Is the Surgeon Champion’s Influence Waning?

◆ With hospitals taking more control over medical device purchase decisions and a perfect storm of changing market forces, healthcare reform and a tougher regulatory environment brewing is the influence of the Surgeon Champion waning? What's it mean for device makers?

The Bone Squad to the Rescue ◆ Dr. Dan Ivanovitch and his “Bone Squad” team are going where many orthopedic surgeons do not dare venture: the world of Medicaid patients and the underinsured. And the bone squad loves every minute of it!

Getting Real About Surgeon Disclosures ◆ A new study about surgeon disclosures hits both orthopedic journals and surgeons hard. We dissect the new study and its impact. We think the authors are naive. They probably think we’re biased. Read on and let us know what you think.

Spotting the Beautiful Evidence in Today’s Literature ◆ With the cacophony of orthopedic resources now available, how does one sort through it all? What results in bias? How do you evaluate the structure of a study? Our experts opine on this and more.

Dr. William Mallon ◆ A former PGA player, Dr. William Mallon is a sought-after shoulder specialist and Editor-In-Chief of the Journal of Shoulder and Elbow Surgery. His intense focus and positive attitude have made all the difference in his career.

Court Trims Synthes’ Medtronic Award .................................................................................................................................

New Direction for HydroCision ..............................................................................................................................................

Applied Spine Assets for Sale ....................................................................................................................................................

RTI Biologics and Athersys to Collaborate ...............................................................................................................................

Another Investor for TiGenix’s Acarios ...........................................................................................................................................

Biomedical Structures Expands Engineering .............................................................................................................................

K2M’s Chesapeake Cleared ............................................................................................................................................................

For all news that is Ortho, read on.
Orthopedic Power Rankings
Robin Young’s Entirely Subjective Ordering of Public Orthopedic Companies

This Week: A continued high unemployment rate, cost containment at the hospital level and a change, as we write about this week, in the power of the surgeon champion have all combined to create the largest wall of worry in years, maybe decades. Naturally, valuations a ridiculously low. The only buyers that seem to be emerging are corporate buyers.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Last Week</th>
<th>Company</th>
<th>TTM Op Margin</th>
<th>30-Day Price Change</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>Kensey Nash</td>
<td>38.72%</td>
<td>27.30%</td>
<td>Up 27% in the last month. The combination of 39% operating margins and cash levels that rival annual sales is irresistible.</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>Integra LifeSciences</td>
<td>15.37</td>
<td>5.92</td>
<td>Fifth least expensive stock in the orthopedics universe and consistently one of the top performers.</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>Orthofix</td>
<td>13.51</td>
<td>(8.92)</td>
<td>The market is just not paying attention. Every financial report is better than the last one.</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>Johnson &amp; Johnson</td>
<td>27.1</td>
<td>4.94</td>
<td>Diversification plus a 3.70% dividend yield. In this market that sounds like a haven in the storm.</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>Alphatec</td>
<td>1.59</td>
<td>(10.27)</td>
<td>Spinal implant companies get no respect these days. Alphatec is cheap, for sure. Investors are looking for a catalyst.</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>Stryker</td>
<td>24.71</td>
<td>2.87</td>
<td>Here also, diversification at SYK is serving it well. Up slightly in a very negative market.</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>CONMED</td>
<td>8.76</td>
<td>4.37</td>
<td>CNMD dramatically beat estimates last quarter. Will they repeat for the September quarter?</td>
</tr>
<tr>
<td>8</td>
<td>NR</td>
<td>Exactech</td>
<td>11.81</td>
<td>9.8</td>
<td>Back on the Power Rankings after beefing up its spine offerings with the purchase from VertiFlex, Inc..</td>
</tr>
<tr>
<td>9</td>
<td>8</td>
<td>Smith &amp; Nephew</td>
<td>22.83</td>
<td>(2.89)</td>
<td>Investors paying 15x future earnings for SNN yet management beat consensus EPS estimates by 23% last quarter. Something doesn’t add up.</td>
</tr>
<tr>
<td>10</td>
<td>9</td>
<td>Zimmer</td>
<td>27.69</td>
<td>(1.03)</td>
<td>Signs up interesting anti-microbial technology. More value for the $$? Perhaps.</td>
</tr>
</tbody>
</table>
## Robin Young’s Orthopedic Universe

