A Safety Review of Medical Device Robots in JAPAN

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Abstract

In Japan, the robot evolution in the medical field has been remarkable, robots now often perform actions that are difficult for humans including assisting with elderly care and conducting medical operations that require specific techniques, and Japanese medical robot technology is among the best in the world. As the workforce population decreases in Japan's ageing society, the demand for robots will be ever-increasing, the use of robots will reduce the increasing medical costs. Unfortunately, there has been insufficient research by Japanese law researchers on medical robots. This paper examines whether the law in Japan is a barrier to the development of robot technology. In Japan, medical treatments that utilise robots are promoted by the government and by private organisations, including the Center of Assistive Robotics and Rehabilitation for Longevity and Good Health and the Japan Agency for Medical Research and Development, which are similar to the National Science Foundation and the National Institutes of Health in the U.S. In Europe, the SPARC robot project promotes the private development of robots. One side effect of robot technology is the challenge they present within legal systems because laws commonly lag behind the rapid technological developments. To address this, we may need to modify existing interpretations by the executive branch and revise statues in parliament; otherwise, judges must interpret the meaning of statutes that competing parties dispute. This paper focuses on the legal issues regarding medical robots, including how the government approves the use of medical devices for older people, and proposes a legal framework that encourages the safe implementation of robots in the medical field.

Keyword: Medical device, technology, robot regulation, judiciary, medical device

I. The Demand and Role of Robots in The Medical Field

1. Law and Technology

Internet technology forever altered our lives in the 1990s, and Lawrence Lessig

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explained that the law, like societal norms, markets, and morals, was one of several tools used to regulate this new online society by controlling human behaviour.\textsuperscript{1} His analysis can be applied to robot technology. As robot technology continues to develop in a rapid way that is interconnected with other technologies that influence human behaviour significantly, the legal statutes related to robots in Japan are lagging behind.\textsuperscript{2}

According to Article 41 of the Japanese Constitution, law-making powers exclusively belong to the Diet,\textsuperscript{3} and judges can not rewrite the law with their judicial decisions.\textsuperscript{4} Thus, in the face of rapid technological developments, courts can apply and interpret the text of existing statutes.\textsuperscript{5} For example, in the realm of Internet technology, there is an absence of relevant, up-to-date statutes that can appropriately address technological developments. As the Internet provides quick, easy, and cheap access to information beyond the national border, legislation of the Internet can be extremely complicated. Similarly, the Japanese government must manage the related challenges of robot technology in the medical field by establishing\textsuperscript{6} or amending new statutes.\textsuperscript{7}

This paper analyses the existing safety reviews of medical robots and examines how legal studies can respond to the high demands of robots in the medical field. Based on this review, it is possible to propose appropriate solutions. Whether the judiciary interprets the terms of existing statutes to address the legal issues arising from robotic developments, or legislature abolishes or amends these statutes to develop more fitting laws, it is clear that Japan must confront the challenges robot technology present to the

\begin{itemize}
  \item \textsuperscript{1} Lawrence Lessig, Social Meaning and Social Norms, 144 U. PA. L. REV. 2181 (1996); LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE (1999).
  \item \textsuperscript{2} Yuichiro Tsuji, THE FREEDOM OF EXPRESSION IN THE INFORMATION ORIENTED SOCIETY (2011).
  \item \textsuperscript{3} Nihonkoku Kenpo [Kenpo] [CONSTITUTION], art. 9 (Japan).
  \item \textsuperscript{4} Tsuji, supra note 2. \textit{See also}, Yuichiro Tsuji, Medical Privacy Issues in Ageing Japan, 18(1) AUST. J. OF ASIAN L. (2017).
  \item \textsuperscript{5} Laurence Tribe, THE CONSTITUTION IN CYBERSPACE (1991).
  \item \textsuperscript{6} Purobaida sekini seigen hou [The Japanese Internet Service Provider Act (ISP Act)], Law No. 137 of 2001 (Japan). Suto-ka koui tou no kisei tou ni kasuru hou [Stalker Control Act], Law No. 102 of 2016 (Japan). Jidou baishun jidou poruno nikakaru koui touno kisei oyobi shobatu narabini jidou no hogo touni kansuru hou [Child Pornography Act], Law No. 79 of 2014 (Japan).
  \item \textsuperscript{7} Penal Code [Keihou], Law No. 45 of 1907, art. 175 (Japan).
\end{itemize}
legal realm.\textsuperscript{8}

In Japan, the cost of social security expenditure is increasing every year, and in 2018, the cost was 33 trillion yen, or 33\% of the general budget. After declaring a dissolution of the House of Representatives in September 2017, the Abe government announced a new economic policy based on a cabinet decision to promote the productivity of Japanese people and included in this were guidelines to facilitate robot use in the medical field.\textsuperscript{9}

In nursing homes or hospitals, robot technology has become an urgent tool for Japan’s ultra-ageing society. One of the legal priorities required in robot technology is funding. For example, Da Vinci is a form of robotic technology that teaches young doctors the advanced skills of experienced veteran doctors. The Da Vinci robot is more efficient than human doctors at training more young doctors in a shorter time. However, Da Vinci is expensive, which means many hospitals in Japan cannot afford to use this technology.

The legal system could help in this matter, as the government could enact subsidies to develop the cost of Da Vinci or could promote the development of cheaper devices so more people may enjoy the advanced medical techniques and treatments. In addition to funding, there are other robotics issues related to privacy and artificial intelligence that create additional legal issues that must be addressed. However, this paper focuses on how the government reviews and approves the safety of robots intended for medical use in the ageing Japanese society.

