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Eight Things That Will Fix Medtech Investing

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Feature Articles / Word Count: 5822 / Article # 2014900059 / Posted: March 19 2014 8:00 AM

Executive Summary

The last five years have been brutal ones for medical device VCs and entrepreneurs, yet there's still cause for hope. In a series of interviews, we asked venture capitalists, entrepreneurs, and executives: what gives you hope and what makes you optimistic about the future of medtech?

The last five years have been brutal ones for medical device VCs and entrepreneurs. Venture dollars are down. IPO investors until recently haven't been interested, and strategic acquirers are tightening the purse strings. Yet, there's still cause for hope.

- In a series of emails and phone calls, we asked venture capitalists, entrepreneurs, and executives: what gives you hope? What makes you optimistic about the future of medtech?
- The answers were peppered with doom and a smidge of despair, but people in the business of creating new companies must be optimists by nature and they inevitably came up with cause for hope.
- Looking up the food chain, investors and entrepreneurs were encouraged by strategic investors taking greater interest in early-stage companies, particularly at the Series A.
- Medtech loyalists also saw value in new models for starting device companies, hoping the lower capital costs will help returns.
- Ultimately, medtech folks are true believers – devices, they say, stand the best chance of changing how health care is delivered.

The timing of the news could not have been worse. In January, just a few days before the health care industry was set to meet at the *JP Morgan Healthcare*

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Conference in San Francisco, renal denervation – one of the highest profile sectors in medtech – imploded on news that **Medtronic Inc.**'s *Symplicity* hypertension device didn't perform well in clinical studies. The news was a kick in the face to an investment sector already on its hands and knees. (*See "SYMPLICITY Results Make Life Difficult For Renal Denervation Programs" — IN VIVO,*January 2014.) Dissemination of the disappointing trial results happened to coincide with the meteoric post-IPO performance of **Intercept Pharmaceuticals Inc.**,yet another success story that just highlighted the differences between the medtech and biopharmaceutical sectors.

Where did things go so wrong? Clearly, the Symplicity trial results are something future device VCs and executives will see as an unfortunate mile marker in the device sector's long journey. After all, Medtronic paid $800 million up front for the technology when it acquired start-up Ardian Inc. in 2010. [See Deal] That payout had been held up as an example of value creation for medtech investors during the dark days but might now be seen as a lesson in not overpaying for an asset. Things had already begun to go south for the sector years earlier. The now defunct interventional pulmonology company Emphasys crash landed at an FDA panel that voted down approval of its pulmonary device, instilling fear in investors and executives that the FDA couldn't be trusted. The IPO class of 2005–2008 didn't perform well, in some cases creating a class of walking dead from which medical device venture capitalists couldn't escape. The stream of mergers and acquisitions flowed steadily, but in cases like Ardian the buyers weren't getting the bang for the hundreds of millions of bucks they paid out for device companies.

All of this bad news left the medtech sector in dire straits. The failure of Symplicity to outperform a control arm in drug-resistant hypertension could require medtech investors to even further de-risk companies before an acquisition is possible. Venture firms raising new funds increasingly are deemphasizing their device programs. Many firms maintaining their device presence are pursuing growth equity opportunities, hoping to capitalize on later-stage device companies that need just a bit more capital to reach a significant milestone. The IPO market for medtech companies has been slow to form. "There is no debate that the medtech industry as we knew it is compressing," offers Joshua Makower, MD, CEO of medical device incubator ExploraMed Development LLC, blaming a "perfect storm" of events. "Even though some of that storm has partially cleared it will take many years to rebuild what's lost."

Anyone who has spent more than a few years in venture capital knows how pendulums swing. Fifteen years ago, all of health care was doomed as a venture sector as information technology and Internet investments boomed. Things turned around a few years later with biopharmaceuticals and then devices recapturing their stride. The device sector marched strongly – and too stridently for some – during the mid-half of the last decade. But its pace slowed after the global fiscal crisis of 2008. Last year, venture capital commitments to medtech fell to 2005 levels. Given the context of other venture sectors, this is a troubling sign. But it's also worth remembering that 2005 was the beginning of a rebound in devices.

