EC approves long overdue GM plants

After a one-and-a-half-year standstill, the European Commission (EC) has cleared the import of ten new types of genetically modified (GM) maize, soybeans, cotton and oilseed rape as either human food or animal feed, and two GM carnations for sale as cut flowers. The commission also renewed the licenses for seven genetically modified organisms (GMOs). The newly approved GM crops and flowers produced by Monsanto, BASF and Bayer CropScience had previously undergone a full authorization procedure, including a positive scientific assessment by the European Food Safety Authority. The approvals follow an earlier proposal to change the rules of GM approval allowing individual countries to restrict or prohibit GM imports even after they have been approved by the EC. These authorizations are a step in the right direction, declared industry body EuropaBio. The crops have been cleared for use in animal feed only, not for human consumption. Only one GM crop is currently grown in Europe: Mon810, Monsanto's maize, in Spain and Portugal.

"There is a need at times to grab big pharma by the lapels and make it clear that they are seriously out of line and are hurting people." Editors at *Neurology* comment on an article in their April issue by Canadian researchers that showed old multiple sclerosis drugs which once cost less than $10,000/year now cost $50,000–65,000, matching the price of newer competing drugs. (*Bloomberg Business*, 24 April 2015)

"No one should confuse any of these companies' behavior with real corporate responsibility. That would require companies to push back against the orchestrated fear of GMOs instead of validating it." The editors of the *Washington Post* in an editorial on Chipotle's announcement that their menu is GMO-free. (*Washington Post*, 29 April 2015)

"We've had people who thought they were at the end of their options and we tested them and found something that wasn't expected that allowed them to be eligible for a drug. When the drug was used, they responded." Jonathan Tait, director of the genetics and solid tumor diagnostics testing laboratory at the University of Washington Medical Center in Seattle, on his group's collaboration with IBM to make tumor profiling "simpler, faster and more widely available." (*The Seattle Times*, 5 May 2015)

Medtronic deal flurry raises artificial pancreas prospects

Dublin-based device maker Medtronic broadened the scope of its diabetes business with five new deals announced this spring. A collaboration with IBM's Watson Health unit in New York, an investment in DreaMed Diabetes' artificial pancreas and the acquisition of care clinic Diabeter in Rotterdam, the Netherlands followed venture capital investments in software company Glooko of Palo Alto, California and stem cell company Semma Therapeutics of Cambridge, Massachusetts. As Medtronic and its main competitor Johnson & Johnson, ramp up data collection, improve algorithms and develop smartphone apps, the focus is shifting toward providing patients with integrated solutions for diabetes management.

"What they're doing in diabetes is the same as they are doing company-wide and that is developing end-to-end solutions for providers," says Debbie Wang, an analyst with Morningstar in Chicago. The new strategy is a response to healthcare reform, as doctors will increasingly be compensated for improved outcomes, rather than for high volume, she says. "So coupling devices with ancillary care becomes an attractive economic opportunity."

Of Medtronic's deals, several respond to its hunger for health data. The partnership announced April 13 with IBM Watson's newly formed Watson Health unit will provide a cache of it, along with analytical capabilities. IBM and Medtronic plan to pull data from electronic medical records, health insurance claims, population health data, and from Medtronic's marketed diabetes devices, to spot patterns in diabetes progression and predict health risks. Francine Kaufman, chief medical officer at Medtronic says the company will focus on at-risk patient populations, such as those who have visited an emergency room. With those data, the company can develop protocols to intervene at the right moment, using the right therapies, she says.

Such data amalgamation could bring to fruition what some people in the industry consider the holy grail of diabetes management: the artificial pancreas. Such a system includes a continuous glucose monitor to track a person's glucose levels, an insulin pump that delivers insulin and potentially other therapies, and an algorithm that links the two devices and determines when and how much insulin is necessary. It would be fully automated, with little to no intervention from the patient.

Medtronic and its competitors already have glucose monitors and insulin pumps on the market. But an integrated system with an algorithm reliable enough to run the artificial pancreas is still in clinical development. That's where Medtronic's collaborations are key. The company plans to improve algorithms it has developed from data collected from its insulin pump and continuous glucose monitor users with IBM Watson's machine learning capabilities, Kaufman says.

Medtronic is also turning to Israeli startup DreaMed Diabetes in Petach Tikva, Israel, to improve its artificial pancreas algorithm. The company announced April 6 that it had licensed DreaMed's algorithm, called Glucositter, which was shown in a small trial to give children with Type 1 diabetes tighter glucose control and fewer and shorter episodes of dangerously low glucose levels (hypoglycemia) over night (*N. Engl. J. Med.* **368**, 824–833, 2013). Medtronic also made a minority investment in DreaMed of $2 million.

Most clinical studies of the artificial pancreas have been like DreaMed's: small, and limited to hospital or semi-controlled settings such as children's camps. So far, results are showing that an automated system is better at managing glucose than are the users themselves. And the pace and size of studies are picking up, says Aaron Kowalski, vice president of research at New York-based JDRF (formerly known as the Juvenile Diabetes Research Foundation), a diabetes funding organization. The US Food and Drug Administration (FDA) in 2012 released guidelines for makers of artificial pancreas systems, giving them a regulatory pathway. And last year the US National Institutes of Health put out a $20 million call for proposals for advanced clinical trials in home settings.

Medtronic is not alone in its vision for a data-driven, integrated model of diabetes solutions. New Brunswick, New Jersey–based Johnson & Johnson is also on the hunt for an artificial pancreas and, like Medtronic, is using back-end data to help it get there. The company is working on its algorithm through partnerships with JDRF, the Joslin Diabetes Center in Boston, and San Diego-based Dexcom, a maker of continuous glucose monitors.

Johnson & Johnson announced also on April 13 that it too had partnered with IBM's Watson Health unit, in this case to create mobile-based coaching systems and apps to address consumer wellness and chronic conditions. The companies are still prioritizing the therapeutic areas of focus for that partnership, but diabetes will likely be one of them, says Ashley McEvoy, company group chairperson at Johnson & Johnson.