

An Increasingly Aging World and Expectations for the Medical Device Industry

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The global medical device market, which had a market size of about 400 billion dollars as of 2014, is predicted to grow at an annual growth rate of 6.5 percent from 2011 to 2017. In 2013, all of the top-ranked companies in terms of profit margin and sales in this market were either European or U.S. manufacturers. The environment in which Japanese manufacturers compete with them will be affected by trends in patient care and the health care policy of each government. Another noteworthy factor that affects this environment is the U.S. manufacturing reshoring initiative.

The problems of the health care industry are not limited to rapidly growing health care costs in developed countries. An aging population and worsening health conditions have increasingly become matters of concern not only in developed countries but also in emerging economies. Compared with the pace at which their economies grow, a rapidly increasing number of older populations in emerging economies presents a serious problem.

Against this background, contributions that are required of medical device manufacturers include: (1) lowering the prices of existing products, (2) optimizing the operations of medical institutions and nursing care facilities, (3) developing innovative products and services and (4) improving the effects of preventive medicine. The areas of contribution (3) and (4) above are primarily aimed at developed countries.

Thanks to the American manufacturing reshoring initiative, U.S. medical device manufacturers, which receive support for strengthening technology development capabilities from the U.S. government, are highly likely to achieve technological innovation at an early stage in the areas of (2), (3) and (4) above and gain first-mover advantage. On the other hand, because of bias in the support measures provided by the Japanese government's health care policy, Japanese manufacturers are likely to fall behind their American competitors. In particular, Japan needs to quickly expand and improve measures to support the medical device industry with an eye to supplementing sales functions.

For more comprehensive discussions about the medical device business, please see the July 2014 issue of *Chiteki Shisan Souzou (Knowledge Creation and Integration)* featuring "Iryo-kiki bizinesu ni yoru jigyo seicho wo gensou ni owarasenai tameni (Don't let projected business growth driven by the medical device business end up being a mere dream)" (only available in Japanese).

I Trends in the Global Medical Device Market and the Industry's Business Structure

1 Growth potential in the global medical device market and top medical device manufacturers in terms of revenue

With a market size of about 400 billion dollars as of 2014, the global medical device market is expected to grow at an annual growth rate of 6.5 percent from 2011 to 2017 (Figure 1). In 2013, all of the top 20 companies in terms of revenue were either European or U.S. manufacturers (Table 1). These major manufacturers have overwhelmingly advantageous positions in the market and enjoy high profit margins.

2 The significance of the medical device market for Japanese manufacturers

Because of its high profitability, Japanese manufacturers have long studied entry into the medical device market and repeated the process of trial and error. Given sweeping changes in the revenue structure of markets such as electronics that have been their traditional sources of revenue, the importance of the medical device market for Japanese manufacturers may grow, but will never decline.

Nevertheless, Japanese manufacturers are likely to face many challenges in their quest to earn high profits in this market. In an attempt to offer suggestions for Japanese medical device manufacturers, this paper explains the macroscopic trends of the health care industry and describes changes in the competitive environment. Following this paper are four other papers that were written for the same purpose in the July 2014 issue of *Chiteki*

Shisan Souzou (Knowledge Creation and Integration), which features the medical device business. The positioning of these five papers is illustrated in Figure 2.

3 Structure and business characteristics of the health care industry

Figure 3 provides an overview of the health care industry including medical devices. Centering on medical institutions (primary markets of medical devices), this industry is so structured as to give rise to industrial changes where all players interact with each other, including patients, the government of each country, manufacturers and service vendors.

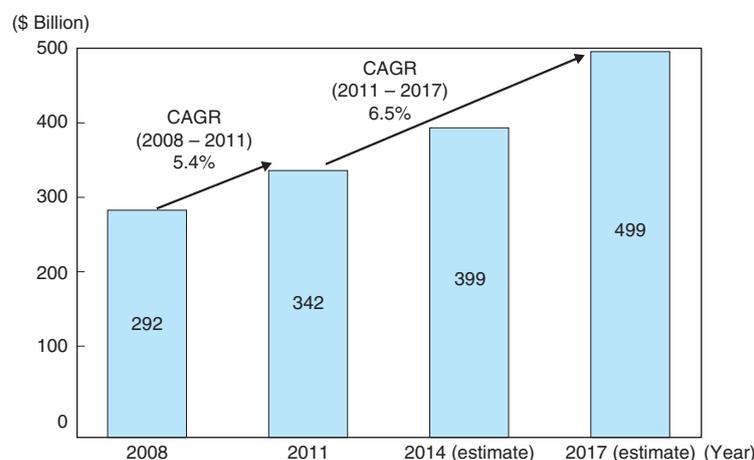
Manufacturers in the health care industry refer to those companies that develop, produce and sell “products that are subject to approval and permission required under the Pharmaceuticals and Medical Devices Law” from among “products that are sold primarily to medical institutions.” These manufacturers are divided into two groups: “pharmaceutical manufacturers” that mainly handle pharmaceuticals for treatment, vaccines, etc. and “medical device manufacturers” that handle products other than those handled by pharmaceutical manufacturers.

The general business format of these medical device manufacturers is that they offer not only their own products but also consumables. In some cases, they also offer related pharmaceuticals and information technology (IT) systems. Therefore, when discussing the medical device industry, it is not realistic to focus only on segmented markets such as “only devices” or “only consumables.”

The products and services handled by medical device manufacturers include:

- Conventional devices that are generally associated with the term “medical devices” such as magnetic

Figure 1. Growing global medical device market



Note: CAGR = compound annual growth rate.

Sources: Espicom Business Intelligence, “Medistat Worldwide Medical Market Forecast to 2017,” Frost & Sullivan, “Analysis of the Global In Vitro Diagnostics Market, April 2013”.

