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NEWSLETTER

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English translation of the Japanese newsletter

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2018 In Celebration of the New Year

As we embark upon this new year of 2018, I would like to extend my best wishes for the new year on behalf of the American Medical Devices and Diagnostics Manufacturers' Association.

Proposal for Value-Based Healthcare

In 2017, beginning with its proposal for value-based healthcare (in February), the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) was involved in activities for “promoting innovation and securing healthcare access for patients” and “sound finance for medical care and elderly care.” AMDD spoke with the government at regular meetings and discussion sessions. AMDD also made statements at the Central Social Insurance Medical Council (Chuikyo) meetings, as well as at the public-private dialogues.

The Chuikyo accepted one of the major concepts in Value-Based Healthcare, “the creation of a post-launch C1/C2 (re) application system,” which ensures the proper evaluation of innovation. We are extremely happy that it has been incorporated into the framework of the fiscal 2018 revision of the Medical Materials Pricing System.

In order to promote further developing and promptly launching innovative medical devices, we intend to continue our efforts to advance the cooperative plan with the Pharmaceuticals and Medical Devices Agency (PMDA). 64% of clinical trials in Japan have been done by innovative medical devices from AMDD member companies; I would like to report that we are making significant contributions in launching products in the Japanese market.

Promote the Value of Medical Devices

In principle, medical devices are used for the treatment and prevention of disease, however they can do more than simply treating a disease. We believe that the value of medical devices can be assessed through broad analysis to comprehensively assess auxiliary benefits, such as the recovery of the patient's productivity, the opportunity cost and enhanced productivity of surrounding caregivers, as well as other cost savings.

Last year, AMDD sponsored a symposium co-organized by the Japan Medical Association and the Advanced Medical Technology Association (AdvaMed). The symposium, entitled "Vibrant Nation: Realizing the Fullness of Ikigai in Japan; The Role of Health Innovation in Delivering Growth, Productivity, and Cost Savings," was centered on a discussion of the value of medical devices, drawing interest from various perspectives.

Establishment of the Medical Technology Policy Institute

In order to research the ways in which medical technologies could make a greater contribution to healthcare in Japan from a mid- to long-term perspective and provide policy recommendations, AMDD established the Medical Technology Policy Institute (MTPI) in October 2017 (see page 3 for details).

With the motto of "Enabling a healthier Japan," AMDD will continue to work together with the Japanese government, relevant industry groups, and academic associations while also maintaining ties with the U.S. government and AdvaMed, headquartered in the U.S. Through collaborative activities, we will contribute to healthcare in Japan. This year, we will continue to transmit appropriate information on medical devices and IVD through various events and newsletters.

Thank you in advance for your continued guidance and support in the year to come.



Mr. Kosuke Kato
Chairman, American Medical Devices and Diagnostics
Manufacturers' Association (AMDD)
Managing Director, Edwards Lifesciences Limited

Regarding the Establishment of AMDD Medical Technology Policy Institute

I am Makoto Tamura, the first director of the Medical Technology Policy Institute established on October 1, 2017. As the chair of the AMDD Special Treatment Material (STM) Committee and as a member of the Chuikyo Expert Committee, I have been involved with AMDD activities mainly related to insurance. I have been recently appointed Director of the Institute.

I would like to take a moment to introduce the goals of the Institute and the aims of its activities for the time being.

Goals of the Institute

While advances in medical devices and IVD continue to be made, the finances of the medical insurance system are being stretched to the limit with the government's massive financial deficit and the advent of Japan's aging society. Although there is now greater recognition of medical devices and IVD, there continues to be an insufficient understanding of these. In this context, the respective AMDD companies are seeking the appropriate evaluation of their innovative products that corresponds to expectations of Japanese patients, but AMDD companies are currently facing a difficult environment.

Last year, AMDD made specific proposals on the Medical Materials Pricing System based on the concepts of value-based healthcare. Several elements of the proposal are likely to be incorporated in the fiscal 2018 Reimbursement Revision. We still believe that there is a need for proposals which reflect the characteristics of medical devices based on accurate evidence.

In light of this, these are the following three goals of the Institute:

- 1) To conduct mid- to long-term research to study the market/policies surrounding the medical device/IVD industry, the situation overseas, and to evaluate the systems and policies that are most suited to Japan's healthcare system in collaboration with relevant AMDD committees.
- 2) To enhance stakeholders' understanding of medical devices/IVD, and to support the collaboration between the AMDD, government, and relevant groups.
- 3) To share the knowledge and experience of the Institute with members of the respective AMDD member companies.

