

慈濟大學 109 學年度 碩博士班、博士學位學程暨碩士在職專班 招生考試命題紙

科目：英文科普文章測驗

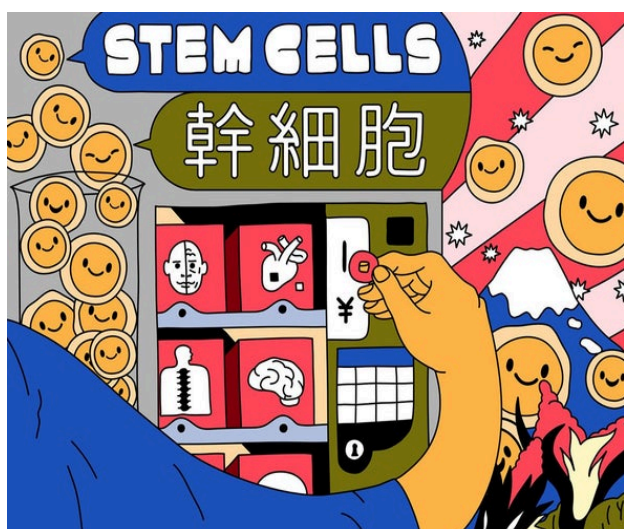
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The article:

By David Cyranoski, Nature magazine on November 14, 2019

Stem Cells 2 Go

Japan has turned regenerative medicine into a regulatory free-for-all. Patients across the world could pay the price



Five years after Japan adopted these regulations, more than 3,700 treatments, including many based on stem cells, are on offer at hundreds of clinics across the country, and a wave of foreign companies has set up shop there. “Japan has become a focal point for the development of innovative therapies,” says Gil Van Bokkelen, chief executive of the biotechnology company Athersys in Cleveland, Ohio, which is pursuing clinical trials of a stem-cell based treatment for stroke and respiratory disease in Japan.

Clinics maintain that they are operating within the law. And government officials argue that Japan’s system is safer than those in other countries because it keeps tabs on the treatments being offered. But the policies might be giving people false hope about how effective these therapies are.

Meanwhile, Japan’s bold experiment in deregulation is beginning to influence others. Taiwan and India, for example, have started to follow the country’s lead, and regulators elsewhere are feeling pressure from companies, patients and other advocates to speed up the approval process. “If we’re left with very different global regulatory standards, it’s going to be a really big problem,” says Peter Marks, director of the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration.

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SAFETY, NOT EFFICACY

Shortly after taking office in December 2012, Japanese Prime Minister Shinzo Abe promised to invest ¥110 billion yen (U.S.\$1 billion) over the next decade into regenerative medicine. The bullish attitude came just months after Shinya Yamanaka at Kyoto University won the Nobel Prize in Physiology or Medicine for his work on induced pluripotent stem cells. Abe boasted that Japan is the world leader in regenerative-medicine research, but lamented the slow pace of clinical application. He soon announced two measures that he hoped would change that (see Deregulation in Two Acts).

Two laws introduced in Japan in 2014 offer a fast track to the market for stem-cell-based treatments and other types of regenerative medicine. The Act on the Safety of Regenerative Medicine allows companies to register a therapy under one of three risk categories.

Japanese Prime Minister Shinzo Abe (front) with stem-cell biologist Shinya Yamanaka (left) and then RIKEN president Ryoji Noyori at a lab visit in 2013. Credit: [Getty Images](#)

Questions (each 20 %; total 100%)

1. In this article, which country enables a five-year regulatory free-for-all in regenerative medicine has given the industry a boost?
2. In this article, which countries would like to establish similar regulations following the first country?
3. In this article, who won the Nobel Prize in Physiology or Medicine for his work on induced pluripotent stem cells?
4. Please elaborate the major issues in regenerative medicine that described in this article.
5. How do you think about the laws described in this article? Are these laws good or not, please elaborate. (Please consider that all laws may contain their good and dark sides.)