

First 3D-printed pill

The US Food and Drug Administration (FDA) in August gave the go-ahead for a 3D printed pill. The drug, Spritam (levetiracetam), a version of a widely used drug for controlling seizures, is made by Aprexia Pharmaceuticals of Blue Ash, Ohio. Although the regulator has previously authorized 3D printed medical devices, this is the first 3D-printed prescription drug to gain approval. The company uses ZipDose technology, which was developed using a 3D platform that originated at the Massachusetts Institute of Technology. Printing layer by layer allows the components to be packaged more tightly, producing high-dose pills containing up to 1 gram of drug in an individual tablet. The pills are highly porous, enabling them to dissolve instantly when taken by patients. The overall aim is to make pill-taking easier for patients, including those who have difficulties swallowing large tablets. 3D printing also opens up the possibility of manufacturing bespoke drugs based on different patients' needs. Aprexia plans to launch Spritam early in 2016.

Syngenta rebuffs Monsanto, again

After a tempestuous trans-Atlantic courtship that took shape several months earlier, the board members of Basel-based Syngenta in August unanimously declined to accept a takeover-merger bid from St. Louis-based Monsanto. The latest offering from Monsanto pegged Syngenta's value at about \$47 billion, and it included a reverse break-up fee of \$3 billion in case the Monsanto bid did not meet approval from regulators in several countries who were expected to raise antitrust concerns. Despite those sweeteners, Syngenta board members said that Monsanto's enhanced offer still "significantly undervalued" the worth of the Swiss seed and agrichemical company and "was fraught with execution risk." Soon after these discussions came to a halt, Syngenta announced plans to build shareholder value, with the first steps being plans to sell off its global vegetables seed business and to resume a share repurchase program. Monsanto officials, reiterating regrets over the collapsed negotiations and missed prospects for "substantial synergies," said the company would continue to focus on growth opportunities from its core businesses of breeding, biotechnology, data science and next-generation biologicals.

“This is a perfect example of the dangers of transparency abuse.”

University of Florida's Kevin Folta blogs about the US Right to Know's portrayal of him as a corporate mouthpiece for Monsanto, after trawling through 5,000 of his personal e-mails obtained by a FOIA request. (kfolta.blogspot.com, 7 September, 2015)



microphone to detect impairments in vocalization. Stephen Friend, president at Sage, a nonprofit organization promoting open science and patient involvement in research, sees the mPower trial as a success. "We now have data from thousands of individuals, and what happens to them before and after they take their medication every day," he says.

Even before ResearchKit entered the scene, drug developers were interested in mobile devices. Basel-based Novartis and San Diego-based Qualcomm Life in January 2015 began a collaboration to collect medical data from trial participants in their homes, and a pilot study completed by GSK and partners Medidata of New York, last November, demonstrated the potential to stream health data in real time using various wearables that interface directly with mobile phones. More recently, the Scripps Translational Science Institute in La Jolla embarked on a 4,000-patient trial to determine whether wearing Scanadu Scout, a wireless sensor that tracks four physiological metrics, can affect a person's health behavior.

For Apple's ResearchKit one advantage stands out: it plugs into devices that many people already carry around. Pickett also

notes that the company has built robust tools for securely recording informed consent from users. There are also minuses. Although the Apple Watch is especially nonintrusive, which is a plus as a monitoring tool, its sensing capabilities are restricted to a handful of measurements, such as heart rate or movement. The dimensions of the Apple Watch screen—even the larger iPhone display—could also be an issue. "It could be a problem for elderly patients that might not be able to see as well or for somebody who is in pain and not able to do a lot in terms of active data entry," says Pickett.

Nonetheless, turning iPhones and watches into devices that boost patient participation and also collect richer and deeper datasets could transform clinical trials. And the opportunity to monitor each individual's response is unprecedented. "My hypothesis is that better tracking of patients at baseline and understanding their fluctuations will allow more accurate measurements of interventions in a way that omics [large-scale data gathering] is not going to give you," Pickett says.

Michael Eisenstein Philadelphia

Cat poop coffee goes biotech

A Brooklyn-based synthetic biology startup wants to reinvent morning coffee—or at least the kind that sells for up to \$80 a cup.

That's the price of *kopi luwak*, considered the Holy Grail of coffees, produced from partly digested coffee 'cherries' eaten by wild civets native to southeast Asia. The authentic *kopi luwak* is made from beans collected

from the civets' dung and is prized for its smooth and less bitter taste and earthy flavor. But the increasing demand for this rare brew has led to the growth of a largely unregulated industry, with reports of inhumane caging and force-feeding of civets and unscrupulous coffee producers using chemical additives to attain a similar flavor. Now microbiologist entrepreneur Camille Delebecque is preparing to launch Cultured



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Coffee, which uses controlled secondary fermentations with seeded microbes—and no civets—to craft a flavor profile inspired by *kopi luwak*. In addition to the choice of beans and roasting conditions, fermentation adds a third possibility for exploring flavor landscapes in coffee, Delebecque says. A Kickstarter campaign to support his company Afeineur exceeded his \$15,000 goal by nearly fourfold.