慶應義塾
Keio University

Tokyo, 1 February 2018 - Researchers at the Keio University Global Research Institute (KGRI) report in the February 2018 issue *Cell Stem Cell*, the impact of Japanese government regulatory reforms intended to accelerate the development of regenerative medicine on the domestic regenerative medicine industry in Japan. The researchers also describe measures being introduced by the Ministry of Health, Labor and Welfare to increase transparency and accountability in this sector.

KGRI Research Frontiers

http://www.kgri.keio.ac.jp/en/research-frontiers/index.html

In 2014, the Japanese government introduced a number of regulatory reforms intended to accelerate the development of regenerative medicine. These included a new legislation, namely the Act on Safety of Regenerative Medicine (ASRM), which created a risk-based approach for the review and oversight of cell-based therapies at private clinics. In an article in Cell Stem Cell, researchers at the Keio University Global Research Institute (KGRI), Project Professor Douglas Sipp and Professor Hideyuki Okano, examine the impact that this law has had on the domestic regenerative medicine industry in Japan. They report the great majority (~97%) of "regenerative medicine" procedures registered under ASRM fall under the most lightly regulated category. This number includes many cell-based interventions, such as immunotherapies for the treatment of cancer that are not primarily regenerative in nature. Sipp and Okano also outline a number of measures that are being introduced by the Ministry of Health, Labour and Welfare in an effort to increase transparency and accountability in this sector.

1. Main Points of Research

·Analysis of the impact of the 2014 Act on the Safety of Regenerative Medicine (ASRM) as

seen from the numbers of "regenerative medicine procedures" registered to date

·Report of recent regulatory enforcement actions in Japan

·Update on the amendments to ASRM intended to improve transparency and accountability

2. Background of Research

In 2014, the Japanese government introduced regulatory reforms designed to promote research and development in regenerative medicine. These included a new legislation, namely the Act on the Safety of Regenerative Medicine (ASRM), which introduced a risk-based approach to the review and regulation of cell-based therapies used in private practice clinics. Although ASRM provided much-needed clarity on the limits and responsibilities of private clinics offering such treatments, there has been a significant increase in applications to deliver Class III ("low-risk") regenerative medicine procedures, many of which are not supported by credible evidence of efficacy.

3. Content of Research and Results

Using publicly available data, Professors Douglas Sipp and Hideyuki Okano, two researchers at KGRI, evaluated the current situation of regenerative medicine in Japan after the introduction of a new regulatory framework in 2014. Sipp and Okano examined the impact of the 2014 Act on the Safety of Regenerative Medicine (ASRM) and found that businesses operating under this law have overwhelmingly focused on the most lightly regulated class of regenerative medicine procedures (Class III), which account for 97% of all such procedures registered for therapeutic use. As determined from registrations of Certified Committees for Regenerative Medicine (CCRM), which are required under ASRM, many Class III procedures appear to be offered by cancer clinics providing cell-based therapies that are not "regenerative" per se.

Sipp and Okano also report that the Ministry of Health, Labour and Welfare (MHLW) has announced new reporting requirements for clinics operating under ASRM. In October 2017, the MHLW announced plans to require businesses advertising Class III regenerative medicine

procedures to publicly list information such as a description of each procedure, contact information, and the name of the reviewing CCRM, which to date had only been required of organizations offering or researching more strictly regulated classes of regenerative medicine. These new rules will provide greater insight into a sometimes opaque industry.

4. Future Developments

Appropriate regulations and enforcement actions will be needed to ensure that Japan's significant investment in regenerative medicine yields safe and effective new therapies. The additional reporting requirements for private clinics operating under ASRM as reported in this article will provide a valuable window of transparency into a sometimes opaque and under-regulated industry. Future work should examine the data on treatments being offered, business entities, and cell types used that will emerge under these new requirements. Such information will provide valuable insights into those studying Japan's novel regulatory framework and its impact on the domestic and international regenerative medicine industry.

5. Special Notes

This article is under embargo until 12:00 p.m. (noon) EST on February 1, 2018 (2:00 a.m. on February 2, 2018 in Japan).

Reference

Sipp, Douglas and Okano, Hideyuki, Japan Strengthens Regenerative Medicine Oversight. *Cell Stem Cell.*
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Inquiries about the research

Keio University Faculty of Medicine, Professor Hideyuki Okano

Tel: +81 3-5363-3747 Fax: +81-3-3357-5445 E-mail: hidokano@a2.keio.jp

http://www.okano-lab.com/

Further information about KGRI

Keio University Global Research Institute (KGRI)

2-15-45 Mita, Minato-ku, Tokyo 108-8345 Japan

E-mail : kgri@info.keio.ac.jp

About KGRI

http://www.kgri.keio.ac.jp/en/about/index.html

Keio University Global Research Institute (KGRI) was established in November 2016 as a result of an expansive reorganization of the existing Keio University Global Security Research Institute (G-SEC), and as a base to facilitate the further globalization of the university to become an international research university that can make positive contributions to the world.