Table 1. Top 20 medical device manufacturers in terms of revenue

	Name of company	Location of head office	Outline of medical device and related product manufacturing business (2013)			
			Sales (\$ Billion)	Profit margin	CAGR of sales ^{Note 1} (2010 – 2013)	Main products/services
1	Johnson & Johnson	U.S.	28.5	18%	5.0%	Orthopedic supplies, surgical systems and instruments, specimen examination reagents and devices, vision care, etc.
2	Fresenius SE & Co. KGaA	Germany	28.0	15%	9.4%	Dialysis devices, medical care services such as dialysis centers, operating hospitals, etc.
3	Siemens Healthcare	Germany	18.4	15%	2.9%	Diagnostic imaging equipment, IT (information technology) systems, etc.
4	GE Healthcare	U.K.	18.2	17%	2.5%	Diagnostic imaging equipment, IT systems, products for research and development, etc.
5	Medtronic	U.S.	16.6	27%	1.6%	Endovascular treatment devices, diabetes therapy products/systems, orthopedic devices and consumables, surgical instruments, etc.
6	Baxter International	U.S.	15.3	17%	5.9%	Infusion and transfusion devices, dialysis products, biomaterials, etc.
7	Philips Healthcare	Netherlands	13.2	14%	4.6%	Patient monitoring systems, diagnostic imaging equipment/system, equipment and systems for obstetric care and newborn babies, hospital IT systems, etc.
8	Hoffmann-La Roche	Switzerland	11.7	21%	1.7%	Specimen examination reagents and devices, IT systems, etc.
9	Alcon (Novartis Pharma)	U.S.	10.5	22%	13.5%	Ophthalmic surgical products, eye drops, contact lenses, etc.
10	Covidien	Ireland, U.S.	10.2	21%	6.6%	Surgical devices, endovascular treatment devices, patient monitoring equipment, etc.
11	Abbott Laboratories	U.S.	10.1	19% ^{Note 2}	1.2%	Endovascular treatment devices, specimen examination devices and reagents, etc.
12	Cardinal Health	U.S.	10.1	4% ^{Note 3}	4.8%	Infusion and transfusion devices, disposable products, general consumables, logistics services for medical devices for clinical departments
13	Stryker	U.S.	9.0	14%	7.2%	General surgical instruments, orthopedic devices, etc.
14	Danaher	U.S.	9.0	15%	29.5%	Specimen examination devices and reagents, dental fillings, dental treatment and examination apparatuses
15	Becton Dickinson	U.S.	8.1	12%	3.0%	Infusion and transfusion devices, syringes, specimen examination reagents, devices and systems, etc.
16	Boston Scientific	U.S.	7.1	2%	-2.9%	Surgical devices, endovascular treatment devices, etc.
17	B. Braun Melsungen	Germany	7.1	9%	6.3%	Infusion and transfusion devices, syringes, sutures, surgical devices, dialysis devices and systems, dialysis centers, etc.
18	Essilor	France	7.0	17%	10.2%	Ophthalmic lenses, eye examination devices, etc.
19	St. Jude Medical	U.S.	5.5	19%	2.1%	Endovascular treatment devices, pacemakers, cardiac surgery products, etc.
20	3M Health Care	U.S.	5.3	31%	5.7%	Dental materials, dental treatment and examination apparatuses, surgical tapes, DDS (drug delivery systems), orthopedic devices, health information systems, etc.
Highest rank among Japanese manufacturers	Terumo	Japan	4.3	13%	8.0%	Orthopedic consumables, endovascular treatment devices, etc.

Notes: 1) CAGR = compound annual growth rate. 2) Operating profit in diagnostics and vascular segments as a percentage of total sales in diagnostics, vascular and other segments. 3) Performance of the medical device segment including logistics and manufacturing businesses.

Sources: Compiled based on the investor relations (IR) material of each company.

resonance imaging (MRI) scanners and artificial hearts

- Consumables and non-mechanical devices that are conventionally called “medical supplies” such as

disposable catheters used for endovascular treatment and dental materials (dental fillings, etc.)

- Devices, consumables and non-mechanical devices used in new technologies such as tissue culture

Figure 2. Positioning of five papers in the July 2014 issue of *Chiteki Shisan Souzou (Knowledge Creation and Integration)*

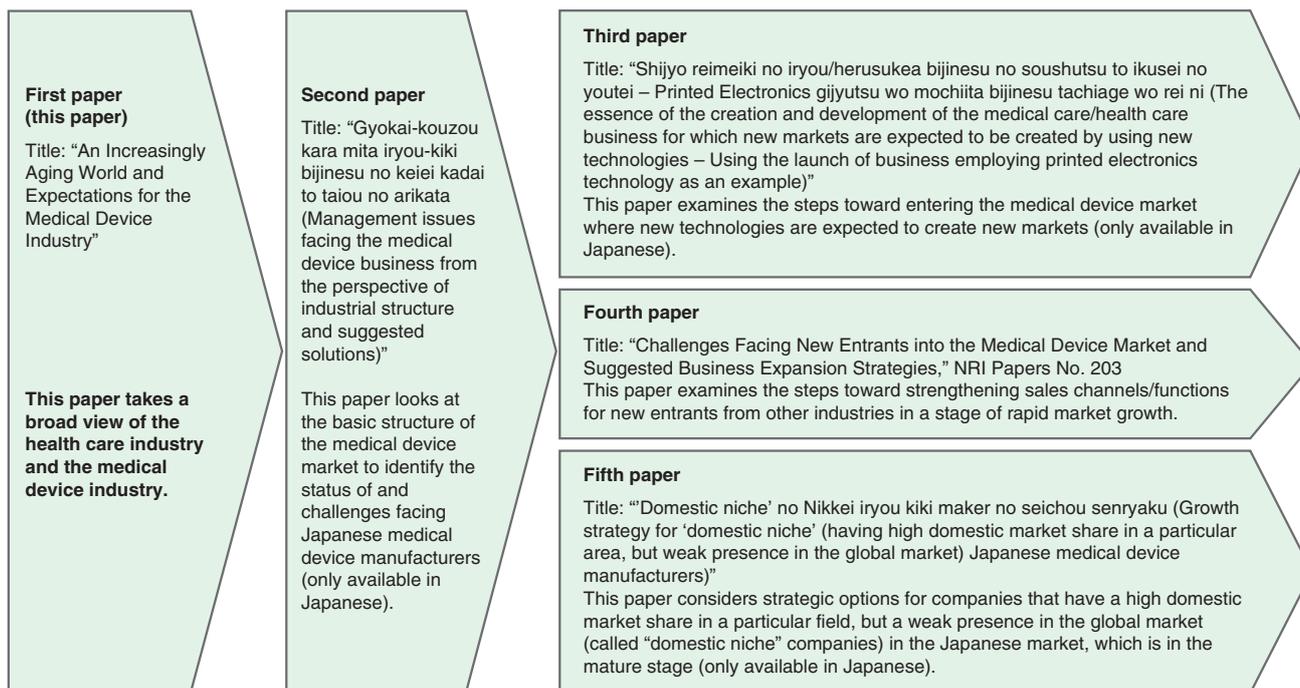
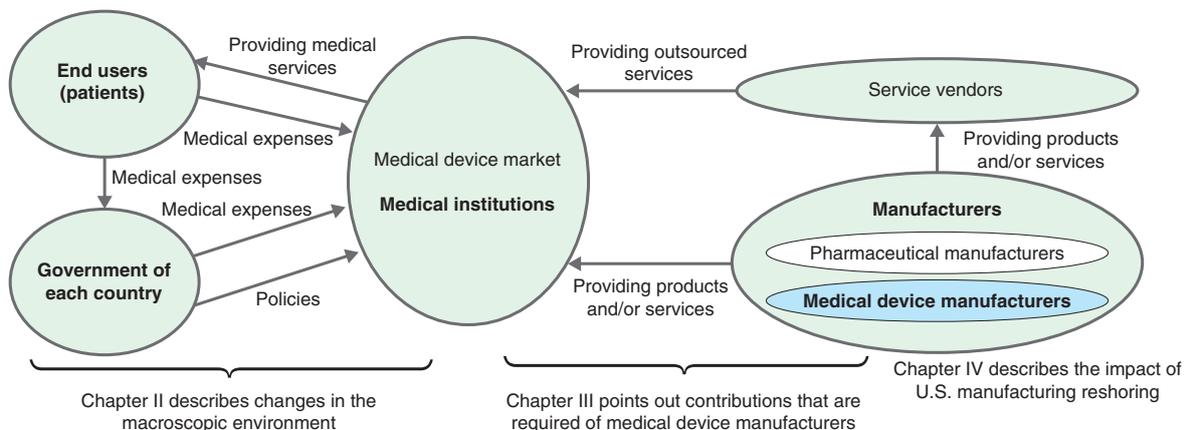


Figure 3. Basic structure of the health care industry and links with Chapters II, III and IV of this paper



equipment and supplies used for regenerative medicine

- In addition to analytical instruments for specimen examination, diagnostic reagents exclusively used for relevant analyses and IT systems
- Pharmaceuticals purchased by users who use the above-mentioned medical devices
- Medical services handled by medical device manufacturers

In Chapter II, the authors discuss the challenges facing the health care industry by looking at changes in the macroscopic environment, in particular, the trends in the medical institutions that are affected by the problems

encountered by patients and the government of each country.

