THIS WEEK

EDITORIALS

REPRODUCIBILITY Listen to early-career researchers. They know what to do **p.465**

BEE ALERT Queens lose vision and direction after mating **p.467**

MASS REVEAL Closest measurement yet for neutrino mass **p.468**

A stem-cell race that no one wins

Japan helped to bring stem-cell technology to the world. Its current regulatory policies risk damaging its hard-won reputation.

In the global race to create companies offering stem-cell therapies, one country is looking to stand out from its competitors — Japan.

It is five years since Japan passed laws regulating stem-cell clinics; in that time, some 3,700 treatments have received the green light. From Hokkaido to the islands of Okinawa, companies in Japan can extract stem cells from skin biopsies and use them in injections for complex conditions such as heart disease.

But, as *Nature* reports on page 482, the vast majority of these therapies have not passed a randomized, controlled, double-blind clinical trial, the global standard to prove that interventions are safe and effective, and the foundation for most medical regulation. Instead, Japan's 2014 Act on the Safety of Regenerative Medicine and a second law, the 2014 Pharmaceutical and Medical Device Act, provide a fast track to market approval.

These laws were passed following the award of the 2012 Nobel Prize in Physiology or Medicine to Kyoto University stem-cell biologist Shinya Yamanaka. The government of Prime Minister Shinzo Abe decided to establish one of the world's more liberal regulatory environments for regenerative medicine.

But it isn't only Japanese companies that are in a rush to commercialize stem-cell treatments. The country is becoming a magnet for scientists and entrepreneurs from around the world who are seeking a rapid route to commercializing products and therapies .

Japan's attractiveness to regenerative-medicine entrepreneurs is prompting other countries to look closely at its regulatory changes. There is undoubtedly a competition under way, and unless something is done, it risks becoming a race to the bottom.

Supporters of Japan's laws justify the fast-track approvals system by arguing that more conventional regulations would drive clinics underground, and regulators would constantly have to work to catch up — as is the case for the US Food and Drug Administration. Japan's solution, they argue, means that companies are compelled to operate in the public eye, which is itself a form of transparency, because clinics are visible and not hidden.

Moreover, the law requires stem cells to be processed in high-quality, certified cell-processing centres, and treatments to pass through an independent ethical-review board — there are 100 of these. An official in Japan's Ministry of Health, Labour and Welfare told *Nature* that double-blind clinical trials are expensive, and that there are ethical issues involved in giving placebos to people with illnesses.

It is possible that some of these justifications have a degree of merit, but there's still no denying that the majority of commercially available stem-cell therapies have not been tested in more rigorous phased clinical trials.

That leads to a second concern. As with all medical therapies, people regard government approval for stem-cell clinics as reassurance that treatments they offer are both safe and viable. Unless people have read the text of the law, they will not know that stem-cell products and therapies have a low barrier to regulatory approval. One doctor told *Nature* that, from a patient's perspective, an approval is an approval, and "everything else is just details".

Japan's dilemma is a global one. Every government can see a pot of gold at the end of the stem-cell rainbow, but countries know that these riches cannot come at the expense of increased risks to patient safety.

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Regulators in the United States, who have also struggled with these issues, are adhering to the international regulatory consensus for medical therapies, and seem to be getting the upper hand in their battles against treatments that have not been rigorously tested.

Japan's government must rethink its approach, and those looking to the nation's present laws as a regulatory role model must also think again.

The world needs the pioneering research that Japan and other countries conduct in stem-cell biology — and it needs promising therapies for chronic disease. But getting from one to the other takes time, and rigorous safeguards should not be circumvented. Policymakers, regulators, researchers and entrepreneurs taking short cuts are potentially putting people's health at risk. ■

Valuing nature

The United Kingdom must listen to diverse voices as it considers biodiversity's economic role.

How much do species and ecosystems contribute to the size and growth of economies? How will the unprecedented rate of biodiversity loss affect economies in the future?

Ecologists and economists have been struggling with these questions for decades, including in the pages of this journal. Governments, too, have tried to weigh in, with variable success. Earlier this month, it was the turn of the UK Treasury to announce the members of an expert panel it has chosen to continue the search for a way forward.

The panel will be chaired by economist Partha Dasgupta at the University of Cambridge, UK. The broadcaster David Attenborough will be its public face, and the team will report back in time for the conference of the parties to the United Nations Convention on Biological Diversity, which takes place in China in October 2020. The panel has issued a call for evidence.

But assessing biodiversity's contribution to economic growth is

fraught with problems because there are so many ways to value nature. Take the contribution of insect pollinators to the economy: this can be worked out by computing the cost of humans or machines required to carry out those tasks if bee populations vanished.

By contrast, valuing a lake is more complex. One method relies on asking people in surveys what they might pay to enjoy the lake and its surroundings — but that assumes that respondents will agree to the principle of payment for its benefits. Some might argue that public spaces are part of a shared commons, and are already paid for through taxation. Others might say that the lake's value to them is too great to be measured in dollars and cents.