2. The Expected Role of Robots as Medical Devices

This section provides an overview of the expected roles of robots in the ultra-ageing society in Japan. A common concern for the elderly is that they might take

\textsuperscript{8} Fumio Shimpo, \textit{Recent Policy Trends of AI and Robot Law in Japan}, 32(5) JAPANESE SOC’Y FOR ARTIF. INTELL. 665 (2017).

a dangerous fall in their homes or on the street. Fear of injury from a fall discourages older people from participating in activities such as walking outdoors, and, as a result their physical condition degrades. Thus, it is expected that robots will be made to assist with mobility. There is a great demand for these types of assistant robots, but legal barriers have prevented them from entering the market.

A pioneering example of this is HAL, a robot invented by Cyberdyne, Inc.\(^\text{10}\) and the University of Tsukuba, which is attached to a person’s lower body and assists with walking. In 2015, the Ministry of Health, Labor, and Welfare (MHLW) approved Cyberdyne’s application to permit the use of HAL as ‘new medical equipment’, whose purpose is to assist patients with muscular dystrophy or amyotrophic lateral sclerosis (two rare and incurable musculoskeletal diseases).

The legal classification ‘new medical equipment’ [shin iryou kiki] is different from the ‘approved medical devices’ [ki shounin iryou kiki] classification in structure, use, effect, and performance. Applications for new medical equipment can be filed only after a clinical trial, so, from March 2013 to August 2014, doctors conducted a clinical trial for the use of HAL\(^\text{11}\) with patients who had rare, and often incurable diseases. Generally, these trials should last at least 12 months in order to be approved; however, Cyberdyne argued for quicker approval in the interests of patients because HAL had already been approved in Europe in 2013 before they filed the application in Japan. This example demonstrates one facet of Japan’s unique and complex procedures for safety approvals of medical devices, and these devices are regulated by numerous statutes. The example of HAL illustrates that these regulations have not been developed in line with the rapid pace of technological development in robots.


\(^{11}\) Investigator-initiated Clinical Study of Wearable Assistive Robot for Lower Limbs Controlled Voluntarily by Bioelectric Signals etc. (Hybrid Assistive Limb [HAL]-HN01) as a New Medical Device to Delay Progression of Intractable Rare Neuromuscular Diseases-Randomized, Controlled, Crossover Study for Gait Improvement as a Short-Term Effect (Study NCY-3001), https://dbcentre3.jmacct.med.or.jp/jmactr/App/JMACTRE02_04/JMACTRE02_04.aspx?kbn=3&seqno=3962 (last visited Aug. 11, 2017).
II. Personal Care Robots for General Use

Several forms of medical technology for personal care, including wheelchairs, corsets, and crutches, are already available and regulated by administrative regulation or statutes. It must be determined if the existing regulations can be applied to innovative robot technology.

1. Legal Classification of Robots in the Medical Field

In Japan, as stated in the revised Pharmacy Affairs Act, equipment used in nursing and welfare services is classified as ‘prosthesis’ [ho sou gu] under the Services and Supports for Persons with Disabilities Act, ‘welfare assistive implements’ [fukushi yougu] under the Long-Term Care Insurance Act, and ‘medical devices’ [iryou kiki] under the Law on Securing Quality, Efficacy, and Safety of Products including Pharmaceuticals and Medical Devices. This classification is important because it determines the implementation of subsidies. For example, in Japan, wheelchairs are classified as ‘prosthesis’ and ‘welfare assistive implements’. Under the Long-Term Care Insurance Act, nursing care benefits include the cost of purchasing welfare assistive implements. Due to the fact that legislators of these statutes did not foresee the use of robotic medical devices or equipment, these devices including nursing welfare robots, are not classified in the existing categories. The Abe government has attempted to manage this through ministerial ordinance, and not with statute amendments. However, some aspects of medical treatment and rehabilitation are classified under ‘medical devices’. Assisting patients with standing, walking, and movement is classified under ‘general equipment’ for daily life support, which can be provided by rehabilitation supporting robots or nursing welfare devices. Prosthetics and

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12 Yakuji hou [Pharmacy Affairs Act], Law no. 145 of 1960.

13 Shougaisha no nichijou seikatsu oyobi shakai seikatsu wo sougou tekini sien suru tameno hou [Services and Supports for Persons with Disabilities Act], Law No. 123 of 2005. art. 5(23) (Japan).

14 Kaigo hoken hou [Long-Term Care Insurance Act], Law No. 123 of 1997 (Japan).

15 Iyaku hin iryou kiki touno hinshitsu, yukousei oyobi anzensei nokakuhou tou nikansuru hou [The Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices], Law No. 108 of 2016 (Japan).
training machines are classified as ‘general equipment’ under the Consumer Product Safety Act (CPSA).\textsuperscript{16} However, the LSQESP requires a stricter safety approval procedure for ‘medical devices’ than the CPSA.

\section*{2. Market and International Standards: ISO 13482}

Statues are just one of several tools that can be used to affect human behaviour.\textsuperscript{17} As discussed, pertinent statutes often lag behind the rapid pace of technological developments. Ministerial ordinances, markets, and international standards may work to maintain safety if statutes are ineffective for the safety of robots.

