

## An overview of the wide-ranging program at the 9<sup>th</sup> annual MedTech Investing Conference

By **JIM STOMMEN**

*Healthcare Syndicate, Editor*

Whatever the agenda topic at the 9<sup>th</sup> annual MedTech Investing Conference, held here in mid-May -- whether it was the status of investing in the sector, the outlook for innovation or looking outside the U.S. for commercialization opportunities – the topic of regulation became part of the discussion. The two-day conference at the Graves 601 Hotel was co-presented by **IBF Conferences** of Massapequa, N.Y., and Minneapolis-headquartered **LifeScience Alley**. The annual conference drew the largest number of attendees in its nine-year history, with 350 attendees.

This roundup package provides for those who attended the 9<sup>th</sup> annual MedTech Investing Conference in Minneapolis in mid-May an overview look at the conference sessions.

In order of appearance, the sessions addressed in this overview include:

- 1) The session on Bariatric/Obesity Innovation, one of the MedTech Vertical Markets sessions on the opening day of the conference, also dubbed Device Specialty Day.
- 2) The Women's Health Innovation vertical market session.
- 3) Dr. Glen Nelson's keynote remarks on "The New Global Economy," presented during a dinner.
- 4) A session on "The Lay of the Land."
- 5) "The Crystal Ball" panel.
- 6) A panel on "A View From the Trenches."
- 7) "So You Want to Go O-U.S.," a session on commercialization opportunities in international markets.
- 8) A panel on "Corporate Buyers and Investment Bakers Speak Out on M&A Activity."
- 9) "FDA Fireside Chat" featuring a discussion with former CDRH director Daniel Schultz, MD.
- 10) The closing session, "An Insider's View of Public Policy & Regulatory Issues," featuring AdvaMed President & CEO Steve Ubl and Medical Device Manufacturers Association President & CEO Mark Leahey.

### *Oversized opportunities seen in obesity field*

The Bariatric/Obesity Innovation session held as part of the afternoon-long Device Specialty Day drew an appropriately plus-sized crowd. The program kept that overflow gathering's interest to the point that the mid-afternoon networking break was almost an afterthought; with attendees hustling back to resume the discussion of what most agreed could be one of med-tech's best market opportunities going forward.

Chaired by David Milne, managing partner of Boston-based venture firm **SV Life Sciences**, the session featured physician experts in the obesity field, VCs and potential corporate partners, along with CEOs of existing firms operating in the sector.

Setting the stage for the discussion, Milne referred to what he termed "the obesity epidemic" in the U.S., citing statistics such as 124 million Americans being considered overweight and fully 11 million fitting the clinical description of "morbidly obese."

Milne said developments in the obesity space are emphasizing a shift from invasive surgical procedures to less-invasive options, with the popular Lap-Band procedure earning a 44% share of the 210,000 to 220,000 procedures performed annually in the U.S. and Canada.

“There are tremendous opportunities in this space,” he said, including significant interest by corporate titans such as Abbott, Allergan, Covidien and Johnson & Johnson.

Mitchell Roslin, MD, chief of bariatric surgery at New York’s **Lenox Hill Hospital**, and Aurora Pryor, MD, of the **Duke Center for Metabolic and Weight Loss Surgery** in Durham, N.C., outlined the current status of efforts to combat obesity.

Saying that surgical intervention “is the only thing that works for the morbidly obese,” Pryor mirrored Milne’s take on the space offering “significant growth potential.”

She said the longtime standby, Roux-en-Y gastric bypass, an invasive procedure that involves the stapling of the stomach, “is declining as a percentage of the total,” with gastric bands and sleeves having moved to the forefront.

Pryor said the goals of new approaches such as gastric restriction, malabsorption, and combined modes of action have goals of minimizing risk, offering a cosmetic benefit over invasive surgeries, having a cost benefit and improving results. She said those goals are more or less met for all but improving results, where “not yet” is the applicable phrase.

Companies developing such products need to focus on the “results” part of the equation, she said. “To improve adoption [of any specific technology], prove the benefits.”

Saying that surgeons are willing to accept less weight loss via a given procedure if patient safety is improved, Pryor added: “We’re going to see a lot more bariatric surgeries being done, and . . . new devices that may reduce risk and increase clinical effectiveness” will be the ones that find acceptance by such surgeons.

Roslin offered a simplified view of the work of bariatric surgeons: “We do procedures that make people less hungry.”

The challenge for companies seeking to innovate in the space, he said, “is to come up with a sustainable business model,” especially given that “no randomized trial in obesity has yet hit its endpoint.”

So the question facing companies and those who invest in them is, “What is the value proposition?”

