

THIS WEEK

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Unknown territory

Japan is making an overdue effort to regulate experimental stem-cell treatments. A clearly defined legal framework is needed to protect patients.

Millions of tourists flock to Japan each year to enjoy its rich cultural and historical heritage. But some visitors are shunning the usual tourist trail in favour of another attraction — experimental stem-cell treatments. In late December, the Japanese newspaper *The Mainichi* reported that a clinic in the Hakata district of Fukuoka in southwest Japan, which has links to the Seoul-based biotechnology firm RNL Bio, has been treating some 500 South Koreans a month with stem cells. Another report late last month in the *Asahi Shimbun* newspaper claimed to have found more than 20 clinics that advertise unproven stem-cell treatments in the country.

Some of the countries in which stem-cell tourism has taken off have immature regulatory systems, including China, Costa Rica and Ukraine. But why Japan?

For starters, Japan's regulations on stem-cell therapies are not just immature — they simply do not exist. Combine that with the nation's reputation for cleanliness and reliability, and Japan becomes the perfect place to give a veneer of legitimacy to an unproven therapy. The country is a "paradise for premature therapies" according to one article in the *Mainichi Shimbun* newspaper. Japan's health ministry has been slow to respond, but is now beginning to move on the issue.

Last week, a ministry subcommittee posted online some of its initial ideas for a new law to oversee the clinical use of stem cells. A final draft will be prepared this month for presentation to Japan's parliament in its upcoming session. Details remain fuzzy, but the document includes significant proposals, such as a requirement that stem-cell therapies be approved through clinical trials, that they take place only in registered and approved facilities and that providers set up ways to compensate their patients if things go wrong.

The introduction of such clearly defined rules and regulations, in contrast to Japan's usual preference for soft guidelines, is a positive and welcome step. Such guidance will be particularly helpful to local government officials, such as those in Fukuoka, who are reportedly stumped as to what to do about the stem-cell tourism there.

The problem is that the regulations with teeth will probably apply to only one of three classes of stem-cell treatment: that deemed the most risky, including procedures based on embryonic stem cells or induced pluripotent stem cells, the risks of which are unknown.

The other two categories are not yet well defined by the guidelines, but are likely to include therapies that are generally accepted and considered safe, as well as those that carry some degree of predictable risk. According to a government representative, a clinic that used these other classes would need only to get the approval of a local institutional review board and then notify the government that it is opening for stem-cell business. There would be no active monitoring by the government. The type of stem-cell treatment offered by RNL Bio — in which stem cells are extracted from a person's fat tissue and then expanded in the laboratory — would fall into one of these more loosely regulated categories, it seems. What, then, would prevent RNL Bio or other companies from

exploiting Japan's laxity, possibly to the detriment of patients?

Self-monitoring by clinics has already been exposed as problematic in the business of stem-cell therapy. The United States has a formidable regulatory system, but it is far from a shining example of how to oversee this emerging field. The state of Texas recently put into place

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regulations that opened up the industry to any company that could pass inspection by local review boards, only to find that the review board that approved the state's highest profile stem-cell company had failed in its duties. The US Food and Drug Administration eventually got around to cracking down.

Regulators everywhere have a difficult job. Desperate patients, looking for any opportunity to try a therapy that could help them, feel deprived of their rights. And some companies complain — with some justification — that overly burdensome regulations are killing the development of promising therapies. Japan should learn from the situation in the United States and elsewhere. It must take care to look at potential loopholes in its laws that could allow unproven therapies on the market and put patients in danger. ■

In a hole

It is in Britain's best interests to keep looking for a site for a deep nuclear-waste repository.

The best way to dispose of nuclear waste is to bury it deep underground. With the right mixture of geology and engineering, researchers think, it should be possible to contain highly radioactive material safely for the many thousands of years that it will take to decay.

Scientists agree on this. The industry thinks the same way, and so do regulators, politicians and most environmental groups. Yet despite the expert endorsement, plans for a deep geological repository in Britain effectively ground to a halt last week, after a local council voted against plans to look for a suitable site. Some scientists view the rejection as a failure of local politics, but they are wrong.

The vote over whether to take early plans for a deep geological repository to the next stage came at a meeting of Cumbria County Council on 30 January. The work would have involved test drilling and surveys to try to find a suitable location for the 1,000 cubic metres of high-level waste and several thousand tonnes of spent fuel currently held in the United Kingdom.

Cumbria has always been the preferred site. At the opposite end of