Devices can certainly bounce back again. An informal poll of venture capitalists, entrepreneurs, and other notables in the medtech sector turned up some clear signs of hope. We'll address the most promising trends in this article. But this turnaround won't be as easy as others have been in the past. Medical device investors who just stick to their tried and true formula might find themselves left behind as the Affordable Care Act and other forces change how health care is delivered in the US, which remains the world's largest health care market.

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TauTona Group sells its adipose tissue injector to LifeCell

Novadaq buys Surgical Marker and related technology from TauTona Group

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Device investors can't count on the potential of quick commercial adoption of spinal implants or other devices to ignite the device sector. Instead, future medtech successes will center on an ability to address health care more holistically, looking at every customer-surgeon, hospital, insurer, and, finally, fully wired and trackable patient.

Difficult Times

Medical devices once were seen as solutions for delivering new ways of treating disease. Today, hospitals, unreimbursed for complications and follow-up procedures, are now watching every dollar. New medical technology is now as likely to be viewed as a part of the problem as the solution. New therapies must prove their economic benefit if they're to be used in hospitals. Surgeons and medical specialists, meanwhile, are protective of their existing businesses and patients. Specialist groups and professional organizations are increasingly less receptive to new technologies, leaving many new companies in limbo with devices that have no codes with which to pursue reimbursement.

These challenges aren't entirely new. William Facteau, the former CEO of Acclarent Inc.,the ENT company acquired by Johnson & Johnson's Ethicon Inc. division in 2009 for $785 million, says getting reimbursement for Acclarent's *Sinuplasty* device was difficult. [See Deal] The company's procedure created a less invasive alternative to sinus surgery. Acclarent trained 6,000 surgeons on the device, but Facteau says a handful of key opinion leaders didn't embrace the technology, slowing adoption. In choosing his next venture, Facteau steered clear of reimbursement needs. His new company, EarLens Corp.,just raised a $38.8 million Series B from corporate and institutional investors; its hearing assist device is private pay.[See Deal]

"I think health care reform still really hasn't played itself out," Facteau says. "The medical device tax [on device sales] is a big issue even though some people won't acknowledge it as such. I think the medical societies are protecting their codes and not wanting to embrace new technology because the system can't afford to pay for it. The requirement for the data and the expense of studies are all real issues facing our industry and I think it's a large part of why people are just not too excited about investing in long PMA types of projects." Facteau, after leaving Johnson & Johnson, spent some time at the Exploramed accelerator where Makower started Acclarent. While there he examined consumer-oriented companies that could avoid entanglements with medical societies – which issue reimbursement codes – and insurers.

Reasons For Hope

Hope does exist in medtech. In the following sections we identify several positive trends. We reached out to venture capitalists, corporate VCs, executives, and, of course, entrepreneurs – all crucial agents of medtech innovation. To be sure, optimism isn't in abundance. There are many hurdles facing the sector, but everyone holds a stubborn belief that medical devices can do a better job at treating patients at lower costs. In other words, medical devices remain the most disruptive force in health care. Evan Norton, divisional vice president at Abbott Ventures, the venture subsidiary of Abbott Laboratories Inc., says the disappointing Symplicity trial doesn't detract from the fact that medical devices can treat the body as well as drugs can or better. New ventures like Holaira Inc.,which is testing a targeted lung denervation approach to treat chronic obstructive pulmonary disorder, and more battle-tested ventures like NeuroPace Inc.,which just obtained FDA approval for its neurostimulation device to aid people with epilepsy who don't respond to drugs, can find a way

into the health care system. Makower says existing medical device companies must simply find a way to navigate through the new terrain. “I believe most will be rewarded in the long term,” he states. “For those who are beginning their venture now, opportunities to improve health care are everywhere and innovators who can think differently about how to navigate the existing obstacles will find their efforts making a difference quickly and they will be rewarded.”

Strategics Invest Early, More Often

When the topic of corporate investing comes up, medtech investors clearly have biopharma envy. Why, they ask, can't large medtech companies follow the example of their pharma counterparts and take a more active role in company creation? Jim Scopa, general partner at MPM Capital, which counts Novartis as a principal investor in a side fund for biotech investing, says that medtech needs similar involvement from corporates. “Right now, the ecosystem needs help; the venture community can’t do it by ourselves.”