In Chapter III, contributions that are required of medical device manufacturers in view of these challenges are discussed, and activities of major medical device manufacturers in an effort to address such challenges are introduced.

Chapter IV describes the US manufacturing reshoring initiative, which is a factor that significantly affects the future competitive environment. Changes that this initiative would bring about to the competitive environment of the global medical device industry are predicted in an attempt to provide suggestions for Japanese manufacturers.

II Increasingly Aging Populations and Worsening Health Indicators throughout the World

1 Aging is an issue common to both developed countries and emerging economies

Coupled with declining birth rates, the increase in longevity, resulting from many new developments in medical technologies, improvements in living conditions and economic growth has been accelerating the global trend in population aging.

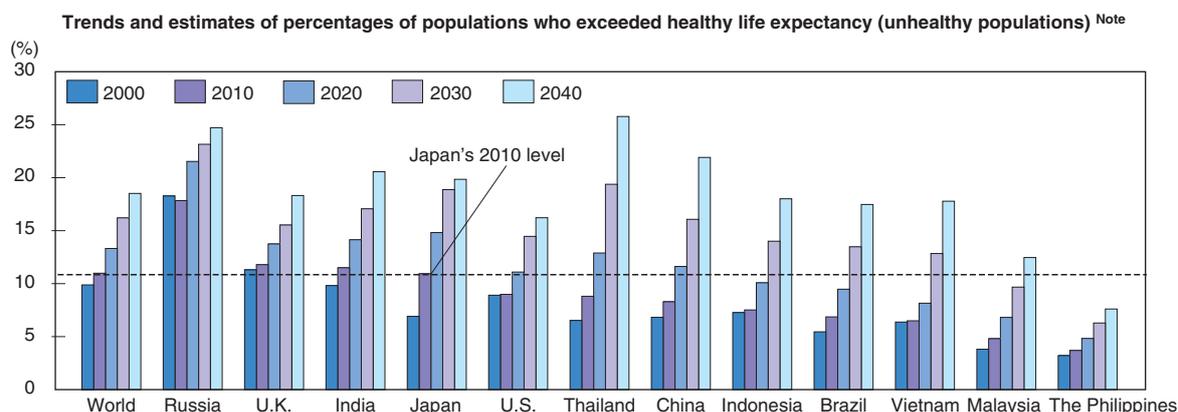
As one of the indicators of the “age at which health status apparently deteriorates,” the World Health Organization

(WHO) has defined and estimated “healthy life expectancy” by country. Healthy life expectancy refers to the number of years that people can expect to live their daily lives independently without the need for nursing care. Let’s look at this indicator for international comparisons.

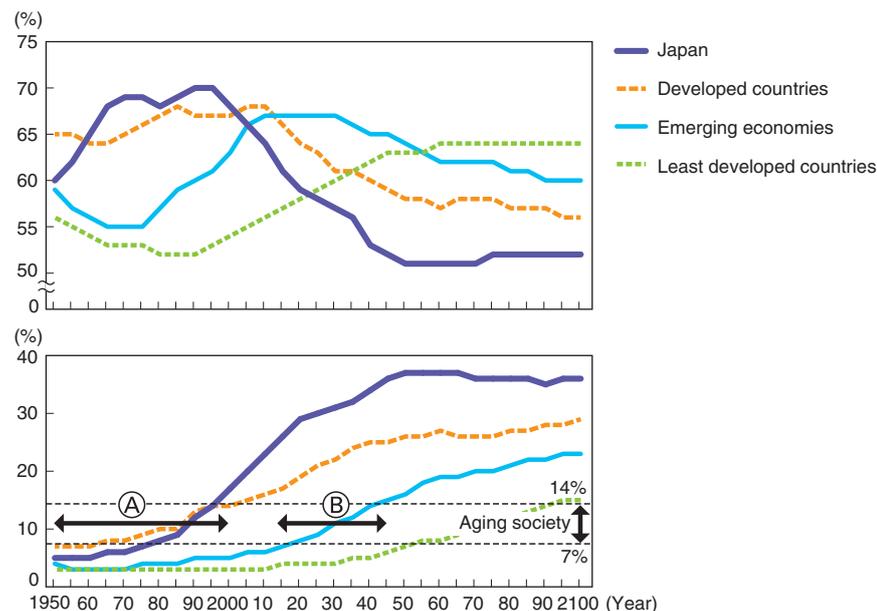
The bar graph in Figure 4, which shows “trends and estimates of percentages of populations who exceeded healthy life expectancy (defined as unhealthy populations in this paper),” reveals that the potential demand for some kinds of medical services or for nursing care has grown to the level of Japan, even in emerging economies.

As of 2010, the countries that exceeded the level of Japan (as shown by a broken line in the bar graph of Figure 4) were Russia, the UK and India in the order of advance in population aging. In these three countries, the proportion of unhealthy population exceeded 10 percent as of 2010. As of 2030, Thailand and Russia are

Figure 4. World’s aging populations and decline in ratio of working-age populations



Trends and estimates of population indices
 Upper graph: Proportion of working-age population (aged 15 – 64 years)
 Lower graph: Proportion of elderly population (aged 65 years and over)



Note: Healthy life expectancy at birth in the year 2000 was the basis for estimates.
 Source: Compiled based on the United Nations “Demographic Projections (Medium Variant Projections).”

expected to exceed the level of Japan. In addition, many emerging economies are projected to reach the 2010 level of Japan (11 percent) by 2030.

2 The proportion of working-age population has been decreasing around the world

On top of such a trend towards a rapidly aging population, the proportion of working-age population who support elderly people with unhealthy status has been decreasing throughout the world. In Japan, the proportion of working-age population aged 15 – 64 years is projected to continue to decrease and fall as low as 51 percent by 2055 (upper line graph of Figure 4), constituting a super-aged society with the highest proportion of elderly population in the world.

By 2020, on average, the proportion of working-age population in other developed countries is also projected to decrease to the 2010 level of Japan (64 percent).

Here, particularly noteworthy is the trend in emerging economies. The proportion of working-age population that was growing steadily is expected to peak in 2015 and will begin to decline, even in emerging economies. Another noticeable fact is that while developed countries took about 50 years to pass through a period of an “aging society” (the proportion of population aged 65 and over is 7 – 14 percent), which is shown as Period (A) in the lower line graph of Figure 4, emerging economies are projected to take only 30 years from 2015 to 2045 to go through such a period, shown as Period (B) in the same graph. This projected trend presents

challenges to emerging economies in that they must evolve welfare policies such as those for medical services and nursing care in a short period of time and with financial conditions that are highly likely to deteriorate, unlike those in the past.