### Top Performers Last 30 Days

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>30-Day Chg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Kensey Nash</td>
<td>KNSY</td>
<td>$29.05</td>
<td>$274</td>
<td>27.3%</td>
</tr>
<tr>
<td>2 Exactech</td>
<td>EXAC</td>
<td>$16.14</td>
<td>$208</td>
<td>9.8%</td>
</tr>
<tr>
<td>3 CryoLife</td>
<td>CRY</td>
<td>$6.02</td>
<td>$170</td>
<td>8.1%</td>
</tr>
<tr>
<td>4 RTI Biologics Inc</td>
<td>RTIX</td>
<td>$2.61</td>
<td>$143</td>
<td>7.4%</td>
</tr>
<tr>
<td>5 Integra LifeSciences</td>
<td>IART</td>
<td>$38.81</td>
<td>$1,130</td>
<td>5.9%</td>
</tr>
<tr>
<td>6 Johnson &amp; Johnson</td>
<td>JNJ</td>
<td>$61.57</td>
<td>169,590</td>
<td>4.9%</td>
</tr>
<tr>
<td>7 CONMED</td>
<td>CNMD</td>
<td>$20.32</td>
<td>$585</td>
<td>4.4%</td>
</tr>
<tr>
<td>8 Stryker</td>
<td>SYK</td>
<td>$48.03</td>
<td>$19,070</td>
<td>2.9%</td>
</tr>
<tr>
<td>9 Average</td>
<td></td>
<td>$10,980</td>
<td>$12,290</td>
<td>2.2%</td>
</tr>
<tr>
<td>10 Orthovita</td>
<td>VITA</td>
<td>$1.85</td>
<td>$142</td>
<td>1.6%</td>
</tr>
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</table>

### Worst Performers Last 30 Days

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>30-Day Chg</th>
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<tbody>
<tr>
<td>1 TiGenix</td>
<td>TIG.BR</td>
<td>$2.05</td>
<td>$63</td>
<td>-20.0%</td>
</tr>
<tr>
<td>2 Alphatec Holdings</td>
<td>ATEC</td>
<td>$2.01</td>
<td>$175</td>
<td>-10.3%</td>
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<tr>
<td>3 Orthofix</td>
<td>OFIX</td>
<td>$28.79</td>
<td>$508</td>
<td>-8.9%</td>
</tr>
<tr>
<td>4 ArthoCare</td>
<td>ARTC</td>
<td>$25.81</td>
<td>$697</td>
<td>-7.1%</td>
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<tr>
<td>5 Medtronic</td>
<td>MDT</td>
<td>$33.30</td>
<td>$35,960</td>
<td>-7.1%</td>
</tr>
<tr>
<td>6 Trans1</td>
<td>TSON</td>
<td>$2.34</td>
<td>$48</td>
<td>-6.0%</td>
</tr>
<tr>
<td>7 Smith &amp; Nephew</td>
<td>SNN</td>
<td>$43.72</td>
<td>$7,770</td>
<td>-2.9%</td>
</tr>
<tr>
<td>8 Wright Medical</td>
<td>WMGI</td>
<td>$14.48</td>
<td>$568</td>
<td>-1.4%</td>
</tr>
<tr>
<td>9 Capstone Therapeutics</td>
<td>CAPS</td>
<td>$50.90</td>
<td>$37</td>
<td>-1.1%</td>
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<td>ZMH</td>
<td>$50.68</td>
<td>$10,180</td>
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### Lowest Price / Earnings Ratio (TTM)

<table>
<thead>
<tr>
<th>Company</th>
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<th>Price</th>
<th>Mkt Cap</th>
<th>P/E</th>
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<tr>
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<td>$33.30</td>
<td>$35,960</td>
<td>9.94</td>
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<td>$14.48</td>
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<td>4 Average</td>
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<td>$10,980</td>
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<td>12.92</td>
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<td>SYST.VX</td>
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<td>33.23</td>
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<td>4 NuVasive</td>
<td>NUVA</td>
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<td>5 Symmetry Medical</td>
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### Lowest P/E to Growth Ratio (Earnings Estimates)

