

## For J&J, Drug-Coated Stents Were an Albatross

Johnson & Johnson (J&J) has ceased development of its Nevo heart stent and stopped manufacturing its Cypher stent. The Cordis business unit has decided to dump these drug-eluting stents (DES) but will continue to sell bare metal stents. DES have not performed as expected in recent years, particularly for J&J. Cypher, which was introduced in 2003, saw annual sales of \$2.6 billion. But the stent was on track to generate only about \$400 million this year, according to Gabelli & Co. analyst Jeff Jonas.

+++++

## Senators Question Medtronic on Bone-Growth Product

Senators Max Baucus (D-MT) and Chuck Grassley (R-IA) have sent a letter to Medtronic requesting documents and information about Infuse, the company's bone-growth product. In the letter, the senators express concern that serious medical side effects were ignored by the company and the clinical investigators who vetted the product, which has since been linked to sterility in men and other complications. The senators are also interested in any financial ties between the clinical investigators and the device maker.

+++++

## Japan's New Policies Geared to Increase Its Competiveness

Japan's two primary medical device industry associations have issued a policy agenda. The Japan Federation of Medical Devices Associations and the Medical Engineering Technology Industrial Strategy consortium are pushing for the creation of a Japan-led medtech community within Asia. Their objective is to help Japan remain competitive in Asia as the region experiences growth.

# Nanotech Poised for Big Leap

Some of the most optimistic predictions about how developments in nanotechnology will affect our lives sound a bit far-fetched. For example, famed futurist Ray Kurzweil expects that, by mid-century, we'll have nanomachines travelling through our bodies, repairing cells and wiping out diseases. By 2040 or 2050, he believes, nanotech will make it possible for us to be immortal.

However, there is some question as to whether researchers will be able to develop nanomachines at all in the coming decades.

"It depends on what you mean by nanomachines," says Sara Brenner, MD, MPH, the assistant vice president for NanoHealth Initiatives and assistant professor of nanobioscience at the College of Nanoscale Science and Engineering (CNSE), part of the University at Albany in New York. "Nanoscale systems with motors are hypothetical ideas at this point," she says. "I don't know if we'll see those in our lifetime."

But other types of nanotechnology are already becoming a reality. CNSE is currently developing a range of nanomaterials and nanodevices. The faculty is working on nanospun fibers and 3-D matrices, which could be precursors to artificial cells and organs, Brenner says. Antibiofouling surfaces in the works could be used in both temporary and permanent medical devices, such as catheters and implants. IBM, a key tenant in the industrial-academic facility where Brenner works, is also developing nanoscale electronics. Some of those components were used in Watson, the computer that recently beat its human competitors on the television game show *Jeopardy!*

Watson's win may be a harbinger of the advance to come in artificial intelligence. "Whether we call it intelligence or not, there's absolutely no arguing

that the pace of innovation in this area is accelerating," Brenner says. "And to the extent that humans learn to design and use those systems, that's where we are really going to start to see magnificent breakthroughs."

But Brenner says we will likely see ex vivo tools and diagnostics, such as the lab-on-a-chip, before in vivo diagnostics and treatment modalities such as implantable biomaterials, drugs, artificial tissues, and organs.

"Product development at this point is staggered, so we will see products working their way to the market anywhere from now through the next several decades and beyond," she says. "How quickly certain products progress does depend on regulatory, health and safety, economic, and other factors—perhaps on the order of 5–10 years."

Applications such as antibiofouling surfaces may be introduced in different ways at different times. For example, nanotechnology that could help prevent the spread of hospital-acquired infections by making surfaces such as keyboards,

door knobs, and table tops more resistant to bacterial adhesion could become mainstream in a few years, Brenner says. On the other hand, nanotech surfaces on implantable structures, such as artificial hip joints and heart valves, will likely take longer to develop. Brenner explains that "this is partly because there is likely less risk associated with new materials being used outside of the body than inside the body, and therefore a shorter and less expensive runway to demonstrate the safety and effectiveness of such applications," she says. "Nanotechnology is already making its presence felt in reshaping traditional diagnosis, treatment, and prevention of disease, and it is all but certain to have a profound effect on health-care in years to come." —Brian Buntz



Sara Brenner, MD, MPH, shown on the left, works on research with Umaru Barrie, a premed student, in one of CNSE's NanoBio Laboratories.