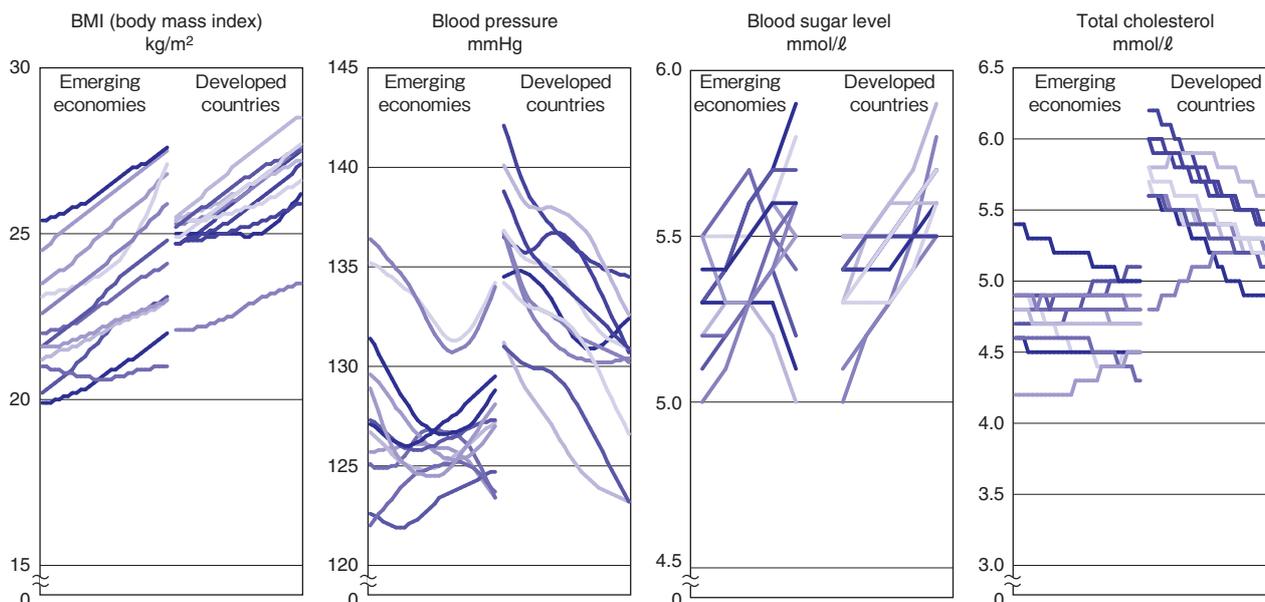
3 Emerging economies face a worsening trend of health status

Figure 5 shows changes in the following indices of lifestyle-related diseases for 1980 – 2009 to make comparisons between developed countries and emerging economies: body mass index (BMI), blood pressure, blood sugar level and total cholesterol.

In developed countries, while the indices of BMI and blood sugar level have been worsening, blood pressure and total cholesterol have been improving. However, in emerging economies, all of these indices show a worsening trend.

Even if these indices worsen, such a trend does not necessarily lead to an immediate risk of developing serious symptoms that hinder daily life. Currently, in emerging economies, the proportion of patients suffering from cardiovascular disease in the total population is lower than that in developed countries. Nevertheless, it is highly likely that the number of patients who need medical services will increase some day. Such increase will lead to people exerting pressure on the government to enhance medical services as well as to medical expenditures increasing at a rapidly accelerating rate.

Figure 5. Changes in health status indicators (metabolic syndrome risk factors) to make comparisons between emerging economies and developed countries for 1980 – 2009



Notes: 1) For indices other than blood sugar level, values for each year from 1980 to 2009 were used; for blood sugar level, values for 1980, 1987, 1994, 2001 and 2009 were used. 2) Because these graphs are intended to make comparisons between emerging economies and developed countries, the names were not indicated. Emerging economies consist of Argentina, Brazil, China, India, Indonesia, Malaysia, Mexico, the Philippines, South Korea, South Africa, Thailand and Turkey. Developed countries consist of Australia, Canada, France, Germany, Italy, Japan, Norway, Russia, Spain, the U.K. and the U.S.
Source: Compiled based on statistics published by the World Health Organization (WHO).

4 Challenges facing developed countries: Controlling medical costs and developing ways to generate funds for nursing care

Given a continuous decline in the proportion of the working-age population, major challenges that developed countries must address include restraining rapidly increasing medical expenses and devising ways to generate funds for nursing care.

Figure 6 shows changes in medical costs as a percentage of gross domestic product (GDP) in developed countries. Except for the U.S., spending on health care as a share of GDP has hovered below 12 percent in the other developed countries listed in Figure 6. This line graph reveals that these countries all face the situation where they are unable to increase medical spending above these levels even if the number of older people requiring medical services increases further. If that number continues to increase, medical spending per elderly person must be held in check. The major issue pertaining to this situation is to achieve fair and reasonable medical charges to prevent excessive rises in medical costs.

At the same time, appropriate measures for a growing number of elderly people requiring nursing care are essential. Another challenge facing developed countries that see their nursing care expenditures go up is how to enhance infrastructure related to nursing care with limited funds, while curbing medical expenditures.

5 Challenges facing emerging economies: Developing real medical infrastructure in preparation for an aging society

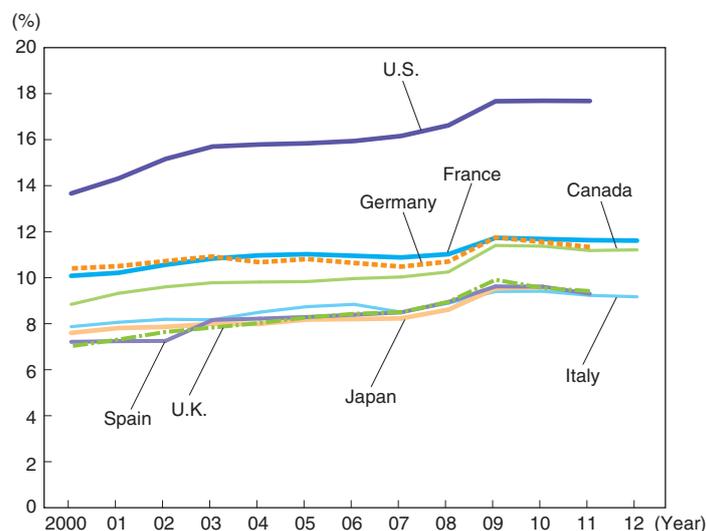
The challenges that emerging economies must address are more complicated than are those of developed countries.

Because medical technologies that are commonly available in developed countries have not yet been fully distributed in emerging economies, the mortality rates for causes other than “cardiovascular disease” and “cancer” are still at high levels (Figure 7). The actions currently needed to address this situation include enhancing medical infrastructure (increasing the number of medical institutions and facilities as well as the number of health care professionals including physicians) and improving access to medical services (creating an environment where all people can receive medical services). By virtue of the measures actively taken for deregulation such as enabling the participation of private and foreign companies in the operation of medical institutions and permitting medical treatment not covered by insurance, the levels of emerging economies have been coming close to those of developed countries in terms of number of physicians and number of hospital beds. However, these countries lag behind in the dissemination of medical devices for treatment.

One of the causes for delay in developing medical infrastructure is attributable to the high cost of existing medical technologies that are commonly available in developed countries. Given current economic levels, even if medical guidelines were to be developed and many physicians were to attain levels of knowledge that would enable them to use treatment techniques similar to those used in developed countries, the number of patients who are able to pay the high medical costs that are equivalent to those in developed countries would be limited.