Posing the question of nature's contribution to economic growth is itself contentious, considering that continued economic growth is a factor in biodiversity loss. We know that species and ecosystems can't withstand unsustainable human consumption and increases in spending — two of the variables that growth statistics record. Should we be measuring biodiversity's contribution to growth when our present form of growth is itself harming the planet?

The experiences of past assessments suggest that Dasgupta and colleagues will not be able to reconcile such a spectrum of viewpoints. But there are other things they can do. It is good to see the team consulting the international biodiversity research network known as IPBES (Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services), which is also undertaking a global assessment of the value of biodiversity and encountering many of the same challenges.

The IPBES assessment team has responded to the diversity challenge by embracing it: they are seeking ideas and inspiration from a wide range of people, including philosophers and historians, alongside ecologists and economists. IPBES is itself structured in such a way that the perspectives of researchers in developing countries and of indigenous peoples' organizations are mainstream, not marginal, voices.

IPBES is not rushing things — its final report is expected in 2022. And it will be posting the text of draft reports online for anyone to comment on. All comments will be considered by the team, says its co-chair, Unai Pascual at the Basque Centre for Climate Change in Leioa, Spain. The Dasgupta assessment team should consider a similarly consultative approach as it starts to plan its work.

"Assessing biodiversity's contribution is fraught with problems because there are so many ways to value nature."

Most of the world's biodiversity hotspots are in developing countries, including areas where biodiversity is protected by indigenous peoples. For many, an economic assessment, especially one led by Britain, will bring back uncomfortable memories of the age when scientists from developed countries came to nations in Africa, Asia and Latin America and took home biological samples for research and commercialization without permission — something the Convention on Biological Diversity now prohibits.

Establishing the value of biodiversity to economies is important, in part because it will help policymakers in all countries to appreciate that there's a cost to losing nature. But at the same time, an economic assessment must take into account the perspectives of the humanities, of developing countries and of members of indigenous communities.

Getting the process right matters. Too often, big policy reviews focus on the final report. As it begins work, the Dasgupta team should keep in mind the words of the late Maurice Strong, founding director of the UN Environment Programme, who famously said, "The process is the policy." ■

The past matters

To navigate the present, we must learn from history.

To count the handful of years between the newest and oldest paper on many a citation list is to know that scientists rarely have cause to look back very far. That's a problem. Research is not just about placing one new brick on top of — or instead of — the last. It is a product, and a shaper, of people, place and society. To navigate that context wisely, the long view is essential.

Why? Because although history might not repeat itself, it often rhymes. Consider post-financial-crash rises in nationalism or the predictable cycles of hubris and horror that have attended new technologies from pesticides to plastics, artificial intelligence to gene editing and self-driving cars. Recall that evolutionary theory begat eugenics; atomic physics led to the bombings of Hiroshima and Nagasaki; and machine learning has sent democracies tottering.

We ignore our past at our peril.

So, from this week, *Nature* readers are invited to walk in the company of leading historians of science as they explore how the past century and a half has forged some of the defining features of today's scientific system.

A series of essays, the last of which will appear in *Nature*'s 150th-anniversary issue on 7 November, charts the rise of government and military funding, industrial research and development, data, ethics and the superpower that is China. The series also meditates on how what we discover alters how we think of our world and ourselves.

Each author was asked the same question: "How did we get here from there?" (with 'there' being 'science in 1869', the year that *Nature* began publishing, and 'here' being science in 2019). Although the pieces range across continents and disciplines, through ribosomes and rebellions, from steam to the stars, together they tell one story: that discovery is always political.

That the powerful have steered — and have been steered — by science is encapsulated in David Kaiser's opening essay on the funding system so familiar today (page 487). Our assumption that a government is failing its people and its future if it underspends on science has its roots in the empire-building of the late nineteenth century and the war complexes of the twentieth. And it is these sweeping, strategic injections of national cash that built the vast edifice of universities, academies, institutions and spin-offs that we take for granted.

And, of course, those who pay the piper call the tune — changing research for decades or more. Climate science — the very idea of data itself, as Sabina Leonelli will explain in a forthcoming issue — got a jump-start when the sprawling Austro-Hungarian Empire of the mid-nineteenth century invested heavily in meteorology to craft a narrative of unification that only a shared weather system could supply.

Seismology sprinted to confirm the theory of plate tectonics thanks to cold-war anxieties about clandestine nuclear tests. Repeated state investments in agricultural science 'saved' China from many fates in the mid-twentieth century, Shellen Wu relates. Early chemical and communications corporations nurtured Nobel prizewinners, Paul Lucier recalls; will Facebook or Google do the same?

We could have chosen so many other signature elements of science. The university, the journal, the laboratory, the paper; peer review, metrics or patents; disciplines, observation, inquiry, experimentation and knowledge. But many of these have origin stories much longer than 150 years.

Our choices are without doubt both idiosyncratic and debatable — do tell us what you'd have picked. Yet we feel they hold an important lesson: that to understand ourselves, our moment, our challenges, options and risks, and to plot a responsible way forward, science has to know where it's come from, the problems and solutions that went before and the mistakes it really must not repeat. ■