Medical Devices: What Those Paying Are Saying

More than ever, medtech companies must demonstrate how their devices will both improve care and save the health care system money. This creates a new barrier to entry for start-ups. But a panel of payors and providers at the recent *IN3* meeting in San Francisco gave tips to device executives on how they might clear those hurdles.

BY MARY STUART

- The Affordable Care Act is reforming health care. Cost reduction is one aspect, but increasingly these changes also mean shifting the economic risks of care from the payors to the providers.
- As risks shift, the buying process is going to change. Medical device companies will be forced to find new sales and distribution channels, new ways of defining clinical and economic benefit, and new offerings wrapped around devices to enhance both their clinical and economic value.
- The consolidation of providers, and in some cases, the merging of payors and providers, is creating a new kind of volume purchasing power never wielded by the group purchasing organizations of the past.
- How should medical device start-ups operate differently today? At the IN3 meeting in October 2013 executives from both the payor and provider worlds shared their wisdom.

Executive Summary >> XXX

Lisa Suennen, a partner at the venture capital firm the Psilos Group, has sat through countless pitches from medical device companies seeking funding. Psilos is a diversified fund focused on health care, and its current $300 million fund invests across health care services, health care IT, and medical devices, with medical devices tending to account for 34% of the mix. Before becoming a founding partner of Psilos in 1998, Suennen had spent 10 years as an executive at Merit Behavioral Care, a specialty health care management organization. Because she operates in both the service and medical device worlds, Suennen says she has realized how insular the thinking of the medical device world is and how out of sync it is with the way health systems operate. "I often see medtech start-ups focused on getting a reimbursement code. But getting a code isn't the same thing as getting it paid for and too few really understand that."

Medtech companies are certainly sensitive to the pressures of health care reform and they're conscious that their products need to bring benefits without increasing costs or even by saving costs, and in fact, that's the way many companies and their investors argue the benefits of a new technology. But a focus on cost, per se, is not the right framing for the issues medical device companies should be looking at, says Suennen. A whole new host of challenges arise as risk shifts from payors to providers, prompting consolidation among providers, shrinking product choice for physician employees of hospitals, and moving buying power to the corporate, rather than physician level of decision-making.

"The volume purchasing power that providers and payors wield is going to be an increasing trend," Suennen says. Industry is familiar with consolidated buying groups such as group purchasing organizations, but this is different, she explains. "GPOs are like shopping centers. 'Here are the 20 things we carry in that category and here is the list of prices.'" But this new environment is about shopping for value, value that will be created in ways that medtech companies aren't necessarily looking at right now: by improving labor produc-

tivity, lowering inventory costs, or decreasing adverse events and hospital stays.

Suennen points to the Psilos portfolio company **OmniGuide Inc.** as a good example of a company that meets the demands of health care today. OmniGuide has developed a surgical laser with a high degree of precision that helps it minimize damage to collateral tissue as compared with other surgical energy modalities. The company has developed its energy-based tool for ENT and gynecology applications. OmniGuide did economic studies on the ENT application to show that its product versus those of competitors resulted in fewer adverse events, shorter lengths of stay, "and a significantly better economic story as compared with alternative products," according to Suennen. In fact, if there is a simple answer to the question of what medtech companies should be doing more of in this environment, it is "economic studies that prove more than just clinical value," she says.

Medtech companies and their investors should also be innovating outside of the traditional clinically focused products that have been their mainstay, by creating service and IT offerings that enhance the clinical and economic value of their medical devices. **Medtronic Inc.**, for example, has begun to do this. In August Medtronic acquired telehealth services firm **Cardiocom LLC** and in September announced the launch of a new Hospital Solutions Business. (*See "Medtronic Signals More To Come On Its Pivot To Hospital Services"* — "The Gray Sheet," *August 20, 2013*.) Others are following suit.

Even in stressing health economics, Suennen believes medical device start-ups don't always understand what that means. "They'll talk about how their product can reduce the number of nurses. But hospitals aren't going to eliminate nurses; they need more nurses. They need to make them more productive in the time they have, or have fewer people in the operating theater so more of them can be out on the floor." To help medtech companies and their investors understand the subtleties of the new payor and provider customers, at the recent *Investment in Innovation (IN3) Medical Device 360° Summit* in San Franciso, Suennen convened a panel of executives from both worlds.

Representing the payors' points of view were Andrew Oliveira, MD, senior medical director for Aetna and Csaba Mera, MD, deputy chief medical officer of Cambia Health Systems. Ken Paulus, president and CEO of Allina Health System lent the hospital perspective to the panel, from the point of view of a large system that has consolidated hospitals and physicians. David Cassak, VP, content for Elsevier Business Intelligence also participated on the panel led by Suennen. Suennen, of course, brings her perspective on a topic she lives with and writes about extensively. She's the co-author of a recently published book, *Tech Tonics: Can Passionate Entrepreneurs Heal Healthcare with Technology?*, and she also writes the blog "Venture Valkyrie."




- **LISA SUENNEN**
  PSILOS GROUP
- **CSABA MERA, MD**
  CAMBIA HEALTH SYSTEMS
- **ANDREW OLIVEIRA, MD**
  AETNA
- **KEN PAULUS**
  ALLINA HEALTH SYSTEM

Lisa Suennen: *We're fortunate to have some experts on the topic of medical devices and reimbursement here. I'd like to start by having you introduce yourselves.*

■ ***Csaba Mera:*** I'm the deputy chief medical officer for Cambia Health Solutions. We're a group of Blue Cross Blue Shield Association licensees in the Pacific Northwest, including Washington, Idaho, Utah, and Oregon. We have approximately two million members, mostly commercial, some Medicare, and some government programs like FEP [Federal Employee Plan]. The majority of the business of Cambia is, of course, health insurance, but we also spun off a subsidiary that invests through a sort of venture capital approach in up-and-coming companies, especially those with technology solutions for what's coming in the future in terms of health plans and the delivery system.

■ ***Drew Oliveira:*** I'm the senior medical director of Aetna. Aetna is a national company and we have about 24 million members in every state. My role is not that of the typical medical director of a health plan, but I support large customers that are self-insured, in terms of their decision-making. We look at innovation in the market in a number of different ways. We have a group based here in San Francisco called Healthagen that incubates and puts out to market differentiating solutions for consumers and providers. We also have an innovation lab that takes some of those additional ideas and tests them to see if they will actually work, across a wide spectrum of solutions, genomic or otherwise.