Firstly, markets demand guarantees from the developers of life support robots to ensure the minimum safety of robots. Accordingly, private voluntary agreements may promote the development of robots more effectively than statutes. Unlike medical devices, life support robots as ‘general equipment’ would not be strictly regulated as medical devices under the LSQESP. The developers are still subject to general tort liability under the Civil Code,\textsuperscript{18} the Consumer Product Safety Act,\textsuperscript{19} and the Product Liability Act.\textsuperscript{20} For example, the developer of a general daily life support robot is prohibited from advertising the robots in a manner that misleads consumers into thinking that the robots can produce medical effects similar to a medical device. In addition, if the robot collects personal data then it is subject to the Personal Information Protection Act of 2016.\textsuperscript{21} Relating to personal data security, in 2015, the MHLW released a report on the maintenance of cybersecurity for medical devices.\textsuperscript{22}

Secondly, regarding safety standards, the Ministry of Economy, Trade, and Industry

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\bibitem{16} Shouhisha sekatsu anzen hou [Consumer Product Safety Act], Act No. 31 of 1973 (Japan).
\bibitem{17} TSUJI, supra note 2. See also, LESSIG, supra note 1.
\bibitem{18} Min pou [The Civil Code], Law No. 89 of 1896. art. 709 (Japan).
\bibitem{19} Shouhisha sekatsu anzen hou [Consumer Product Safety Act], Law No. 31 of 1973 (Japan).
\bibitem{20} Seizoubutu sekinin hou [Product Liability Act], Law No. 85 of 1994 (Japan).
\end{thebibliography}
(METI) helped establish an international standard for general daily life support equipment (personal care robots) referred to as ISO 13482. Following this announcement, the Center for Robots and Robotic Devices was established in 2014, in Tsukuba city, to implement and uphold the international standard.

ISO 13482 led by Japan, is a voluntary regulation, not a legal statute, and it excludes medical devices. ISO 13482 classifies robots into three categories—mobile servants, person carriers, and physical assistant robots—and establishes requirements and guidelines for each. Under ISO 13482, after a risk assessment has been conducted under ISO 12100, the risk mitigation procedure follows, consisting of a three-step review to ensure the robot (1) has an intrinsically safe design, (2) has safety measures, and (3) provides a user manual. If the robot is not equipped with a safety measure that is controlled by the device, the approval of the robot will be reconsidered. Additionally, the PL/SIL (Performance Level / Safety Integrity Level) is reviewed under ISO 1384901 or IEC 62061, which are conducted by a neutral third-party organisation in Japan.

According to ISO 13482, each classified robot has a specific use: physical assistant robots reinforce human physical capacity to conduct certain physical tasks, mobile servant robots carry packages, and people carrier robots transport a person to their destination. The ISO/IEC Guide 51:2014 ‘provides requirements and recommendations for the drafters of standards for the inclusion of safety aspects in standards. ISO/IEC Guide 51:2014 applies to any safety aspect related to people, property, or the environment, or to a combination of these’. This guide is revised to incorporate the protection of consumers; when the committee on consumer policy joined, the term ‘vulnerable consumer’ was added to the guidelines. This means that workplace risk is

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more easily managed than at-home risk. The term ‘harmful event’ was replaced with ‘hazardous event’ and safety was defined to ensure that unacceptable risk should not exist. In 2013, for example, the wearable robot suit for welfare use invented by Cyberdyne, Inc., passed ISO/DIS 13482. In 2016, a robot called HOSPI, an autonomous transport robot built by Panasonic, passed the Japanese Industrial Standards (JIS) and ISO 13482. Both HAL and HOSPI are pioneers of the robot industry for Japan’s ageing society.

ISO 13482 is an advanced international standard; however, it has produced certain criticisms.27 The first was how its lack of specific numeric values for standards may create an evaluation framework that is too abstract. As well, due to its short history as a standard, there has not been an accumulation of information regarding accidents and the potential dangers related to the use of robots. Thus, when it comes to determining acceptable or unacceptable risk, the risk is subject to the purpose and use of life support as well as the use of the environment. The Japan Quality Assurance Organization recommends that the PDCA (plan, do, check, action) cycle might improve this standard by examining past failures, but this might be too much of a burden for future-oriented technology.28

In addition to establishing ISO 13482, in 2016, the METI established the Japanese Industrial Standards (JIS) B8445, 8446-1, 8446-2, and 8446-3 that work to supplement the ISO. The JIS committee uses these standards to promote utility with respect to an economic or social activity, to ensure effective production, and to maintain fairness in the interest of consumers.29 The JIS has promoted the development of technology, ensured the safety and health of people, and helped to conserve the environment for human lives. JIS B8445 clarifies the scope of sources of danger relevant to robots and


JIS B8446-1 establishes safety standards for autonomous mobile robots (whose purpose is to transport, clean up, and provide guidance without the presence of a manipulator) to ensure that they do not fall and can remain in standby mode without powering off. JIS B8446-2 creates safety standards for low power output and physical assistive robots that help people move, maintain stability, and operate objects. The JIS is regulated under the Industrial Standardisation Act that is based on a statute that was passed by parliament.\textsuperscript{30} Generally, JIS committee members are manufacturers, professors, and agencies. Based on the JIS committee’s expert advice, a Minister established standards that do not have any legally binding power, so it is up to manufacturers and consumers to determine if they will employ these standards.\textsuperscript{31}

3. Medical Device Robots under ISO 13485

The LSQESP, which distinguishes medicine from medical devices, was amended and enacted in November 2014. Medical devices are classified into four levels by their risk. Level I identifies machines, including dental equipment, whose risk to people is minor. Level II machines, such as x-ray equipment and MRI machines pose a risk only somewhat greater than those categorized as Level I. Da Vinci is Level III, meaning a medical machine that has a relatively high risk to human health if a problem occurs. Machines classified as Level IV pose the highest risk, such as Implantable Left Ventricular Assistance Devices for the heart. The amended LSQESP relinquishes Level III certification to a third-party certificate organisation.\textsuperscript{32} Medical devices that possess the potential to infringe on human life and health must make sure their safety and quality are maintained.

