

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

the country from London, the county is already home to the Sellafield nuclear site that once produced plutonium for the nation's nuclear weapons. Sellafield still houses most of the country's nuclear waste, and so to build a repository nearby would be sensible, as long as the conditions are suitable.

The government has looked at Sellafield once before. In the 1980s, an independent group was set up to try to locate a geologically suitable waste dump in Britain. The body eventually settled on Sellafield, and set out to build a £200-million (US\$315-million) 'rock characterization facility' at the site. In 1997, the proposal was abandoned after local planners rejected it — in part, because of fears that the facility might become a de facto waste dump.

This time, the government vowed to do things differently. The old executive was abolished and in its place new plans were laid out that promised transparency, democratic inclusivity and scientific scrutiny. The plans mirror those of nations such as Finland and Sweden, which are successfully building waste repositories.

So why has the process come up empty again? The answer is a lack of political will at almost every level of government. Critics say that the Nuclear Decommissioning Authority, the body responsible for the repository, never did much to try to sell the facility to local residents or to address their concerns about what it might do to property prices or tourism. At a national level, politicians offered only the vaguest promise of 'economic development' in exchange for taking the waste. Meanwhile, local politicians advocated an alternative plan: to build more short-term storage at Sellafield, thereby creating jobs in the near-term without making long-term commitments.

The United Kingdom is not alone in its nuclear torpor. In the United States, efforts to build a repository are in the doldrums following a decision to withdraw from a proposed site at Yucca Mountain in Nevada. A panel has recommended a site-selection exercise similar to the one carried out in the United Kingdom, but there is little reason

to believe that it could do any better. The very act of looking at places other than Yucca Mountain will require a change to legislation — unlikely given the nation's current political paralysis.

In the meantime, the bills from neglecting the waste are piling up. The US Nuclear Regulatory Commission faces a costly lawsuit from states and utility companies seeking to have their nuclear waste taken away, as required by federal law. In the United Kingdom, the endless

“There are moral, financial and environmental reasons to make deep geological disposal work.”

clean-up of Sellafield drags on; it has cost more than £67.5 billion so far, according to a report released this week by a parliamentary committee. At the Fukushima Daiichi nuclear plant in Japan, spent fuel stored above ground at reactors is likely to have been a major source of contamination following the earthquake and tsunami in 2011. At the last count, the clean-up there is expected to

cost trillions of yen, or hundreds of billions of dollars.

The bleak situation might encourage some on both sides of the Atlantic to search for a quick fix. Already, there is talk in the United Kingdom of officials trying to bypass Cumbria County Council by going directly to the local communities of Allerdale and Copeland, which supported the survey work. In the United States, some in industry would like to see the plans for a repository at Yucca Mountain revised, despite Nevada's promise to fight it tooth and nail. Advocates of these solutions may feel that they are in the right, but they are guilty of political myopia: although it might be possible to nudge the projects forward briefly, they would quickly become bogged down again in a mire of legal and civil challenges.

It seems likely that both nations must start again. Scientists can help by reminding politicians that there are moral, financial and environmental reasons to make deep geological disposal work. Given the enormous costs of inaction, it is in everyone's interest to keep trying. ■

Body of evidence

The identification of a long-dead king is not simply an academic event.

Headline writers and bloggers dusted off their copies of *The Complete Works of William Shakespeare* this week to gleefully report the identification of the skeleton of King Richard III, found beneath a car park in the English midlands. The fascination with Richard, the last king of the Plantagenet line and the last English monarch to fall in battle, goes beyond the known facts of the historical record; Richard is known as much as the misshapen villain of Shakespeare's play as the man who ruled until his violent death in 1485.

The king's mortal remains were identified by a mixture of science and history. The skeleton was male and about the right age, and radiocarbon dating suggests that he died around the end of the fifteenth century. Death was due to a forceful blow to the back of the head with a sharp blade, consistent with a sword or a fearsome medieval weapon called a halberd. He ate a high-protein diet containing plenty of seafood, so was clearly of high status. The spine was twisted, a sign of adolescent scoliosis, providing some basis for Shakespeare's deformed monster. The corpse was mutilated after death. It was found in the right place. And analysis of mitochondrial DNA from the bones matched samples taken from two descendants of Richard's family — the Canadian-born furniture maker Michael Ibsen and a second royal relative who chose to remain anonymous.

If that person chose to conceal their identity to avoid a media fuss, then they certainly made the right decision. The unveiling of the findings by researchers at the University of Leicester, UK, who found and

investigated the remains, at a press conference on Monday morning, led news bulletins and was immediately scrutinized and argued about online. Prominent historians scoffed at the media scrum and dismissed the academic significance of the find. Others accused them of jealousy and snobbery — would a similar discovery announced with equal fanfare by the University of Cambridge or Oxford face such hostility, they questioned?

Even some of those who praised the work could not resist bestowing a patronizing pat on the head, and pointed out that little old Leicester was enjoying its day in the Sun. (They may or may not have heard of DNA fingerprinting, which was developed by Alec Jeffreys in the same department of genetics that investigated the car-park skeleton.)

Certainly, the way the discovery was announced, the introduction of DNA evidence without the backing of a peer-reviewed paper, and the fact that there was a television documentary primed and ready to go will leave a sour taste in the mouth of some purists. The University of Leicester has managed to unite the two cultures of science and humanities in a way that few have before. “Science by press release” cried some scientists. “History by press conference” complained some historians.

They should get out more. The discovery of a 500-year-old slain King of England is an event that goes beyond the boundaries and the conventional audience of academia. The DNA evidence may be impossible for outsiders to verify until a paper is published, but molecular sleuthing alone will never be able to confirm the identity of the bones with total assurance anyway. And, given the strength of the other evidence, it does not need to. “There are lots of us out here

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who've been intrigued by and researching this for years and years,” one historian responded to an online critic. “This is really exciting for me — it's kind of the 15th century's Higgs Boson [sic] moment.” Let them enjoy it. ■