risk for colon cancer. "One might suggest they [should] change the age and frequency of colonoscopy," Nussbaum says. "These are details that do not seem to have been taken into account by FDA in their discussion. That leads me to wonder if they are aware of them."

"It seems laboratories can throw in a wider group of disease risks once they show they know how to perform the testing," says regulatory attorney Gail Javitt of Epstein Becker Green in Washington, DC. FDA has tried to get at that issue by putting much of their faith in labeling and in the other special controls, she says, which should help rein in potential maverick testing outfits. Tests are constrained by having to be among those for well-established disease-gene associations, by having to meet a standard of technical validation and by having to present information in a way their customers can truly understand.

The FDA appears comfortable that with proper labelling, personal genome tests are ripe for consumer consumption—with some significant exceptions. Several categories of genetic risk tests are excluded from the scope of the new regulations and remain subject to more rigorous premarket review if sold directly to consumers. They include tests intended for prenatal screening, determining predisposition to cancer that could lead to taking medical action, pharmacogenetics testing or assessing the presence of deterministic dominant variants. "They've taken a lot off the table that scares people," Javitt says.

Direct-to-consumer tests may help individuals make decisions about lifestyle choices or inform discussions with healthcare professionals. In deciding whether to authorize a certain test, FDA is trying to weigh up the risks and benefits of having this information. One way to do this is to draw a line between what information is medically actionable and what is not. Under their current risk-based strategy, the agency appears to be saying there is not much risk in telling people scary stuff that is probabilistic, but there is risk in telling people things where they might go seek treatment inappropriately, says Harvard medical geneticist Robert Green. "I don't think their categorization makes a whole lot of sense," he says.

Also, as tests proliferate in quantity and complexity, it will become harder to ascertain their quality. Even an upgrade to an existing test throws up a number of unknowns related to the algorithms' sensitivity and specificity.

Direct-to-consumer testing is growing in power, says Caplan, because of the societal shift toward patient and consumer enfranchisement. "There is a huge movement toward making autonomy and choice the top values that govern healthcare and even all walks of life," he says. "Anything that even hints at the need for an intermediary or someone to interpret, the political winds are blowing against that."

"I worry that the wrong information is going to end up in the hands of patients, but it may be that the best way to get medicine on board with the genetic revolution is to offer alternative paths of information to patients," adds Kohane. "Given the fact that doctors have essentially abdicated their expertise/leadership in this area, a broadening of access to this knowledge can only help."

The proposal to reduce the premarket review burdens for genetic health risk assessment tests will become final after a comment period ending early in 2018. "It's hard to see who would object to the reduced requirements so as to change FDA's view," Javitt says. Once the agency agreed to authorize 23andMe's test in April, they created a classification that is available to all laboratories who want to offer these tests, she says.

Mark Ratner *Tequesta, Florida*

PODCAST

First rounders: Susan Windham-Bannister

Susan is president and CEO of Biomedical Growth Strategies and was the founding president and CEO of the Massachusetts Life Sciences Center (MLSC). Her conversation with *Nature Biotechnology* covers her childhood in segregated St. Louis, her work at MLSC helping grow the life sciences sector in Massachusetts through Governor Deval Patrick's $1-billion initiative, and race relations in Boston and the United States.
http://www.nature.com/nbt/podcast/index.html

Bluebird's BCMA CAR-T impresses at ASH

Bluebird Bio and partner Celgene reported updated data from their CAR-T cell asset bb2121 targeting B-cell maturation antigen (BCMA), prompting talk of a looming race between anti-BCMA assets. The data were presented at the American Society of Hematology (ASH) conference in Atlanta in December. Bluebird's bb2121 are autologous T cells engineered *ex vivo* with an anti-BCMA02 CAR lentiviral vector to target tumor necrosis factor receptor superfamily member 17 (BCMA) and 4-1BB as a co-stimulatory domain. The Cambridge, Massachusetts–based biotech reported in its CRB-401 phase 1 dose-escalation trial in relapsing/refractory multiple myeloma an objective response rate of 94% in 18 patients at 40 weeks. These results included 7 confirmed complete responses, 3 unconfirmed complete responses and 16 good partial responses. Safety was good although cytokine release syndrome was seen in 10% of patients, and there was one case of neurotoxicity. Neither the escalation study nor the phase 2 KarMMa trial run by Celgene of Summit, New Jersey, will require BCMA expression as a criterion for enrolment; because the CAR is exquisitely sensitive it can pick up BCMA expression levels far below those detected by assays, according to bluebird's chief medical officer, David Davidson. Bluebird's competitors are Chinese firm Nanjing-based Legend, Novartis, Memorial Sloan Kettering Cancer Center and the US National Cancer Institute, all of which have BCMA-targeting CAR-T cell therapies in development. (*Nat. Biotechnol.* **35**, 590–600, 2017).

"Biotech solutions can be sold on a mythos that a group of improbable scientists with a unique set of talents invented a technology that they should be allowed to sell for as much as possible. Keep in mind, though, that most of these technologies were developed over decades by many academic scientists and paid for by taxpayer." Jim Kozubek, scientist and author, opines on the consequence of "big science" for academic researchers. (*Los Angeles Review of Books,* 25 November 2017)

"[Gene drives are] basically the strongest chemical that there is.... If you didn't have to spray, that is a huge deal," says Nick Matteis, an executive with The California Cherry Board, a group that supports gene drive research to combat the spotted wing drosophila, which is threatening commercial cherry orchards. (*MIT Technology Review*, 12 December 2017)