ISO 9001 is the quality standard for general electrical equipment, machinery, and chemical products in the manufacturing industry and architecture industry, but has been insufficient for the quality management of medical devices. Thus, a specialised standard

\textsuperscript{30} Kougyou hyoujunka hou [Industrial Standardisation Act], Law No. 185 of 1999 (Japan).


\textsuperscript{32} The 2013 version of ISO 13485, which was replaced by the 2016 version, would have been abolished in 2019.
for medical devices was required. The first standard, ISO 13485, was released in 1996 and has been revised several times. The recent amendments added washing, pollution prevention, hygiene control, labelling, and risk management to the international standard for medical devices.

ISO 13485 covers organisations that design, develop, manufacture, transport, and set medical devices. The 2016 amendment does not mention risk mitigation; however, it adopted the PDCA cycle in the system construction and certificate procedure, which offers improvements based on past failures. This change might provide a better quality experience, but might be far from the ideal response. Robot technology is future-oriented, not past-oriented, and the feasibility and practicality of a medical device might be ignored if PDCA is incorporated into the statute.

III. Comparative Law Approach for Safety Reviews

1. Legal Problems of Existing Statutes Caused by Robots as Medical Devices

This chapter reviews the legal problems caused by robots classified as medical devices in Japan. Although these medical devices might create privacy infringements and other product liabilities, this paper focuses on the procedures of safety reviews to approve the robot as a medical device. The University of Tsukuba’s innovative report to the government in September 2014, highlighted the problems with the approval procedure and challenged the Japanese public law studies for the safety approval of the MHLW. The report indicated that, at that time, medical device robots went through the same clinical trials that are required to test the side effects of medicine under the former Articles 80-2 (1) and (2) of the Pharmaceutical Affairs Act. The report argued that clinical trials for medical devices took too long; accordingly, the report suggested that the requirement for robot clinical trials should be relaxed, taking into consideration the special features of medical device robots. Furthermore, it suggested that a

33 Yakuji-hou [Pharmaceutical Affairs Act], Law No. 145 of 1960 (revised), art. 80-2(1)(2) (Japan).

34 Id. arts. 14(2), 14(3).
comprehensive review was not necessary and only certain matters, such as safety and effectiveness, needed to be reviewed for robot clinical trials.

As medicine only becomes available in the market after passing a clinical trial, this procedure had been used to review medical devices. The report also criticised the procedure that prohibited clinical trials until after the medical device was approved under the former Article 14(3) of the Pharmaceutical Affairs Act. The report proposed that the approval procedure should be conducted alongside the clinical trial, especially for low-risk medical device robots.

To decrease the approval procedure time, the report advocated for creating an exception for previously approved medical devices, relaxing its effectiveness review, and requiring minimum safety checks. Under this framework, robots that had earned a foreign certificate, such as the Communaute Europeenne (CE), were approved more easily than those without CE, and their effectiveness was reviewed after being sold on the market.

Another problem the report presented was how to subsidise medical device robots by law. In Japan, the National Health Insurance (NHI) program covers general medical treatments. However, advanced medical treatments such as those used for diseases like cancer, are not covered by the NHI, even though they cost more and are more effective for serious diseases. When advanced medical treatments are required, the patient must pay the full cost as set forth in special or specified medical care coverage (hokengai heiyou ryouyou hi). If a medical device robot, which is not approved as a medical device for advanced medical treatment, is used for medical treatment, the patient might be responsible for all the costs incurred. The report argued that the general medical insurance should be granted for treatment that requires advanced medical devices, even if those devices were not yet pre-approved.

This report encouraged the government to move forward with reviewing existing safety regulations. After this report, the MHLW announced that the NHI would cover the reimbursement of HAL for patients with muscular dystrophy or amyotrophic lateral

35 Id. art. 14(3).

sclerosis.\textsuperscript{37}

Advanced medical treatment approvals review many items, which takes a long time.\textsuperscript{38} The report proposed that the advanced medical treatment approval procedure should be simpler and shorter, taking clinical research into consideration. Essentially, the report suggested that the requirements for approving advanced medical treatments should be relaxed.

With respect to public nursing care insurance in Japan, there is an important social context to consider. Japanese citizens over 40 years of age are required to contribute towards public nursing care insurance.\textsuperscript{39} Accordingly, the report insisted that robots should be covered under long-time nursing insurance.

In Japan, the Road Traffic Act regulates pedestrians, bicycles, and cars, as well as public streets, but this Act does not specifically cover medical devices for walking support.\textsuperscript{40} The report proposes that the scope and definition of ‘pedestrian’ should be broader under the Road Traffic Act, such that it defines and covers devices that support walking.

The report concluded that these legal statute reforms would make medical devices more practical, reduce the social welfare cost, facilitate swift medical treatment, and act as a preventive health measure. In addition, more private robot companies should enter the market to reinforce competition. Moreover, more patients should be offered the option of advanced medical treatments via robots if they are helpful to their condition. If public insurance covered advanced treatments using medical device robots, patients would be presented with a safer and healthier environment, and more development in robot technology would be achieved.

With the lack of human resources in the ultra-ageing society, it is understandable


\textsuperscript{38} Kokumin Kenko Hoken hou [National Health Insurance Act], Law No. 192 of 1958 (revised, no. 28 of 2015), art. 63(2) iii (Japan).

\textsuperscript{39} Kaigo hoken hou [Long-Term Care Insurance Act], Law No. 123 of 1997, art. 8(12) (Japan).

\textsuperscript{40} Douro koutsu hou [Road Traffic Act], Law No. 105 of 1960, art. (2)(3)(1) (Japan).
that robots could solve some of the problems. For example, devices that support walking should be more accessible to the general public, and this could increase the levels of human resources. In order to make these devices more accessible, the approval time of the device should be shorter if there is no apparent risk in a relaxed clinical test.