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<thead>
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<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>PEG</th>
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<td>$28.79</td>
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<td>0.61</td>
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<tr>
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<td>0.70</td>
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<tr>
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<td>ATEC</td>
<td>$2.01</td>
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<td>1.73</td>
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<tr>
<td>4 Average</td>
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<td>$10,760</td>
<td>$17,700</td>
<td>1.70</td>
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<tr>
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### Lowest Price to Sales Ratio (TTM)

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>PSR</th>
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<tbody>
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<td>$20.32</td>
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<tr>
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<td>EXAC</td>
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<td>1.09</td>
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### Highest Price to Sales Ratio (TTM)

<table>
<thead>
<tr>
<th>Company</th>
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<th>Price</th>
<th>Mkt Cap</th>
<th>PSR</th>
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<td>225.98</td>
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<td>$1,270</td>
<td>2.96</td>
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</table>
Are we experiencing the waning of the “Surgeon Champion” era?

Are market forces, healthcare reform and tougher regulatory environment around the globe making commodities out of products staying too long in the marketplace and driving down prices?

Will these forces continue to push down prices and shift decision making over device purchases into the hands of the hospital’s technology committees and business office?

If Bill Hawkins, the Chairman and CEO of Medtronic, and Ed Dougherty, Senior Vice President of B&D Consulting, are right, the answer to both of these questions is an unequivocal, “Yes!”

Hawkins and Dougherty spoke separately with investors at the beginning of September and outlined their views of structural changes that may alter the way device companies develop, market and sell their products to a changing customer base.

The Rise of the Hospital

Hawkins said during a Morgan Stanley conference on September 13, that while the device companies still market to surgeons, hospitals are increasingly becoming the main focus of sales efforts.

More hospitals are acquiring physician practices, have more physicians on staff and are responding to reimbursement pressures associated with healthcare reform legislation. Hawkins said hospital technology committees are starting to work with their physicians to cut costs and at the same time, hold those physicians more accountable for total costs.

He predicted the device sector on average would see product prices decline 2% to 3% in the near term as the weak economy stalls demand and health reform sharpens the focus on cost savings.

Demand for many medical procedures, once thought to be relatively insulated from economic forces, has slowed...
as patients react to higher insurance deductibles by postponing or going without treatment.

The end of COBRA (Consolidated Omnibus Budget Reconciliation Act) health insurance subsidies to help the newly unemployed pay for coverage further weakened demand, Hawkins said.

Hawkins said Medtronic still expects to offset price pressures to some extent through new product introductions.

With certain surgeries such as spinal procedures, Hawkins said, a surgeon might opt to take a less aggressive approach initially and wait to see if a follow-up procedure is necessary.

While device selection is still primarily in the hands of surgeons, Hawkins said power is shifting to the “economic” buyer within the hospital.

Increasing Product Shelf Life

Device makers according to Hawkins have historically passed on price increases by introducing new and improved products that could command a higher price tag. He noted that a tougher regulatory environment around the globe has slowed the introduction of such new versions.

The result is that companies are keeping products in the marketplace longer than in the past. As they remain in the marketplace they begin to become commodities, allowing buyers to make decisions based on price instead of features.

Broader Decision Issues

Dougherty, whose B&D Consulting is a division of the Baker & Daniels law firm, delivered a similar message about the changing “customer” base during a Wells Fargo conference call on September 11. He told listeners that decision makers are changing. The surgeon’s influence is waning and hospital technology committees are taking a more objective look at the total cost of full care for a patient.

Dougherty told OTW that the process for evaluating medical devices for purchase and use in the hospital inpatient setting has evolved beyond the traditional manufacturer-surgeon champion relationship.

“While the surgeon’s input is likely to continue to carry weight, broader issues are increasingly being considered,” said Dougherty.

Dougherty noted:

- Hospitals are forming technology assessment committees, similar to drug formulary (pharmacy and therapeutics) committees charged with reviewing the published, peer-reviewed evidence, economic impact and likely impact on their specific patient demographics
- Purchasing decisions are also being made in terms of broader “episodes of care”—how will a specific device/specific intervention improve clinical outcomes, enhance productivity and improve quality (OR throughput, etc.)
- Acquisition cost will always be an important factor for medical devices, but manufacturers are increasingly being called on to provide broader clinical and economic data—and hospitals and payers are increasingly able to evaluate and use this data.

