San Francisco, California. O'Neill has said that the FDA should approve drugs on the basis of safety alone, allowing the patient to take the gamble of whether the drug will work.

That is such a radical divergence from past practices that it is hard to believe someone with O'Neill's views would be confirmed by the US Senate, says Douglas Sipp, who studies stem-cell policy at the RIKEN Center for Developmental Biology in Kobe, Japan. "But nobody knows what Trump is going to do from hour to hour," he adds.

STEM-CELL 'CLINICS'

In 2014 and 2015, the FDA issued a series of proposals to regulate a wide swathe of clinics that claim to perform stem-cell therapies — which have not been proved to work. There are about 570 of these in the United States, according to one study (L. Turner and P. Knoepfler *Cell Stem Cell* **19,** 154–157; 2016), and their numbers are growing. The proposals have been condemned by the stem-cell clinics and patient advocates who want access to the therapies without having to wait for them to be proved effective.

But many scientists have called on the FDA to crack down on untested cell therapies. They cite concerns for patient safety and fears that such treatments will damage the reputation of all stem-cell therapies. The FDA's proposals have not yet been finalized.

FOOD FROM GENE-EDITED ANIMALS

Gene editing — which allows researchers to make targeted changes to genomes — has swept through academic and industry labs, and poses challenges for regulators who must adapt old rules to new technology.

The US Department of Agriculture has already said that several gene-edited crops do not fall under its regulatory purview. All eyes are on the FDA, which regulates genetically engineered animals, to see how it will handle the menagerie of gene-edited livestock to come. In July 2015, the Office of Science and Technology Policy ordered the agencies that regulate genetically modified foods to determine if their regulations need updating, but it remains unclear whether and how the FDA will regulate gene-edited animals.

MEDICAL TESTS DEVELOPED IN LABS

On 31 July 2014, the FDA notified Congress of its plans to expand regulation of some medical diagnostics. They would encompass tests that are developed in laboratories rather than sold as a kit, in an effort to cope with the growing complexity and importance of such tests for patient diagnosis and treatment, particularly in cancer.

Industrial and academic labs say the plan would hamper a field that is crucial for the advancement of precision medicine. Others have argued that the lack of regulation has created a wild west of unreliable tests.

The FDA has not finalized its plans, making it easier for the next commissioner to influence their ultimate form. Scott Gottlieb, a physician, investor and fellow at the American Enterprise Institute, a think tank in Washington DC, is also rumoured to be under consideration for the job, and has said that the current proposals could stifle medical innovation. But Gottlieb has acknowledged that some tests — particularly those involving multiple variables — may require some oversight. ■

CORRECTIONS

The News story 'Major rethink for outbreak response' (*Nature* **540,** 494–495; 2016) stated that a funding shortfall pertained to EDCARN. But it is the overarching WHO health-emergencies programme that is currently underfunded.

The News Feature 'What's killing the world's shorebirds?' (*Nature* **541,** 16–20; 2017) misidentified a picture of a dunlin (*Calidris alpina*) as a red knot (*Calidris canutus*).

The graphic in the 2016 News Review (*Nature* **540,** 496–499; 2016) erroneously said that the NIH was getting behind preprint publishing. It is in fact a consortium funded by the NIH that is mandating the practice.