Aims of Activities

For the time being, we are thinking of conducting two main activities. The first is to conduct and promote research on medical devices/IVD. The second is to gather information on product development for medical devices/IVD and to provide this information in a clear format. As I also work as senior research fellow at the Medical Device Strategy Institute of the Japan Association for the Advancement of Medical Equipment, we are planning on conducting the majority of these activities cooperatively between both institutes.

<Conducting and Promoting Research on Medical Devices/IVD>

First, the Medical Technology Policy Institute of AMDD is planning to conduct an independent research study. As mentioned earlier, AMDD made specific proposals on the Medical Materials Pricing System based on the concept of “Value-Based Healthcare.” As there was concern that the meaning of the term and concept of Value-Based Healthcare can be interpreted in various ways, I organized discussions and wrote a paper entitled, “The Meaning of ‘Value-Based Healthcare.’” This paper was published in the Shakai Hoken Junpo, in January of this year.

Furthermore, we intend to actively conduct research studies in collaboration with external researchers and experts.

Amidst discussions of the issues related to manufacturing and sales approvals and insurance reimbursement for medical devices, the Institute of Comparative Economic Studies at Hosei University is about to commence a project called the “International Comparative Study of the Issues and Future Outlook for Japan’s ‘Insured Medical Materials System’” (led by Professor Takuma Sugahara). By actively participating in this project, MTPI hopes to clarify the issues faced by the industry and conduct research in collaboration with external experts.

<Gathering and Providing Information on Product Development for Medical Devices/IVD>

In order to facilitate an understanding of the characteristics of medical devices/IVD and to promote familiarity, we are planning on creating something like behind-the-scenes insights in product development, which will be provided to relevant parties in a clear and easy to understand context.

With regards to this, MTPI will gather materials from AMDD member companies and develop medical device case studies, similar to those at business schools.

As the “cases” will have a certain degree of in-depth information and as they will be written as stories, even individuals who are not very familiar with medical devices will be able to easily understand the information.

The Institute is still in its infancy, and we hope to grow with the help of your words of wisdom and advice. Thank you in advance for your guidance and support.



Dr. Makoto Tamura

Director, Medical Technology Policy Institute, American
Medical Devices and Diagnostics Manufacturers’ Association
(AMDD)

Senior Research Fellow, Medical Device Strategy Institute, Japan
Association for the Advancement of Medical Equipment

Representative Director, Healthcare System Planning Institute

Graduated in 1982 from the Department of Health Sciences, Faculty of Medicine, University of Tokyo, and in 1984 from the Graduate School of Medicine, University of Tokyo. Also studied at Northwestern University Graduate School of Management. Worked as a research associate in the Faculty of Medicine, University of Tokyo in 1995 and worked as professor at the International University of Health and Welfare from 1999. Became Vice President of Guidant Japan and Vice Present of Boston Scientific in 2004 and Vice President of Abbott Japan in 2010. Established the Healthcare System Planning Institute in 2017, and took the role of Representative Director. Served as a member of the Chuikyo Expert Committee from 2011 to 2017.

***Kenko Keiei* (Health and Productivity Management) as a Business Strategy**

Recent Trends in *Kenko Keiei*

Health and productivity management has been widely implemented in the U.S. and Europe for 20 to 30 years. In Japan, however, only recently have people become familiar with this practice, called “*Kenko Keiei*.” The term finally became popular when *Kenko Keiei* was addressed in Abenomics as the backbone of Prime Minister Abe’s policies.

A noticeable activity around *Kenko Keiei* was the creation of “Nippon Kenko Kaigi” (Japan Health Council). Nippon Kenko Kaigi is composed of not only the private sectors, such as economic and healthcare organizations, but also insurers and local governments, with the purpose of effectively extending the healthy lifespan of Japanese and addressing issues around appropriate healthcare.

The Council has identified eight action guidelines to be addressed by 2020. Of these guidelines, ones with specific numbers, such as “Having 500 companies engaged in *Kenko Keiei*,” and “Having 10,000 companies engaged in efforts to pursue *Kenko Keiei*” are considered important. The “500 companies” refers to large corporations, while the “10,000 companies” refers to small and mid-sized companies. As of 2017, 47% of the targeted number of companies are engaged in *Kenko Keiei*, but the number of companies working towards *Kenko Keiei* has already exceeded the goal of 2020 by 121%.