The Report of the University of Tsukuba shows the inconsistency of several statutes. Although some statutes encouraged the innovation of robot technology, others seemed to inhibit their approval for use. For example, HAL was first used as a personal care robot; however, Cyberdyne, Inc. later applied for approval for Hal as a medical device because of several barriers in the existing statute on personal care.

Generally, in Japan, special statutes precede general statutes. If caring for the ageing society is an urgent mission for Japanese people, and all possible options are available, it is easy to argue that these statutes should be overhauled and amended by parliament. In 2014, the parliament revised the Pharmacy Affairs Act. The purpose of these revisions was to specify necessary regulations for welfare, formally distinguish medicine from medical devices, and establish the regulations for manufacture and selling of medical devices. The standard for manufacture of medical device and quality management was simplified. After 5 years, the LSQESP will be revised in 2019.

In Japan, a statute must be passed in the two Houses of the Diet to be promulgated. More statutes in Japan are drafted by ministers than members of the Diet. Under the parliamentary system, the Cabinet Legislation Bureau has also been influential in law-making. Statutes in Japan are products of the government's compartmentalised public administration government. Ministries compete with each other to acquire regulatory and budgetary power. For example, MHLW and METI’s jurisdictions overlap with robot technology. Even in the 1990s, the reform of administrative branches promoted consistency of policies under the Cabinet Office; however, some obstacles remain because each ministry struggles to receive funding, which generates a political struggle over power among ministers in the bureaucracy.

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42 Id.
Consequently, Japanese manufacturers have to communicate and negotiate with several ministers to receive approval for their medical devices.43

Unfortunately, statutes related to robots that help care for an ageing society might be a product of compromise at the public hearing or committee level. It should be noted that well-organised interest groups have a stronger influence over parliament than individual voters.44 Robot innovation encouraged by law might protect only the existing interests of ministries and established companies, and this hinders competitiveness. Although the use of robots would take human jobs, it is generally agreed they would save human and financial costs for the services required for older people in an ageing society. However, this might not be so simple in Japanese legal studies. Existing robot manufacturers might take advantage of the circumstances and intentionally delay reforms in the approval procedures to occupy and monopolise the market. Thus, when reviewing approval by the government for robots in medical treatment, we should be vigilant in monitoring the administrative agencies that control the approval procedure.

As the Tsukuba report suggests, medicine and medical devices are different. It is still important to note that even medical device robots might use special new materials and provide new functions. Applicants might not anticipate the required standards for new functions, and the agency has not yet experienced this kind of review. In Japan, an independent administrative agency, the Pharmaceuticals and Medical Devices Agency (PMDA),45 has jurisdiction to monitor and control medical devices. Although the PMDA may offer helpful advice to device manufacturers, it might not provide a sufficient amount of time to review new devices.

2. Regulations in the United States

This section reviews the U.S. approval procedure for medical devices. In 2011, the

43 Id.


Obama administration launched the ‘National Robotics Initiative’ to invest in the development of robot technology. This initiative aims to encourage increased worker productivity in the manufacturing sector, assist astronauts in dangerous and expensive missions, help scientists accelerate the discovery of new, life-saving drugs, and improve food safety by rapidly sensing microbial contamination.46

In the U.S., four federal statutes47 control medical devices. In 1976, the Medical Device Amendments Act, the basic principle of medical device regulation, was established. The Food and Drug Administration (FDA) is a regulatory agency that created three classes of medical devices based on risk.48 All three Classes are subject to the same control. Class I requires general control to demonstrate the safety and effectiveness of medical devices under the FDA. General control obligates device manufacturers to register their facilities, list their medical devices, and follow a quality system requirement or Code of Federal Regulations.49 Medical devices must show that they observe the requirement of 21 C.F.R. 801 or 809 before a premarket application is filed. Class II requires special control, including specific performance standards, post-market surveillance, patient registries, guidelines, recommendations, and other appropriate actions under the FDA. Class II devices need premarket notification that requires applicants to submit clinical trial data and certification. This is referred to as the 510(k)50 submission. Class III needs general control and premarket approval. Device manufacturers are required to submit not only a clinical trial certification but also the underlying scientific research and information regarding the efficacy and safety of the

49 21 C.F.R 820.
device.

With the U.S. regulations, the court reviews administrative decisions under the Chevron doctrine.\textsuperscript{51} The regulatory agency has a ceiling on human, financial, and time resources for monitoring and maintaining the safety of medical devices.\textsuperscript{52} A similar regulatory scheme might apply to the Japanese safety approval procedure.

3. EU Regulations and GHTF

In Europe, individual states have had their own regulations for medical devices since 1998. The European Conformity (CE) mark is a comprehensive standard that categorises the risk related to devices into six classes.\textsuperscript{53} A designated organisation certifies EC to products in class IIa, IIb, III, and some parts of class I that require sterilisation. For products that do not require sterilisation in class I, manufacturers conduct conformity assessments under the Medical Devices Directive (93/42/EEC, MDD)\textsuperscript{54} and place a CE seal, which does not have an identification number, on their products. These manufacturers are under domestic legal regulation. In some cases, they need to apply for approval to an administrative agency such as a national or member state government. In addition to the Medical Devices Directive (93/42/EEC, MDD),\textsuperscript{55} the Active Implantable Medical Devices (90/385/EEC, AIMD)\textsuperscript{56} and the In Vitro

\begin{itemize}
\item \textsuperscript{52} Daniel Farber, Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law, 23 HARV. ENVT. L. REV. 297 (1999).
\item \textsuperscript{55} Id.
\end{itemize}
Diagnostic Devices Directive (98/79/EC, IVDD)\textsuperscript{57} regulate medical devices.

