only proper clinical trials can make that case. And the agency's critics are right to point out that this process is lengthy and expensive — perhaps too much so.

The proposed change in the law — the REGROW Act — would tackle this problem by simply doing away with the need for proper trials. It would effectively borrow a fast-track system that Japan created for stem-cell treatments and regenerative medicine. *Nature* has previously expressed concern about this system (see *Nature* **528,** 163–164; 2015). It is not a fit and proper model to export, chiefly because it grants "conditional approval" to treatments with minimal safety data and little attention to efficacy.

Therapies approved under this scheme can be marketed for a given period — around six years — after which time the treatment provider must report back on whether the treatment it has been selling to patients was safe and effective.

In other words, patients (who in Japan have to pay up to 30% of the cost even of treatments covered by national insurance) are subsidizing clinical trials. Most of these treatments, as the history of phase III trials shows, will probably fail. People who took an ineffective drug (and probably spurned other treatments to do so) will not get their money back.

Japan still has to prove that data collection under this system will be rigorous enough to prove a treatment's efficacy. And if the system works and drugs are found to be ineffective, the regulatory agency will then have to fight the uphill battle of reining back treatments that were already on the market but are now de-approved.

Overall, Japan will most probably see a flood of safe but ineffective treatments. That scenario would discourage anyone from going through the costly steps required to create therapies that really do work (if you can sell garbage for the same price, why not stick with that?). That would be a shame for a field with such promise. Is this the way the United States wants to go?

Another reason for saying that the FDA is not unduly harsh on restricting stem cells is the large number of clinics that already operate and sell unapproved treatments. A study released last week reported 351 businesses offering stem-cell treatments at 570 clinics in the United States (L. Turner and P. Knoepfler *Cell Stem Cell* http://doi.org/bkpv; 2016). Although the study does not directly accuse these clinics or businesses of wrongdoing, many of them promise stem-cell treatments for neurodegenerative diseases for which no stem-cell treatment has so far proved effective.

"The assumption that these treatments work is at the heart of the problem."

These treatments, which usually claim that a certain type of stem cell can transform into another type of mature cell able to ameliorate such diseases, require approval by the FDA. The existence of these clinics shows that the FDA is not strict — never mind too strict — in its regulation.

That the FDA moves so slowly to crack down on existing unapproved stem-cell treatments makes the prospect of conditional approval — an opportunity to embed ineffective treatments in the US health-care system — all the more worrisome.

The best way for the FDA to respond to the mood that has seeded the REGROW Act is to agree on a more efficient way to approve cell treatments. It is working to do so, but tensions are high. A hearing planned for April was overwhelmed by prospective participants. It is now scheduled for September — stretched to two days and with a public workshop added.

The FDA should strive to keep this debate on the proper topic — how to create a more efficient system that still scientifically evaluates whether treatments are safe and efficacious. To fall short would be a setback for science, and for patients. ■

Beyond Zika

The spotlight on Zika virus should help to spur broader research into birth defects.

In the time it takes you to read this article, a baby will be delivered in the United States with a birth defect. That's about 120,000 every year. For the many individuals with severe cases, childhood and beyond becomes a struggle with mental or physical disabilities, hospital visits and day-to-day worries. And that is in one of the world's richest countries. In low- or middle-income countries, surveillance of birth defects is often absent or so weak that health authorities simply don't know the scale of the problem, making it difficult to develop appropriate prevention measures and care.

The harsh realities of birth defects are shown in recent photographs of babies born in Brazil with abnormally small heads — a condition called microcephaly that seems to be linked to the mosquito-borne disease Zika. The threat of the Zika virus has put birth defects on the political and public-health agenda in a way not seen since the rubella virus (the cause of German measles) led to a pandemic of such defects in the mid-1960s.

Zika therefore provides an opportunity to greatly raise awareness of birth defects, and to bolster support for research and improved public-health action on their many other preventable causes. Researchers must urgently make this case to funders and their political paymasters before the flurry over Zika inevitably ebbs (see page 17).

One target should be the eradication of rubella. It is a scandal that, worldwide, some 100,000 babies are born annually with congenital rubella, despite the availability of a cheap and effective vaccine. The virus spreads slowly and is a low-hanging fruit for eradication through accelerating vaccination in poorer countries.

Another easy target is the compulsory addition of folate vitamins to food staples to protect against neural-tube defects, such as spinal bifida, in developing fetuses. Despite a wealth of evidence that compulsory fortification works, as well as its adoption in the United States, most countries (including all European ones) have yet to follow suit.

The longer-term challenge is to develop the research infrastructure needed to find and prevent the causes of birth defects — in particular because a whopping three-quarters of occurrences have no identified cause. Some will prove to be random events, and others will have genetic or multifactorial origins, but it is likely that many are down to environmental or infectious exposures that public-health authorities can do something about.

This sort of research requires long-term commitment and investment, and the nurturing of highly specialized research communities. Of all the types of epidemiological research, studies of birth defects are perhaps the most difficult. Although their combined human and public-health impact is enormous, individual congenital abnormalities are relatively rare in comparison with, say, lung disease. This means that population-scale databases are needed to capture and record birth defects, and to achieve adequate statistical power.

Amid the political climate of Brexit, there is a certain irony that one of the most developed surveillance systems for birth defects, the European Surveillance of Congenital Anomalies (EUROCAT), was conceived with far-sighted vision in 1974 by the then European Economic Community in the wake of the tragedies of rubella and the drug thalidomide. Such registries may seem mundane, but they are crucial if we are to underpin exploration of the causes and risk factors of congenital anomalies and to provide an early-warning system for new causes of birth defects.

Birth defects should be a top public-health priority to protect the youngest and most vulnerable members of our society. It is staggering in 2016 that they are not. ■