Roslin ran through a variety of approaches for gastric restriction, including space-occupying technologies, duodenal blockers, stents, pacing and endoscopic suturing.

For the latter, he cited the TOGA System from Palo Alto, Calif.-based **Satiety**, terming it “an engineering tour de force,” but one that “isn’t going to be cheap.” The transoral gastroplasty (hence TOGA) procedure has a price tag of \$7,500, but that hasn’t kept what Roslin said were some 20,000 persons who sought information on becoming part of the company’s 10-center clinical trial for the device.

Noting that early data have shown sustained weight loss, Roslin said one major concern involves reimbursement. “Until there is reimbursement,” he said, “where is the market going to be?”

He also cited the dual-balloon approach from **ReShape Medical** of San Clemente, Calif., with overseas data indicating weight loss of 40 to 60 pounds at six months and U.S. clinicals now getting under way.

Following an abbreviated mid-afternoon break, a VC/Corporate panel discussed opportunities and investment trends in the obesity space.

Jan Garfinkle, founder and managing director of **Arboretum Ventures** of Ann Arbor, Mich., moderated the panel, with participation by Milne, along with Mike Carusi, general partner in Palo Alto, Calif.-based

**Advanced Technology Ventures**; Evan Norton, director of **Abbott Ventures**, of Lake Forest, Ill.; and John Onopchenko, managing director of **Synergy Life Science Partners** in Portola Valley, Calif.

Onopchenko said obesity is a “patient-driven” space, with patient choice being “a big influencer of the market.” What he is looking for as a potential investor in the space is “a dramatically safer procedure.”

Norton said, “There are a lot of great ideas out there, but they’re navigating in some murky waters.” He said obesity/bariatrics is definitely a “white space” type of investment. “We’re going to have to see more cards turned over.” He said companies will have tall hurdles to scale in order to get what he referred to as “that big check.”

In making investment decisions, said Milne, “You have to dig deep into the data – there isn’t any 10-year data yet.” He said that while less-invasive clearly is the direction the space is going, “surgical is where reimbursement is right now.”

For Carusi, it’s clear that technologies will drive the space. The question, he said, is “How do we get to market soon with the FDA and reimbursement challenges that companies face?” Noting that his firm has made “multiple bets because we didn’t know where it [the obesity sector] was going,” he added that “we’re now starting to see clinical data in this space.”

Onopchenko said that “[gastric] restriction works – it’s tough to beat that. The bets we place are on how long the technique works.”

Milne agreed. “Permanence is a question. [Investors are] struggling with the question of how does the FDA view it?” He added that VCs are spending more on their investments in the space because there isn’t anything out there in the way of proven solutions to build on.

He said his guess is that “clinical data will be the driver” in terms of new technologies gaining traction against the entrenched surgical companies. “If you’re a surgical company, you have some substantial business to defend there.”

Milne said he thinks it will be another two to three years before any of the newer, less-invasive technologies will make any substantial gains in the space. “You need to see what element of obesity you’re trying to solve.” He emphasized that he does see the space as a market to be dominated by devices, not drugs.

Carusi said, “You’re going to have to do multiple studies – expect a lot of smaller studies to be done.” Onopchenko concurred, saying that the challenge for companies is, “in order to get a big check written, you’re going to have to show some darned good data.” But, he said a good transoral technology with good clinical results could be a “game-changing” event.

A final session featured top officials of **GI Dynamics**, **ReShape Medical** and **Valentx** discussing their companies’ efforts to date in the sector.

### ***Women’s health sector rife with opportunity***

Session chair Linda Grais, MD, a partner with **InterWest Partners**, of Menlo Park, Calif., introduced the program on Women’s Health Innovation by noting, “It’s important to have more choices that are feminine-specific.”

Giving an overview on the women’s health space was Charles Carignan, MD, president/CEO of Boston-based **NinePoint Medical** and a former exec at several other firms active in the sector.

Citing the fact that “the Pill” had just turned 50, he said that development was revolutionary as it gave women control over their health and fertility. Carignan said it was the “beginning of a changing tide” as it relates to drugs and devices that address specific issues of women’s health.

Women’s health is a “multi-specific area,” he said. In the last 10 to 15 years, the focus has been on bone health, breast health, sexual, conception, fibroids and women’s version of joints, such as replacement knees.

Carignan cited a number of specific innovative companies in the space, including **Conceptus**, which took a device first used for brain aneurysms and used it to deal with infertility; **Novasys Medical**, focused on incontinence issues; **VascularControl Systems**, which created a less-invasive treatment with an external device to treat fibroids; **Caldera Medical**, which developed an innovative system for sterilization in an outpatient setting; and **Viveve**, which has made great progress in sexual health/vaginal rejuvenation with laser technology.