Well, medtech companies have started moving in the right direction, investing in the early stages. Medtronic, for example, joined with angel investors to supply a $5 million Series A for hearing assistance device start-up EarLens. Covidien PLC partnered with venture firms New Enterprise Associates and Lightstone Ventures to create **Fire1**,a cardiovascular company. Abbott Ventures is reaching out directly to entrepreneurs, seeking innovative solutions to problems that the company had identified and is agreeing to fund the ventures.

The relationship between VCs and corporate investors in medtech clearly is changing. Institutional VCs need corporates for capital and for validation. An early-stage investment from a corporate adds legitimacy to a start-up. But both parties acknowledge that the parent companies of corporate investors need venture capitalists just as badly. Large medtech players are growing at a sluggish clip, and most don’t have the internal tools to develop the next blockbuster that could impact that growth rate. Steve Almany, MD, managing director at BioStar Ventures, says, “All the strategic companies are constantly looking for new products and/or new platforms that are synergistic with their core businesses, and can add meaningful revenue growth over time. They will continue to pursue both an organic and M&A strategy in achieving this objective.”

With their growing importance, corporate acquirers increasingly are looking to venture programs as a way of becoming comfortable with new technologies or fields before making a purchase. Abbott Ventures’ Norton says “pure auction deals” are difficult to justify in this market, particularly if a strategic is looking to buy a start-up outside its core business. Competing bidders with an existing business have clear advantages because they can justify the price tag more easily, especially if their existing personnel and market contacts allow them to seamlessly launch a newly acquired product or device.

“All the strategic companies are constantly looking for new products and/or new platforms that are synergistic with their core businesses, and can add meaningful revenue growth over time. They will continue to pursue both an organic and M&A strategy in achieving this objective.”

– Steve Almany, MD, BioStar Ventures

Corporate investors will play a growing role going forward including pharmaceutical companies such as GlaxoSmithKline PLC and Merck & Co. Inc.,which both have invested in device companies over the past year. But the medtech corporate investors aren't likely to become as involved in venture investing as pharmaceutical companies that invest more broadly in venture funds and start-ups. "The gross margins on the biotech side are so incredibly high," says Norton. "They can spin the roulette wheel more times than a medical device firm. We have to be more conservative."

A few venture capitalists wonder if medtech investing would benefit from a new relationship with medical device companies in which strategic buyers could acquire certain sales rights to a product, as is done in the pharma industry, rather than purchase the company outright. But such a change isn't likely in medtech unless markets in Asia grow to such a size that regional players have the incentive to acquire the right to sell a device in that country. MicroPort Scientific Corp.,for example, entered into a joint partnership with Sorin Group SPA,enabling it to sell the Italian company's cardiac rhythm management devices in China. [See Deal]

But venture capitalists looking at corporate investors as saviors may want to hold on to their confetti. Corporate investors obviously have capital to invest, but not nearly enough to make up for what the sector has lost from recent years. Even if they did, corporate investors are ready to push back on pricing or find ways to work directly with entrepreneurs whenever possible. Abbott's Norton, who says he doesn't want his comments to be seen as "anti-VC," envisions strategic investors working "more directly with entrepreneurs" with a "reduced involvement from venture capitalists, unless they're enlightened VCs who are open to thinking about the model differently." Norton increasingly favors a deal structure that puts entrepreneurs in a better position to recoup a large return if and when their company is acquired.

Medtech companies may continue to redefine themselves and expand their reach out of devices. Venture capitalist Lisa Suennen, who recently announced she wouldn't be raising a new fund with Psilos Group, says that medtech companies are "starting to think outside of their own box and ask how they fit within the health care system more broadly." Medtronic, most notably, acquired telehealth company Cardiocom LLC and has branched out into running catheter labs in Europe. [See Deal] This effort may not translate into more product acquisition, but these companies might stave off shrinking growth by pushing into other aspects of health care.