■ ***Ken Paulus:*** I'm the president and CEO of Allina Health System. We're a large, multi-hospital delivery system. We have 12 hospitals employing about 1,500 physicians. We have a home health company, a reference laboratory company, a retail pharmacy company, and a hospice company. When you put all that together, we take care of about one in three people in Minnesota and into western Wisconsin.

LS: *It's great to have you here. I wanted to have somebody from the delivery side as well as the payors because many hospital organizations are becoming payors themselves. Ken, I know Allina is evolving into a sort of risk-based pro-*

vider, and these present interesting dynamics for medical devices.

How do you think about medical devices in the context of your organizations? Do you generally think about them as creating or saving costs? Can you think of examples where the clinical benefit of a new medtech product outweighed the cost, or vice versa? Csaba, would you like to start?

■ ***CM:*** Sure. In terms of our approach to medical devices, Regence [the largest health insurer in the Northwest] has a medical policy unit staffed by clinicians and masters- and PhD-level folks who understand how to interpret clinical studies. We perform evidence-based review of any new medical devices for which coverage is requested, whether it's a new hip implant, a drug eluting stent, or the super-duper *da Vinci* robotic surgery equipment [from **Intuitive Surgical Inc.**].

We look for the evidence and science supporting improved health outcomes. We're quite rigorous in our approach. The Blue Cross Blue Shield Association also has a technology assessment team of experts, and they develop medical criteria in the same manner as us. We have to be in alignment with the Blue Cross Blue Shield Association medical policies. There is an advantage to this. The Blues across the nation insure about 100 million people, and that allows for consistency for Blue members.

"We don't let any pharma or device reps visit physicians in Allina . . . The relationship and sales model will change dramatically . . ."
– Ken Paulus

Artificial cervical discs might serve as a good example. Until very recently, we did not cover them. By now, there is almost seven years' worth of data, and earlier this year, we began to cover them based on the evidence that has accrued. In appropriately selected patients, the artificial disc has a benefit – it allows more mobility for people with a severe cervical disc problem – and actually may be a less expensive procedure than a cervical spine fusion.

LS: *What about the flip side, where cost outweighed clinical benefit?*

■ ***CM:*** On the flip side, you have robotic surgery, which really is cool, because it allows for some extreme precision for certain kinds of procedures, for example, nerve-sparing prostate surgery. But the CEOs of certain hospitals decided they wanted this really cool thing because some of their doctors wanted it, and then other specialties got into it. A number of OB/GYNs thought, "Wow. I'm going to start doing robotic hysterectomies." Well, recently, a *JAMA* paper made it very clear that there's absolutely no benefit and no advantage to doing robotic hysterectomies over standard surgical hysterectomies.

What's the difference to payors? In the hands of a skillful OB/GYN a hysterectomy will probably be less than $10,000 total, and that includes the facility fee, professional fee, everything. Just recently we got a bill for a robotic hysterectomy from a fairly small, rural community surgery center that had decided it would be really cool to have a da Vinci robot. The professional fee for the surgeon was a couple thousand, then we got an $85,000 charge from the outpatient surgery center for the use of the da Vinci robot. How we deal with that – and this will be informative to the folks who promote medical devices – we just plain don't cover the robot. We'll pay what you would expect if you'd done the surgery without the robot.

But it goes back to evidence. As a matter of fact, in most of our medical necessity policy development, cost is very rarely addressed. We'll talk more about that later.

LS: *How about you, Drew, do you consider cost more directly in your analysis?*

■ ***DO:*** Actually, not really. We are similar in that respect. We will evaluate the evidence. Do you have enough clinical data to support the use of that device? It can't be anecdotal, and it can't just be a series of five or six patients.

LS: *Csaba just said that it was after six or seven years of data that cervical discs got covered. Is that typically what you would require for a device?*

■ ***DO:*** It depends. I think we covered the artificial disc a lot sooner than Regence did, although we don't cover multiple levels, only a single level. We base our decision on certain clinical evaluation criteria and once that's done, then we assess the financial impact to the plan. Sometimes we have to have our underwriters raise our forecast for the next year. In general, new medical technology probably accounts for a two-and-a-half percent cost increase each year. You asked about cost savings; we typically don't see that on the medical device side.

You might see some cost savings on the productivity side, or there may be some new devices in the middle. For example, back in May we looked at *Sedasys* [computer-assisted sedation system from **Johnson & Johnson**]. It allows a non-anesthesiologist to deliver propofol during a procedure. It monitors the vital signs, it does all this really interesting stuff, and it's pretty safe. You're supposed to have an anesthesiologist on site to monitor propofol. Suppose you're a GI doc doing colonoscopies. Having an anesthesiologist giving propofol for every single one of those procedures increases the costs for the procedures by two-and-a-half times. In that case, Sedasys might actually save some money. However, on the West Coast, most colonoscopies are not done with an anesthesiologist; they're done with conscious sedation, so in that case Sedasys would increase the cost.

Whether there are cost savings or not just depends, but we generally see the new technologies as cost-increasing. A lot of da Vinci robots have been purchased, and now hospital systems come to us and say, "We need higher rates next year because you're not paying for them, and we want you to."

As we get into more of the accountable care structures, and maybe you can touch on that, Ken, where hospitals are at risk for the costs, they're going to be much more sensitive to what types of devices they have. Will they have 15 types of hip implants? Or just two? And which ones will yield good results, consistency, and affordability?

■ ***LS:*** *So Ken, are you hospital guys out there jacking up pric-*

es using the robot? Or are you thinking about changing that now that you're going to share risk? How's that working?

■ ***KP:*** We have six robots at Allina, believe it or not, with 12 hospitals. I think we have more robots than all of Canada, just to give you some perspective. But you asked if I could put my finger on any technologies that save costs, and I can't.

This morning I sent an email to the nurse leaders of our 12 hospitals, and I said, "Can you guys think of any?" The first response was "Nope." We've purchased plenty of new technology; we're very technologically savvy and probably one of the most advanced in the Midwest in terms of testing new technology. But 12 nurse VPs at 12 different hospitals couldn't think of any products that actually save money. Finally, one of the nurses in the cardiac division came up with a noninvasive cardiac monitoring technology that they think will save money.

LS: *Why is that the case?*

■ ***KP:*** A couple of reasons. One, you can't just look at money savings from a price point of view. You need to look at labor costs and productivity. It's our number-one cost in the health care system: nurse time, physician time, and tech time. During the presentations this morning, I didn't hear anything about how a device will reduce tech time or nurse time in the OR, the recovery room, or the bedside. That's really important.