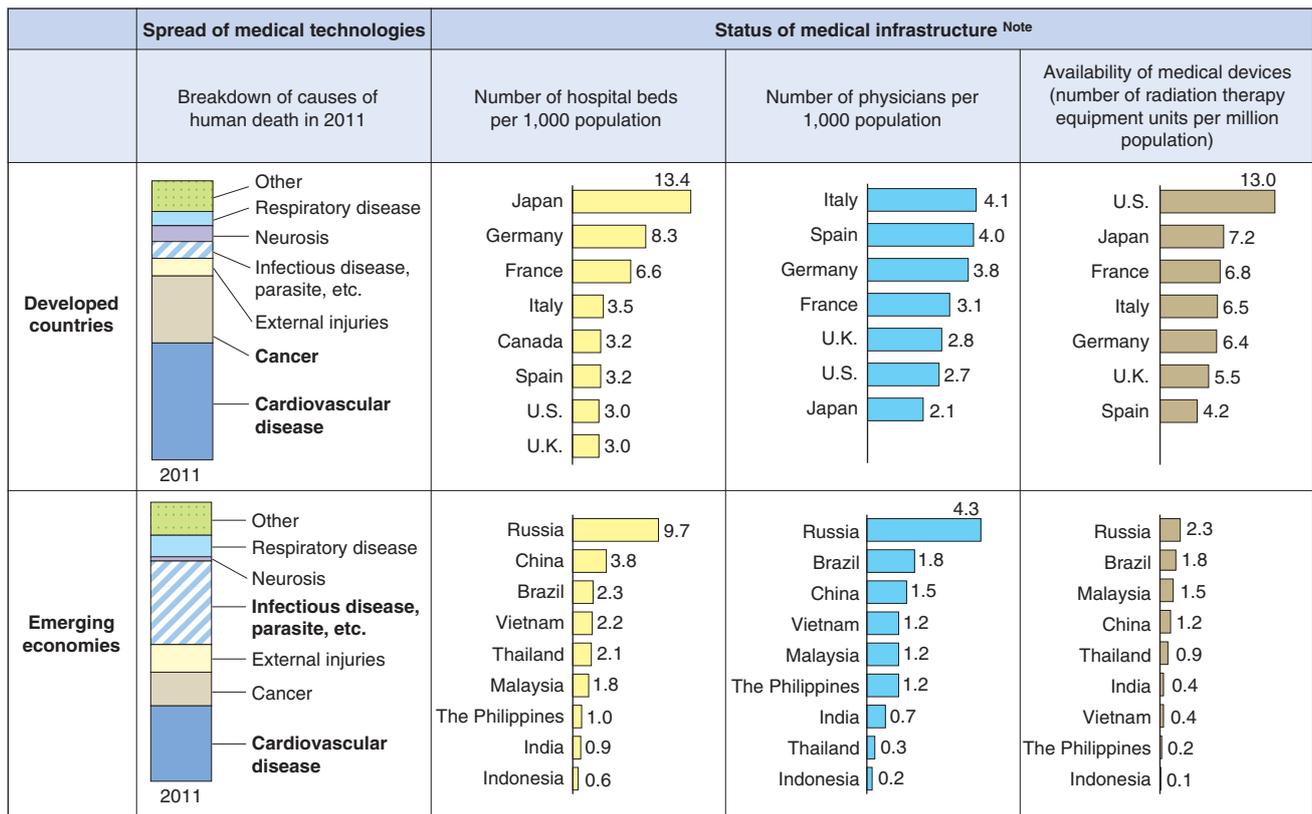
Furthermore, to achieve growth, the health care industry of emerging economies must pay attention to the time needed to develop medical/nursing care infrastructure, which is urgently required to address a rapidly growing aging population. Despite their relatively low economic levels, emerging economies are experiencing

Figure 6. Changes in medical costs as a percentage of gross domestic product (GDP) in developed countries



Source: Compiled based on OECD.Stat data for developed countries.

Figure 7. Health care in developed countries and emerging economies: Current status and background factors



	Economic level	Proportion of elderly population	
	Per capita spending on health care in 2011 (\$)	Proportion of unhealthy population in 2010 (%)	
Developed countries			
Emerging economies			

Note: Data available for 2004 – 2012 were used.

Source: Compiled and estimated based on statistical data published by WHO and the Organization for Economic Cooperation and Development (OECD).

acceleration in the pace at which the number of elderly people is increasing. Therefore, efforts must be made to significantly restrain medical spending per elderly person over the long term. At the same time, spending on health care as a percentage of GDP will increase at an earlier stage than it did in developed countries, which is highly likely to put pressure on government finances.

Assuming these situations, emerging economies would have no time to construct new medical institutions that require large amounts of investments and to repeat the process of trial and error involving scrap and build approaches. They must develop medical/nursing care infrastructure that is affordable within their economic capabilities quickly and without failure.

III Contributions Required of Medical Device Manufacturers

Given the issues facing developed countries and emerging economies as explained in Chapter II, the contributions that medical device manufacturers should provide can be classified into the following four areas (Figure 8).

- (1) Lowering the prices of existing products
- (2) Optimizing the operations of medical institutions and nursing care facilities
- (3) Developing innovative products and services
- (4) Improving the effects of preventive medicine

1 Lowering the prices of existing products

One of the measures adopted to restrain medical costs in developed countries is to lower the prices of existing medical devices and pharmaceuticals. For example, activities are widespread for medical institutions to form a joint procurement organization (known as a group purchasing organization (GPO) in the U.S.) to leverage the purchasing power of the organization to obtain discounts on products (medical devices, pharmaceuticals, etc.). In particular, in the areas of mature technologies,

lower-priced products have been actively introduced. A typical example is a government effort to promote the widespread use of generic drugs. Medical device and pharmaceutical manufacturers and distributors will continuously find themselves under pressure to cut prices for products based on such existing and mature technologies.

Furthermore, because the high prices of existing technologies and products constitute a bottleneck to the development and widespread use of real medical infrastructure in emerging economies, their needs for cutting prices are strong and deep-rooted.

2 Optimizing the operations of medical institutions and nursing care facilities

The left pie chart in Figure 9 is a breakdown of hospital costs, and reveals that personnel expenses such as wages account for more than half. The issue of high labor costs is also prominent in nursing care facilities, making the saving of labor costs a major challenge common to both medical institutions and nursing care facilities. Even with innovative breakthroughs in therapeutic and diagnostic technologies, it is not possible to improve the efficiency of on-site operations. Efforts are being made to find other means to optimize such operations.

One of the initiatives that have already been implemented for this purpose is the introduction of information technology (IT) in the health care industry. In the U.S.,

Figure 8. Contributions required of medical device manufacturers

Contributions required of manufacturers (Lower row: Advantages to users)	Major markets	Specific products/services and manufacturer activities
1. Lowering the prices of existing products ----- Reduced purchase prices of medical devices and pharmaceuticals	Developed countries and emerging economies (aimed at wealthy consumers) Emerging economies	Reuse support services for used and disposable medical devices, generic drugs, biosimilar drugs, strengthening structure for transactions with GPOs, localization in emerging markets, reverse innovation, use of CRO and CMO
2. Optimizing the operations of medical institutions and nursing care facilities ----- Reduced labor costs		Introducing IT systems with connections inside and outside medical institutions, using drug delivery systems (DDS) as part of modified dosage forms, home care monitoring and notification sensing systems (printed electronics, etc.), power-assist robots for nursing care, improving hospital operation by RFID tags, IT systems for medication administration management, telemedicine systems
3. Developing innovative products and services ----- Dramatically reduced total costs for medical devices, pharmaceuticals and labor		Minimally invasive therapy, personalized medicine, regenerative medicine, robotic surgery
4. Improving the effects of preventive medicine ----- Lowered risk of developing disease, reducing the burden of health care costs in the future		Use of biosensors (printed electronics, etc.) and big data for health monitoring and management services and telemedicine systems

Notes: CRO = contract research organization, CMO = contract manufacturing organization, GPO = group purchasing organization, RFID = radio frequency identification.