New Start-Up Models

Doug Kelly, MD, general partner at Alloy Ventures, sums up medtech's best hope succinctly: "Creativity comes from constraints, and will result in surprising transformations." Indeed, medtech innovation faces one principal constraint – an access to capital. Let's be clear: things are bad. But they've been worse. Yes, annual tallies of medtech dollars put

Medtech Companies With Corporate Venturing Programs

- Abbott
- Baxter
- Boston Scientific
- Edwards Lifesciences
- Covidien
- General Electric
- GlaxoSmithKline

- Johnson & Johnson
- Merck
- Novartis
- ResMed
- Stryker

2013 at the same level as 2005 in terms of dollars committed, according to the PricewaterhouseCoopers/National Venture Capital Association *Money Tree* report. But many good deals were done in 2005. In fact, blue chip venture firms like Domain Associates began sitting out device investing in the years that followed precisely because *toomuch* capital was beginning to flow into the sector.

But the strength or weakness of a sector isn't measured by dollars committed but rather by dollars returned. That's where device investors need help if they're to compete with technology-oriented venture funds capable of generating quicker returns in this market. Medical device companies once were seen as a fast, low capital route to an exit. But negative forces due to what it takes to obtain regulatory approval and reimbursement have driven up both capital spent and time to exit. "That means that to generate higher and more timely returns, VCs will be investing later at lower prices, or that new start-ups need to plan for much faster development cycles to de-risk their products and enterprises, or that acquiring companies will need to take on more risk," Kelly states.

How can investors accomplish all that? Some solutions have been discussed and even utilized in the past, and the constraints of today make them even more important. Device VCs once again are backing companies that employ a virtual model. Canaan Partners, for example, reportedly invested $1.5 million in **MitraSpan Inc.**,a start-up developing mitral valve repair technology. General partner Wende Hutton says the company, with fewer than five employees, has successfully started testing the device in human patients. The virtual model has been tried in devices, but it's found greater success in biopharmaceuticals, enough success that device investors are giving it a new emphasis. It's not a panacea, but a virtual company can speed the development of companies that don't require extensive capital expenditures if the programs can be managed remotely by experienced management and if products can be sold into existing sales channels. "I think there are opportunities that fit that model, but not all do," she says.

Hutton says starting capital on short money isn't necessarily a prescription for a so-called small ball exit. "With a $600 million fund, we don't get into deals thinking we're going to sell for a little payout," she says. "We're only investing in deals that we think at the outset have high potential." But a new breed of incubators is finding success in starting companies – or perhaps just a new product – and selling out early for a relatively small payout but a quick return. TauTona Group and Pavilion Holdings, two physician-led company creators, have recorded relatively early exits that put them in position for attractive internal rates of return. (*See* "Surgeon-Led Firms Find Formula For "Small Ball" Exits" — *START-UP*,February 2014.) TauTona just recorded its second exit, the sale of its adipose tissue injector (aTI) used in aesthetic and reconstructive surgery, to **LifeCell Corp.**[See Deal] Proceeds generated from that sale and the gains from its first exit – the sale of *Surgical Marker* to **Novadaq Technologies Inc.** in September – could return the $50 million the group raised for its debut fund in 2010.[See Deal] TauTona has eight more investments from that fund to develop.

Geoffrey Gurtner, MD, who co-founded TauTona with Michael T. Longaker, MD, says TauTona thought the traditional venture capital model was flawed, with too much capital being committed to untested ideas. The two Stanford surgeons

successfully raised $50 million from institutional investors, by passing VCs completely and creating an entity where multiple projects could be created, tested, evaluated, and, if necessary, dumped with minimal loss. “Our goal is to create an ecosystem where the physician-inventor or the engineer-inventor can make a return that will be meaningful to them, and we can return money to the LPs,” Gurtner says. VCs, he says, just add another layer of expense that might make their model unworkable.

Venture investors themselves recognize that things must be done differently. Alloy’s Kelly says early involvement from strategics could help remove some uncertainty while sending early product development and testing offshore could save capital. “We are seeing more and more creative ways of developing really revolutionary medtech products in much shorter periods of time,” he says. “A lot of companies that would have gotten funded 10 years ago will never even make it to the starting line now, and that is a good thing, because most of them were destined to fail anyway because they didn’t provide enough value. Companies getting funded now are truly battle tested, not just by VCs.”

“Our goal is to create an ecosystem where the physician-inventor or the engineer-inventor can make a return that will be meaningful to them, and we can return money to the LPs.”