I think to some extent the issue of complexity in health care is just exploding, so training and education are critical. How easy is it to use a new technology? Is it easily accepted and adopted, or is it very, very complicated? I think the third part of this links to standardization. We are seeing fewer and fewer choices over time, and more single-source or maybe dual-source relationships with big supply organizations. So having your product be part of a larger distribution organization would probably make a big difference.

We couldn't come up with a lot of examples of price or cost reduction. We could come up with examples that provided quality improvement and helped us reduce safety or quality exposures, but none that helped us dramatically.

LS: *Wow. Csaba, you had something to add?*

■ ***CM:*** Well, I just wanted to say there are times when cost enters the consideration. This isn't necessarily new technology, but when we first started seeing endoscopic procedures as an alternative to open procedures, people went from staying in the hospital for two or three days to going home the same day after a gall bladder operation. The same thing applies to some of the procedures on knees, where somebody has a damaged meniscus or something that can be repaired through a scope. That has created significant cost savings overall, especially to the people paying most of the bills, meaning the employers.

Getting back to the question of how we consider cost when we look at the evidence, a really good example is radiation therapy for moderate-stage prostate cancer. A number of years back, my alma mater [Loma Linda University School of Medicine] was one of the first to build a proton beam radiation therapy unit, which was incredibly expensive. It was going to take them a couple hundred years to pay it off! They tried to do some studies to say that it was better than other forms of radiation therapy for certain cancers, but none of them really panned out. This is how we take cost into consideration. Yes, proton beam therapy works for moderate-stage prostate cancer, but so does IMRT [intensity modulated radiation therapy], which is considerably cheaper, and it's just as good. There's really no clear evidence that the proton beam is less toxic or has better outcomes. In this case, we're not going to cover proton beam for that particular condition because it costs more and it's not more effective than IMRT. Those are the cases in which we actually factor cost into medical policy development.

LS: *Drew, would you like to weigh in?*

■ ***DO:*** Well, I was listening to the presentations earlier today and a lot of the innovations were really interesting, but they were additions rather than replacements. An early diagnostic test, for example, might result in more tests being done, and while they might be really good tests, they might not change the work flow of providers and might actually result in an increase of some of the standard testing or procedures. How do you guys deal with that sort of process from a provider standpoint?

■ ***KP:*** That is a really good point. If it doesn't lower labor costs, shorten length of stay, reduce readmission rates, or do something concretely to actually turn the tide on medical cost, I'm not sure we're that excited about it. It's so hard to be a nurse or a doctor today. They have to be trained on a large number of technologies at this point that don't relate to each other; the technologies don't talk to each other and they don't integrate with the electronic medical record. The complexity of their world has gotten out of control. We do look at work flows and try to figure out if the new technology creates new problems.

LS: *We have a lot of start-up companies here today, and I'm wondering at what stage should they come talk to health plans? When they're still in development or when they have data already? When do you want them to discuss with you how they fit into your world? Drew?*

■ ***DO:*** It depends. We could get involved at a fairly early level if it makes sense; we can use our membership or claims data to assess that value and that cost. If you're farther along and you've got clinical trials, then we don't want to know until you have published data because that's the point where we're going to be able to start saying whether we're going to cover it or not for the general group.

LS: *Are you open to companies coming in and brainstorming and asking you whether you'd be interested in such and such a thing? Is that something you have considered?*

■ ***DO:*** Yes, we do have a group that can look at those things. It meets about every two weeks and we go through different innovative processes and decide yea or nay on whether we're going to [fund] them or not. We don't want every single company coming to us, but we want to look at those that pertain to a health plan, health promotion, wellness, things like that that we can help with. We're not a provider. So if it's more of a provider-based product, you have to work with providers.

LS: *How does it work at Regence?*

■ ***CM:*** We're open to being approached even prior to FDA approval as long as there are some preliminary studies. For example, Medtronic got really excited about their artificial pancreas device, where you have an insulin pump and a continuous glucose monitor that constantly talk to each other. It also has a suspend feature, where, especially in the middle of the night, if a person with diabetes has a hypoglycemic episodes, the little gadget will actually turn the insulin off and leave it off for a certain time. They came to us months before it was FDA approved, and we looked at their presentation. Our medical policy development team actually has a mechanism for vendors coming to us. They can submit dossiers and we'll work with our medical director team to determine at which point we'd like to have them come in. We're open to that. But again, we apply the same rigor in our review of these requests.

On that note, I'd like to say that what's offered as data amazes us. For whatever reason, many new devices, and the same goes for some drugs, are rushed into the market with the barest scientific evidence. If you develop some device for GERD, for the treatment of reflux – and it would be really nice if someone could invent one that actually works without major surgery – it's not enough to show us just 50 patients. GERD is highly prevalent; there are millions of people with it. You also need to have a decent sized, well-controlled study. There were a couple of these small studies for GERD in particular. The small studies may be OK for rare diseases, but they're not OK for common conditions.

LS: *Ken, you're in Minneapolis, in the middle of the device capital of the world. Do you get lots of companies asking to come in talk to you?*

■ ***KP:*** Device companies really don't call delivery systems very often. I don't think I've ever had a call from a company in my time at Allina. Now I do get calls from the CEO of Medtronic or St. Jude Medical. But small start-ups never call, and I assume that's because they think we're not in the market. Well, we are in the market. I think the plug-in point is ultimately going to change. We used to be in a cottage industry with a lot of small offices and independent physicians. Device developers could just call physicians and ask their opinion. I think that's going away. We're consolidating as fast as we possibly can to prepare for health care reform and risk-taking. As we get bigger, we're not even giving Medtronic sales reps access to our institutions. We're asking them to instead link to the executive level and pitch their ideas there. I think over the next three to five years, the connection will change from a very personal company-to-physician relationship to a more corporate relationship with a company like ours. We're a $3.5 billion company and we'll likely be a $6 billion or $8 billion company five years from now. There will probably be 30 to 50 big health care delivery systems around the country that will make up most of health care. Your relationship with us is going to change quite dramatically and I don't think it's going to take long.

LS: *I heard gasping out there among the entrepreneur audience. That's really interesting because it speaks to the change that needs to happen in medical device sales organizations and marketing processes. The "old school" way isn't going to work anymore. It's going to be a much more data-focused corporate endeavor, and cost is one of those data points. Ken, you told me an interesting story about knee implants. Would you share that with us here?*

■ ***KP:*** We were looking at our implant costs for one of our ortho products, a knee implant. Our expenditure per year was something like $70 million. We offered 13 different implants at our hospitals, which is a big number.

