Exit Interview: Medtronic CEO Hawkins Sees Burgeoning Challenges, Opportunities

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Executive Summary

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"Everybody's going to look for every excuse not to pay for something" in the current environment, Hawkins told fellow device company execs, venture capitalists and researchers at the Wilson Sonsini Goodrich & Rosati Medical Device Conference 2011 in San Francisco June 13.

Moreover, going forward, reimbursement challenges could be a bigger threat to industry than evolving FDA regulatory requirements, he suggested. "We're going to see improvement" at FDA, Hawkins predicted. But "I'm more concerned about the black box around reimbursement."

Hawkins' remarks came on the official first day of his successor at the helm of Medtronic, incoming Chairman and CEO Omar Ishrak. Ishrak's appointment was announced in May. (See "Medtronic Mines GE For New..."
The comments were made in an interview at the conference with David Cassak, VP-content and managing director-medical devices at Elsevier Business Intelligence, publisher of "The Gray Sheet." Below are excerpts from their conversation, in which Hawkins discussed the industry and lessons learned during his four-year tenure as head of Medtronic.

David Cassak for "The Gray Sheet": I don't think it is overstating it to say that what's going on with the FDA right now has put a chill on this industry. Give us your view of what you think is going on in Washington.

Bill Hawkins: Clearly the FDA has had a huge impact. We've been in this cycle for the last couple of years where there has been the issue of consistency and unpredictability. Washington is recognizing that it has got to do something. We're not seeing it right now, but I think we're going to see improvements.

There is a broad initiative to look at the sand in the gears that has slowed down real innovation in many different industries, and particularly ours. A number of people have been very vocal, and that makes a difference. Word has gotten to the president, and that word is getting down to the FDA. And we're not seeing right now an immediate change, but we're going to see improvement on this.

I'm more concerned about the black box around reimbursement. I think the bigger impact is going to be what happens as payers, in response to health care reform, and hospitals, in response to health care reform, push back on the adoption of new technologies; they are going to push back on the current utilization of what we do. That's going to have a bigger impact on us than what happens with the FDA. We're going to get through the FDA.
speaks with David Cassak
of Elsevier Business
Intelligence/"The Gray
Sheet" at the Wilson
Sonsini Goodrich & Rosati
Medical Device
Conference 2011 in San
Francisco. (Photo: Katie
Cooney/WSGR)

TGS: Do you think this is a system that will reach a
limit as to what it is willing to pay for innovative
technologies?

Hawkins: I think what's going to happen is that
everybody's going to look for every excuse not to pay for
something, unless you have rock solid clinical evidence
that demonstrates not just a clinical utility, but an economic
benefit of what we do. It's going to be a boon for clinical
research organizations.

What we need as an industry is to find ways of helping
FDA and others to figure out how to improve the efficiency
of clinical trials, because the economic burden for all of us
for doing these studies is enormous. And you're going to
have to do them. My sense is that FDA is what we all think
about today, and I don't want in any way to underestimate
the issues we're all facing. But I'm more concerned about
what's going to happen on the payer side.

TGS: Thirteen months after you become CEO, the
global economy went into the toilet. What kind of
impact did the recession have on Medtronic?

Hawkins: Historically, our industry has been somewhat
immune to economic downturns or economic cycles.
Health care, the demand for what we do, is not going
away. In fact, you could argue in a downturn, when there
are these modest sorts of blips, we didn't see any real
impact. And so when the current economic downturn hit,
we underestimated what a profound impact it would have.
And there's a lag factor for us. It didn't hit us in 2008. It
was almost a year, year and a half later.
When it first happened, I think we all underestimated how profound that impact had been and still is. And it's real. Today, we can see it in utilization trends, which are significantly different from what we saw in the 2007 and 2008 time frame.

**TGS:** Medtronic continues to be an aggressive dealmaker, investor and acquirer. But where could you point to specifically and say, 'We did this differently because it's 2009 rather than 2007'?

**Hawkins:** It was not just the economic downturn, but it was then the prospect of health care reform, and sort of that double whammy, and then if you think about what happened to valuations of our industry, they really plummeted.

**TGS:** Medtronic is an organization that has worked collaboratively with pharmaceutical and biotech companies. How do you read close collaborations between drug and device companies?

**Hawkins:** I think what you're going to see going forward is the pharmaceutical business getting back into the device space. Because they're looking at things a little bit like how we're looking at them, in terms of 'how do you differentiate yourself?' And if you really are serious about treating heart failure or diabetes, it's not just taking a pill. There are certain drugs that need to be targeted directly to the site. And there's a need for technology that gives you access. Or they may need technology that helps you to navigate. And so I have a sense that you're going to see more and more that the lines are blurring, and you're going to see more and more overlap between what we do and what the pharma world does. I think that pharma - they're trying to figure out how they're going to get growth, and how they're going to differentiate themselves.