– Geoffrey Gurtner, MD

A Device IPO Market

Some favorable forces, such as the surging IPO market, need little explanation. Clearly, medtech investors would benefit from a second exit route, an alternative to acquisition, one they haven’t enjoyed fully in seven years. Last year’s IPO of **LDR Holding Corp.** and other companies demonstrated a willingness on the part of public investors to commit capital to medtech, particularly those companies earning tens of millions in sales. [See Deal]

Justin Klein, MD, general partner at New Enterprise Associates, says public markets are becoming more receptive to earlier-stage companies. A year or so ago, “companies that went out – including Zeltiq, Globus, Tornier, and AGA Medical – had huge scale,” he says. [See Deal] [See Deal] [See Deal] [See Deal] “We’re now seeing companies like Tandem, Amedica, Inogen, and LDR, all with lower revenues.” **Tandem Diabetes Care Inc.**,the maker of an insulin pump, generated over $2 million in revenue in 2012. In the first six months of 2013, the company recorded $10 million. This is the kind of revenue growth strategic acquirers want.

Hanson Gifford, III, managing partner of The Foundry, agrees the tide may be finally turning for companies with an established revenue ramp. “Inogen just went out, and there are rumors that Ulthera, Trivascular, Access Closure, Glaukos, and several others may be on the verge of filing. Granted, these are older companies, but a rising tide will lift all boats, including the more recent companies addressing huge markets with promising technologies. A wave of potential IPOs may also help strategics to get off the dime and move faster on M&A, rather than playing a waiting game.” [See Deal] **TriVascular Inc.**,maker of an AAA graft, did file for an IPO just prior to press time.

The Affordable Care Act? Yes.

> "A wave of potential IPOs may also help strategics to get off the dime and move faster on M&A, rather than playing a waiting game."
>
> – Hanson Gifford, The Foundry

Yes, the same Affordable Care Act that implemented the punishing tax on medical device sales (even for unprofitable start-ups) can be a boon for medical devices because it is disruptive. Lisa Earnhardt, chief executive officer for Intersect ENT Inc.,says such change brings opportunity. "Companies that deliver value to patients, physicians, and the health care system will continue to attract investment dollars and create meaningful businesses. The medical device industry is uniquely positioned to improve both the efficiency and effectiveness of the health care system." The introduction of accountable care organizations created by the Act may even create an opening for devices that bring an up-front cost to a procedure but can provide better or more cost-effective care over the long run. "Most view ACOs with skepticism, though the most forward-looking will be successful at both improving care and efficiency," she says.

> "The medical device industry is uniquely positioned to improve both the efficiency and effectiveness of the health care system."
>
> – Lisa Earnhardt, Intersect ENT

Sharon Stevenson, PhD, managing director of Okapi Venture Capital, says having more Americans covered by insurance is a positive for the industry. "Yes, the device tax is difficult, particularly for small venture-backed companies, as it is based on revenue, not profit. I do believe there should have been a cut-off beneath which no tax is paid," she states. "But, in the aggregate, I think the reforms to the system will ultimately help medtech. Eventually, and after great pain, the US health care system will become more rational and transparent; that cannot help but be a good thing for a company with a quality product that can be sold at a reasonable price."

With the burden of saving costs pushed onto hospitals, devices that can shorten procedure time, reduce the likelihood of infection or complications, or just reduce expense will be necessary. "This penalizes established, grandfathered-in technologies in favor of novel technologies that lower complications," Alloy's Kelly offers. "This is seen by many people as a bad thing [too little money to run the trains, hospitals being driven into bankruptcy because of high costs], but I think that it will lead to better health care and a better patient experience."

In pursuit of savings, hospitals also will partner with insurers to drive down the price of standard technologies such as large joint implants or stents. A year ago, UnitedHealthcare, for example, partnered with several large US hospital chains in a venture called SharedClarity to negotiate exclusive deals with device suppliers, basing its selection on the cost-effectiveness of the devices. (*See* "UnitedHealthcare Teams Up With Hospitals To Scrutinize Device Outcomes" — *"The Gray Sheet,"* Apr. 15, 2013.) UnitedHealthcare is providing claims data on more than 40 million members to help in the

assessment. SharedClarity this month announced the awarding of its first contracts with Medtronic and Abbott to provide bare-metal and drug-eluting stents to SharedClarity's hospital partners. One of SharedClarity's partner systems reportedly expects to save 40% in device costs.