He also noted that a considerable number of big companies have incorporated women's health elements among their businesses, including Johnson & Johnson with its Gynecare division ("Birth control is bigger than Band-Aids," Carignan said); **Coloplast**, big in pelvic floor materials; **Hologic**, which is strong in breast and bone health; and **Zimmer**, which strongly promotes its gender-specific replacement knee.

Carignan noted that many companies are looking for expansion and acquisition in Japan, where they are behind in meeting specific needs of women.

He said there still are "great investment opportunities out there in women's health." There still are many unmet needs, he said, as seen in the "high number of baby boomers demanding that things can be done better."

Carignan said baby boomers are having a "tremendous impact" on the medical-products industry, with lots of motivation due to anti-aging efforts, continued sexual health and the like.

While the FDA environment is more challenging now, he said it also is responsive to the health needs and demands of women, including the establishment and expansion of the Office of Women's Health. Carignan said that clinical trials require different approaches to acquire women and to retain them, as they tend to drop out more readily.

Looking toward the future, he said that medical solutions will continue to improve women's health and we'll see an even greater convergence of diagnosis and treatment. Noting that medical and residency programs are starting to address separating obstetrics and gynecology, Carignan said that new technologies and different skill sets are driving such a separation.

He also said that recognition of gender-specific systemic diseases, female heart disease, endocrinology, orthopedics, etc. will provide more opportunities for med-tech companies.

### ***Commercializing Healthcare Technology - Glen Nelson looks at the state of med-tech***

An interesting view of the state of things for medical technology came from Glen Nelson, MD, retired vice chairman of hometown device giant **Medtronic**. Nelson, who now chairs his own firm, **GDN Holding**, minced no words in a keynote address during an opening-night banquet, saying of the U.S. healthcare system: "We have a system where care is unevenly delivered, and that which is delivered is at an unsustainable cost."

Noting that "our costs [for healthcare] are two to three times those of the rest of the world, but we lag most of the rest of the world in life expectancy, so it's hard to argue that we are getting our money's worth," Nelson said care in the U.S. is marked by "slow adoption [of new technologies] and a lack of coordinated care."

But, he added, "I believe we're at the breaking point, and change is inevitable." Healthcare reform, he said, "affords us the opportunity to broadly apply electronic healthcare records" to the existing system. Saying there are "more questions than answers" when it comes to how healthcare reform will play out, Nelson pointedly noted that the law passed earlier this year "doesn't do anything to address the quality and cost of care."

While saying that the U.S. "provides most of the new medical innovation in the world," he added that the more stringent regulatory climate that faces developers of new products in dealing with the FDA today "adds to the cost of bringing new technology to market."

Nelson said that what is needed "is faster access to new technology," which he said could be accomplished better with stronger post-market surveillance than with higher pre-approval hurdles. One fallout from higher

hurdles such as more stringent 510(k) requirements, he said, “is that clinical research is moving offshore and challenging the U.S. as a leader in medical innovation.”

Noting that “some think we could see a merger of CMS [the Centers for Medicare & Medicaid Services] and the FDA,” Nelson said, “We might think that would be a good thing, but that would also lead to a new, more cumbersome bureaucracy.”

From his perspective of observing a domestic healthcare system in action for more than 50 years, he said the key to maintaining the U.S. lead in medical innovation is to continuously take down the barriers” that limit such innovation getting into the hands of physicians.

### ***Investments down, but interest in sector seems strong***

A session labeled “The Lay of the Land” focused on the changes and challenges seen as most impacting CEOs, investors and interested corporate entities.

In a discussion about issues surrounding the FDA’s 510(k) program, B. Kristine Johnson, a former Medtronic executive who now serves as president of **Affinity Capital Management** of Minneapolis, cited the agency-sponsored “town hall” meeting held in the Minneapolis suburb of Bloomington the day before the start of the MedTech Investing Conference. “My take-away from that meeting is that the hurdle is being raised, whether it’s a 510(k) or PMA [premarket approval] product. “In the long term, that will have an impact on deals.”

She said the hubbub over 510(k)s “is being driven by changes being eyed by the agency,” adding that “the lack of communications and transparency around the process is troubling.”

Johnson said the fact that there has been a slowdown in product review times at the FDA, coupled with “many more” rejections of applications, “brings a more cautious approach by VCs.” She added that, “in the absence of a clear path” to approval, VCs are looking to get involved with companies “at a later stage, when the path is clearer.”

In the short term, she said, “we have the chilling effect of uncertainty.”

Johnson said one unfortunate reality is that with the bar being raised, “technologies that address smaller markets won’t get funded by the venture community – they can’t justify the kind of investment it takes to drive these costly trials.”