I happened to be at a dinner meeting with a well-respected group of 70 orthopedic surgeons, with which we have a great relationship. They mentioned how profitable their ambulatory surgery centers were. I said, "Explain to me how you guys are doing so well." We got to talking about implants, and I said, "Well, how many implant options do you offer for knees?" One implant. I asked, "So why do you ask us to offer 13 in our hospitals?" And they answered, "Because we're not in the profit stream there. We really don't care what happens to the bottom line of the hospital. We care about our surgery centers." I found that very enlightening!

Within a couple of months, we came back to them to winnow the number down from 13 to two. We immediately saved several million dollars, and they played a big role in getting us to this place. That's going to happen throughout the industry. We are just scratching the surface of the opportunity to standardize and ruthlessly take cost out. There will be a lot fewer choices long term.

LS: *Drew, do you know how many truly new medical devices were approved by Aetna or by your section of Aetna in the last year?*

■ ***DO:*** I actually have no idea. Because sometimes they'll be in a policy or they'll be embedded in one of our 900 policies, and sometimes we don't actually evaluate them because they're part of a hospital process. If we're going to pay the hospital a fixed price for "X" procedure, we don't care as much about which implant you use, we just assume you're using one of high quality that's going to get good results. But we're not going through and saying, well, of the 13 we would only pay for number 3, and if it's not our approved implant we're not going to pay for it. We're not going to do that.

■ ***KP:*** That's where I see the change. With health care reform, risk is slowly transferring from health plans to delivery systems. As it transfers to us, and we have to take costs down dramatically to make up for fee schedule reductions that Obamacare has built into it; we are very interested in taking down supply chain costs. We really didn't care before. Here's another example. There's a TAVI [transcatheter heart] valve that costs as much as the reimbursement that we get from the government. We lose money in every case that we do. At what point do we say that's just not a workable approach? We're looking very differently at these kinds of things, whereas we never noticed before, because we used to be able to pass on the cost to the insurance companies or the government. That's changing quickly.

LS: *How about Cambia? How many medical devices did you guys approve last year?*

■ ***CM:*** About the same as Aetna. That is, I have no idea. Similarly, we don't go into the operating room. We don't tell cardiologists to use this or that kind of stent. On the really big things, as I mentioned,

IMRT and the proton beam, yes we'll get into that business, but that's less common.

■ ***DO:*** One way we do factor in cost is by narrowing down our network of providers. We've run one program for the last eight years that looks at what it costs physicians for an episode of care. If they're doing a hip, a knee, a back surgery, or taking care of a certain condition, we look at the total cost for that condition, and we apply it to that physician. Then that rating will say whether they're in or out of this narrower network. So if they like to use the really expensive stuff, and they go to the ambulatory surgery center that costs $85,000, it shows up in our fees. But they're not going to make that cut into that top 30% or 40% of providers that are more efficient and deliver the same quality of care.

David Cassak: *Let me direct this to Ken, but I'd be interested in the panel's view. As we see more doctors become employees of hospitals and institutions, what's your view of the impact that will have on product companies?*

"We are just scratching the surface of the opportunity to standardize and ruthlessly take cost out. There will be fewer choices long-term." – Ken Paulus

■ ***KP:*** We employ most of the physicians in Minnesota and western Wisconsin. It started with primary care, and the trend is now moving to specialty care. Quite frankly, today specialists can't make it alone. Some of the biggest, most profitable specialties in the past, cardiovascular surgery, cardiology, things that used to be very much stand-alone practices in most of the non-academic world, are coming in and saying, "We're done."

Once they come into a big company like us, we require new standards: compliance and conflict of interest. We get to the point where they can't really talk to you suppliers directly. There's very much of a corporate structure. It's unfortunate, but it's a reality. In fact, to be very blunt about it, we don't let any pharma or device reps visit any physicians anywhere in Allina. So if you're employed by us, none of those visits, no free lunches anymore, nothing. The relationship and sales model will change very dramatically in the very near future.

DC: *Ken said that Allina has six robotic systems and Csaba said something about not paying for the robot. Are there other ways of justifying the cost of the systems? I come from New Jersey, and I always hear hospital systems marketing da Vinci and other things. Is there a value to advanced technology, even if you don't get reimbursed for it?*

■ ***KP:*** In the old fee-for-service world it was an arms race. We have the latest technology, the robot, and across the street they don't. It was a volume game and we bought those robots for that reason. Was it a mistake? I think it was. We probably have too many robots. A lot of studies suggest that the robot technology isn't as good as a well-trained lap surgeon. I think we went too far in a system that rewarded that behavior. Now we're going to a system that pays based on a budget to take care of the patients that we're responsible for. Once we're paid that way, I doubt we'll add another robot any time soon. It's going to change pretty dramatically.

Question from the Audience: *Studies tend to look at a single application, a single mode of treatment; let's use wound healing as an example. Wound healing is a complex process, and there's no particular device that can take you from one end of the healing process to the other. It requires a multiplicity of treatments in a managed clinical pathway to get to a superior end result. As payors and providers, how are you going to take those integrated approaches, and how do you see that affecting industry? Because it may be that when you do the right therapy and the right rehabilitation with that medical device, you get lower recidivism and a lower overall system cost. Those are tough studies and they need Big Data. I guess I'm asking, how do we shift to actuarial analysis of multi-modality interventions that are synergistic in order to get to a cost-effective outcome? And then, when do you look at the outcome? At three months or do you look at your system costs in a year?*

■ ***AO:*** You're right. That partnership between the payors and the providers didn't exist before. Providers didn't see the whole longitudinal cost structure. Now providers might tell us that they want to use eight certain modalities for wound care to see what works better. For something small like that, we can look at the claims, we can bundle it, we can do a lot of different things to see if it was cost-effective. Was it better or not, than the usual care, for that pathway?

LS: *As the cynic whose PR department won't fire me if I say it out loud, I would tell you that the time period you should think about is the time period related to the payment. If a hospital's reimbursement is based on 30 days with no readmission, then make sure it works for 30 days. If a payor is going to pay for a member who will be there for 18 months or 24 months before they move to another health plan, that's the time line.*

■ ***DO:*** With a lot of these arrangements, you are probably going to be looking at one-year horizons in terms of how they perform, and then really resetting that target from a financial standpoint with a provider. With Medicare it might be that 30-day readmission rate, but that's sort of a different deal.