Under annexe IX of the MDD,\textsuperscript{58} the medical devices are classified into four categories based on risk. Class III devices carry the highest risk, Class II\textsubscript{b} carry moderately high risk, Class II\textsubscript{a} carry moderate risk, and Class I carry the lowest risk. The manufacturer is required to observe a harmonised standard and demonstrate that the benefit of the device outweighs the risk.\textsuperscript{59}

In 2014, the EU committee, private research organisations, and companies established the EU SPARC Project to promote the development of robot technology.

In comparison to the U.S. and European regulations, Japanese procedures for medical devices\textsuperscript{60} are categorised into four similar classes for approval and registration. As discussed in Section I, Class I is for general medical devices with low risk, and, based on this classification the manufacturers will apply to PMDA for notification, and approval is not required. The notification document must include the name, purpose, effect, structure, and material of the device. Class II requires certification by a third-party organisation. The risk associated with the device is higher than that of general medical devices but lower than that of Class III. The Class III designation is for medical devices with a high risk to people. Manufacturers of Class III devices apply to PMDA and the MHLW. The approval documentation includes classification, name, effect, structure, and materials of the device. The Class IV designation is for medical devices with the highest risk, such as pacemakers and artificial heart valves. Class III and IV are called ‘specially controlled medical devices’, requiring the approval of MHLW in general. However, certain Class III devices require only third-party certification.

Japan follows the procedure set forth by the Global Harmonisation Task Force (GHTF), which is made up of Japan, the U.S., the EU, and Australia, and also

\begin{itemize}
\item \textsuperscript{58} supra note 52, MDD, Annex IX.
\item \textsuperscript{59} Id.
\end{itemize}
includes participation from regulators and industry representatives. The Steering Committee manages the group, and research groups study premarket regulations. The GHTF was expected to harmonise and standardise the regulations by reviewing, monitoring, and improving the technology standards, and sharing safety information across borders. The purpose of the GHTF overlaps with the ISO; therefore, a Memorandum of Understanding was concluded between ISO and GHTF. Regarding the ISO 13485 amendment in 2003, the GHTF suggested revisions to ISO 13485. The GHTF was dissolved and the International Medical Device Regulator's Forum (IMDRF) took over and was convened in 2012 as stronger body than the GHTF. IMDRF member states include Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, and the U.S.

In terms of regulation and management of medical devices, regulations are becoming more uniform among these member states and regions. If countries share similar social problems such as an ageing society, then the demands for medical devices are similar, and, as a result, applying uniform regulations would reduce the cost of approving and marketing medical devices. Even with this uniformity, there are still domestic circumstances that complicate the approval process. For example, as mentioned before, in the U.S., human resources, time, and finances are insufficient to conduct proper reviews.

Another potential problem for Japan arises from the judiciary review and administrative adjudication. As in the U.S., Class I to IV is designated by notice or administrative agency regulation. In some cases, technology and speciality would provide the administrative agency with discretion, and the court would grant the agency deference by Chevron doctrine. Under this process, the court would review only the procedure, not the contents of the administrative adjudication, which is what occurred in a case regarding permission to establish a nuclear reactor.\footnote{Saiko Saibansho [Sup. Ct.] Sept. 22, 1992, Heisei 1 (gyo Tsu) no.130, 46(6) SAIKO SAIBANSHO MINJI HANREISHU [MINSHU] 571 [hereinafter nuclear reactor case].} In that case, the court acknowledged there was some room for judicial review of an administrative agency adjudication when scientific and technological issues were present.
IV. The Problems with Using Robots For Medical Treatment in JAPAN

Safety reviews should not prevent the development of robots, and there is a need to maintain objective safety without political compromise. The administrative agency reviews safety, and the judiciary may blindly endorse administrative decisions without careful judicial review. The uniqueness of Japanese robot statutes is that it is not parliament, but the ministers who are willing to write the international standards.

1. The Role of the Judiciary in Japan

This section reviews the judiciary’s role in the development of medical device robots. If the robot is for general use, not for use as a medical device, then the general Civil Code and other statutes, such as Products Liability law and the Consumer Product Safety Act, will control the product. However, when it comes to developing medical device robots, the process involving the user and the government is different from the judiciary’s role in developing general use robots.

For medical device robots, the government may establish regulations for the developer to protect the life and health of the user. In the approval process for medical devices, generally, only developers and administrative agencies are involved. The judicial review of the medical device approval process is more lenient than the review of regulations on free speech. The court reviews the medical approval process if the governmental purpose is considered important, and the means to achieve the goal must be substantially connected to that purpose. In the Pharmaceutical Affairs Act decision of 1975, the government regulated the distance required between pharmacies, stating that once a pharmacy was opened, another could not open within a certain distance. In this case, the government argued that its purpose was to protect people’s health from low-quality medicine produced by excessive competition among pharmacies. The Supreme Court struck down this distance regulation because the means of the regulation was not substantially related to the purpose. If there were other less restrictive

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alternatives, distance regulation was not appropriately tailored to achieve the goal. According to the Court, the government could have regulated this by inspecting the pharmacies without prior notice to check the quality of medicine being sold. The Court suspected that regulation of the distance between pharmacies led to illnesses. The theories of Japanese public law indicated that this decision applied the less restrictive alternative test.63

Robot regulations take the form of administrative ordinances made by ministers or statutes in Japan. The purpose of this ordinance regulation might be sustained, but the court carefully reviews the means to achieve this aim. The purpose of provisions for safety might disadvantage or inhibit the protection of an existing interest group. The Tsukuba report suggested that the less restrictive alternative measure test should be applied for safety approvals. The developer of medical device robots must apply for approval to ensure its safety. If the application is denied, the developer may file actions for the revocation of administrative dispositions.64