J.P. Peltier, a managing director at Minneapolis-headquartered **Piper Jaffray**, also decried the lack of clarity on the issue, saying “it has an unfortunate impact on investment. We’re seeing a paralysis [on innovation moving forward], and some technology is going unfunded.”

Wahr likened dealing with the agency to keeping a marriage together. “Sometimes you just need to say ‘Yes’ in dealing with FDA,” he said. “As a company or investors, you need to start your internal clock on what you think they’re going to want” in the way of data, and when. “That clearly has gone up.”

Saying that his device firm “is a PMA company,” Dennis Wahr, MD, president/CEO of **Lutonix**, of Maple Grove, Minn., added: “The benefit is that at the end of the day you have the clinical findings that are needed” to satisfy the FDA.

On the broader question of innovation, Chad Cornell, vice president of corporate development at Minneapolis-headquartered med-tech behemoth **Medtronic**, said, “The question is, “Who’s going to invest in this business model, in this space?” He said that he looks at certain cardio indications, for example, and sees many with not a lot of companies, especially not a lot of new companies.

One result, he said, is that “big companies will look to take development-stage companies out earlier in their existence. “We will probably buy earlier, at less dollars,” Cornell said, “and then do our own 510(k) and PMA trials.

So where are the opportunities? Wahr said he’s an optimist by nature, “so I think there are opportunities everywhere.” He said, for example, that he believes the interventional cardiology space is rife with opportunities. “I think interventional cardiology will be dramatically different 10 years from now than it is today.”

Cornell said, “The higher the clinical evidence that is required, the higher the barriers for companies.” As a potential acquirer, he said Medtronic is beginning to view clinical evidence as a barrier to entry by potential competitors in a space.

Noting that “we are innovating in different ways now,” he suggested that companies “may start innovating around lowering costs, rather than just to advance technology.”

Johnson is another who believes opportunity is knocking. “The opportunities definitely are there,” she said. “The challenge for investors is that they have the appropriate amount of capital for the particular investment – we need to be smart about how our capital is spent.”

### ***Regulatory path uncertainty a concern for VCs***

A standing-room-only audience heard a group of veteran venture capitalists opine on the outlook for healthcare investing in 2010 and beyond in a panel dubbed “The Crystal Ball.”

Asked by moderator Bill Harrington, a partner in **Three Arch Partners** of Portola Valley, Calif., how the FDA’s “shift to the right” affected their portfolio companies and prospective investments, the panelists were blunt in their assessments.

“The regulatory process is as uncertain as I have ever seen it,” said Peter McNerney, partner in Minneapolis-based **Thomas, McNerney & Partners**. “At both the 510(k) and PMA [premarket approval application] levels, it’s unclear as to the requirements and interpretation” by the agency.

“It causes us to rethink” investments, said Mike Carusi, general partner in **Advanced Technology Ventures** of Palo Alto, Calif. “Predictability [in the regulatory process] is the key word for investors. In theory there is a known path with PMAs, but that isn’t as predictable as in the past.”

On the subject of early-stage vs. later-stage investing, panelist John Freund, managing director of **Skyline Ventures**, also of Palo Alto, said, “A lot of VCs are looking for later-stage opportunities, but we still do early stage if it looks like a good opportunity.”

For those entrepreneurs whose companies are in the early stage, his advice is simple: “You need to find the firms that are doing early-stage deals.”

As for corporate investors in VC-backed companies, McNerney said, “Corporate investors are in a good position these days, and they know it. But for a company, it is real validation of what they’re doing when they get corporate interest.”

Harrington said his group “is seeing more strategic [corporate] investments earlier. We’re also seeing more corporate interest in ‘white space’ investment, so they can see if a particular space is something they may be interested in.”

Noting, for example, that his firm is “looking much more closely at cost effectiveness these days,” Harrington asked the panel how healthcare reform will impact their decision-making on investments.

“The dilemma is that [as a firm developing new medical products] you now need to both add value and reduce costs, and that is a higher hurdle that affects our decisions on companies to back,” McNerney said. Saying that the healthcare system – Medicare in particular – is going to be underfunded, he added that in the short term, “approved products will get more utilization” due to the addition of millions of new individuals to be covered under healthcare reform.

Carusi said, “You need to work through all the constituencies involved – how you navigate the waters [of change] is very important.”

Harrington touched on what he characterized as the “lackluster” returns experienced in recent venture investing, saying that the recent consolidation of the industry will continue.

“To limited partners, we’re just another asset,” Carusi said, “and they are questioning the risk/reward profile of healthcare and are pulling back on the amount they invest with us.