**TGS:** Talk a little bit about emerging markets.

**Hawkins:** One of the things that we put a lot of focus on, going back five, six years ago, was emerging markets. When I took over at Medtronic in 2007, 70% of our business was in the U.S. Today, 55% of our business is in
the U.S. So we've moved pretty efficiently. And that's not just because of the slowdown in the U.S. markets. It's because of the acceleration that we've seen, and principally in the developing markets. And we put a very good, focused strategy in place aimed first and foremost at China, second, Latin America, and thirdly, India, and then some of the other emerging markets.

It's not easy. But the fact that you've got 1.4 billion people in China, and the same in India, and the governments are trying to keep control of society, the great equalizer is health care. And I think they're going to be investing more and more in technologies that are going to help address the same diseases that we have here. Ten percent of our business is in emerging markets; in the next five years, it will be 20%.

TGS: You made your first major decision as CEO in October 2007. Tell me what that was and how you dealt with that issue.

Hawkins: For a guy like me, who started off as a biomedical engineer and worked his way up, it was an exciting time. We had a whole pipeline of some interesting products, and this is before, obviously, the economic meltdown of 2008, before the change in the administration and health care reform. And we were kind of at the tail end of the "good ol' days."

And I'll never forget. I came back from being on the road for two or three weeks. And literally the day after I got home, I got a call from the guy who runs our cardiac rhythm business, who said he needed to see me immediately. And basically he wanted to tell me that we had been tracking the performance of a lead, the lead for our defibrillators, that six months prior, we had one hospital who reported an unusually high failure rate. So we did a number of things to really look at whether this was more than one hospital, and we had physician panels and a lot of other people who helped us early on to see if there was something.

We didn't see anything, but we commenced a clinical study. And it would take us six months to really get more
information. At the end of that six months, we had the information, and he wanted to tell me that in fact we did see a trend that would suggest that this lead, in 289,000 patients, had a higher failure rate, and was potentially a higher failure rate than our existing leads. There's no one who has a product that has a 100% success rate or 0% failure rate. All products have some failure rate associated with them. So you're always trying to look at those kinds of data points and figure out whether you should take action or not.

Now we had this information that suggested that a predecessor lead was performing better than the newer lead. We brought in and flew in experts from around the world. But ultimately it was my call. And I remember after literally working all weekend with all the people that I needed to, it was really my call as to whether we were going to voluntarily suspend the shipments. FDA was engaged with us, but they were not telling us to do this. It was something that we, ultimately, would have to make our own decision on. We ultimately decided that we were going to voluntarily suspend the shipments. And I knew that this would just be a shock wave throughout the industry as well as the company. And indeed it was. Our stock price dropped. It was a big event. (See "Fracture Data Spurs Medtronic To Suspend Sales Of Fidelis ICD Lead" - "The Gray Sheet," Oct. 22, 2007."

TGS: Did withdrawal of the product imply that already implanted leads needed to be explanted, or was it simply a matter of stopping shipments of new leads?

Hawkins: That was the whole issue. The failure rate was not that different from existing leads on the market. In fact, it was probably better than most other leads, but compared to our flagship lead, it wasn't performing like what we expected. And in these situations, you don't want people to overreact and then explant leads, and the consequences of explanting them are much more dire to the patient than keeping them in. This was a lesson for me as a new CEO on how to manage the public communication of such a big deal.
I look back and the way that we handled that is one of the things I'm most proud of - the way we orchestrated the communication with the press, with our customers, with our employees, and everybody else. It clearly hurt us. But I think everybody openly accepted us for the courage to do the right thing, notwithstanding what the impact was going to be to the financial performance of the company.

TGS: Do you look back and think perhaps if you had simply ridden it out, it would have been okay?

Hawkins: No. Not for one minute did I look back and have any regrets. No question in my mind. Knowing what I know now, I am even more convinced that we absolutely did the right thing.

TGS: What were you doing in your role as chief operating officer at Medtronic before you took over the CEO role? What would be your day-to-day, or week-to-week, agenda?

Hawkins: When I took over as COO, after the company had gone through this acquisition spree, you end up with a portfolio of businesses. And the real question was, are we going with Medtronic as a portfolio company, or are we going to try to do something really to take advantage of our size and our scale and our breadth and our depth to distinguish ourselves? And so, I remember very well the first conversations I had with the executive leadership team, and I put the question to the group: 'Are we going to be a portfolio company, clearly run it sort of decentralized, like Johnson & Johnson did, or are we going to find a way to leverage our size and scale?' And ultimately, we concluded that really what we wanted to do was something very different.

We wanted to really try to create one Medtronic. We wanted to have the bigger focus be chronic disease management and not just be a device company, not just a pacemaker or a stent company or a pump company, but be a heart failure company, a diabetes company, a company that was going to address this growing demand for neurodegenerative disease therapies. And really in that, you bring not just the device, but biologics and information
technology. And so we really positioned the company to be an integrator of technologies and therapies, to be able to really have a bigger impact on some of these disease states.

TGS: Was that a hard thing to translate for the individual businesses and operating units? Or was it harder to translate to the customer?

Hawkins: I would say it was probably internal challenges. The fact of the matter is our customers wanted more from us. They didn’t want to see three different people coming in with three different products to treat heart failure. They wanted to really have someone they could partner with that really could help them think about the broader disease of heart failure.

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