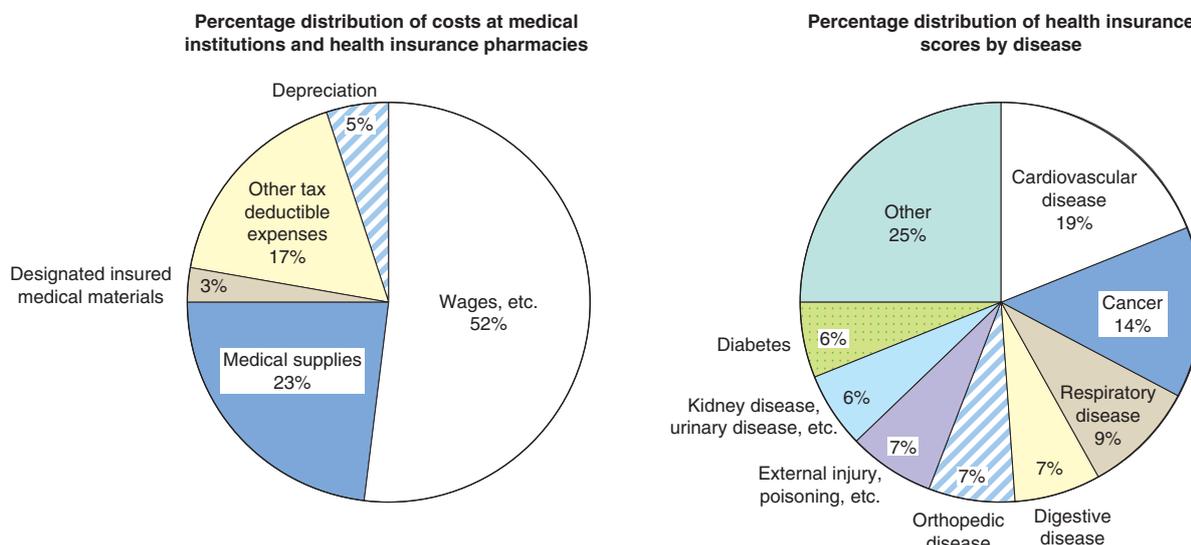
as part of the Obama administration’s health care policy, the “Health IT” initiative is being promoted. This program intends to restrain medical expenditures by optimizing on-site medical operations and by requiring medical institutions to introduce an IT system to share patient information among health care professionals and across medical institutions.

Furthermore, as shown in Figure 10, many developed countries tend to spend more for in-home care than for care in a facility. It is reasonable to assume that the aim behind this tendency is to reduce labor costs that account for a large proportion of total spending on nursing care by making greater investments in developing nursing care infrastructure that relies on “free (unpaid) caregivers” within a person’s family.

The need for the optimization of on-site operations has not yet become apparent as a major challenge in emerging economies. Nevertheless, even in these countries, because they have only limited time for the development of infrastructure, they are expected to introduce new technologies in their still-early stages on a trial basis and to quickly improve operational efficiency after going through the verification of the possibility of deploying such technologies in their own countries.

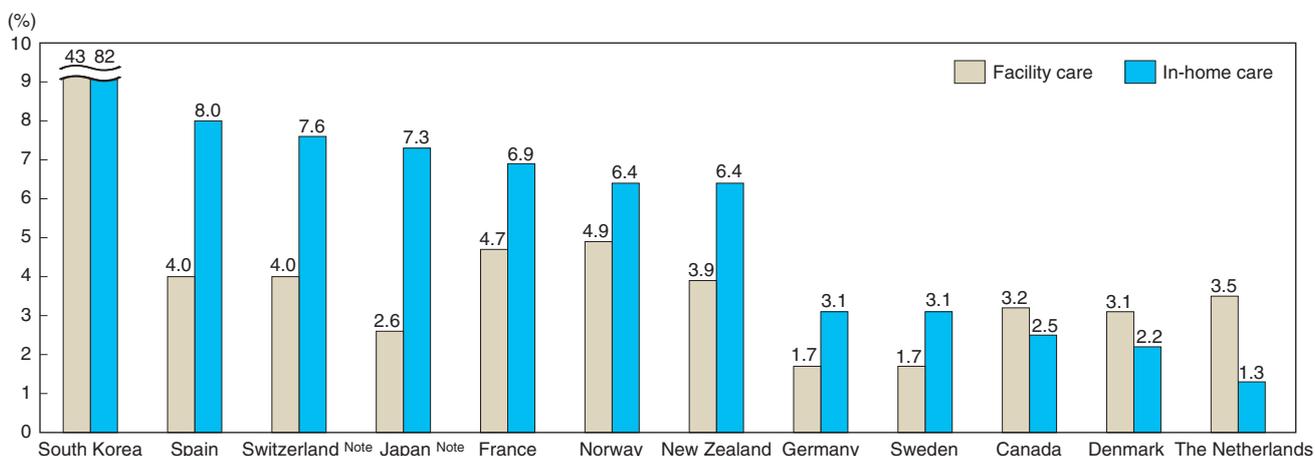
Technologies that are expected to contribute to reductions in labor costs include sensor systems, robots and remote (home care) medical systems, which lead to improved work efficiency of on-site health care staff members. In particular, high expectations are placed on telemedicine as a means of providing medical services

Figure 9. Percentage distribution of health care costs and health insurance scores in Japan



Sources: Left pie chart: Material for 2013 published by the Central Social Insurance Medical Council of Japan. Right pie chart: “Survey of Medical Care Activities in Public Health Insurance 2012,” statistical survey conducted by Japan’s Ministry of Health, Labor and Welfare.

Figure 10. Average annual rate of increase in spending on nursing care in developed countries (2000 – 2011) by type of care



Note: For Switzerland, increase rates are for 2008 – 2011; for Japan, they are for 2000 – 2010.
Source: OECD statistics.

with considerably low capital investment and at a low ratio of labor costs as compared to constructing a conventional medical institution. Because telemedicine also makes it possible to provide medical services beyond country borders, this technology warrants great expectations for developed countries facing the formidable challenge of managing rapidly growing health care costs.

3 Developing innovative products and services

The right pie chart in Figure 9 is a breakdown of spending on health care by disease, and reveals that “cardiovascular disease” and “cancer” account for a large proportion at 33 percent. For the diagnosis and treatment of these diseases that are ranked high in terms of spending, there is a growing demand for innovative alternative technologies that can contribute to the reduction of total costs including labor costs.

Promising technologies in this regard include minimally invasive therapy (this is a general term for treatments that reduce a patient’s physical burden as compared to conventional methods), personalized medicine and regenerative medicine. While these technologies are not related to lowering the unit price of existing pharmaceuticals and medical devices, such technologies lead to a significant reduction in the labor costs of health care staff members, thereby cutting total costs.

For example, endovascular surgery, which is a form of minimally invasive surgery, involves making small incisions in the limbs through which catheters are inserted for treatment. Because this therapy does not involve surgical operations to open the chest, abdomen or skull, which cause considerable physical burden on the patient, it leads to faster patient recovery with shorter hospital stay after surgery. As such, the technology

contributes to the restraint of overall health care costs including labor. In developed countries, various forms of minimally invasive therapeutic approaches including the above-mentioned endovascular therapy are now being increasingly adopted, with the length of hospital stay being reduced.