“The reality is that all funds will be smaller and maybe 50% of funds will go away, but that isn’t necessarily bad,” he added.

McNerney said, “In 2003, 2004 and 2005, a lot of money went into healthcare because maybe investors had too much in other high-tech fields, so I think that maybe we have seen that there was too much money going into healthcare and there will be a shakeout.”

In Carusi’s view, the current scarcity of dollars flowing into the life sciences “is a healthy thing. Now is a good time to be doing early-stage investing; when these things start to get robust, the dollars will come back in.”

Harrington said of healthcare investing: “The burden is on us to demonstrate superior returns.”

Freund noted that “it’s not just the venture industry that is down – it’s the entire investment industry.”

The session closed on a discussion of where the participants see healthcare venture financing positioned by the middle of next year, with at least modest upswing being the prevalent attitude.

“I think it will be pretty similar to today,” Freund said. “We’re seeing stronger corporate earnings,” which he said portends well for IPOs to make a return as an exit possibility.

Carusi said, “Well, I’m fairly buoyant now – we have moved away from survivability and now are looking at growth. We’re already seeing some financings get done, and I think that will improve over the next 12 months.”

“I’m similar,” McNerney said. “Things do look a little better now, but we need some strong exits and liquidity events. A year from now, I think we’ll be more optimistic.”

### ***Docs weigh in on innovation & medical practice***

Another conference session offered “A View From the Trenches,” with a set of physicians offering their views on where healthcare in the U.S. stands today and where it is going.

The lively discussion was directed by moderator John Deedrick, managing director of Rochester, Minn.-based **Accuitive Medical Ventures**, who asked the panelists their views on healthcare reform now that a bill has been passed and changes are eventually going to be implemented.

Eugene de Juan, MD, a noted practicing ophthalmologist and founder/vice chairman of **ForSight Labs** of Menlo Park, California, said “the game has changed” for new technology. “It’s not just a matter of solving a medical problem, but solving it in an economical way.” He said the innovations generated by physicians from this point forward “are going to have to be more simple, not more complex.”

“Yes, things have changed,” said Robert Ganz, MD, of **Minnesota Gastroenterology**, based in Plymouth, Minn. “Insurers are going to hold the line on new technology – they aren’t going to pay for it without top clinical results and the backing of the professional societies.”

Noting that clinical studies likely will all need to be randomized, controlled, multicenter trials, he added: “It is going to be a lot more expensive to get new technology out there, and it is going to take longer.”

“We all realize that reform is here,” said David Schultz, MD, founder and medical director of **MAPS Medical Pain Clinics** of Minneapolis, “but there is no cost reduction built into the system.”

So, Deedrick followed up, “Should we now be thinking about innovation simply as a cost issue?”

“Cost is a huge issue,” said de Juan. “Establishing clinical parity [with existing products] at a lower cost will be the endpoint.”

Schultz said, “Cost will be the overriding concern in the U.S. over at least the next decade.”

“It’s cost,” agreed Ganz. “In insurers’ minds, new technology always increases costs.”

Citing the age-old art vs. science discussion, Schultz said that in practicing medicine in the 1980s and 1990s, “art prevailed, but going forward, cost reduction will prevail and science will be used as the weapon.”

Ganz had a succinct closing view on the discussion: “Data and politics will drive healthcare in the future.”

Deedrick asked the panelists whether their respective areas of specialization would be considered “conservative” or “aggressive.”

De Juan said, “Oh, we’re conservative.” Despite the broad popularity of LASIK surgery (at least before the economic decline hit this pay-out-of-pocket space), he characterized ophthalmology as “a very dated field – anything that you do that introduces any risk isn’t well-accepted.”

Ganz said his field is pretty basic: “Food goes in, food goes out, and if it doesn’t, you’re in trouble.”

As for new products, he said “we have a real problem in GI, getting the professional societies to support new technology.”

Schultz said pain management is “a very aggressive field.” As for “needs” he might see the space having, Schultz said, “We’d like to be able to keep people at home with epidural pain management,” as opposed to epidurals only being done in healthcare provider settings. “That would revolutionize pain management.”

Deedrick recast the “needs” question into one focused on patients, asking, “What do your patients have on their minds?”

Ganz described his area of work as “really a lifestyle field – patients don’t usually die from gastroenterology-related illnesses.” What they do find, he said, “is that they can’t eat the way they want, can’t sleep the way they want, can’t go to the bathroom the way they want.”

Schultz said his patients “know what they want,” which historically has been narcotics-type drugs for pain relief. “But we have an interventional focus, so we want to try and avoid such drugs” in favor of such solutions as neurostimulation devices, for example.

De Juan said, “Most of the people I see are afraid they’re going blind, so we kind of refer to what we do as ‘ophthalmic psychiatry.’”

