

# AMDD *Vol.15*

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## NEWSLETTER

January 2014

English translation of Japanese newsletter

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### Looking Forward to a Year When a Long-held Wish will be Fulfilled

It is a great pleasure to deliver the greeting message on behalf of the AMDD for the beginning of 2014.

Last year the new Abe Administration designated the medical field as one of the key factors in its national growth strategy and in November, the government enacted “The Law of Ensuring Quality, Effectiveness, and Safety of Pharmaceuticals, Medical Devices, etc.” (known as the “Pharmaceutical and Medical Device Law” for short), which was a long-cherished wish for us. This law replaced the previous Pharmaceutical Affairs Law, and contained a newly developed “chapter” that allowed us to treat “medical devices” separately from pharmaceuticals, which have long been regulated together.

As a result of these achievements, it is expected that the medical device industry in Japan will grow steadily. In that light, I want to express my appreciation to the Diet members who have worked towards enacting this law, and all other parties involved, including the relevant administrative agencies such as the Ministry of Health, Labour and Welfare.

Unlike the development of pharmaceuticals, which mainly focuses on identifying active medical ingredients in laboratories, the development of medical devices is an incremental process and requires ingenuity to develop clinical solutions for treating diseases and injuries. Under the previous law, the review and approval process was time consuming, even for minor improvements. The reason for this delay was that the regulations for manufacturing medical devices was the same as pharmaceuticals, in spite of their obvious differences. This situation created a difficult environment to foster the medical device industry in Japan.

The newly established law will be enforced from this November, one year after its establishment, and is designed to introduce medical devices to the market and to streamline regulations. To make effective use of this law, AMDD will work towards defining the enforcement details by submitting its manufacturers' views and requests to the Ministry of Health, Labour and Welfare, and related agencies, in collaboration with AdvaMed, the U.S. Government, the U.S. Embassy, and other medical device manufacturers groups.

AMDD's mission is to improve the QOL (the quality of life) for its patients and realize healthier life expectancy by delivering the world's most advanced medical devices to patients in Japan as quickly as possible. The newly established law is regarded as a giant step towards shortening the review and approval period, while also providing adequate considerations for safety. To achieve our goal, we will continue to work with relevant agencies to reduce corporate burden and encourage consistent worldwide regulations.

Additionally, we are actively working to represent our views more accurately for the insurance reimbursement price revision in April and will continue to take further actions to strengthen coordination among members in the future.

This year marks the fifth anniversary since AMDD was established. Sixty-four member companies provide advanced medical technologies to patients in Japan, mainly in the fields ranging from cardiovascular therapeutic devices such as cardiac pacemakers, artificial cardiac valves, and stent grafts, materials for orthopedic surgery materials such as artificial joints, intraocular lenses, diagnostic imaging systems, gene diagnosis, to in-vitro diagnostics (IVD) products and system components. AMDD intends to make further efforts to introduce advanced medical devices to the market. I would appreciate your continued patronage.



**Takashi Shimada, Chairman**  
American Medical Devices and Diagnostics Manufacturers'  
Association  
President, Medtronic Japan Co., Ltd.

## **The Integrated Reform of the Social Security and Tax Systems, and the Reform of the Medical and Nursing Care Systems**

### **The Progress of the Integrated Reform of Social Security and Tax Systems, and the Social Security System Reform Promotion Law**

The Integrated Reform of Social Security and Tax Systems is designed to simultaneously accomplish the two goals of building a well-developed and stable social security system and restoring fiscal soundness, pursuant to the changes in our social economy.

This reform was first considered in 2011 under the Administration of the Democratic Party of Japan, and the relevant bills were submitted to the Diet in 2012. As a result, an agreement was reached among the three parties of the Democratic Party of Japan, the Democratic Liberal Party, and the New Komeito, resulting in the establishment of ten bills in total.