Question from the Audience: *How do you look at productivity costs? You mentioned time, training, education; that's a part of the formula we might not factor into current business models.*

■ ***KP:*** Absolutely. In fact, it's a much bigger cost. If you sold us a device for, say, $10,000, that's a relatively small number for us. The bigger number is how many nursing hours it takes, how much tech time, OR time, or physician time. That's a much larger cost for us. We looked at a wound care product about three months ago. I took the company over to the wound care nurse meeting and they walked

it through. Then I asked the nurses five questions. The number-one question was, would you use it? But the second question was, where does this fit in your work flow? They said, "You know what? It doesn't fit into our work flow very well." By the end of the discussion, we decided to pass on adding the technology.

■ ***DO:*** That's provider productivity. From where we sit, we're usually talking with employers; they're buying health insurance from us and they're worried about their own productivity. Does the device or procedure increase the productivity of the employee from the standpoint of recovery? All those microinvasive surgeries that have replaced some of the big surgeries offer recovery times in days rather than weeks, and that's really important for an employer.

■ ***KP:*** We have 25,000 employees and quite frankly we never look at medical technology and ask whether it will get somebody back to work faster. I don't think that's ever come up. I don't know if employers are asking that question either.

> ***LS:*** *I was actually at a meeting of the Pacific Business Group on Health with one of your colleagues. They had a bunch of medical device companies parade through. The audience consisted of the senior benefits people from every Fortune 500 company in the Bay Area, everything from PG&E to Google. They were pretty ugly to these device companies. They really wanted to know how it was of value to them, short term, for their employees, how it would make a difference in the cost of their health plans. They came right out and said, "I'm not interested in cool, I'm not interested in science, I'm interested in the efficiency of my health plan."*

■ ***DO:*** When you look at it from their lens, the health care costs are going to be about one-third and their productivity costs about two-thirds. They think about presenteeism and absenteeism. Are they going to get back to work and be productive? Do I have to retrain people? Do I have to deal with disability, etc.? They will accept a slightly higher health care cost if it's going to mean something better on the back end.

> ***Question from the Audience:*** *How do members of the panel assess new technology? I'm from Partners Healthcare in Boston, and we have seven hospitals. We have a very set process to do this.*

■ ***DO:*** Well, I think there are two parts to the question: what happens in the hospital, and what happens in the health plan. So from the health plan standpoint, we do have a very rigorous process in terms of how we evaluate the data. We're not delivering the care, so we're not choosing which device to use, but we'll look at those types of devices. If it's Medicare and we have to cover it, that's one thing. But if it's a commercial plan, we want to see evidence that it works. We will evaluate it with rigor. We also evaluate every policy on an annual basis. We will look at any new information that is published, even evidence that some provider brings to us, when asking us to reconsider. We do this all the time.

■ ***CM:*** We have a similar process at the Blues. We apply evidence to the process. We don't go looking at the 17 hips that are out there to figure out which ones we'll allow; we expect the health care delivery system to do that, and health care reform is causing pretty rapid alignment in that direction, as you heard Ken say earlier.

> ***Question from the Audience:*** *In medicine there is a saying, "Pay me now or pay me more later." How have you factored into your thinking that you might have to pay more now to save costs later? Is there a process for that?*

■ ***KP:*** I don't think we explicitly look at that when we set our policies. We will look at the clinical evidence and talk about hopefully saving money five, or seven years from now, but I don't think we actually make determinations based on that point of view.

> ***DC:*** *Along that same theme, one of the things that's often stated in the device world is that devices are instruments in the hands of physicians, and the argument is that as we iterate them they get more effective and less expensive. That obviously represents an up-front cost for you guys. Is that at all a winning argument? That we know this technology is expensive now, but if you just ride with us, within five or 10 years we'll have really efficient and great technology in the space?*

■ ***CM:*** Well, metal-on-metal hips seemed like a great idea at the time and now they are getting recalled. On the other hand, we mentioned that after several years, we do have some pretty good data about artificial cervical discs. Unfortunately, it's just going to take the time running out to a certain number of years. I know that's tough when you have a competitive environment with entrepreneurs and VCs. But that's the direction we're going in. Because of the unsustainable increases in national health care costs, there may be less of the Wild West approach to getting lots of stuff out there really fast.

A#2013800219

COMMENTS: Email the author: *M.Stuart@Elsevier.com*

RELATED READING

"Medtronic Signals More To Come On Its Pivot To Hospital Services" — *"The Gray Sheet,"* Aug. 20, 2013 [A#01130826009]

ACCESS THESE ARTICLES AT OUR ONLINE STORE
www.ElsevierBI.com

KANTAR HEALTH

Evolution: Impact on R&D and Business Development

By Ian Hicks, Senior Vice President, Kantar Health

Introduction

Research and development (R&D) continues to be a key but challenging and costly necessity for innovation and the survival and growth of life sciences companies. Given the global impact of the 2008/2009 recession on the biopharmaceutical industry, many companies instituted additional cost-management actions and restructuring across all aspects of their businesses. Some companies were more adept than others, and some still appear to be in serious transition. As noted by Robey at The Motley Fool, "Merck, AstraZeneca and Eli Lilly are examples of companies that announced restructuring in an effort to cut costs." They were more recently followed by Ariad, Novartis and Bristol-Myers Squibb (BMS). Robey added that "big pharma has really struggled with the patent cliff and inflated R&D expenses."[1] However, perhaps it is also a sign that management is thinking more clearly; BMS said it is evolving "its strategic focus in R&D to ensure continued leadership in delivering innovative medicines for patients with serious disease."[2] It would seem that this statement reflects increasingly broader thinking of life sciences executives.

A number of companies had foreseen the looming challenges on the R&D front and realized that high investment costs were unsustainable. Our research indicated that Novartis had initiated a different approach to R&D funding to reduce risk and increase positive opportunity exposure in 1996. We have noted that life sciences management appears to be adopting increasingly different approaches to R&D funding and thus it is realistically a work in progress and part of the daily business continuum. Novartis implemented some downsizing in one part of the organization but is increasing headcount at its Boston facility. The circumstances in the life sciences industry generate many questions regarding the cost of R&D, retaining personnel, regulatory and technological advancements, market access and biomarkers.