The concept is gradually spreading and gaining attention in Japan, but a new development can be seen in the U.S. and Europe. There has been a conceptual shift from the “disease-free model” to a “productivity model.” Health management is not entirely about employees’ health; “Health and Productivity Management” — managing health and promoting productivity — is what companies should aim for. There have been further research results reported in the U.S., indicating that companies that are passionate about *Kenko Keiei* have seen good business results. *Kenko Keiei* is becoming an important issue that needs to be addressed by companies.

Supporting *Kenko Keiei*

Starting several years ago, the Ministry of Economy, Trade and Industry began to select companies from those listed on the Tokyo Stock Exchange as *Kenko Keiei* brands. 20 companies, one company from each industry, have been certified. These companies benefited from the exceptionally talented people who joined, based on the good image.

However, as only one company per industry was selected, there were discrepancies in the level of *Kenko Keiei* depending on the industry. And there were also exceptional companies

that were not selected. Small and mid-sized companies and nonprofit organizations were also excluded from the selection. In an attempt to remedy this, METI started to certify corporations that conduct exceptional *Kenko Keiei*, not limited to the listed corporations, and certify them as “Certified *Kenko Keiei* Organizations (White 500)”. Currently, 235 organizations have been recognized in the large enterprise category, while 318 organizations have been recognized in the small to medium enterprise category.

A *Kenko Keiei* Advisor System was also established to advise small and mid-sized companies on *Kenko Keiei*. In 2017, the Health Insurance Bureau of the Ministry of Health, Labour and Welfare published the “Collabo-Health Guidelines,” which links companies with insurers. Doing these activities has led to a growth in efforts to support the initiative from a variety of directions.

The Future of *Kenko Keiei*

The Health and Productivity Management (HPM) Policy Research Unit at The University of Tokyo, with which I was affiliated, is also working to substantiate this issue. Of the total costs associated with the health of employees in the U.S., medical expenses do not account for the largest costs, rather it is *presenteeism* — a condition where an individual is present at their workplace, but is unable to perform sufficiently due to physical or mental health issues. Of Japan’s total health-related costs, the percentage of medical expenses is less than the U.S., but the basic composition is almost the same; presenteeism accounts for the largest portion of health-related costs. It is becoming clearer that the risks tied to presenteeism are largely psychological factors such as mental issues and job satisfaction.

A characteristic of Japanese management, as identified by the sociologist Kunio Odaka, is “compassion for employees’ welfare that extends even to their private life outside of work,” and I believe that this is precisely the base for *Kenko Keiei*. Factors, such as stability of employment, flexibility of human resources, unity between employees and the company are all aspects of Japanese management that have been considered outdated. They surprisingly match the concept of *Kenko Keiei*. The major difference between Japan and the U.S./Europe model is whether or not it is based on evidence.

Going forward, in order to increase the number of “White Corporations” recognized for outstanding *Kenko Keiei*, we must accumulate evidence and implement a PDCA (plan do check act) cycle. As collecting evidence poses a considerable burden for small and mid-sized companies, outsourcing through the *Kenko Keiei* Advisor System, must be promoted.

A report from the American Hospital Association recommends rooting *Kenko Keiei* in the culture of the organization, measuring ROI (return on investment), and valuing sustainability. The last point, valuing sustainability, can be seen as a recommendation directed towards Japan, where the movement is currently catching on.

Going forward, Japan faces pressing issues, such as a super aging society, low birthrate, declining population, and medical and long-term care. I believe that *Kenko Keiei* can play a major role in addressing the issues.



Dr. Hiroya Ogata
Professor Emeritus
Kyushu University

Graduated from the Faculty of Economics and the Faculty of Engineering, The University of Tokyo in 1978 and entered the Ministry of Health, Labour and Welfare in the same year. Assigned to Paris as a OECD Secretariat in 1981. Appointed First Secretary of The Permanent Mission of Japan with the International Organizations in Geneva in 1989. Appointed Director of the Chiba Environmental Hygiene Bureau In 1993. Appointed head of the Department of Empirical Social Security Research at the National Institute of Population and Social Security Research in 1998. Appointed professor at the Graduate School of Medical Sciences, Kyushu University in 2001. Appointed to his current post in 2013 after serving as specially-appointed professor in the Health and Productivity Management (HPM) Policy Research Unit at the Policy Alternatives Research Institute, The University of Tokyo.

AMDD Held 9th New Year Party

On January 15, the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held a New Year Party at the Imperial Hotel. In his opening remarks, Chairman Kosuke Kato (Managing Director, Edwards Lifesciences Limited) mentioned he greatly appreciates the introduction of the re-functional application system in the Reimbursement Revision, and this would directly lead to an assessment of innovation in medical devices. He also spoke of his aspirations stating that, "We need to do all that we can to ensure that there is a balance between the extension of healthy lifespans and the sustainability of social security spending."