Firstly, the “Social Security System Reform Promotion Law” was enacted, specifying the basic concept and policies for the future reform of the social security system. Then, two amended laws were enacted on the national tax and the local tax, containing the basic policies on the hike of VAT, that is, the increase to 8% from April 2014 and the increase to 10% from October 2015. As for the annual pension, four laws were enacted along with the establishment of several amended laws such as: 1) a permanent raise in the share of tax revenues for the basic pension to one-half from the conventional one-third or more, 2) consolidating the annuity system for salaried employees, 3) shortening the period to qualify a person as a pension recipient to a period of 10 years, 4) expanding the coverage for survivors’ basic pension to motherless families, and 5) expanding the coverage for the employees’ pension (and health insurance) to short-time workers such as part-time workers. In addition, welfare benefits to low-income elderly and disabled persons (the benefits for supporting the pensioners) are also included. As for the countermeasures to the declining birthrate, three laws were enacted such as: 1) a new law for the new children nurturing system, 2) the amended law to promote eliminating the childcare waiting lists, and 3) the amended law on certified children centers.

### **Reports by the National Assembly on the Social Security System Reform**

The “National Assembly on the Social Security System Reform” was newly established under the Social Security System Reform Promotion Law, thereby specifying that legislative measures shall be taken within one year after the promotion law is enforced, pursuant to the review results. The national assembly, chaired by Mr. Atsushi Seike, President of Keio University and consists of 15 members, was founded, and a summary report was developed on August 6, 2013.

The main focus of the report emphasized the significant challenges facing an aging society in a country with one of the world’s oldest populations, and its aim to develop a social security system that mutually supports all generations so that highly motivated people can continue to work. In addition, a proposal was made for a two-step reform: 1) a reform focusing on the measures to be taken in four to five years after the VAT hike, and 2) a reform anticipating the extremely aged society with fewer children in and after 2025 from a mid- and long-term viewpoint.

While many laws have been enacted in the fields of annuities and the birthrate decline as mentioned above, no full-scale amended laws have been established in the field of medical and nursing care. Consequently, specifics of the report focus on reforming the medical and nursing care systems; specifically, reforming the medical and nursing care delivery system and building a comprehensive regional care system, reforming the medical insurance system including the burden sharing of the financial management of the National Health Insurance among prefectures, reviewing the current position of medicine and rebuilding the medical system on a prioritization and efficiency basis, and developing legislation for countermeasures against intractable diseases.

## **Establishment of the Social Security System Reform Program Law and Enrichment of the Social Security by Tax Revenue Increase**

The “Social Security System Reform Program Law (the Law relating to the Reform Promotion for Ensuring a Sustainable Social Security System)”, was submitted and established at an extraordinary session of the Diet in autumn 2013, and contains the bigger picture and the steps required to establish a social security system reform.

In the future, amendments will be made sequentially in light of the review items specified under the Program Law and the prospected time of submitting bills. In the ordinary Diet session of 2014, a bill to revise the Medical Service Law will be submitted to create a reporting system on hospital bed functions with an aim of dividing and linking hospital bed functions, rebuilding the medical service delivery system, building a comprehensive regional care system, as well as developing visions for regional medical services. In addition, a bill will also be submitted to revise the Long-Term Care Insurance Act to review the Community Support Project for building a comprehensive regional care system, promoting preventive cares, and reviewing the medical services received at home and at facilities, and a new bill on the countermeasures against intractable diseases.

Under the Integrated Reform of the Social Security and Tax Systems, of the 5% increase in VAT, 4% is supposed to be used for stabilizing social security and fiscal reform, and the remaining 1% is supposed to be used for enriching social security.

The portion of 1% amounts to approximately 2.8 trillion yen (on an FY2017 basis); 0.7 trillion yen will be appropriated for countermeasures to the birthrate decline, 1.5 trillion yen for medical treatment and nursing care, and the remaining 0.6 trillion yen for the annuity.