Dougherty told us that he and his colleagues have heard a number of their clients comment that they are not confident that they understand the key interests or priorities of these “new customers and decision makers.”
Purchasing and Evaluation Committees

“They have noted that they understand how to engage surgeons on the clinical value and patient-specific impact, but have not understood how to engage with the purchasing and evaluation committees within the hospitals. This will be an important area for companies to focus on,” added Dougherty.

Wells Fargo analyst Mike Matson summarized Dougherty’s comments this way:

“Device manufacturers need to adapt to a new environment. Device manufacturers with a broader range of products and services may be better positioned to respond to the shift in payers’ and providers’ focus on cost for the entire continuum of care vs. per service or device.

“However, gaining access will come at the cost of some price concessions. Manufacturers also need to focus on devices that can improve productivity and overall quality of care without increasing cost. Device suppliers also need to provide compelling evidence to decision makers in terms of clinical and economic data, as well as work with professional societies to align products with treatment guidelines.”

Bigger is Better

Hawkins told his Morgan Stanley audience the same thing in responding to a question about the risks of the healthcare reform legislation.

“Big is better,” said Hawkins.

He said healthcare reform was full of insurance reform. “We sell through hospitals.” If the payer mix is unfavorable to hospitals it puts more pressure on hospitals that will be more aggressive with their physicians to try to get them to lower cost. According to Hawkins, larger companies can reduce a hospital’s transaction costs by having one big supplier versus many little ones.

In fact, Hawkins believes this environment will be a benefit to companies that have a broad product offering. Such companies, he said can work with the economics by offering modest price discounts over many products.

Validating Effectiveness

Another risk cited by Hawkins is the move toward comparative effectiveness.

“We’re well positioned in validating the effectiveness of our products with strong clinical evidence.”

Hawkins said Medtronic was spending an increasing percentage of the company’s research and development dollars on clinical studies and evidence-based medicine instead on institutional investments. Such investments in evidence will give Medtronic an advantage with payers and fuel innovation. Such investments will allow Medtronic to “protect and grow” their business.

Dougherty’s Predictions

Dougherty sees the elimination of fee-for-service as payers move toward a single payment to cover devices and all service providers per episode of care. This will likely drive increased scrutiny of providers’ coding and billing and reduced payment for unspecified services or treatment outside of professional society guidelines.

Hospital consolidation of private physician groups is also aimed at reducing procedure and device volumes, and shifting to economy of services-based pay and incentives. Moving certain procedures from inpatient to outpatient settings can also reduce costs to providers without cutting reimbursements for providers.

While the reimbursement gap between private and public payers may narrow a bit, private payers are still expected to reimburse above Medicare fee level in order to attract/retain customers (i.e., employers) in a competitive environment.

Dougherty believes there will be more transparency in pricing as hospitals share pricing information with their physicians.
Trends Here to Stay

Neither Hawkins nor Dougherty ever used the term “Obamacare” once during their presentations. Both men noted that these shifting structural movements have been in place for a long time and transcend whoever sits in the White House. Neither sees these forces changing much even if healthcare reform is repealed.

There is some bitter irony here. We are just emerging from an era where surgeons had been the focus of prosecutors and regulators for their, sometimes, alleged questionable financial relationships with device manufacturers. Surgeons were accused of putting their pocketbook interests ahead of those of their patients.

If it’s true that power is shifting to hospital economists, whose best interest will they serve and who will watch the counters?◆
The Bone Squad to the Rescue
By Jacqueline Rupp

Cue bluesy background saxophone. Fade in image of Chicago’s rough and tumble streets: cars rolling by, steam spewing from manhole covers and rundown storefronts littering the landscape. Toss in some medical jargon and you’ve got yourself the makings for a primetime network drama.

Except this scene isn’t a Hollywood set and the characters are real people with real orthopedic problems. And that’s where this drama really begins.

Welcome to Dr. Daniel Ivankovich’s world. The orthopedic surgeon and team leader of “The Bone Squad” and founder of the Chicago Musculoskeletal Initiatives has made a career treating the uninsured of the Windy City. 