Where management is willing to be proactive and look forward, embracing evolution and change rather than shying away from it, rewards can be expected to follow. Trying to maintain "business as usual" is indeed an option; however, we suggest that embracing the need to act firmly and rapidly while thinking and acting smaller is crucial if companies are going to be successful. Overall, the creation of smaller specialized operating units might be an answer, with the parent company becoming a financial holding company.

The cost of R&D

In January 2012, Daniel Hoffman noted that big companies typically utilize large R&D operations that require substantial funding, around 15% of their product sales. With sales, marketing and administration possibly burning through another 30% of total revenues,[3] are these activity levels sustainable? Hoffman added that there is increasing utilization of contract research organizations and that larger life science companies are taking on a financier's role by funding smaller companies' research. The creation of ever larger companies seems to be increasingly questionable, owing to the sheer cost of maintaining and "feeding the machine."

Forward-looking companies

Prior to Hoffman's observations, David et al. observed in 2010 that pharma "embarked on a range of initiatives – in particular, externalizing more R&D to increase the number of drug projects and thus the chances of getting a major new product to market. In fact, over half of late-stage pipeline compounds are now externally sourced … since 1996, Novartis AG, for example, has nearly doubled its pipeline exposure by allocating over $650 million, less than 15% of its annual R&D budget, to its venture funds. These venture investments are made through three complementary vehicles, the

Ian Hicks is Senior Vice President at Kantar Health, leading the Business Development and Licensing team. With over 38 years of pharma experience, he has significant international licensing and distribution experience. He can be contacted at Ian.Hicks@kantarhealth.com.

original Novartis Venture Fund, the Novartis Option Fund – focused on securing options to specific programs; and a co-investment fund with MPM Capital."[4]

In an effort to achieve enhanced new product R&D, Merck announced plans to rejuvenate its $8 billion R&D department through the recent hiring of a new R&D chief, Roger Perlmutter. Analysts are offering mixed opinions;[5] however we believe that Merck is simply one of a number of companies that has made the determination to become more forward-looking in its approach to R&D and less of a process-oriented company.

Reverting to consideration of companies becoming more creative in their funding of R&D and thus increasing their exposure to opportunity, David et al. commented on companies such as GlaxoSmithKline that, faced with constrained resources, "wanted wider access to scientific talent and opinion. It therefore created its Center of Excellence for External Drug Discovery, which since its formation, in 2002, has forged nearly 15 deals … with minimal upfront research funding, commitment of nonfinancial resources, or day-to-day governance responsibilities." They further noted that Eli Lilly, Merck, Novartis and Pfizer have the opportunity to invest in new technologies. Amgen and Biogen Idec have committed $100 million each to their corporate venture arms.[4]

Carroll[6] noted in Fierce Biotech, "Pharma clearly contributes the lion's share of R&D cash in the industry, but it's the biotechs that are roaring. An extra few billion dollars may not look like much when a single company like Novartis commits $9 billion to research, but it helps account for a completely different attitude about development efforts in a high-risk field like drug development."

Retaining talented personnel in times of change

In February 2011 Dafydd Wright from RSA Interims, part of the RSA Group, who are leaders in life sciences executive research and interim management, commented on "how the most successful firms keep hold of their most talented members of staff. And keeping these staff on your books often leads to the greatest achievements." On one hand this might be questioned should an R&D organization not be productive. Perhaps the problem was identified in a survey of nearly 400 life sciences executives, which found that "while over 90% identified talent management as a key priority for 2010, only 26% had an active strategy in place for retaining talent, and 68% had no clear leadership succession plan."[7] Therefore, it appears that when top, talented personnel are managed well, encouraged and motivated through good leadership, outstanding results can be expected. Leadership and embracing change seems to be the key.

Regulatory and technological environment

A number of reports have emerged in the media in which patients and advocates of patients with life-threatening diseases expressed concerns at the rigid FDA requirements for the development of new therapeutics where there is an unmet medical need. Through various mechanisms, the FDA Safety and Innovation Act of 2012 (FDASIA) emerged to address "the issue of drug development for serious illnesses: a new 'breakthrough therapy' designation for investigational drugs and expansion of the statute regarding accelerated approval."[8] The FDA has now implemented this designation.

Bernstein's Tim Anderson, in reviewing Novartis in July, noted the potential value of achieving a shorter priority review designation from the FDA for a new product, which is different from Breakthrough Therapy Designation (the two are not mutually exclusive).[9] He added that Novartis is among the better R&D organizations, which should partially predict future new product flow beyond the near term.

It is worth noting the apparently complex environment surrounding biosimilars. The regulatory environment, as applied to biosimilars, appeared to take substantial time to be developed, and it remains questionable whether biosimilars really present a major threat to some larger companies. No automatic switching rules from branded to biosimilar therapeutics appear to exist, and the discounting for a biosimilar might not be as large as anticipated some time back.

Rising impact of biomarkers

The increasing prevalence of biomarkers is yet another factor to consider within the context of R&D and its impact on business development and licensing (BD&L). Increasing familiarity and differentiation between diagnostic and predictive biomarkers leads to important considerations regarding potential patient segmentation as well as specific or targeted drug decisions and utilization. This needs to be considered in light of the FDA enforcing the need for a validated companion diagnostic assay to be approved in conjunction with any new drug seeking approval in a biomarker-defined indication.[10] This does benefit the payers who are able to demand greater rigor of appropriate testing of a patient before authorizing use of a biomarker-dependent therapeutic. They thus have a mechanism to manage a patient's treatment, hopefully to mutually benefit, namely better outcome for the patient and at a controlled or known cost. Considerable variance remains in how payers apply biomarker policy; however, we see this as an area to be well aware of and maintain vigilance. We predict that despite

rapid development in this space, we are still in the infancy of development on this front.