### **Mr. Takeshi Karasawa**

Director General for Social Security, the Ministry of Health,  
Labour and Welfare

Mr. Karasawa graduated from the School of Political Science and Economics, Waseda University in 1980 and entered the Ministry of Health, Labour and Welfare; he has held the posts of Deputy Director-General for the Nursing Care Insurance System Preparation Office, Director of the Public Relations Office under Minister’s Secretariat, Counsellor for Policy Evaluation, Director of the Family Welfare Division under the Equal Employment, Children and Families Bureau, Director of the Day Care Division under the same Bureau, Director of the National Health Insurance Division under the Health Insurance Bureau, Director of the General Affairs Division under the same Bureau, Counsellor for Personnel Division under Minister’s Secretariat, Director for Personnel Division under Minister’s Secretariat, Deputy Director-General for the same division, and has held this current post since 2012.

## Patient's Voice

### Regaining Sound and Speech through a Cochlear Implant



Mr. Norio Matsuda, President  
ACITA (Association of Cochlear Implant Transmitted Audition)

ACITA (Association of Cochlear Implant Transmitted Audition) is a society for cochlear implant users. Cochlear implants involve implanting an electrode into the cochlear, which enables a person to regain their hearing acuity by directly stimulating their auditory nerve. These operations are typically performed if a person with serious hearing impairment cannot hear well even through the help of a hearing aid.

The society was originally founded by four implant users at the Tokyo Medical University who wanted to create an opportunity to exchange information, and to regain their sound and speech. From our original membership of 16 people in May 1988, the society recently celebrated its 25th anniversary in June 2013. Needless to say, we are always hopeful for the future; the pronunciation of ACITA in Japanese means “tomorrow”.

The purpose of this society is to enrich and spread wellbeing for cochlear implant users in collaboration with doctors, speech-language-hearing therapists, manufacturers along with other groups, and to provide information through bulletins. Furthermore, we hold nationwide consultation meetings on cochlear implants to promote and spread accurate information through educational campaigns. September 9th is designated as “Cochlear Implant Day”.

In addition, information is exchanged at discussion sessions of our regular conference with an aim of improving hearing ability, alongside educational campaigns conducted at nationwide branches. Cochlear implant users work as advisors to convey their own stories and experiences with regaining their hearing, and hope to share that joy with as many people as possible.

The number of regular members has now reached over 1,000, while the number of actual implant users is estimated to exceed 7,000. Needless to say, implant users are enjoying their improved QOL with the help of cochlear implants. These users can now enjoy talking on the phone, listening to music, or chatting with their grandchildren, all activities which they were unable to do previously due to hearing loss.

However, the effects of using a cochlear implant are not immediate because of the rehabilitation and training required that could take at least six months to two years. During this time, users improve their speech by first improving their hearing ability through conversations, reading aloud, listening to the radio and listening to other types of sounds in their daily lives. Even after regaining their hearing, one or two MAPs (programs) a year are required for adjustment. Furthermore, the degree of hearing ability regained will vary among individuals.

The adaptive standard for using a cochlear implant is defined as a person whose hearing level reaches 90 dB or more for adults and children (aged one and a half years or older), who cannot clearly hear even with the help of a hearing aid and who cannot understand spoken words. In recent years, the number of people with impaired hearing has markedly improved since the number of infants with congenital hearing disorders using cochlear implants has increased, and the number of adults and children with cochlear implants on both ears has increased.

ACITA

<http://www.normanet.ne.jp/~acita/>

## **Voice from the Local Government**

### **From Aomori to the World**

#### **~Aiming to be a Regional Model for the Next-Generation of Healthcare**



Mr. Koichi Murashita, Assistant Section Manager  
Department of Commerce, Industry and Labor, Aomori Prefectural  
Government Office

While all of Japan is faced with an aging society and fewer children, this challenge is most prevalent in Aomori Prefecture. The region also exhibits the lowest levels of male and female life spans in Japan, despite the nation enjoying one of the highest life expectancies in the world.

