

▶ But scientists argue that more of the CAP money should go towards environmental protection. Reforms in 2013 were meant to make CAP greener, such as a rule requiring farmers to grow at least three crops to maintain biodiversity, but this did not assuage all concerns. “It’s pretty hard to make the Common Agricultural Policy worse than it currently is,” says Dieter Helm, an economist at the University of Oxford.

In September, Helm wrote a report exploring ways in which a post-Brexit United Kingdom might replace CAP (go.nature.com/2jksoc). His preferred option is a radical overhaul that would eliminate automatic subsidies to farmers. Instead, the government could target investment at rural programmes that provide proven benefits, such as reducing pollution or increasing biodiversity, he suggests. These could involve payments to farmers who modify their farms to provide such green benefits.

Richard Brazier, who studies the environmental impact of land use and agriculture at the University of Exeter and was a witness in the parliamentary inquiry, also spots an opportunity to reform CAP. His specialism is landscape restoration, in which farmed land is altered to provide better ‘ecosystem services’ alongside food production. One example is reintroducing beavers to benefit flood management. A UK-specific agriculture policy could aim to rewild between 1% and 10% of farmed land, he suggests.

He recommends that any new policy removes existing barriers to rewilding, such as CAP rules that effectively penalize farmers for transforming woodland or ponds into wildlife habitat that does not produce crops. The parliamentary report also mentions the possibility that rewilding, and the removal of these disincentives, could feature more prominently in UK-only laws.

But there are risks associated with losing CAP. The government has guaranteed to fund existing CAP payments until 2020, but on 4 January, environment minister Andrea Leadsom pledged to “design a domestic successor to CAP” while scrapping various pieces of EU legislation — including the three-crop rule — and “cutting the red tape that comes out of Brussels”.

Even researchers who have criticized CAP in the past fear that modifications could undermine its environmental benefits. Lynn Dicks, an applied ecologist at the University of East Anglia in Norwich, co-authored a highly cited critique of the 2013 reforms (G. Peèr *et al. Science* **344**, 1090–1092; 2014), but in 2013 she also reported that many schemes designed to protect wildlife produced consistent benefits (L. V. Dicks *et al. Conserv. Lett.* **7**, 119–125; 2014). “I think we’ve been quite innovative actually, within the CAP,” she says. “It’s terrifying to me that we might lose all of it.” ■



This hornless calf was created using gene-editing technology.

COURTESY OF RECOMBINETICS

POLICY

The issues facing Trump’s FDA chief

The next leader of the agency will have an opportunity to reshape its approach to regulation.

BY HEIDI LEDFORD

US president-elect Donald Trump wants to speed up drug approvals and broadly reduce government regulations. What that means for the US Food and Drug Administration (FDA) is not yet clear — but if Trump’s choices for other posts are any guide, he will look for an FDA commissioner to shake up the status quo.

The next FDA chief could shift the agency’s stance on everything from medical testing to clinics that claim to provide stem-cell therapies.

Until Trump announces his pick and that person is confirmed by the US Senate, the drug industry will struggle to map out its future, says David Fox, a partner at the law firm Hogan Lovells in Washington DC. “People in this industry need to plan substantially in advance,” he says.

Nature looks at what the next administration could push forward — or sweep away.

SWIFTER DRUG APPROVALS

The FDA has struggled to balance pressure for speedy drug approvals with its desire for convincing clinical data. The situation came

to a head in September 2016 when the agency approved a drug to treat Duchenne muscular dystrophy.

Patient advocates cheered eteplirsen, made by Sarepta Therapeutics in Cambridge, Massachusetts — one of only a few treatments for the devastating genetic disease. But some FDA reviewers were dismayed that the agency had acted on the basis of a clinical trial that included only 12 children and did not demonstrate changes in symptoms or disease progression.

Industry and patient advocates have been left to guess at what standards the FDA will apply to future decisions on drugs to treat rare diseases. “The new commissioner is going to face the aftermath of the Sarepta approval,” says Fox. “It’s a very big issue: his or her role is to help the agency manage the patient voice and maintain a certain standard.”

By law, the FDA must require “substantial evidence” of efficacy and safety before it approves a drug, but that term is subject to interpretation, says Fox. And the agency could soon come under tremendous pressure to lower the bar. One person thought to be under consideration to head the agency is investor Jim O’Neill of Mithril Capital Management in

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.