Courts use arbitrary and capricious standards to review administrative discretion for an administrative disposition. According to this standard, the court would intimate a review if the approval procedure by the administrative agency, with the aim of protecting human life and health, was abused. In some cases, the court stands in the position of the administrative agency to review its disposition. In other cases, the court reviews only the procedure and respects the agency’s disposition.65

Developers would argue that their right to conduct business is protected by Article 2266 of the Japanese Constitution, which refers to the freedom of occupation, and that denial of approval infringes on their constitutional rights to be a developer of medical device robots. The government is surely obligated to balance disorderly development with the preservation of safety for the protection of older people in Japan’s ageing society. If the regulations were too strict such that they deny the possibility of such an

63 Tsuji, supra note 39.

64 Gyousei Jiken Soshouhou [Administrative Case Litigation Act], Law No. 59, 2015, art. 3(1)(2) (Japan).

65 Nuclear reactor case, supra note 59.

66 Nihonkoku Kenpo [Kenpo] [CONSTITUTION], art. 22. (Japan).
occupation altogether, as seen in the Pharmaceutical Affairs Act decision in 1975, the Court would use stringent judicial review to overturn the regulation. In the Pharmaceutical Affairs Act case of 1975, the Court focused on the fact that the distance regulation substantially denied new applicants the ability to enter into an occupation, therefore infringing on the freedom of occupation.

If a court believes that the medical device robot in question infringes on the safety of potential patients, which would have negative effects on public welfare, the regulation will survive. Accordingly, the goal of the regulation would be to maintain the safety of the robots for public welfare. The robot industry would bear the burden to prove that the regulation is unconstitutional. The robot industry might argue that the procedure should be relaxed for medical device robots because this procedure was originally intended for the approval of medicine. If the industry is proved to be successful, this procedure will not be suitable for medical device robots, and it will be too strict to be sustained. In the alternative, the industry could argue that approval would deprive them of the constitutional right of occupation under Article 22 of the Constitution.

The Tsukuba report suggests that the agency approval process should be quicker. However, this creates a greater possibility that an administrative agency will ignore an application for safety approval. As for this possibility, cases concerning disease induced by pollution are also helpful for the judiciary when reviewing administrative adjudications. In the famous Minamata case, the Supreme Court found the State Redress Act to be illegal because the administrative agency did not exercise their power as designated by law.

The Administrative Case Litigation Act (ACLA) permitted litigation to reveal inaction of an administrative agency. In 2004, the ACLA added mandamus actions to seek orders that an administrative agency should make an original administrative disposition or an administrative disposition and provisional injunctive order. It is still

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69 Gyousei jiken soshou hou [Administrative Case Litigation Act], Law No. 139 of 1962, arts. 3 and 38 (Japan).
unclear how these provisions apply in a robot safety case.

Risk management procedures as regulations would ensure accountability and reduce certain arbitrary permission or denial of permission, but research on risk management has paid little attention to Japanese public law (except for a few studies by a few young scholars). As mentioned before, risk management does have some limitations due to the insufficient accumulation of evidence in the new technology field. The composition of the committee for risk management may cast doubt on its fairness, given that sometimes, government-patronised scholars are appointed by the ruling party in the committee. In the nuclear reactor permission case, for example, the Court focused on the expertise of the committee and the discretion of the administrative agency. The courts in Japan do not endorse the administrative disposition blindly, examining either the review procedure or the administrative disposition from the perspective of the agency. Thus, it should be noted that the risk management method is not perfect and it is just one of several tools available to help maintain fairness and hold administrative agencies accountable.

Safety approvals for medicine take a certain amount of time because they concern the protection of human life and health. Although a quicker approval procedure for medical device robots is necessary, the standards and approval procedures should not infringe on the interests of users in the mid- or long-term under Article 31 of the Japanese Constitution. The unnecessary length of time it takes to approve medical device robots because of the government's compartmentalised public administration should be diminished as well.

In Japan, administrative ordinance regulations control more than statutes. The administrative agency regulation has the advantage of being flexible and can produce quicker responses than statutes passed in parliament. Administrative ordinance regulation might be a product of ministerial protection in Japan’s compartmentalised public

70 Id. at art. 37(5).

71 Saiko Saibansho [Sup. Ct.] Sept. 22, 1992, Heisei 1 (gyo tsu) no.130, 46(5) SAIKO SAIBANSHO MINJI HANREISHU [MINSHU], 1090.

72 Id.

73 Nihonkoku Kenpo [Kenpo] [CONSTITUTION], art. 31 (Japan).
administration government. However, with respect to new technology, we should be careful not to have excessive expectations for the possibility of legal regulations that will encourage robot technology development.

Japanese public scholars are required to introduce some advantages and disadvantages of robot law and administrative regulations. Several unexpected problems related to existing statutes may emerge due to rapid technological development. Research on robot law has only just begun in Japan. Thus, there has been relatively small amounts of interdisciplinary examination of robot law as it relates to legal studies and other disciplines, such as the medical field. Law professors are not unfamiliar with the special technology of robotics. In the face of high technologies, sometimes even distinguished professors might present an opposing or unrealistic argument.74

There are several statutes for robots in the medical field in Japan; however, these statutes originally had independent purposes. The example of HAL and the Tsukuba report demonstrate that HAL was an exceptional case that is expected to produce innovations in medical technology development. Law professors might be afraid that this exceptional treatment might create a loophole in legal regulation by protecting business entrepreneurs for the sake of promoting innovation, which is not a principle protected under the equality principle of the Japanese Constitution.75

If we view legal regulation as a tool to influence human behaviour, we should remember that law-making in parliament and subsequent interpretation in courts takes time. Compared with the Diet, the administrative agency regulation lacks the legitimacy of democracy. Instead, it reflects expertise and flexible responses. If Japanese people need to reach a consensus on the developing demands of using robots in the medical field in their ageing society, new legislation is preferable over interpreting existing statutes. New statutes or amendments to existing statutes would supersede existing statutes.

