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Commentary

Japan's challenges of translational regenerative medicine: Act on the safety of regenerative medicine

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ABSTRACT

The first issue of *Nature Medicine* published 20 years ago featured an article that reported Japan's critical situation regarding clinical trials, calling for major reform. Twenty years later, Japan has enacted three laws to promote the use of regenerative medicine as a national policy. The first law to be enacted was the Regenerative Medicine Promotion Act, which represents the country's determination to work toward the promotion of regenerative medicine. Subsequently, the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMD Act) and the Act on the Safety of Regenerative Medicine (RM Act) came into effect. The PMD Act created a new category for regenerative medicine products, and established the process for obtaining approval for cell therapy and other regenerative therapies through the implementation of clinical trials. The RM Act specified the regulations that doctors, review committees, and cell culture/processing facilities must adhere to when providing regenerative medicine in medical care, not only in clinical research but also in private practice.

Previously, researchers in regenerative medicine only had a set of guidelines to follow for conducting clinical research. Now, with the enactment of the RM Act, all areas for improvement that had been enumerated 20 years ago—such as the lack of appropriate review committees and governmental control—have been addressed by law, creating a system that gives the highest priority to patient safety. In this paper, we present the particularly noteworthy points of the RM Act, along with the actual current conditions of regenerative medicine in Japanese medical care.

1. Perspective

In the first issue of *Nature Medicine* published in 1995, Fukushima [1] emphasized inadequacy in the implementation of clinical trials in Japan. In the report, the author pointed out the lack of infrastructure for informed consent, as well as institutional review board (IRB), and governmental control, indicating the need for an overhaul of the entire field of translational medicine in Japan. In 2014, approximately 20 years after this initial report, Japan enacted the Regenerative Medicine Promotion Act, followed by two other associated Acts concerning translational regenerative medicine [2,3] (Fig. 1). The first is the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMD Act, renamed from the Revised Pharmaceutical Affairs Act), which newly created a category for regenerative medical products in addition to the existing categories pharmaceutical products, medical device products, quasi-drugs and cosmetics. Furthermore, by adopting a system with conditional and time-limited approval for regenerative medicine products, the PMD Act established the process for obtaining approval for cell therapy and other regenerative therapies through the implementation of clinical trials [4]. The PMD Act regulates the production and marketing of regenerative and cellular therapeutic products by firms.

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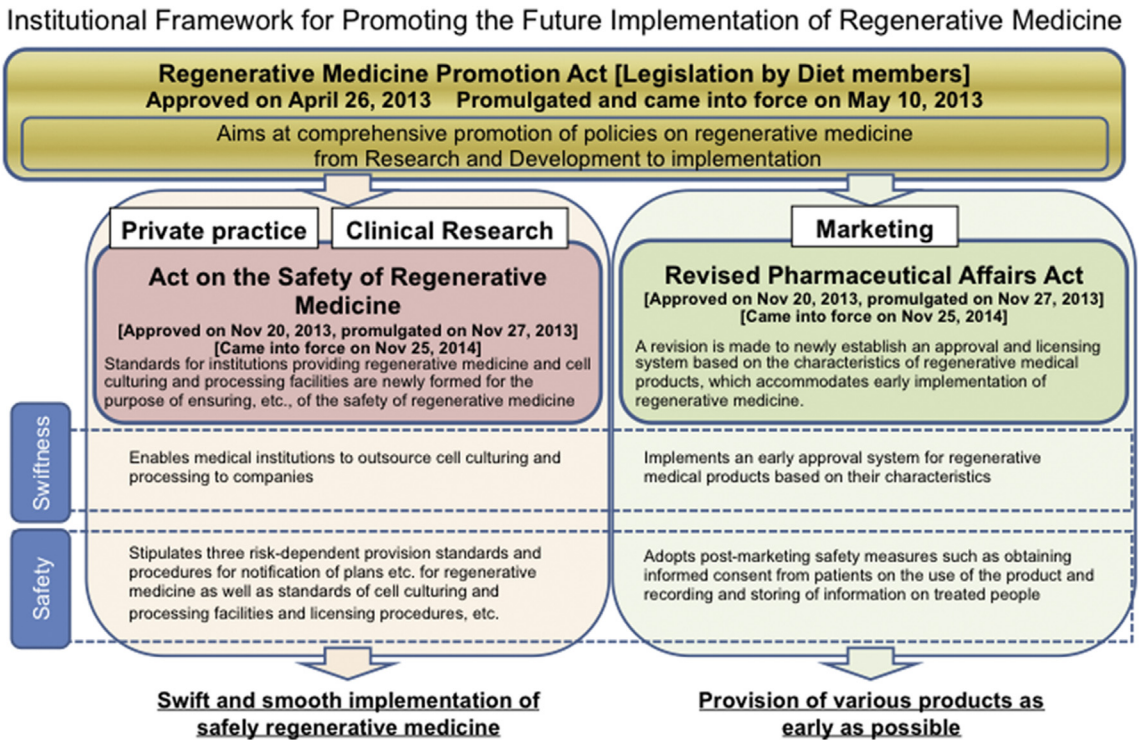

