downward pressure on companies' ability to invest in R&D. For the period April 2002 to March 2006, the total revenue loss from these reimbursement reductions is expected to be about \$3 billion – a significant share of which would have gone toward R&D. ²

¹ LEK Acumen Consultant. 2005

² LEK Acumen Consultant 2005

Japan appears to be making these changes, in part, as a way to avoid correcting the existing inefficiencies in its health care delivery system. Yet, because of its country's practices, Japanese patients often must wait two, three, or even five years longer for access to technologies that are already available in most other countries. Japanese patients are being denied access to our most advanced medical technologies.

An Inefficient Health Care System in Japan

Japan's hospitalization practices are the major contributor to high healthcare expenditures in Japan, with patients staying five to six times longer in hospitals than in other developed countries. For example, the average hospital length of stay in the U.S. is 6 days compared to 37 days in Japan, and these additional days clearly escalate the cost of care without significantly contributing to the quality of patient care. Japanese doctors own the hospitals in Japan, so there appears to be little incentive to diminish costs by better managing hospital stays.

The monetary cost of the inefficiencies of this system is huge. Japan's MHLW has estimated that excessively long hospital stays alone inflate annual costs by at least \$20 billion. This figure was found by comparing the average length of stay for Japan in total to a "best practice" length of stay in its most efficient district – leading to a reduction of stay length to 28 days. Using this same methodology, we estimate that Japan could save over \$68 billion by bringing its hospitalization lengths of stay down to the average in other developed countries (7.3 days) and \$71 billion if Japan reduced its hospitalization durations to the U.S. average of 6 days.

In addition, Japan has the highest ratio of beds to population of any of the 30 OECD nations and four times the number of hospital beds per person than in the U.S., which increases costs and reduces efficiency in several ways. First, Japan maintains many hospitals that would otherwise be closed. While we are sensitive to cultural differences between Japan and the U.S. or Europe, even the country's own Ministry of Health, Labor and Welfare (MHLW) has recognized that the current number of beds is excessive.

Second, Japan's diffuse hospital settings prevent the cost savings offered by specialized centers. A source of savings in specialize centers is the enhanced expertise doctors achieve when performing specific operations many times. The Japanese system limits the opportunities for Japan's health care professionals to develop optimal skills for performing complex medical procedures. Doctors who implant only a few devices each year would not receive as much training to perfect their skills as doctors practicing in specialized surgical hospitals, where a doctor might perform several implants (such as pacemakers) on a daily basis.

Unquestionably, this system substantially drives up costs for our industry. Since clinicians in Japan are often less familiar with the technical specifications and use of our products, service costs – including physician training and assistance during procedures – are much higher for industry. Medical technology products are often handled by two or more layers of distributors in Japan, each adding their own mark-up or margin. In comparison, the vast majority of medical technologies in the U.S. are sold directly without distributors.

A Slow Regulatory Process for Medical Devices in Japan

In addition to the overall inefficiencies of its health care system, Japan's new technology approval process remains the slowest and most costly in the developed world. Even after creating a new agency last year to process applications for medical technology products, Japan had a backlog in February of over 491 applications filed before April 2004. When new applications are included, the backlog is reportedly much longer. A problem for this new agency is the number of staff reviewing applications for approval of medical technology products – about 40 officials, compared to over 700 in the U.S. Due to the long approval process, the medical technologies patients receive in Japan are often several generations behind the products in the U.S., Europe, and even developing countries like China, India and Thailand. Lengthy approvals also translate to higher costs for the U.S. medical technology industry, which must maintain out-of-date product lines just for Japan.

Japan should be examining ways to streamline its regulatory system, achieving greater efficiencies and facilitating patient access to the most advanced technologies available. We have made such suggestions to the Regulatory Reform Council, established by Prime Minister Koizumi, on some changes. We also have been working with MHLW officials and are willing to continue doing so.