### ***Good opportunities for commercialization OUS***

A panel dubbed “So You Want to Go O-U.S.” dealt with some “What you need to know first” issues for those contemplating going to Europe or other international markets to commercialize their med-tech products.

Moderated by Doug Mowen, managing director of the Life Sciences Advisory unit of **Pricewaterhouse Coopers** in Minneapolis, the panel included Martha Goldberg Aronson, former senior VP at Medtronic; Michael Berman, who sports the catchy title of medical device venture catalyst at his Minnetonka, Minn.-based firm, **Berman Medical**; Martin Chambers, global vice president of sales for **Rox Medical**, of San Clemente, Calif.; and Andrew Weiss, president/CEO of start-up device firm **CoAxia**, located in Maple Grove, Minn.

Weiss sees opportunity knocking for both U.S. firms looking to commercialize elsewhere and for European and other international firms that might, as in the case of French firm **CoreValve**, make their technology attractive to a U.S. buyer (Medtronic in CoreValve’s case).

For Chambers, the value of going outside the U.S. with a product “is in getting proof-of-concept” accomplished. “The bottom line is creating an investment value proposition for your product. You want to prove that you can generate revenues.”

He added some thoughts about international distribution: “Everyone talks about using distributors OUS, but why would you in essence put your company in the hands of others?”

Who you work with is very important, Chambers said. “It’s important that you control the experience; the quality of the adoption of your product is important.”

Wearing her former hat as a corporate strategic investor, Aronson gave a nod to Chambers’ latter point. “Strategics are interested in the quality of the centers you’re working with, and the quality of the data produced.”

In setting a strategy for OUS commercial development, said Berman, “you have to manage your board and investor expectations – you need to do a good job of scouting the environment.”

With a nod toward Berman’s point, Weiss offered some advice on timelines. “It takes about a year to get going in Europe, so you have to set reasonable expectations.”

Berman added the caveat that “as daunting as it is to go to Europe” to commercialize a product, “it is even more daunting to go elsewhere in the world, where, for instance, they have a different word for everything.”

He said there are “opportunities outside of Europe, but it’s hard – Americans tend to be comfortable only with what they know.” Noting, for instance, that there are almost 200 million people in Brazil, he said, “There is a lot of opportunity out there, but you have to pick your spots.”

Chambers added: “You have to come back to the question of what are you trying to do? If you’re trying to get acquired, it makes no sense to spread yourself too thin [by trying to commercialize OUS]. You want to do something well.”

Aronson said “it is quite daunting to think about expanding around the globe, but if you decide to do so, remember that there is a large and growing pool of talented people all around the world.”

On the subject of assessing possible markets, Weiss said, “I look at India and China as having large opportunities to treat many, many people with low-cost treatments, but high-tech treatments mean a different level of assessment; for high-tech, you need to go after the right patient population.”

He added that intellectual property protection “is very important – you need to pursue strong patents in those countries that are crossroads of commercial activity.”

Chambers added that those seeking commercial opportunities OUS “need to be very aware of the business practices in those countries.”

He said Canada is a particularly good country to go into. “You can get approvals earlier there than in the U.S.”

Weiss also touted Canada, saying that country has “very good centers and tremendously strong research facilities – it’s a great place to do clinical trials.”

Berman said that, as in the U.S., “it’s harder and harder to get approvals OUS as well, but the FDA continues to get worse [to deal with than Europe].” That being the case, he predicted that U.S. companies both large and small “will be seeking OUS commercialization soon>”

### ***In challenging environment, the top-quality deals get done***

Given the virtual absence of initial public offerings over the past couple of years, corporate buyers have held the keys to the exit for venture-backed companies.

The general dismal state of the economy has impacted that sector as well, with merger-and-acquisition activities slowed considerably from the free-spending days prior to the global financial downturn – a period one panelist referred to as a “buying frenzy.”

But, as corporate buyers and investment bankers pointed out during a panel discussion at the conference, the financial environment for mergers and acquisitions, while still challenging, is looking up.

The panelists also made clear that it most definitely is a buyers’ market, and they are drawn to “cream of the crop” deals while less-dazzling deals are going undone.

Jeff Hoffman, managing director and head of West Coast healthcare investment banking for **JP Morgan Securities** in San Francisco, exclaimed, “What a difference a year makes!” He said improvement in the business climate means that “all the capital markets are operating, so the big guys are out there looking at things.”

Fellow panelist Kevin Davies, managing director and head of healthcare investment banking for New York-based **RBC Capital Markets**, was less buoyant, saying, “It’s a challenging environment, but it is getting a little better. We are cautiously optimistic about M&A activity.”

