Evaluate Vantage

December 30, 2016

Medtech news over the Christmas period 2017

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There has been no time off for the lawyers over the festive week, with three medtech companies facing legal difficulties with shareholders, payers and competitors. Like Jacob Marley visiting Scrooge, a case against Medtronic has come back from the dead, and Alere is fighting any way it can to keep its hopes of being bought by Abbott alive.

On the regulatory side, the FDA has released the final version of its cybersecurity guidance. The recommendations are sensible, but they are just recommendations: without legal force it is unclear how meaningful an effect the guidelines will have.

Litigation

December 28

Medtronic has received an unpleasant holiday surprise from 8th US Circuit Court of Appeals in St Paul, Minnesota: a revived lawsuit accusing the company of covering up negative side effects of its Infuse bone graft. The court found that an earlier judgement that the shareholders had sued too late had been in error, and that a case could still be brought.

Infuse, which contains recombinant human bone morphogenetic protein-2, was approved in the US in 2002. In 2011 a journal article suggested that studies conducted by researchers with financial ties to Medtronic understated Infuse's risks. A year later, the US Senate Finance Committee stated that Medtronic had been "heavily involved" in designing the biased studies. In 2013 shareholders sued Medtronic alleging that this behaviour had inflated the company's stock. The case will now be returned to the lower court for further proceedings.

December 28

Alere is also having its day in court, having filed suit against the Centers for Medicare & Medicaid Services with the aim of forcing it to reinstate coverage of devices from Alere's Arriva diabetes division. The CMS revoked coverage in November, saying that Arriva had billed Medicare for claims on 211 dead patients (*Abbott tries to escape Alere's grasp, November 7, 2016*). Alere is appealing against the CMS's decision for a second time – the first appeal was denied – and expects a hearing within 30 days and a decision within three months.

But that is not enough: it has also filed a federal lawsuit to force CMS to stay the process and reinstate coverage while its appeal to the CMS is heard. A decision on this new lawsuit is expected by January 5, Alere said. Even if both these endeavours are successful it remains highly doubtful that Abbott's $6bn buyout of Alere will go ahead.

December 23

Neovasc has had to fork out $70m in its mitral valve patent dispute with Edwards Lifesciences, but it has at least prevented Edwards getting hold of the cash – for now, anyway. The smaller group has obtained a stay of judgement as part of its appeal against Edwards' Cardiaq subsidiary, preventing Cardiaq from enforcing the award pending the outcome of the appeal. Instead Neovasc will deposit the $70m into a joint escrow account.

In May, a federal jury in Massachusetts found that Neovasc misappropriated trade secrets from Cardiaq when developing its Tiara transcatheter mitral valve. A further $21m in damages was later added. Edwards inherited the lawsuit when it acquired Cardiaq Valve for $350m in 2015 (*Edwards' $350m CardiAQ buy ups mitral valve stakes, July 13, 2015*).

If Neovasc's appeal is unsuccessful it will need significant financing to remain solvent, according to analysts at Leerink. However, if Neovasc wins in court it could be in a good position, as Tiara could be the first transcatheter mitral valve to reach a market worth around $9bn.

Regulatory

December 27

The FDA has issued final guidance on how best to protect medical devices from cybersecurity threats once they are already on the market. The agency says manufacturers should continuously monitor and address cybersecurity concerns once a device is being used by patients.

The steps it recommends that medtech companies take include: having a way to monitor and detect cybersecurity vulnerabilities in their devices; assessing the level of risk a vulnerability poses to patient safety; working with cybersecurity researchers to identify potential vulnerabilities; and upgrading software to address cybersecurity issues before they can be exploited.

It also suggests timeframes; if a company finds that a class III medical device – a pacemaker, for example – can be reprogrammed by a hacker it ought to inform patients and doctors and put interim fixes in place within 30 days. It should develop, validate and deploy a permanent fix within 60 days. That said, the guidance is a list of recommendations rather than binding regulations, raising questions of how seriously industry will take it.

Deals

December 27

Nikon and Verily Life Sciences have formed a partnership in which the Optomap technology developed by Nikon's Optos subsidiary will be combined with the Google unit's machine learning technology to improve retinal imaging. The technology is intended to allow enhanced screening of diabetic retinopathy and diabetic macular oedema by diabetes specialists, allowing patients to be referred to ophthalmologists more efficiently.

Optomap can produce ultra-widefield high resolution digital images of around 82% and 200 degrees of the retina, which the company claims no other device can do. Details of the deal, particularly on the financial side, are scant, but adding the Google unit's artificial intelligence expertise to Optos's strong commercial presence among eyecare specialists could be a sound idea.

Trials

December 29

Humacyte has begun a phase II trial of its bioengineered blood vessel technology, Humacyl, as an artificial bypass graft in patients with peripheral arterial disease. The study will enrol 20 PAD patients in whom Humacyl will be surgically implanted above the knee; the study will test whether it can improve circulation and repair human arterial blood vessels.

The graft is made using cadaveric human aorta cells, grown in a bioreactor on a tube-shaped biodegradable scaffold. An extracellular matrix grows as the scaffold degrades, and the cells are then removed from the matrix to make it non-immunogenic. PAD is the second indication for which the technology is being developed; it is also in a 350-patient phase III study assessing its use as a haemodialysis graft in patients with end-stage renal disease.

December 23

Presbia's Flexivue Microlens was CE marked in Europe in 2009, but it has yet to make it to the US. It got a little closer, however, with the release of two-year data from its three-year US approval trial. The device is implanted in the patient's non-dominant eye to correct presbyopia – longsightedness that is often age-related.

The interim data show that the 421 patients enrolled up to November 30 had an average gain of five lines of uncorrected near visual acuity – the ability to see close objects without prescription enhancement – in treated eyes. Around 83% of patients achieved at least 20/40 uncorrected distance vision, and 98% of achieved at least 20/40 best corrected distance vision in the treated eyes. The company says it expects to conclude the trial and submit the data to the FDA in September 2017.

Analysts at Jefferies point out that the FDA approved Revision Optics' Raindrop implant on similar data: near visual acuity improving by five lines and 98% of patients achieving uncorrected near visual acuity of 20/40 or better. They write that US approval could come in the first half of 2018.

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