## OTHER STORIES

Study: Patients Willing to Pay Extra For Easy-to-Use Devices 14 |  
510(k) Process is Harder on Small Companies 15

## Study: Patients Willing to Pay Extra For Easy-to-Use Devices

A study by Cambridge Consultants found that a majority of diabetes patients would shell out extra cash for user-friendly devices. The study examined people who rely on devices like insulin pumps on a daily basis. Out of 240 patients, 77% said

they would likely pay a premium (about \$5 more, out of pocket) for a device that was easier to use than what they were currently using. And while 28% of patients who were given the option to choose a device simply went with what their physician told them

to use, 21% said that they do their own research and make their own decisions. This is significant, says study author Melanie Turieo, because it confirms that usability, which has not always been a top priority for device makers, is important to patients.

Diabetes patients, she says, might be slightly more accustomed to making their own choices about treatment because there are a lot of options available, says Turieo, who consults with device makers about human factors. However, she says the number of respondents who reported actively making their own decisions was “surprisingly high.”

“They go out there, they look at the different options, and they have a lot more input to that decision than I think we realized,” Turieo says.

Device makers, Turieo says, are often not thinking as much about usability as their cus-

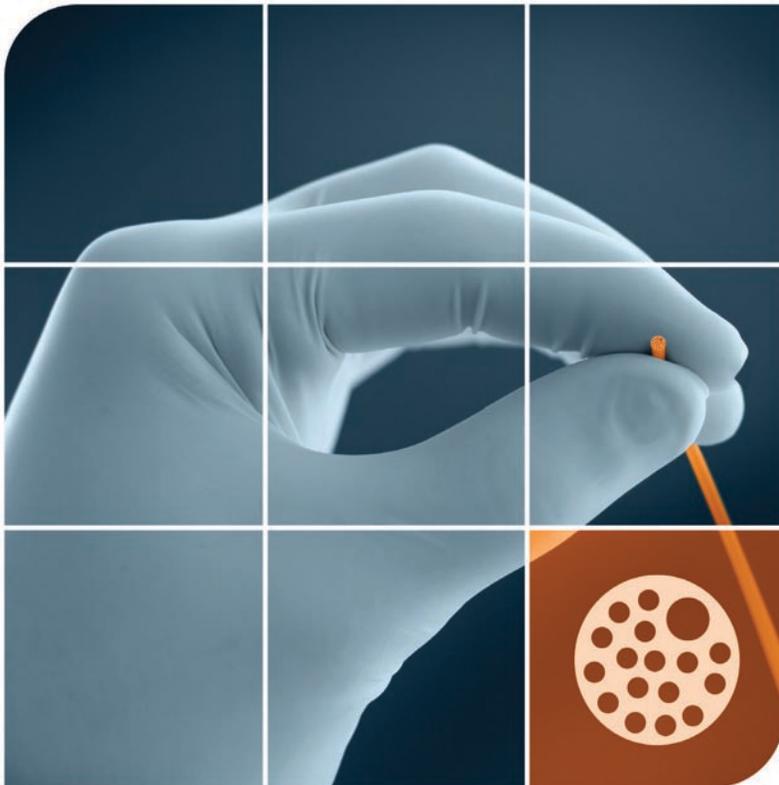


**Melanie Turieo says it's important for medical device makers to consider their users when designing products.**

tomers are. “The traditional thinking about medical devices has been, these are things that people have to use; they don't have a choice,” she says. While device makers think that “it would be nice to make [devices] easy to use,” Turieo says that they often take the attitude that the devices simply “are what they are.” Even 10 years ago, Turieo says, patients would have been thinking along the same lines. But now, that's changed, influenced by the same forces that have dramatically reshaped much about how we live our lives: an onslaught of cheap, high-quality technology and access to the Internet.

One of the key lessons of the survey, Turieo says, is that there is likely a link between compliance and ease of use. Regardless of how effective or advanced a device might be from a technological or treatment point of view, it is crucial, Turieo says, that it be easy for people to use. “It's not just [about] the technology,” she says. “If [a technology is] too burdensome, if it doesn't integrate into people's lives, if they feel like it's driving their lifestyle as opposed to fitting into it, then they're just not going to use [it],” she says.

—Thomas Blair



### The Unattainable at Your Fingertips.

ExtruMed™ Extrusion Services for Silicone and Thermoplastics

Bring Vesta your most challenging tubing requirements. Unprecedented specifications. Unthinkable timeframes. Unbelievable functionality. And we'll put it all within reach. Our expert design assistance and ExtruMed precision extrusion solutions help achieve the impossible every day. Together, our molding, extrusion and assembly services have helped our global customers launch more than 3,000 medical devices. Yours could be next.