From the corporate ranks, Shawn McCormick, senior vice president/CFO of growing device firm **ev3** of Plymouth, Minn., said, “The corporate buyer is getting much more focused compared to the buying frenzy of a few years ago. Buyers now are focused on finding the highest-quality assets, and they are willing to pay more for more certainty” with the technology being acquired.

“I don’t believe the fundamentals have changed as to what drives value,” McCormick said. For an acquisition target, he said, the key questions are: “Do you have revenues? Do you have good clinical data? Where do you stand on reimbursement?”

As a potential acquirer, he said, “companies with just a ‘me too’ product don’t add value to our shareholders.”

Noting the “volatility” that has roiled his company’s business in the past couple of years, Isaac Zacharias, director of business development for **Boston Scientific** in Maple Grove, Minn., said the company has become “much more disciplined in what we’re looking at” in the way of potential deals. “Our CEO and CFO have to see that a company has the answers to the things we worry about.”

Hoffman cited big players **Covidien**, of Mansfield, Mass., and **C.R. Bard**, of Murray Hill, NJ, as being active acquirers, and noted that **Abbott**, of Abbott Park, Ill., which has built up its cardiovascular franchise in recent years, has more recently become a new entrant in the ophthalmology space with its February 2009 acquisition of Santa Ana, Calif.-based **Advanced Medical Optics**.

He said that because mid-cap companies are getting more access to capital in an improving economy, “so it’s a more vibrant market now. It’s a good market, but it’s driven by the buyers.”

Davies hewed to the “quality deals” theme, saying that changing regulatory requirements bring with them “a lot of risk regarding clinical trials and their costs.” That means “there are not going to be buyers for many venture-backed companies.”

He said clinical data is a key element in determining the value of an acquisition target. “The price may depend very much on the quality of your clinical data.”

To a conference attendee who asked if a large company has any advantage in getting product applications through the FDA, McCormick said he thought that historically they had a disadvantage, but his view is that “I don’t think anyone has an advantage today.”

If you’re going to attract a corporate buyer, he said, “You have to have your data and processes wrapped up.”

As for factors that can trip up a potential deal, Hoffman said, “It’s a lot harder now. Acquirers look at things like sales practices and off-label usage, which is a huge deal right now, physician relationships, clinical trial design.”

“Marketing practices is a huge deal right now, and so is off-label usage,” Zacharias said. And “unwinding” international distributor agreements “is time-consuming and costly for us.”

McCormick added: “At one point in time, it was all about the revenues, but that has changed.” Noting that inappropriate practices can derail a potential deal, he said, “Even if you’re not generating revenue, you need to be sensitive to what revenue-generating companies are sensitive to.”

On the question of whether a company should be operated on the expectation that it is going to be acquired, Hoffman said, “I think you have to assume that you’re going to be independent and run it that way.”

As for segments offering opportunity, Hoffman cited peripheral vascular, obesity/diabetes and neurovascular as good spaces for growth, while Davies said that obesity “seems like the best ‘white space’ area – we could end up with hundreds of companies being involved in that space.”

### ***Schultz discusses the process of change at FDA***

Former FDA device center director Daniel Schultz, MD, was the subject of the conference's annual "FDA Fireside Chat" segment, in which he was interviewed by Mark DuVal, president of **DuVal & Associates**, a Minneapolis-based law firm that focuses on regulatory issues.

Schultz, who resigned as director of the FDA's Center for Devices and Radiological Health in August 2009, now is senior vice president for medical devices and combination products at **Greenleaf Health**, a well-known regulatory consulting firm based in Washington.

Though it seemed clear to outsiders that Schultz had been nudged out the door by new FDA Commissioner Margaret Hamburg, his comments couldn't be characterized as "FDA bashing." He said that when he became CDRH director in 2004, his goal was "to create the most efficient regulatory system possible. We were able to put a matrix together [that featured] people working together" toward that goal.

He said all those with an interest in how the agency operates would "hope there isn't a tendency to just wipe the slate clean and start all over again with something new." Schultz said there are a number of broad-based initiatives ongoing at the agency on which the jury is still out, and expressed the hope that FDA leadership "will spend time learning about what was done in the past and how that can apply moving forward."

As for changes coming to the FDA's 510(k) program, under which so-called "me too" devices gain market clearance, historically under less-rigorous requirements for clinical data, Schultz acknowledged that there is "a sense of uncertainty, and that is a concern."