Once again, the pharmaceutical industry can be used as a model. Physicians are expected to adhere to formularies when prescribing drugs. "Interchangeable" devices can be handled the same way, says Domain Associates general partner Nimesh Shah. This pricing pressure is only beginning, so large medical device suppliers will need to find sales to offset the losses from devices that become mere commodities. "It's incumbent upon our companies or the investments that I'm making to be in those areas where we think innovation will drive meaningful change in cost or in the outcomes."

Relationship With The FDA

The Food and Drug Administration, once seen as a significant hurdle to success in medtech, increasingly is seen as a cooperative partner. The agency is scoring points from investors and entrepreneurs for its flexibility and communications. One device CEO recently noted he had the phone number for the head of the division overseeing his company's technology in his cell phone and could call him directly at any time. "The relationship between the FDA and the medtech community has never been better," says one investor.

The agency issued some signature approvals including the November awarding of a premarket approval to NeuroPace for its *NeuroPace RNS* system, which employs depth leads and cortical strip leads to sense the onset of an epileptic seizure and disrupt it before it happens. The approval comes several years after approval of the system's initial elements, but the approval still is seen as a positive. In an unsuccessful story, the disappointing clinical performance of Medtronic's renal denervation device, Symplicity,hasn't elicited many harsh words toward the FDA. More questions and criticism have been leveled at the technology or Medtronic for its handling of the trial.

Clearly, the clinical demands for projects requiring premarket approval can be expensive and onerous, but investors and entrepreneurs note the data are necessary to secure reimbursement from insurers. Indeed, officials at FDA's Center for Devices and Radiological Health (CDRH) in December disclosed a nascent effort to expand on the center's parallel-review program with CMS to bring private payors and device firms together earlier in the development process. (*See* "CDRH Preps New Program To Streamline Approval-To-Reimbursement Path" — *"The Gray Sheet,"* Dec. 19, 2013.) The agency earned industry praise by opting to merely revise rather than revamp its 1997 guidance on 510(k) device modifications.

The FDA also inserted itself more aggressively into mobile applications. Although this isn't necessarily a positive for mobile health investors, it does seem to address the discrepancies some have seen between the regulation of mobile health apps and medical devices. Our sister publication *The Gray Sheet* examined the regulatory status of a mobile app for urinalysis made by **Biosense Technologies Pvt. Ltd.** (*See* "99 Cent Urinalysis App Raises Questions About mHealth Standards" — *"The Gray Sheet,"* May 20, 2013.) The questions over parity led the FDA to send a letter to Biosense pushing for a 510(k) submission for the firm's *uChek* app. In September, FDA issued its final guidance on mobile medical apps, emphasizing a light regulatory touch for apps. Still, the guidelines received mixed reviews, with some pushing for measures to curtail the FDA's reach.

The March Of Technology

Every decade or so, technology investors and companies – satisfied with themselves and their success – promise to save the health care system. Tech experts foresaw shaving billions off health care costs through the creation of electronic medical records or the finding of some new electronic means for doctors and patients to talk to one another. A decade ago, the so-called e-health movement left minimal impact on the health care industry. But the attempts this time around may bear fruit.

The highly – and over – publicized bids of tech giants Apple and Google are too early to embrace or to dismiss. No one is really certain of their intentions at this point and time. New Enterprise Associates' Justin Klein knows a few employees in Apple's foray into health care. The effort got a publicity boost when it was reported the tech giant met with the FDA. Some interpreted the meeting as a sign that Apple was ready to develop devices that actually treat the sick, but Klein says Apple's plans likely aren't as ambitious, that the company met with the FDA to determine how they could work in health care without requiring FDA approval. Google, he says, is functioning a bit differently, more as a venture capital firm looking for the next big ideas. "I think it's great to have them involved," he says. "Health care more broadly should embrace what is being done in the tech world."

Medical device investors who haven't hung health care IT shingles on their firms' doors are circumspect about the penetration of technology, but they're mostly encouraged. Okapi's Stevenson offers, "The intersection of IT and devices is truly exciting. We will see a move toward all things mobile. If battery/power problems can be dealt with, we will see many new devices that collect data for 24 to 72 hours continuously and wirelessly, allowing much improved diagnosis and monitoring."