AMDD Chairman
Kosuke Kato



Minister of Health,
Labour and Welfare
Katsunobu Kato

In the guest remarks, Minister of Health, Labour and Welfare, Katsunobu Kato said encouraging words, "Through constant discussion and exchange of opinions, I hope to promote the prompt adoption of exceptionally innovative medical devices and IVDs, and further the enhancement of healthcare in Japan." After congratulatory remarks from Arlene Mayeda, Commercial Attaché at the U.S. Embassy and Akira Kuba, Senior Managing Director of the Japan Federation of Medical Devices Associations, the New Year Part started with a toast given by Kenichi Matsumoto, President of the Japan Association of Medical Devices Industries.

AMDD Held a New Year Press Conference

On January 15, the AMDD held the 2018 New Year Press Conference prior to the 9th New Year Party. Reflecting activities which focused on Value-Based Healthcare proposals in 2017, AMDD explained the industry's current issues, such as the HTA, as well as the outlook for 2018. Director Makoto



New Year Press
Conference

Tamura also gave a presentation on the Medical Technology Policy Institute, that was established last October, explaining the background leading up to its establishment and future outlook.

Value of Medical Technology

<Diagnosis and Treatment for Cardiac Disease>

TAVI, a new and novel fundamental treatment option for patients considered high risk for aortic valve therapy with open heart surgery

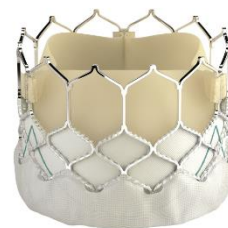
“Aortic stenosis,” a condition where the aortic valve of the heart becomes as hard as rock and has difficulty opening, has increased with Japan’s aging society and people’s life-style choices. In early stages, the condition is often asymptomatic, but as it progresses, symptoms of cardiac insufficiency arise, including chest pain, fainting, breathing difficulty, and swelling.

Aortic stenosis cannot be cured with medications. It is treated through a surgical procedure which replaces the malfunctioning original valve with an artificial valve. Generally, open heart surgery is performed, using a cardiopulmonary bypass to temporarily stop the function of the heart. This makes it unsuitable for elderly patients with reduced stamina or patients who suffer from multiple diseases. Unfortunately, there was no other treatment available.

However, in 2013, a new therapy known as transcatheter aortic valve implantation (TAVI) was introduced to Japan. In this method, the artificial valve is thinly folded and inserted with the catheter to the blood vessels in the upper leg. TAVI is passed towards aortic valve, and implanted inside of the old one. This enables patients, who were unable to undergo the open heart surgical procedure, to have access to a radical treatment without stopping the heart. As TAVI avoids large incisions compared to conventional surgical procedures, it also reduces the number of days in the hospital.

The medical device used in TAVI has been repeatedly improved and continues to develop with the input of healthcare professionals. With the advent of innovative new devices and the evolution of medical technologies, the number of patients who are treated and regain their health is expected to increase.

(Text: Rena Ogata, Edwards Lifesciences Limited)



AMDD Held the 6th Internal PR Meeting — Diversity and the “Sales Woman Network” —

On December 5, 2017, the AMDD held the Internal PR Meeting in Tokyo. The attendees were people from PR/communications, HR, and diversity related departments in AMDD’s member companies. The event’s theme was diversity and women’s empowerment.

2017, which marked the 6th event of its kind, continued the theme from the previous year, “Diversity in the Medical Device Industry.” Ms. Sachiko Fumoto, Executive Officer at Nikkei BP and the Head of the Nikkei BP Marketing Strategy Institute, was invited as a guest speaker and gave a special lecture on “Diversity in the Medical Device Industry – from an Outside Point of View.” Participants from the member companies listened earnestly to her interesting lecture, which included her own points of view, experiences, and academically proven theories. She also discussed the importance of diversity, and gave examples of other companies that have addressed these issues.

At the Internal PR Meeting, facilitators from the August 2017 “Sales Woman Network” event also participated as panelists in a panel discussion, and presented the excitement and energy of the SWN event. They also presented saleswomen’s common ground, that “sales is fulfilling work”. Attendees were reminded that the industry needs to address women’s empowerment at the Internal PR Meeting.



A scene from the
panel discussion



Ms. Sachiko Fumoto

Value of Medical Technology

Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.