Fig. 1. Japan has enacted three laws to promote the use of regenerative medicine as a national policy. The first law to be enacted was the Regenerative Medicine Promotion Act, which represents the country's determination to work toward the promotion of regenerative medicine, following which the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (PMD Act) and the Act on the Safety of Regenerative Medicine (RM Act) came into effect.

The second law is the Act on the Safety of Regenerative Medicine (RM Act), which established a framework for regenerative medicine provided both in clinical research (not including clinical trials complying with international guidelines, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use [ICH]-Good Clinical Practice [GCP]) and private practice (not covered by health insurance) and clarified the measures necessary for ensuring patient safety. Under the Medical

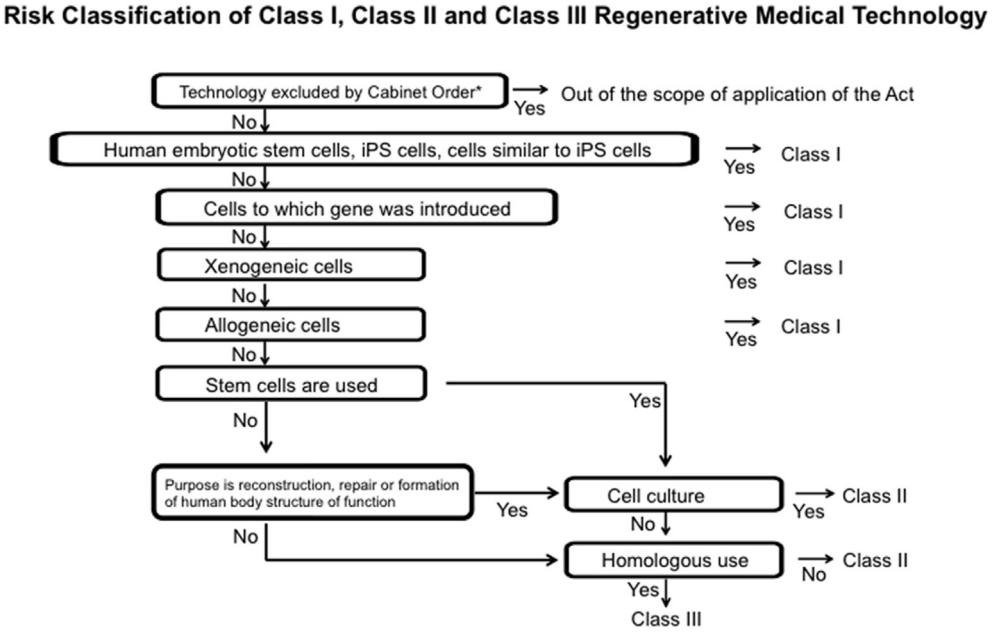

Fig. 2. Risk Classification of Class I, Class II, and Class III Regenerative Medical Technology. *: Medical technologies such as blood transfusion (excluding those that use gene-transferred cells), hematopoietic stem cell transplantation (excluding those that use gene-transferred cells), and assisted reproductive technology (excluding those that use embryotic stem cells established from human sperm or unfertilized eggs) are excluded by the cabinet order.