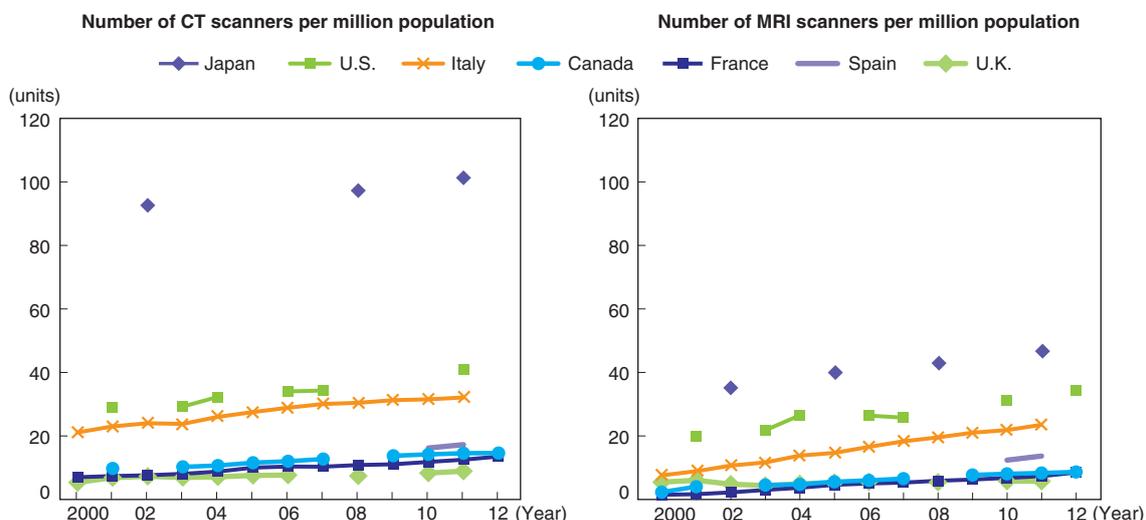
The needs for such technological innovation will never be abated as long as we live in a society with an ever-growing number of elderly people and where managing health care costs per patient constitutes a major problem.

4 Improving the effects of preventive medicine

In developed countries, efforts are also being made to reduce the number of patients by giving greater emphasis to preventive medicine, thereby restraining overall health care costs. The number of diagnostic imaging equipment units that are in use, such as computed tomography (CT) and magnetic resonance imaging (MRI), has been continuously growing in developed countries, indicating ongoing enhancement of health checkup infrastructure to promote preventive medicine (Figure 11).

Nevertheless, as explained in Chapter II, some health indices (BMI and blood sugar level) still show a worsening trend in developed countries. For the improvement of such indices, effective preventive services must be developed and distributed. For example, measures to prevent lifestyle-related diseases and similar diseases include the provision of health management services and the development of related technologies. Other measures involve the development and practical application of technology for early disease detection and telemedicine services for people who do not have easy access to medical services.

Figure 11. Changes in the number of diagnostic imaging equipment units in use in developed countries



Notes: CT = computed tomography, MRI = magnetic resonance imaging. Source: OECD statistics.

To enable the widespread use of preventive medicine technology, major challenges involve not only technological development but also securing financial resources (health insurance coverage must be expanded to include preventive care and health insurance societies need to allocate a budget for preventive care). The U.S. has been going through a trial and error process to practically use health management services and telemedicine. While the lack of health insurance coverage is considered a bottleneck blocking the popularization of preventive care, there are already some cases enabling the coverage of part of those services by health insurance in the U.S.

5 Major manufacturers responding to the needs for both price reduction and technological innovation

From the perspective of manufacturers, the four areas of contributions as described at the beginning of Chapter III, which are required of medical device manufacturers, can be summed up in two areas, i.e., “lowering the prices of existing products” (Item (1)) and “technological innovation” (Items (2) to (4)), which enables the provision of new added value. Major medical device manufacturers emphasize enhancement of their technological innovation capabilities. At the same time, they are responding to increasing pressure to lower prices that they have never experienced before in order to remain competitive with their existing products, which currently constitute a main source of revenue. Some of the activities of major manufacturers working for this purpose are introduced in the following paragraphs.

(1) Responding to pressure to reduce prices

In their efforts to reduce the prices of existing products, Boston Scientific and Covidien, medical device giants, have either curtailed or sold their manufacturing operations, and outsourced these operations to contract manufacturers. GE Healthcare was able to reduce the prices of some of its products to one-seventh by transferring its development and manufacturing functions to emerging markets. Fresenius, a manufacturer of dialysis equipment and large dialysis systems, adopted the strategy of making the best use of the high functionality of its medical devices by operating dialysis centers and hospitals. By showing other hospitals how to offer medical services in such a way as to generate profits, the company is attempting to avoid price competition.

As such, there are quite a few major manufacturers that take the market demand for lower prices as a management issue and work to satisfy such need.

(2) Enhancing technological innovation capabilities

Rather than improve or localize existing products, 3M Health Care plans to shift its focus of investment in

research and development to the development of highly innovative products.

In addition to its 20 research and development (R&D) centers, Covidien established four new facilities, three of which are located in Europe and the U.S.

In 2013, Johnson & Johnson opened four innovation centers (three in Europe and the U.S. and one in China). These facilities were established for the purpose of promoting joint development and business creation particularly with local start-up companies, and include a merger and acquisition (M&A) team in addition to a research staff.

IV The U.S. Manufacturing Reshoring Initiative and the Future of the Medical Device Industry

1 The U.S. initiative aims at enhancing innovation capabilities

The U.S. manufacturing reshoring policy primarily aims at incorporating stable, high added value that can be brought about by manufacturing functions into the country’s GDP. Among such functions, focus is placed on the markets of “process-driven innovation” where it is easy to conceal the manufacturing process in a “black box” and thus, manufacturing functions are unlikely to flow overseas (Figure 12). In the medical device industry, new markets being created by new technologies fall under this category. Specifically, they include regenerative medicine and printed electronics. When a market created by such technology starts to grow, the objective of the policy is to retain critical manufacturing functions within the country and to promote the sales of products throughout the world. For this purpose, the policy supports technology development activities that facilitate market creation by U.S. manufacturers. The core areas for which support is provided consist of the following four.

- (1) Preferential tax treatment: Expanding research and development tax credit, reducing the effective tax rate, etc.
- (2) Support for research and development activities: Expanding a company’s budget for research and development, support for innovation clusters, giving priority to the repair of research facilities
- (3) Support for the expansion of activities in overseas markets: Promoting the protection of intellectual property rights in global markets
- (4) Support for human resource development: Support for education with a focus on science, technology, engineering and mathematics; support for the education of technical human

resources needed by manufacturing at educational institutions, etc.