So far, however, instead of facilitating patient access to medical technology, Japan has been compounding the problem by imposing more burdensome and costlier regulations that discourage innovation. Its revised Pharmaceuticals Affair Law (PAL), which covers medical technology products, went into effect on April 1, 2005. Even our largest companies are experiencing difficulties meeting PAL's complicated provisions. Some of our smaller companies have indicated they may have to exit the Japanese market because of PAL requirements. The initial and on-going costs of \$1.5 billion through 2010 are monies that otherwise could have been invested in furthering innovation for patients who need it most.

Continued Reductions in Reimbursements for Medical Devices in Japan

At the same time our industry is facing these onerous and costly regulations, MHLW is threatening severe reimbursement rate cuts. In Japan, the government sets the maximum reimbursement rates, which usually act as ceiling prices for all medical technology products. These prices are reviewed and usually reduced every two years.

Before 2002, Japan adjusted prices according to a process it called "reasonable-zone" or "R-zone." In brief, MHLW surveys its hospitals for prices paid to distributors, and allows for a reasonable margin (or "zone") for discounts off of the government's reimbursement rate. While there are some difficulties with this system – as identified in bilateral Market-Oriented, Sector Specific (MOSS) negotiations between the U.S. and Japanese governments – our industry recognizes that it is at least based on factors in the Japanese market.

In 2002, however, Japan also adopted a system called Foreign Average Pricing (FAP). This system calls for the establishment and revision of reimbursement rates on the basis of prices paid for medical technology products in the U.S., France, Germany, and the United Kingdom (U.K). The prices of medical technology products in Japan are designed to be based not on that market's requirements, but on completely unrelated conditions in foreign markets.

The U.S. medical technology industry has several strong objections to this method of calculating reimbursement rates.

- As a methodology for setting reimbursement rates, it is not economically sound to compare prices in foreign markets that operate under vastly different conditions. Japan's regulatory system is far costlier to comply with than European or U.S. regulations. In addition, the overall cost of doing business in Japan is far higher than in the U.S. or Europe. Just in terms of basic cost of living, Tokyo is ranked the most expensive city in the world, with Osaka number 2. Tokyo is about twice as costly in general as New York City and about 2.5 times as expensive as a mid-western city, like Minneapolis. No U.S. city is in the top 20 cities on this list.³
- Operating in Japan compounds costs by our industry compared to selling in other countries. For example, the added expenditures for product redesign, development, distribution, research and marketing all increase the cost of supplying Japanese patients by hundreds of millions of dollars each year.
- Conditions in the three European countries included in the FAP analysis are different from both the U.S. and Japan. The European Union member states use a product approval system that, in many cases, is more streamlined than the U.S. process. However, France, Germany and the U.K. also maintain pricing interventions that place a ceiling on medical technology pricing.
- Comparing prices even within markets – let alone across national boundaries – is difficult. Our member companies sell products under a variety of terms and conditions. In the U.S., our companies can often offer lower prices to buyers willing to commit to much larger volumes for longer periods of time, but Japan does not have such buyers and offers minimal channels for efficient selling and distribution of medical technologies. Additionally, Japan's FAP system is an attempt to compare prices for products that are not the same in Japan as they are in other countries. Due to Japan's regulatory delays, U.S. manufacturers must incur the cost of maintaining older or outmoded production lines for sale in Japan.
- Japan established its FAP system and continues its plans to cut reimbursement rates because of the "perception" that prices for certain medical technology products are much higher in Japan than in other countries. As previously noted, there are many reasons prices are higher in Japan than in other countries. In addition, Japanese doctors and others in Japan, often obtain this perception by comparing U.S. hospital purchase prices to the official Japanese reimbursement rates, which are usually higher than the prices medical technology products are sold in Japan.
- As previously mentioned, the net effect of Japan's reimbursement rate cuts could have a detrimental effect on the funds available for research and development (R&D) of innovative products that are intended to lessen the time, pain and expense of treatments for a wide range of illnesses.

Ironically, Japan's planned reimbursement decreases are likely to have no perceptible effect on moderating Japan's health care budgetary expenditures. While some of the other practices mentioned in this testimony are very inefficient and obvious drivers of inflation of Japan's health care costs, medical technology products account for only about 8% of Japan's total health care spending, and products targeted for price cuts represent less than 0.7% of all health care expenses. Virtually all technologies targeted for these cuts are made by non-Japanese companies.