Given these challenges, we have developed and are promoting the “Aomori Life Innovation Strategy (November 2011)” with the aim of developing new industries to help tackle the issues from a commercial standpoint resulting from our aging population. Through this strategy, Aomori has taken the lead ahead of other prefectures in promoting industry, and is now aggressively expanding the life sciences sector. This strategy focuses on the major fields of “medical-industrial collaborations”, “services”, and “products”; specifically, medical-industrial collaborations is proposed as a key policy objective in promoting strategic alliances with leading companies (including foreign companies) by focusing on developing new medical devices.

Pursuant to this policy, we have been actively planning and conducting collaborative events to match business opportunities between leading medical device manufacturers and local companies. For example, we have continuously held an event titled “GE Day in Aomori” in collaboration with GE Healthcare Japan Corporation since 2012; in addition, we conducted the “MOT Program of Medical Device Development” by inviting AMDD members such as Nippon Becton, Dickinson and Company, Ltd. as a lecturers. In September 2013, we held the “2013 Medical Innovation Forum in Aomori” and invited Mr. Hiroyuki, President of Johnson & Johnson K.K. to speak, and in October, we co-hosted an event with the AMDD titled the “Special Forum in Promoting the Medical-Industrial Cooperation – Opening Up a New Future through Medical-Industrial Cooperation”.

Specifically, we concluded a strategic partnership agreement with GE Healthcare Japan Corporation in 2012. We are now working on a collaborative demonstration study to establish a new model of providing medical and healthcare services in remote areas by using a multifunctional small car called the “Health Promotion Car”, which is an unprecedented attempt in Japan. This activity is drawing a lot of attention at home and abroad.

We, the Prefecture of Aomori, are making every effort to create a new era by advancing the global life sciences industry by collaborating with several global enterprises such as AMDD. In doing so, we hope to grow business and develop a win-win situation for creating innovations in Japan by promoting interactions between local companies with advanced technologies and by furthering mutual understandings.

### **2014 AMDD New Year’s Party – Celebrating the Establishment of the “Pharmaceutical and Medical Device Law”**

At the AMDD New Year’s party held on January 17, 2014, the New Year’s greeting by Chairman Takashi Shimada (President of Medtronic Japan Co., Ltd.), and other presenters focused on the “Pharmaceutical and Medical Device Law” that was enacted last November. Mr. Shimada, delivered a speech saying how 2013 was a productive year and that further efforts and cooperation should be made to review the contents of the law in preparation for its enforcement in the future.

Mr. Kiyomi Akaishi, Parliamentary Secretary of Health, Labour and Welfare, also delivered a speech as a guest. He said that the reimbursement for medical services would be revised in 2014, and that more detailed discussions would be made by the Central Social Insurance Medical Council so that a revision could be made based on the innovativeness of medical devices and exemptions on categorized functions. Mr. Andrew Wylegala, Minister in charge of commercial service at the U.S. Embassy, delivered a congratulatory address on the establishment of the “Pharmaceutical and Medical Device Law” and compared it to the American independence. Mr. Samuel Kidder, Executive Director, the American Chamber of Commerce in Japan (ACCJ) stressed in his speech that the U.S.-Japan collaboration would be increasingly vital, anticipating that this year would be a positive year in various aspects such as the TPP and economy. Mr. Koji Nakao, Chairman of the Japan Federation of Medical Devices Associations (JFMDA), expressed his wishes for advancing the entire

industry in collaboration with the JFMDA, AMDD and EBC. Lastly, Mr. Kenichi Matsumoto, President of the Japan Association of Medical Devices Industries, led a cheer to start the 2014 new-year meeting, with guests from every sector of society.



Left: Mr. Takashi Shimada, Chairman of AMDD  
Right: Mr. Kiyomi Akaishi, Parliamentary Secretary

## The 5th AMDD Annual General Meeting Held

AMDD held its 5th annual general meeting on September 12, 2013. In the meeting, Chairman Shimada delivered the opening message and individual committees reported on their activities, which mainly focused on organizing a better environment for the medical device industry, including moving towards revising the reimbursement for medical services planned in 2014.