Furthermore, it is possible that statutes could incorporate risk assessment. As we saw in ISO risk management, the law first provides that the committee must review risk fairly and objectively in terms of neutral scientific knowledge, independent of

74 Tsuji, supra note 2.
75 Nihonkoku Kenpo [Kenpo] [CONSTITUTION], art. 14 (Japan).
political pressure. Thus, the committee examines whether the probability of danger is established by objective science and reviews if general causation is proved by general science. The concern is that risk management is distorted by political appointment, and if that is the case, then incorporating risk management into statues would produce a double-edged sword. Secondly, following risk evaluation and the establishment of objective standards for risk, a statute creates a general outline for the composition of the committee, appointment power, and budget. Administrative agency regulations offer detailed, but flexible guidelines to allow for the rapid development of technology. The committee would reflect public opinion, cost-effectiveness, and feasibility. We lack experience with new technology, and will learn from the accumulation of experience. Accordingly, it would be valid to state that risk management is one tool that can help maintain human health and accountability.

The administrative regulation, which lacks public consensus, might be a product of the self-satisfaction of technology developers, and may be far from the common sense of the general public. Thus, risk communication should be written into statutes, requiring that risk information is shared and exchanged among users, developers, committees, and administrative agencies. For example, the Administrative Procedure Act has a provision requiring a public comment period when establishing administrative regulations. APA might provide opportunities to understand the risk of the introduction of robots.

V. Conclusion

In Japan, existing statutes have created certain barriers to the innovative development of robots in the medical field because the law lags far behind constantly developing robot technology. Another barrier to innovation in this field is the compartmentalised public administration where there is no ministry specifically for robots, and statutes are drafted by ministers with independent purpose provisions under different ministerial jurisdictions. The coordination among these varied ministries might delay technological development.

76 Gyousei tetsuduki hou [Administrative Procedure Act], Law No. 2014, art. 39 (Japan).
Even without special legal regulations, the developers of robots for life support follow general Civil Code and ensure minimum safety levels of robots in the market. The ISO is one helpful tool that encourages uniform standards for new technology in the market. The JIS is another tool used to encourage standards domestically; however, it does not have legal binding power and so private voluntary agreements may promote the development of robots more successfully than statutes.

ISO 13482 is used by METI to assist with the establishment of an international standard for general daily life support equipment (personal care robots). It is a voluntary regulation, not a legal mandatory standard, and its provisions exclude medical devices. Although it is an advanced international standard, it is not perfect. The lack of specific numerical values for its standards has been criticised as being too abstract, and its limited history means that only minimal information related to accidents has been accumulated. When it comes to the acceptable or unacceptable risk of personal care robots, ISO 13482 provides that the risk is dependent upon the purpose and use of the life support as well as the environment in which the robot will be used.

The LSQESP was amended and enacted in 2014, distinguishing medicine from medical devices. As medical devices possess a potential to infringe on human life and health, their safety and quality must be maintained. In 2016, a new version of the ISO 13485, the international standard for quality management, was released. This version does not mention risk mitigation; although, it adopted the PDCA cycle for system construction and certificate procedure in the hopes that medical devices can be improved by examining past failures. However, because robot technology is future-oriented, rather than past-oriented, it may not be prudent to incorporate PDCA into the statute because the feasibility and practicality of medical devices may be ignored.

The University of Tsukuba’s innovative report submitted to the government highlighted the problems with the safety approval system and presented an argument for reforming legal statutes to make medical devices more practical, reduce the social welfare costs, facilitate timely medical treatment, and institute preventive measures to reduce the risk of medical robots. Given that special statutes eclipse general statutes in Japan, it would be feasible for the Japanese people to push for the overhaul and amendment of statutes that currently regulate medical device robots to improve the lives
of a significant proportion of older people. However, because statues in Japan tend to be the product of the government's compartmentalised public administration, the ministerial influence on the statute may promote laws that protect only the existing interests of ministries and established companies, hindering competition in the medical device robot market.

As for the government’s approval procedure for robots used in medical treatment, we should take care to examine how the administrative agency wields its control on the approval procedure. In the U.S., the regulatory agency has limited human, financial, and time resources with which to monitor and maintain the safety of medical devices; these same circumstances may occur in the context of Japan’s safety approval procedures.

Under the GHTF, the regulations of medical device robots amongst the member states have begun to become more uniform. Ultimately, this could help improve the technological developments in the robotics field because countries are facing similar social problems, such as an ageing society, could complete a dual/uniform approval which can reduce costs and save time.

Aside from the approval procedure itself, Japan must also address any lingering issue that may arise when the judiciary reviews an administrative decision. It is important to distinguish between the instances in which the courts may review only the approval procedure (giving deference to the administrative agency) and the instances in which the courts can review the agency’s decision based on the facts of the case (as was decided by the administrative agency).

Although the approval procedure is not a perfect risk management tool, it works to ensure the safety of the robots. Risk management is essential to maintaining fairness, accountability, and human health. Even though a quicker procedure is necessary for approving the use of medical device robots, we must ensure that the standards and procedures do not infringe on the interests of the user under Article 31 of the Japanese Constitution. Moreover, it is important to reduce the political influence linked to the administrative ordinance regulations by requiring that the committee review the risk of each medical robot device based on objective science.
Received: August 11, 2018

Accepted: August 20, 2018