Some big questions about small devices

*a conversation with Lisa Suennen, part 1*

Lisa Suennen is a co-founder and Managing Member of Psilos Group, a healthcare venture capital and growth equity investment firm with over $577 million under management. Ms. Suennen has headed Psilos' West Coast office since the firm's founding in 1998 and focuses on the medical device, healthcare information technology and healthcare services sectors. She serves as a Director on the Board of several Psilos portfolio companies, including AngioScore (chairman), PatientSafe Solutions, OmniGuide and Ver-aLight (chairman).

Ms. Suennen holds an M.A. in political science, a B.A. in political science and a B.A. in mass communications, all from the University of California, Berkeley. Ms. Suennen is also Vice Chair of the National Advisory Council of the Institute of Governmental Studies at the University of California, Berkeley and a visiting lecturer at the U.C. Berkeley Haas School of Business. In 2011 Ms. Suennen was awarded the U.C. Berkeley Institute for Governmental Studies Outstanding Alumni Award. She has also recently been named to the Advisory Board of the U.S. Health and Human Services Office of the National Coordinator Investing in Innovations program.

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**Sophie:** It is reported that biotech drug development spending declined 20% in 2010 and the number of drug approvals declined, according to an Ernst & Young report that is set to be unveiled at the BIO convention later this month (June). Do you concern about this and what are opportunities for medical device industry?

**Lisa:** It doesn't fundamentally concern me to hear that drug approvals are down as there are far too many "me-too" drugs and devices already, not to mention too many that don't have an impactful enough difference on patients to be worth paying for. I'd be much more concerned to know that meaningful medical breakthroughs are not making it to market due to capital constraints and FDA or other regulatory reasons. It is essential for both new drugs and new medical devices that seek to commercialize in the US to demonstrate that they can improve quality and reduce healthcare costs. The number of new products isn't really the right thing to think about; it's the number of valuable new products.

I am concerned that the US medical device industry, where my firm Psilos Group invests significantly, is struggling to maintain its competitive edge because circumstances have made it exponentially more costly and difficult to get a product to market. The healthcare industry is one of the nation's largest job creators and yet we are adopting policies around regulatory approval, reimbursement, taxes and capital formation that are creating ever-increasing barriers to medical device industry success. It would be a travesty to yield our
supremacy in this field to another nation.

**Sophie:** The ability of a medical product to gain market share is often highly dependent on its prospective payor reimbursement strategy. Many entrepreneurs, especially small companies often consider FDA regulatory clearance or approval as the gating item behind the success of their venture. What do you think are the best strategies to garner the reimbursement?

**Lisa:** Leaving reimbursement strategy to the end is one of the biggest mistakes that medical device entrepreneurs make. As an investor that spans both insurance/payer services and medical technology, I am always amazed that representatives of these two industries so rarely talk with each other, much less understand each others' respective business drivers. If you are a medical device entrepreneur you must never forget that the entity that really pays for your product is a health insurer or the government. That means these guys are your real customers and you forget about them at your peril.

Yes, FDA approval is a critical step in a medical product's birth, but reimbursement is the path to adulthood. This must be attended to from the very beginning. The best strategy to ensure both reimbursement and market adoption in this day and age of skyrocketing healthcare costs is to deliver a product that creates real value in terms of clinical quality improvement and measurable cost-effectiveness. Our healthcare system pays already for far too many useless medical products and services, from unnecessary imaging to failed back surgeries to interventions to correct medical mistakes. To gain reimbursement from CMS or a private payer today, you must be able to demonstrate to them that your product can actually do at least the same or more for less money or far more efficiently.

Moreover, medical device entrepreneurs need to engage early with the entities that hold the true fate of the new product in their hands. The best thing you can do for your nascent medical technology company is to get to know the people at United Health, Aetna, Humana, Cigna and CMS who are the key to your success. There are hundreds of new devices invented each year and the average payer only approves payment for a handful annually. Properly anticipating and responding to the economic and clinical decision-making that underlies payers' reimbursement decisions is critical to medical device success. FDA approval is necessary, but not sufficient.

**Sophie:** In the past, we have seen lots of new medical devices and technologies such as
digital mammography, cardiac stents and orthopedic implants that could be “profitable in a clinical environment”, but didn’t see much effort on proving that these new, expensive technologies actually improve outcomes beyond existing treatments. What kind of collaboration do you think it needs to be established to build the evidence pool?

Lisa: I am not sure this is an issue of collaboration as one of intellectual honesty married with the changing realities of our healthcare system. It has become quite clear that we cannot afford to continue to pay for medical products and services that do not contribute to improved health of those who utilize them. Payers of all types have made it clear that they are done reimbursing for things that don’t deliver something of clinical value. As a nation we spend somewhere in the neighborhood of $20-$40 billion/year just as the result of medical errors and it wasn’t until very recently, when CMS started withholding pay for "never events" that hospitals stopped getting paid both to make the errors and to fix them. Of course it would be helpful if the mountains of public and private sector data on clinical outcomes were more readily accessible for companies to use to make analysis of medical technologies a little easier, but the real issue, I believe, is one of will and market dynamics.

The increasing pressure from payers to demand proof of efficacy and value as the gateway to reimbursement is the biggest changing market dynamic. When I first started in this business, and my firm told entrepreneurs that we would, at least initially, assume their product worked but please start by telling us how it reduces health care costs, they would stare blankly at us or try to convince us that this was not an important question. The idea of doing a true health economics study comparing their product to an alternative treatment approach was anathema. This has really begun to change and more often than not entrepreneurs are coming to us with both a clinical and a cost-efficiency story. Many in my industry think "comparative effectiveness" is the enemy, and no doubt the devil is in the details of how it is implemented, but if we don't start worrying about health economics and the relative value of new medical technologies, our economy is going to die on the table. I recently read a column by New Yorker business reporter James Surowiecki in which he says that the U.S. doesn't have a debt problem, it has a healthcare problem. While that is obviously an over-simplification, in many ways he is right.