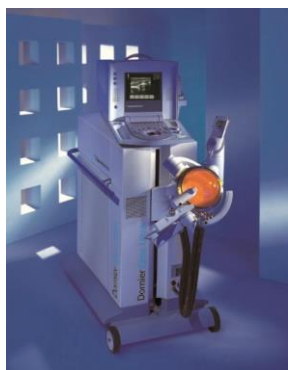
Since Mr. T. Karasawa, Director General for Social Security, the Ministry of Health, Labour and Welfare, was unable to give a special lecture due to some unexpected matters, Mr. Tadayoshi Mizutani, Deputy Director-General for Social Security Office of the Ministry, took the platform instead. His first lecture focused on the constructive discussions between the U.S. and Japan's common goal of speeding up the introduction of innovative medical services to Japan. His second lecture focused on the Integrated Reform of the Social Security and Tax Systems now under discussion. (For details of the Integrated Reform of the Social Security and Tax Systems, see the article contributed by Mr. Karasawa on Page 2.)

### Value of Medical Technology (Diagnostic and Treatment Devices)

#### Extracorporeal Shock Wave Therapy for Pain – ESWT

Through the course of his research on aerospace technology, Mr. Claude Dornier of Germany discovered the properties of shock waves and invented an extracorporeal shock wave lithotripsy (ESWL) device through collaborative research with a medical institution. A shock wave is defined as a pressure wave with many explosions when energy is instantaneously released or accumulated in gas, liquid, or solid matter.

The extracorporeal shock wave therapy is a new therapy in the field of orthopedics, in which extracorporeally generated shock waves are irradiated on the affected part of the patient's body. The use of this therapy has grown mainly in the U.S. and Europe, and has been used to treat pain disorders such as inflammation of the tendon. It is now widely used as a minimally invasive, safe, and effective treatment method. In Japan, the extracorporeal shock wave pain therapy was approved for insurance coverage in January 2012 for intractable plantar fasciitis. Since no alternatives are available except traditional treatments and surgical operations, this new therapy is attracting the attention of many medical sites.



(Shino Taguchi, Dornier MedTech Japan Co., Ltd.)



## AMDD Participated in an Event Conducted by the Aomori and Fukushima Prefectures

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) participated in an event held in the Prefectures of Aomori and Fukushima last October, as part of its activities in collaboration with local governments.

The collaborative event, “Opening Up a New Future through Medical-Industrial Cooperation”, was held at the Aomori International Hotel (in the City of Aomori) on October 18, 2013 in cooperation with AMDD and the Aomori Prefecture. Medical speeches were delivered by intellectuals in industry, government, and academia, in addition to a speech delivered by Mr. Mimura, Prefectural Governor of Aomori, and the keynote address given by Mr. Shimada, Chairman of the AMDD. Presentations and exhibitions introduced the technologies of local companies aiming to enter the medical device market, and relationships were developed between the companies in Aomori and AMDD. In addition, six AMDD member companies: Abbott Japan Co., Ltd, GE Healthcare Japan Corporation, Edwards Lifesciences Ltd., Nippon Becton, Dickinson and Company, Medtronic Japan Co., Ltd., and Johnson & Johnson K.K., delivered presentations and exhibitions to introduce themselves as global manufacturers.

Furthermore, at the “Medical Creation in Fukushima 2013” held on October 30 and 31 in Koriyama, Fukushima Prefecture, AMDD participated as a sponsor similar to last year. At the AMDD booth exhibited at the entrance, the AMDD image video and product slide show were displayed, in addition to the panel exhibition introducing AMDD’s activities and its history of developing advanced medical devices.



Left: The exhibitions at the collaborative event with Aomori Prefecture  
Right: Mr. Shimada, Chairman of the AMDD, and Mr. Mimura, Prefectural Governor of Aomori

### 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.