## Faster approval for breakthrough devices

The US Food and Drug Administration is proposing to expedite approval of certain medical devices. The agency has issued a draft guidance for a new, voluntary program delineating how the agency intends to accelerate approval of high-risk devices, diagnostics included, that address unmet public health needs. Under the proposed Expedited Access for PreMarket Approval, or EAP, the agency would offer device developers earlier and more interactive engagement with its staff—including the involvement of senior management and greater collaboration on collecting the requisite scientific and clinical data to support approval. Notably, under the EAP, companion diagnostics for a drug reviewed under the accelerated drug approval pathway may be considered for EAP. In a related new draft guidance, the agency addresses pre- and post-market data collection for class III medical devices, which are those with highest risk, to place a greater reliance on post-market collection as a basis for approval, where appropriate. "Both documents illustrate the FDA's continued efforts to work earlier and closer with device developers in order to expedite the introduction of new technologies in the US market," notes ADVI, a Washington, DC–based healthcare advisory services firm. Manufacturers often turn to the EU, which has fewer hurdles in the regulatory process, for device commercialization. *Mark Ratner*

## NIH 'hubs' aid translation

In April, the National Institutes of Health (NIH) in Bethesda, Maryland, launched the NIH Research Evaluation and Commercialization Hub (REACH) program. The initiative will support proof-of-concept centers, or hubs, through grants of up to $1 million a year for three years. The focus for the REACH hubs, modeled in part on the Innovation Corps program of the National Science Foundation, is on converting research innovations into drugs, devices, vaccines or other products that help meet healthcare needs. Initially, NIH expects to fund three such hubs with a total of $9 million drawn from funds already appropriated to the agency. The program also provides access to expertise in regulatory, reimbursement, business, legal and project management. "That could serve to ensure these innovators are better equipped to advance their research projects and launch the next generation of biotech companies," says Cartier Esham, executive vice president, Emerging Companies Section for the Biotechnology Industry Organization (BIO) in Washington, DC. High-level impetus for the NIH program comes from the President's Council of Advisors on Science and Technology (PCAST) and its 2012 report on lagging drug development. "These are encouraging signs," says Garry Neil, who heads R&D at Medgenics in Wayne, Pennsylvania, and whose focus is rare diseases. "But much more needs to be done if we are going to reach the ambitious goals set in the PCAST report." *Jeffrey L Fox*

for Monsanto. A breeder would need to know a great deal about the characteristics of the particular plants he or she is working with, such as maturity, root strength, stalk strength and disease resistance characteristics. "Without this information, seed from a random corn plant wouldn't be immediately useful to a breeder trying to develop hybrids that will meet the needs of particular growers," Helscher adds. Deducing this information about the plant would be daunting and would take several years of work, but it can be done, he says.

The accused men, however, seemed to have some knowledge of the plants' characteristics, given that they were apparently targeting seed with elite properties. They were first seen acting suspiciously on May 3, 2011. Mo Hailong, director of international business at DBN, was found on his knees, presumably digging up seeds in a field in remote Iowa where inbred seeds belonging to DuPont Pioneer had been planted the day before. Pioneer officials later told the FBI that that particular field was growing "one of the company's two or three most highly anticipated inbred corn seed products" not yet on the market, according to the criminal complaint.

If he is found guilty, Mo faces up to ten years in prison and a $5 million fine. Mo's attorney, Mark Beck, a partner at Orrick, Herrington & Sutcliffe in Los Angeles, told *Nature Biotechnology* he was in the process of preparing the case for trial and could not comment on it at this stage. DBN and Kings Nower Seed declined to comment for this story.

The FBI is investigating several potential insiders at US seed companies who are suspected of providing the men with the locations of important fields, according to documents filed with the US District Court in the Southern District of Iowa.

The Mo case is not Pioneer's first encounter with trade secret theft. In a case decided in 1991, Pioneer sued rival Williamsburg, Iowa–based Holden Foundation Seeds for developing some of its seed products using one of Pioneer's inbred lines. The US District Court decided in favor of Pioneer and ordered Holden to pay Pioneer $46.7 million. The decision was upheld by an appellate court in 1994, but shortly after, the two parties settled out of court for an undisclosed amount, according to Kershen. Holden was later acquired by Monsanto.

**Emily Waltz** *Nashville, Tennessee*

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**"We could have as many as five states by the end of this year with mandatory labeling. Is the FDA going to allow them [the states] to dictate national policy, or will they step in with a federal blueprint?"** Colin O'Neil, director of government affairs at the Center for Food Safety in Washington, DC. The war over GMO food labeling goes on. (*Los Angeles Times*, 6 June 2014)

**"If we don't change the basic pricing structure of pharmaceuticals, this system will collapse."** Steve Miller, CMO for Express Scripts, America's largest pharmacy benefit manager, on the pricing ruckus that erupted with the approval of Gilead's $89,000 HCV treatment Sovaldi. (*The Economist,* 7 June 2014)

**"Does anyone think Merck will introduce a drug with an advantage and then price it at significantly less than Sovaldi?"** Matthew Herper of *Forbes* predicts no relief in sight for high-priced drugs following the news that Merck bought Idenix, a maker of HCV drugs, for $3.9 billion in cash. (*Forbes,* 10 June 2014)

**"Cloud computing is the great leveler. It opens up new avenues for talent development."** Mark DeLong, director of research computing at Duke University, on an agreement between Google and the foundation Autism Speaks to house 10,000 complete genomes of children with autism. (*The Wall Street Journal*, 9 June 2014)

**"This is probably the biggest phase 1 trial ever conducted in oncology. We were excited to see that pembrolizumab [anti-PD-1 antibody] was effective in previously untreated patients as well as in those who had multiple prior therapies, including ipilimumab [Yervoy, anti CTLA-4 antibody]."** Antoni Ribas of UCLA Jonsson Comprehensive Cancer Center on trial in patients with advanced melanoma. (*MedPage Today*, 5 June 2014)

**"The question is, can you extend the person's life with quality? That's what you're trying to achieve."** Paul DiSilvestro of Women and Children's Hospital of Rhode Island in Providence. DiSilvestro was commenting on data presented at ASCO in June, showing that combining PARP inhibitors extends progression-free survival in ovarian cancer patients, but with additional toxicities. (*BioCentury*, 9 June 2014)