Instead of trying to balance its budget on the backs of the medical technology industry, Japan should look to major reforms of its inefficient hospital system. Such reforms would provide huge savings and would be good for Japanese patients and for Japan's economy.

U.S. Government Support

The U.S. Government has provided our industry with tremendous support in trying to convey this message to the Japanese government. We have enjoyed bipartisan Congressional support, with these hearings serving as just the most recent manifestation of that support.

Our industry has also benefited from continuous support from the Executive Branch. We want to thank the Departments of Commerce, State and Treasury, the Office of the U.S. Trade Representative (USTR), and the U.S. Embassy in Tokyo for their hard work on our behalf. Since the mid-1980s, Executive Branch agencies have included regulatory and reimbursement issues in the MOSS negotiations. More recently, these issues have also been a topic for high-level USTR-Commerce negotiations with Japan under the Regulatory Reform Initiative.

We believe that U.S. government support has been a major reason that total U.S. medical technology exports have flourished world-wide for many years, exceeding imports. In fact, this past year was the first time that total U.S. imports of \$25.2 billion ever exceeded exports in the medical technology sector.

While U.S. exports of medical technology have enjoyed a surplus with Japan, we see disturbing signs that this too could change. During the 1980s and 1990s, our industry's exports rose steadily. Since Japan introduced its FAP system in 2002, U.S. exports have basically stagnated at essentially the same level of exports in 2004 as in 2001. At the same time, Japan's exports of medical technology products in 2004 rose by 10%, contributing modestly to Japan's burgeoning total trade surplus with the U.S. of \$75 billion – an increase of 14% last year. With added regulatory hurdles and reimbursement reductions, U.S. exports to Japan could deteriorate further.

The World Trade Organization (WTO) recognizes that standards and regulations can be non-tariff barriers (NTBs). While we are not alleging a WTO violation, we do believe that Japanese policies are essentially creating new NTBs for our industry to try to overcome.

Recommendations

We have several recommendations to help ameliorate the situation in Japan and, at the same time, facilitate patient access to advanced medical technology products. AdvaMed members want to cooperate with the Government of Japan to find solutions that are mutually beneficial to patients, Japan, and our industry. We have met frequently with officials from MHLW and other government agencies, including at senior levels, to seek such solutions. We respectfully request that such solutions be based on actual operating conditions in Japan and not on circumstances in other countries.

In terms of the regulatory environment, AdvaMed members will continue our efforts to understand and comply with existing regulations. At the same time, we ask that MHLW seriously examine our suggestions to facilitate patient access to advanced technologies.

- **Regulatory Improvements.** Japan should urgently address the growing backlog of product applications and to reduce the review times of new product applications – particularly in light of Japan’s User Fee system and its commitment to meet performance measures. One concrete step would be to quickly expand the number of experts employed in Japan to review product approval applications for product safety and efficacy, which would help reduce the considerable backlog. As part of this effort, the expertise and training of reviewers could be broadened to include necessary skill sets, such as a background in engineering and biostatistics. Another step would be for Japan to accept results of scientific studies conducted in the U.S. We have made recommendations of this nature to the Government of Japan, and we would hope they receive serious consideration.
- **Reimbursement Improvements.** We seek a fair, transparent and predictable system based on actual operating conditions in Japan. We believe such a system should reward innovation by providing higher payments for truly innovative products. If there is a clear demonstrable reason to reduce some product prices, we would welcome the opportunity to work with MHLW on a transparent system that would limit the size of reductions in any given year and would allow us to build such cuts into our long-term planning, instead of being unpredictable and dictated every two years.

Conclusion

Thank you, Mr. Chairman, and the other members of this Committee for providing us the opportunity to submit the views of our industry in the context of a hearing on overall U.S.-Japan trade relations. We hope you and other members of Congress will continue to recognize the importance of the medical device industry, as well as access to foreign markets for the sustained growth of our industry and U.S. jobs. In our relationship with Japan, Congressional and Administration involvement is critical to maintaining our exports to this important market.