Rise Of The Patient

The enthusiasm surrounding technology has less to do with technology and more to do with empowering patients. Intersect ENT's Earnhardt says, "Patients are a powerful new force in health care as they become better informed and more involved. The patient's voice should and will be heard more loudly moving forward in health care decisions." Beyond voices, the patients' bodies also will be heard through devices tracking critical data about their health, data that will help determine their care, perhaps with devices that function automatically. Pacemakers have performed independently for decades. Insulin pumps can now monitor and deliver insulin when necessary. NeuroPace's seizure-blocking device is an early incarnation of what's to come as sensor technology continues to evolve.

"If battery/power problems can be dealt with, we will see many new devices that collect data for 24 to 72 hours continuously and wirelessly, allowing much improved diagnosis and monitoring."

– Sharon Stevenson, Okapi Venture Group

Alloy's Kelly often references the "quantified self" movement, which gives name to the near constant collection of data about what we eat, how far we run, what

we're reading, or how much weight we're losing. "In its current iteration, very highly motivated people are able to have real health and athletic improvements by actively monitoring themselves," Kelly states. "Since a big part of our health care costs stem from the people the least motivated to change their habits, for whatever reason, when these decisions become less invasive, more automated, more socialized, less pathologized, that is when I think you will see big effects, and big interest from large companies, including large companies not currently in health care." Kelly says engaging those "least motivated people" will open up opportunities for new sensor-enabled medical devices that will be able to "manage chronic diseases by making tiny [and probably mostly automated] decisions many times a day, versus making some big decision at 3am like cracking your chest or implanting a very invasive device." The challenge for medical device investors and entrepreneurs, Earnhardt says, will be finding a way to incorporate patients in customer needs analysis. "Those that do will be winners as they redefine value in health care."

Medicine Going Retail

Empowered patients could create two developments that benefit medtech investors and companies. First, the rise of retail medical providers, while not accepted by medical societies, is growing. Alloy's Kelly says physicians resisting the retail movement aren't accepting reality that although retail care may not be on par with in-office care, in many cases it's good enough. "Retail medicine is in its infancy, but is a huge and profound trend and potentially the beginning of the disintermediation of traditional health care providers and payors. Since medtech often takes technologies out of the hands of specialists and puts them into the hands of generalists, this is going to have a big impact."

The rise of retail, along with the advances of sensors and other IT, are drawing new players into health care. Lisa Suennen, who now works as a consultant advising on the intersection of health care and IT, says she's seeing interest from consumer companies like Virgin America and L'Oreal as well as tech firms such as Samsung, AT&T, Verizon, and, of course, Qualcomm. "They're starting to talk to the big medtechs trying to work out deals with them. This is going to take a while but it's the birth of a new sector in medtech."

"Retail medicine is in its infancy, but is a huge and profound trend and potentially the beginning of the disintermediation of traditional health care providers and payors. Since medtech often takes technologies out of the hands of specialists and puts them into the hands of generalists, this is going to have a big impact."

– Doug Kelly, Alloy Ventures

Okapi's Stevenson says the arrival of parties new to health care can be challenging. "They often do not come with a traditional med device background but more likely a tech or empowered-patient background. Obviously, this at times presents problems, but often is accompanied by an unusual creativity," she says. "If those people can be partnered with people who understand how to grow a company and the health care market [with all its Byzantine characteristics], good things can happen."

Venture capitalists have a different type of retail in mind. Canaan Partners, for example, has invested in **Butterfly Health Inc.**,maker of an over-the-counter personal hygiene device for women who suffer from minor bladder leakage. The firm committed $21 million to Butterfly's commercial rollout, which includes Internet sales and advertisements in *Martha Stewart Living* magazine. "It's unlikely that I would have done this deal five or 10 years ago," says Canaan's Hutton. "I would have been focused more on the classic medical device paradigm. But I was attracted by a great entrepreneurial team and a whitespace that has a need. We're really looking for opportunities where we can navigate around reimbursement wars and around issues of distributing into hospitals. We will live and die by the patient demand."