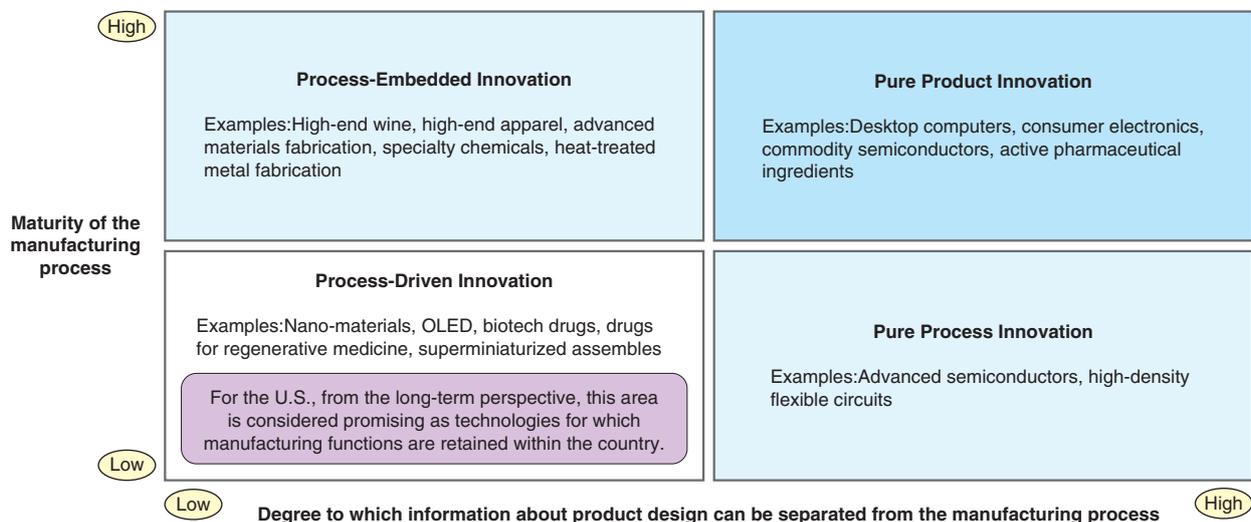
2 Strengthening U.S. manufacturing competitiveness toward the creation of new markets by using new technologies

The impact of the U.S. policy for manufacturing reshoring on the medical device industry will be felt in the form of further increasing competitiveness of U.S. manufacturing, which is already the “largest” in the world (Figure 13).

Actually, major U.S. medical device manufacturers are actively incorporating research and development functions and external technologies that are available within

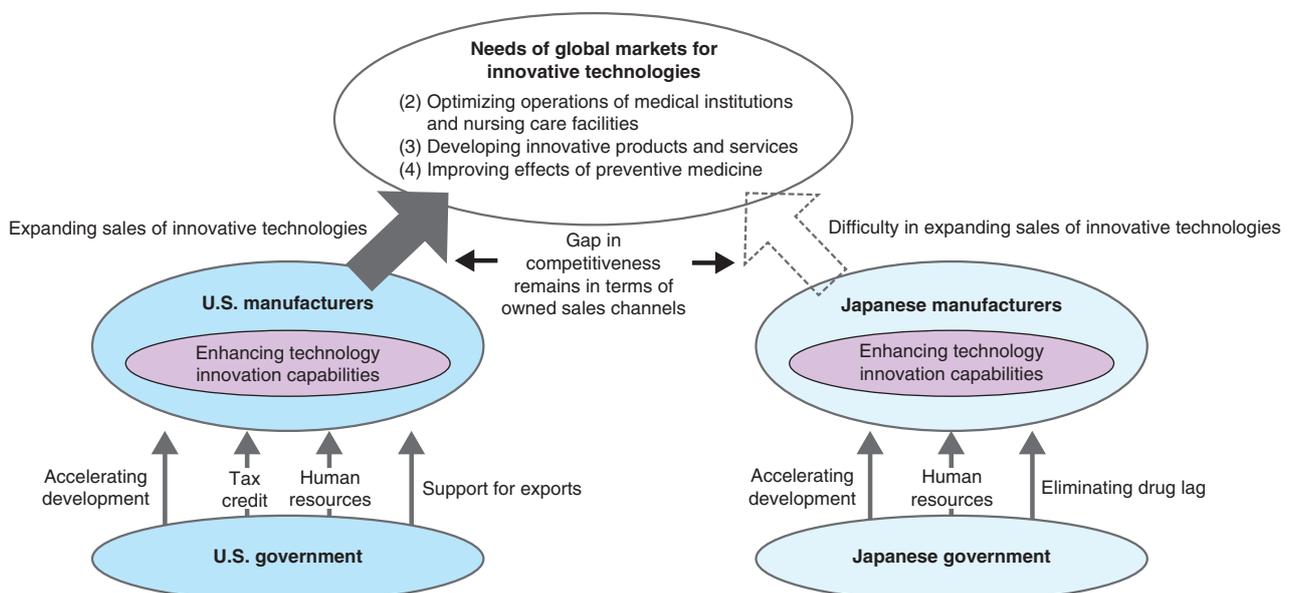
the U.S. The strategies behind these moves consist of not only quickly entering a new market and expanding that market ahead of competitors but also expediting market creation by skillfully leveraging U.S. government policies. These manufacturers have already drawn clear blueprints for enjoying high profitability by succeeding in technology innovations ahead of competitors and retaining manufacturing functions in the form of a black box within their companies. Traditionally, the strengths of U.S. manufacturers have been in their high capabilities of technology development, which have been enabled by their huge investment abilities. Their strategies will make such strengths even more overwhelming. A major challenge facing Japanese manufacturers, which are highly likely to fall behind their American competitors, is what

Figure 12. Four important areas of the U.S. manufacturing reshoring initiative



Note: OLED = organic light emitting diodes.
 Source: Gary P. Pisano, Willy C. Shih, “Does America Really Need Manufacturing?,” *Harvard Business Review*, March 2012.

Figure 13. Impact of U.S. manufacturing reshoring initiative on global medical device industry



Note: The numbers above correspond to the numbers assigned to the core areas of the U.S. policy described in Section 1.

survival strategies they develop and implement in response to these moves.

3 Japan's highly biased support policy

In Japan as well, policy support for the medical device industry has been expanding. Nevertheless, it is hard to say that specific support measures are adequate for Japanese manufacturers. As part of the Japan Revitalization Strategy, Japan's Cabinet Office established the Headquarters for Healthcare Policy to provide support for the medical device industry. In concert with this policy, the Ministry of Economy, Trade and Industry and the Ministry of Health, Labor and Welfare have each been implementing measures to support this industry.

Japan's policy support that centers on the promotion of technology development and the elimination of drug lag appears to be comparable to U.S. policy support. However, as explained in Chapter I, no Japanese manufacturers ranked in the top 20 in terms of revenue in 2013. In addition, there is a major gap between Japanese and U.S. manufacturers in terms of owned resources (customer base, expertise in responding to regulations in each country, investment abilities, etc.). In particular, most Japanese manufacturers have not yet been able to establish sales channels providing access to users including medical institutions on a global scale. Because major U.S. manufacturers have already established strong global sales channels with their country-specific sales expertise, they are able to expand product sales relatively easily once they launch new products. In contrast, it is predicted that expanding product sales is very difficult for Japanese manufacturers. This is because enhanced sales functions are critical to the sales of medical devices. No matter how excellent the technology is, in most cases products would not sell by simply relying on that technology. The lack of appropriate sales functions has long hindered market entry as well as overseas expansion on the part of Japanese manufacturers.

To enable Japan's medical device industry to be on a par with competitors in global markets, in addition to the policy support that has traditionally been provided, efforts must be made from an early stage to promote/support industrial structural reforms to enable manufacturers to be equipped with advanced sales functions. To

achieve this goal, in addition to developing their own sales capabilities, companies should consider the options of entering into sales partnerships with other companies and/or undertaking mergers and acquisitions (M&A). However, there are still quite a few manufacturers that opt for doing business independently by relying only on their own technological strengths. What is required of the government is to lead the entire industry in such a direction as to bridge the gap between such a technology-dependent concept and reality based on the characteristics of the medical device industry. The government should display such leadership.

The challenges facing Japanese manufacturers and strategies to address such challenges including the structural characteristics of the medical device market, sales functions that manufacturers should develop and the importance of sales functions are discussed in the other four papers, which are introduced in Figure 2 in Chapter I, one of which is available in English (NRI Papers No. 203).

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