He said that for some 510(k) products, "the bar will be raised," which he said is most appropriate, citing an example of a device that when initially approved 10 years ago was "mechanical" in nature. "The device doing the same thing today is full of computer chips," Schultz said. "You can't expect the agency to just ask for old data they were asking for 10 or 20 years ago." Clearly anticipating substantial change in the 510(k) process, he said, "There are going to be changes, some in 510(k)s, some in PMAs [premarket approval applications]. He added: "The question is how these changes will be communicated and how quickly they will be made."

Noting that his view is that the FDA "is very adverse to risk," DuVal asked, "Is there an imbalance today between protecting the public health and moving innovation forward?" Schultz said, "There are times when there is a grey area – the review staff needs to know that it's okay to take some degree of risk as long as you can justify it."

On the possibility of wholesale changes stiffening up the 510(k) program to the point where there is little difference in clinical requirements between 510(k) and PMA, he said, "To me it's better to focus on areas there are real problems rather than saying that we need to revise the 510(k) program overall."

***For industry association heads, regulatory questions are key***

**AdvaMed** President/CEO Steve Ubl and Mark Leahey, who holds the same posts with the **Medical Device Manufacturers Association** (MDMA), discussed a variety of public policy issues facing their members and the industry as a whole. The discussion was led by Kevin Wasserstein, managing director of **Versant Ventures**, of Menlo Park, Calif.

Filling the final agenda spot in the late afternoon, Leahey and Ubl kept the attention of the remnants of what had been a standing-room-only crowd earlier in the day. Ubl set the tone by noting that “never has there been a time when public policy has been more important . . . we have challenges across the board.”

Leahey lamented the state of the regulatory environment: “We’re at a point with FDA that it can’t get much worse.”

Saying that “advocacy is not a spectator sport,” Ubl told company members in the audience: “It has never been more important for you to interact with your elected representatives. It’s incredibly impactful for small groups of companies to meet with members of Congress on the FDA. You need to tell them what the added costs of regulation will do to you.”

He said the new FDA leadership “has inherited some challenges,” and as a result, “we’re seeing a greater emphasis on enforcement.”

Leahey said the agency leaders “are operating in a political environment. When members of Congress say ‘the process is broken,’ they have to react in ways that are not always positive” for the med-tech industry.

Ubl noted that recommendations for changes to the 510(k) program are expected to be made public next month, with the changes themselves anticipated to be implemented beginning this fall.

Turning to healthcare reform, he said, “There are a lot of opportunities within the law, [but] while millions more will be insured, the reality is that they are not going to be heavy users of medical technology,” since they will be younger and generally more healthy. “That’s the issue we have with the device tax,” which Ubl said “directly hits us in an already difficult fiscal environment.”

Leahey said the device tax “is a whack on the top line” for device companies.” In a perfect world, he said, “that tax will be repealed before it takes effect in 2013.” At the very least, he said, “having some sort of relief for small companies is important, and we’ll be working hard on that.”

Ubl said he is “not optimistic about repeal of the tax in the short term, but we [AdvaMed and MDMA] are working closely together to get relief for small companies.”

Leahey hailed the big-company members of Ubl’s organization for helping push the concept of relief for smaller firms. “Their large companies have stepped up to recognize that there is benefit in getting relief from the tax for smaller companies,” he said.

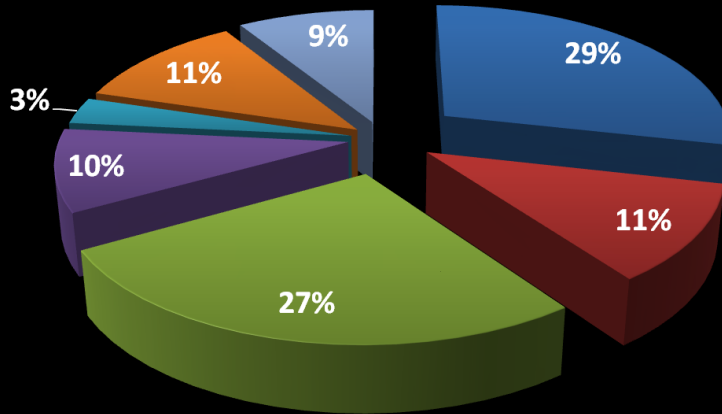
“There are warning signs out there on the decline of innovation in the U.S. and companies choosing to do business elsewhere,” Ubl said. “As a matter of industrial policy, what are all these new regulations and policies doing to innovation in the U.S.?”

Leahey said, “The message is that the quality of care is being compromised because of this environment.”

# 2010 AUDIENCE DEMOGRAPHICS

**350 Delegates from 28 US States and 4 Countries**

- Investment Professionals
- Corporate Business Development Executives
- C-Level Executives from Medical Device Start-ups
- Academia, Industry & Government Representatives
- Clinicians/Physicians
- Service Providers
- Manufacturers and R & D Executives



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