Enter market access

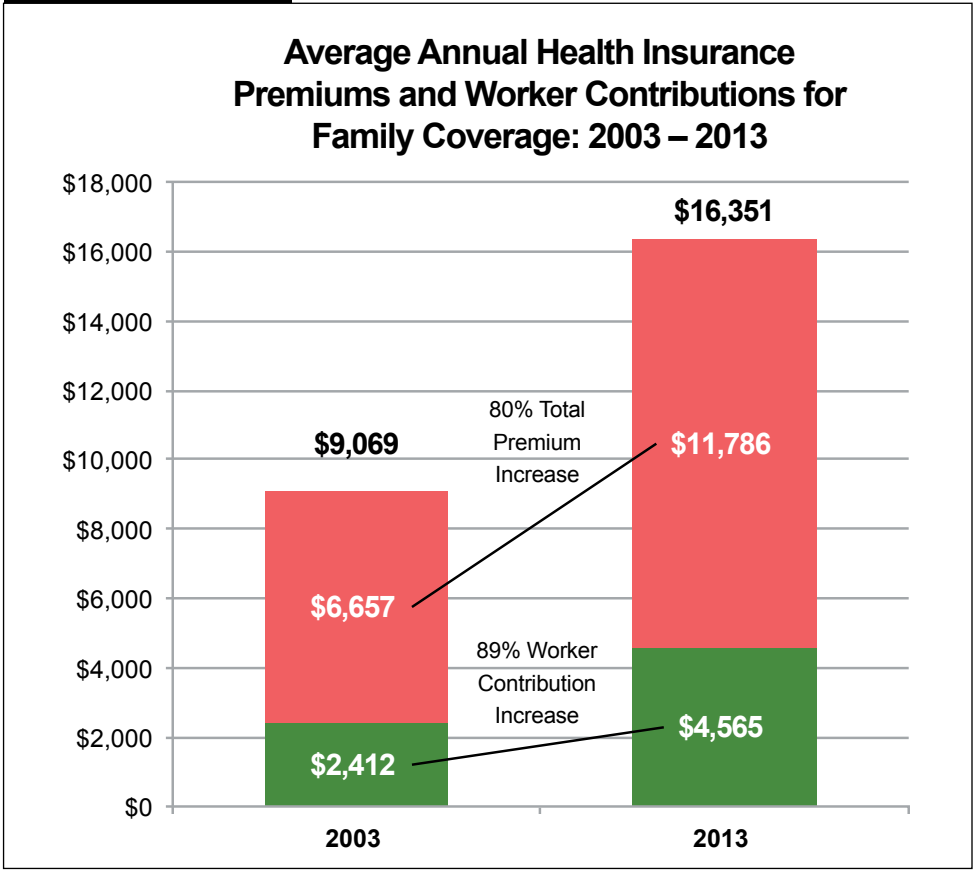
While contending with R&D issues, life sciences executives must also undertake business development and related activities while simultaneously considering how a new therapeutic is to be priced and reimbursed. Commercial healthcare coverage is marked by rising premiums, deductibles and cost-sharing.[11] This raises the question as to whether a new, potentially highly effective therapeutic for a serious medical condition will be covered and reimbursed at levels executives feel might be appropriate. Figure 1 provides the graphic depiction of increased costs for patients from 2003 to 2013.[11] Payers have adopted increasingly more stringent guidelines for the utilization of costly treatments. The essential intention is to manage costs where feasible through prior authorization requirements, higher tier levels with increasingly higher copayments or possibly coinsurance. As noted in Kantar Health's Oncology Market Access, "Most oral cancer drugs are managed and placed on specialty tiers, which are traditionally Tier 4 or higher. The specialty tiers increase the patient's inability to afford treatment, as an average copay of $79 is 172% higher than the most common tier (Tier 2) for commercial payers. Interestingly, since 2007, the average specialty tier coinsurance was lower than the third tier, most often known as non-preferred. Cancer patients can be on multiple drugs, for numerous conditions, resulting in significantly high out-of-pocket costs."[12]

The implementation of the Affordable Care Act, and its subsequent challenges, has led to differing opinions from multiple sources. There have been reports in the media supporting the point of view that cost increases for patients are likely, and the opposite opinion that costs are being reduced for patients has also been expressed. Overall, we anticipate net outcome of these developments could create a degree of pressure from patients and advocate groups to push for lower pricing of newer therapeutics. For example, San Francisco's Proposition D would have required the city to negotiate directly with drug manufacturers to improve access to certain therapeutics (in this case, HIV medications and negotiations with Gilead). Could this be a common scenario in the future?

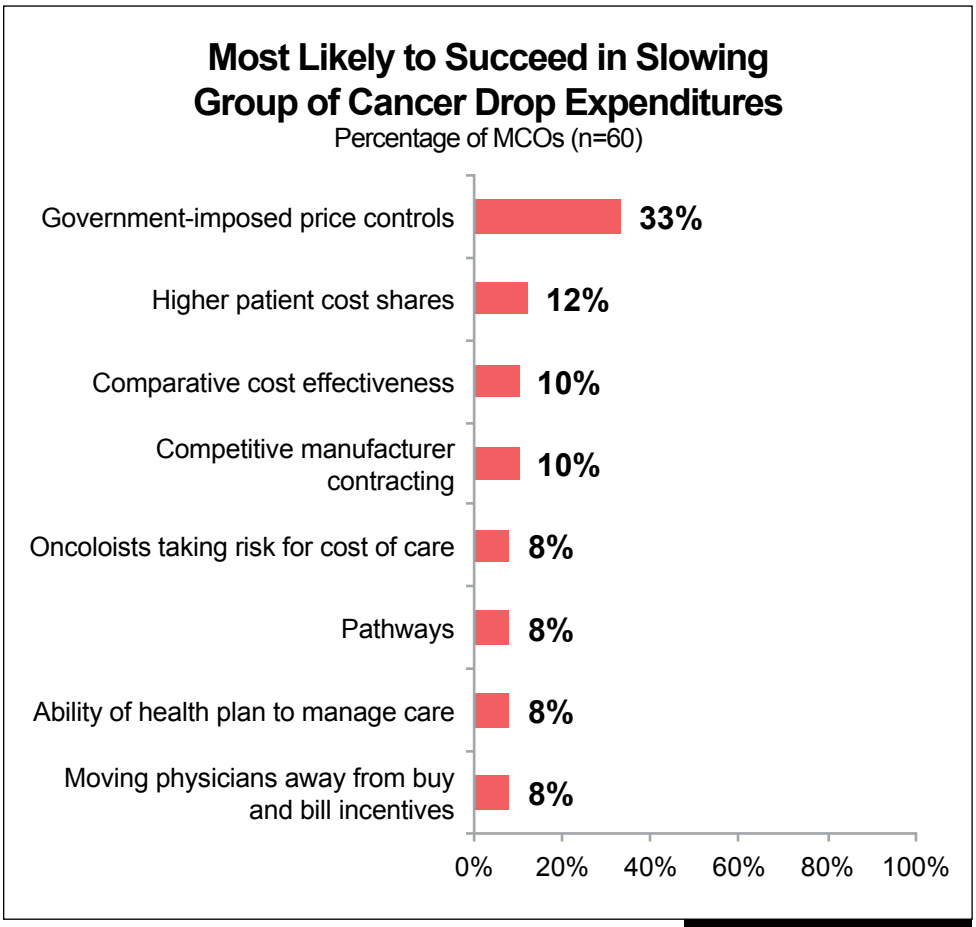
In 2012 at Memorial Sloan Kettering, oncologists – not pharmacists – decided against the inclusion of Zaltrap® on the hospital's formulary. They felt they could not justify the utilization of an agent that is twice as expensive as the current standard of care but with similar efficacy. This action is certainly not widespread, but it must be considered by life sciences executives. In The New York Times, doctors Bach, Saltz and Wittes commented, "The burden of this cost is borne, increasingly, by patients themselves – and the effects can be devastating. In 2006, one-quarter of cancer patients reported that they had used up all or most of their savings paying for care."[13]