Let's talk. Nothing's off limits.  
[www.vestainc.com/possible](http://www.vestainc.com/possible)



## 510(k) Process is Harder on Small Companies

Two-thirds of small medical device companies obtain initial clearance for new devices in Europe. That was the finding of an industry-wide survey on FDA's 510(k) approval process conducted by a research team at Northwestern University.

It's also a problem, says a spokesman for the Medical Device Manufacturers Association (MDMA).

"Tomorrow's innovations are being developed today overwhelmingly by small and mid-sized medical technology companies," says Brendan Benner, MDMA vice president of public affairs. Companies, he says, are turning to overseas markets for launch because FDA's review process is too unpredictable. "This means that patient care and job creation are also moving in that direction," Benner adds. "The fear is that if this continues, many of these jobs will never return, and patients are waiting months if not years longer until they have access to these innovations."

The survey, funded by the nonprofit Institute for Health Technology Studies—whose board includes device company executives—also showed that the road to device approval is longer for small companies than for bigger players. Companies with fewer than 100 employees are more likely to seek presubmission meetings and spend more time in the pre-IDE process than their larger counterparts. Overall, small companies wait nearly twice as much time for 510(k) reviews to be completed.

It's no surprise, then, that more small firms, which are more than twice as likely as large firms to seek approval for new products rather than existing line extensions, feel FDA requests affect time and financial resources.

"In speaking with companies of all sizes, they all face similar challenges attempting to navigate the moving goal posts at FDA," Benner says. "However, given that larger companies already have products on the market generating revenues, they have a better

### A Longer Line for the Little Guys

**10.8**

Average length, in months, of the pre-IDE process for small companies

**7.4**

Average length of the same process for large companies

**330**

Average total review time, in days, of submissions by small companies

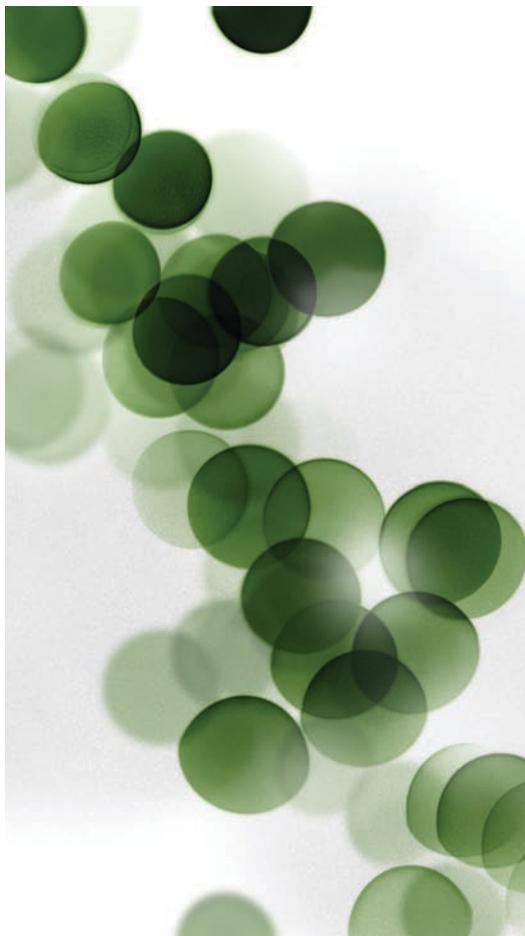
**177**

Average length of the same process for large companies

Source: A Comprehensive Analysis of the FDA 510(k) Process.

ability to subsidize delays than a start-up who is working on the initial product."

—Jamie Hartford **M**



## How can you mitigate risk, be first to market and succeed with your clients?

Nelson Laboratories is a leading provider of full, lifecycle microbiology testing services for medical devices, pharmaceuticals, and natural products. While we are known for exceptional quality and rigorous testing standards, we are also keenly aware of the bigger picture. It's what we call The Science of Success: It's partnering with you to achieve your business goals and being fully committed to your long-term success.

To learn more about The Science of Success™ call 800-859-3298 or visit [nelsonlabs.com](http://nelsonlabs.com)

**NELSON**  
LABORATORIES

The Science of Success™  
[NelsonLabs.com](http://NelsonLabs.com)