Also noteworthy is the increasing utilization of pathway implementation by health plans as part of their increased effort at cost-control initiatives.[14] The U.S. healthcare system still allows free pricing of therapeutic innovations;

Figure 1



Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2003–2013



Source: Kantar Health; Payer Survey, June 2013

Figure 2

however, restrictions on utilization by medical specialists are increasing. The question that then arises is, "Might we be faced with some form of pricing control, especially for Medicare and Medicaid patients, in the future?" We only need to examine the cost-control mechanisms in place in other major industrialized countries to develop a set of potential scenarios. Our research notes that price controls could become a reality in the future. Kantar Health's survey with managed care organizations found the implementation of price controls was an option for the future (Figure 2).[14]

In review

The challenges of R&D and potential impact on BD are almost no different from what they may have been a decade or two ago. The old question of "how rapidly can we develop a new agent to treat an unmet medical need while containing cost and achieve a reasonable price?" still seems to apply. But therein lies the trap. The environmental situation has become so much more complex. It is not only cost control and changing reimbursement, but also how to get one's message out to the intended target audiences. Numerous practices and hospitals will not permit representative visits without appointments. Cost control is always a concern, as is the market into which a new therapeutic may be commercialized, but along the way the myriad superb technological developments has simply escalated the complexity to levels that could not have been dreamed of two or more decades ago. The need for life sciences companies to find ways of being smarter regarding their R&D process has become apparent. The implications for management are clear: Embrace change and surround yourselves with people who question and actively seek evolution and change. The status quo could be very harmful to a company.

On the personnel front, what can be done to retain highly qualified and valuable personnel, but direct them to think "outside the box and away from the not invented here" trap? Their knowledge and expertise are critical, but they do need to be encouraged to "dare to think differently" as well.

Consider the impact of diagnostic, prognostic and other companion markers. These help the process of patient segmentation on multiple levels but also add a level of complexity that had not existed in the past. Looking forward, these same companion markers are considered to be a likely part of cost-control mechanisms implemented by payers, both private and government.

Patient assistance programs are likely to be more important in the evolving world to ensure as many treatable patients as possible can achieve the right therapeutic despite potentially high prices. Looking toward assisting the underinsured is an opportunity for volume but a challenge for product pricing.

Pricing and reimbursement will continue to evolve, with ongoing downward pressure

on pricing of innovative new therapeutics. It might become important to consider a lower price and higher volume model when assessing the potential of a product. However, complications will remain where volume may not be achievable in smaller niche indications.

Companies seeking to out-license a new technology or therapeutic with anticipated revenue generation from royalties will have to gather as much information regarding potential commercial markets as any licensor to ensure revenues are maximized. The challenge will be negotiations on an equal knowledge footing while availability of resources may be vastly different. The environment has changed dramatically, and trying to enter the market successfully as a small company is extraordinarily risky. For every Alexion that is successful, there are many more that do not commercialize successfully. Small companies that focus on their strengths and develop a web of successful partnerships and licensing deals may have a greater chance at sustainable independence.

The author would like to thank Tony Russell, PhD, MBA, Senior Director, Commercial Strategy at Alder BioPharmaceuticals for his thoughtful insights influencing this article.

References:

1. Robey S. A Busy Day of Layoffs in Pharma. The Motley Fool. 8 Nov 2013
2. Bristol-Myers Squibb Evolves R&D Strategy. Bristol-Myers Squibb 2013.
3. Hoffman D. Why Big Pharma Needs to Become Smaller Pharma. Philly .com. 25 Jan 2012.
4. David E, Mehta A, Norris T, Singh N, Tramontin T. New frontiers in pharma R&D investment. In Vivo: The Business & Medicine Report. Nov 2009.
5. Carroll J. Is there a major R&D overhaul coming at Merck, or just more streamlining? Fierce Biotech.10 Sep 2013.
6. Carroll J. Biotech R&D spending roars ahead as Big Pharma grimly holds the line. Fierce Biotech. 12 Sep 2013.
7. Wright D. Retaining pharma top talent. Pharmafile. 25 Feb 2011.
8. Sherman R, Shapley S, Robb M, Woodcock J. Expediting Drug Development — The FDA's New "Breakthrough Therapy" Designation. NEJM. 14 Nov 2013;369:20.
9. Anderson, T. (2013). Bernstein Research. Novartis: Outlook Remains Comparatively Robust, but Analyst Meeting Provides Only Incremental Details; November 22, 2013.
10. Gochenauer G, Hawthorne S. Biomarkers in Oncology: Do They Help or Harm? PBIRG Annual General Meeting 2013.
11. Claxton G, Rae M, Panchal N, Damico A, Bostick N, Kenward K, Whitmore H. Employer Health Benefits 2013 Annual Survey. Menlo Park, California, and Chicago: The Kaiser Family Foundation and Health Research & Educational Trust; 2013.
12. Rock T. Patient Access Affordability and Assistance Programs. Reactions. June 2013.
13. Bach P, Saltz L, Wittes R. In Cancer Care, Cost Matters. *The New York Times.* 14 Oct 2012.
14. Source: Kantar Health; Payer Survey, June 2013.

Partnering with Kantar Health

Kantar Health is a global healthcare consulting firm and trusted advisor to the world's leading pharmaceutical, biotech and medical device/diagnostic companies. The firm combines evidence-based research with deep scientific, therapeutic and clinical knowledge, commercial development know-how, and brand and marketing expertise. To learn more about our capabilities, contact us at info@kantarhealth.com, or visit our website at www.kantarhealth.com.