Windy City Orthopedic Blues

Chicago’s health care problems are like those of many other U.S. cities. But the need for care extends beyond the stereotype most have of the uninsured. Middle class and working class people comprise a big chunk of Chicago’s growing Medicaid population. Orthopedic-related problems are a major reason this population seeks care. “Back pain, obesity-related knee osteoarthritis in women, and alcohol and sickle-cell related hip osteonecrosis is quite common,” explains Ivankovich. “Pediatric and adult fractures are seen in the clinics and ERs on a daily basis. Hip fractures are quite an epidemic in this community as well….And there are more gunshot-related injuries than I’d like to acknowledge. It’s very sad.”

But Ivankovich says it also puts orthopedics front and center in the delivery of comprehensive musculoskeletal medicine, especially if you take into account diabetes and vascular-related wound issues and limb compromise. “Orthopedic issues are responsible for 20-45% of what many primary care providers are seeing in these communities.” Ivankovich adds that the biggest obstacles to orthopedic in his opinion are:

- Access to care
- Transportation to care
- Education about care and preventative medicine

Failure to treat orthopedic problems early can have a snowball effect which not only hurts the patient but can have even larger consequences in the community. For example, when an arthritic and painful knee deteriorates and prevents the patient from working their standard of living deteriorates. Among the Medicaid population, lack of care, poor diet and exercise increases the risk of a disability and ultimately becoming fully dependent on government for

“ We wanted to be like a modern day Mod-Squad for musculoskeletal medicine. ”

Bone Squad Logo and Downtown Chicago/Steven Wallace/RYY Publications
**ACTIFUSE Indications**

ACTIFUSE is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. ACTIFUSE is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e. extremities, pelvis and spine including use in posterolateral spinal fusion procedures with appropriate stabilizing hardware. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

**Important Risk Information for ACTIFUSE**

ACTIFUSE is contraindicated where the device is intended as structural/load-bearing support in the skeletal system. ACTIFUSE has not been cleared for use in vertebroplasty. Other conditions representing contraindications include: severe vascular or neurological disease; uncontrolled diabetes; severe degenerative disease; uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol; hypercalcemia, abnormal calcium metabolism; existing acute or chronic infections, especially at the site of the operation; inflammatory bone diseases such as osteomyelitis; malignant tumors; severely impaired renal function. Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. Do not overtighten or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage the surrounding tissues, or may lead to fat embolization or embolization of the device into the bloodstream. The effect of mixing ACTIFUSE with substances other than sterile saline/water, autologous blood, or bone marrow aspirates is unknown.

References:

**Control Freak**

With the ACTIFUSE® MIS System, his desired outcome is well in hand.

- Extended-reach applicator helps ensure precise placement and controlled delivery of ACTIFUSE ABX bone graft substitute
- Patented silicate substitution process and optimal physiochemistry for accelerated bone formation
- Ready for use without mixing or thawing
- Easily viewed on X-ray

For more information about ACTIFUSE, visit www.apatech.com

**For more information about ACTIFUSE, visit www.apatech.com**
support. “When you’re handicapped and can’t walk, it’s very hard to live in an impoverished area. You get victimized in a multitude of ways.” In Dr. Ivankovich’s world, orthopedic care is much more than a life style decision but rather a key part of the economic and life saving fabric of his community.

The Mark of Medicaid

Could conditions improve for the uninsured when Health Care Reform is ushered in? It’s not that simple according to Ivankovich. “Health care reform won’t make much difference at all. Reform will cover uninsured patients via Medicaid. We’re pretty much the only clinicians accepting Medicaid. Until there’s a vehicle to make care more inclusive, the status quo will remain.”

Covering the uninsured through Medicaid won’t make specialists see them. Although he specializes in spine and large joint care, there are few orthopedic surgeries that Ivankovich turns down, from amputations to arm and hip issues. His pay for working with this particular population is, he estimates several hundred thousand dollars less than his colleagues at the larger hospitals or private clinics.

But Ivankovich is quick to point out that you can reap special rewards from this kind of practice. Results are more dramatic for the patients he treats. They aren’t just looking to get back to better golfing, they are leaving a wheelchair to walk again.

But the issues of the inner-city are complex and other problems contribute to the challenge of working with the Medicaid population:

- Poor compliance with medication instructions, either because of finances or home situation
- Low rates of compliance with post-operative follow-up treatments or physical therapy
- Poor living conditions, including homelessness, physical or other abuse, drug use and obesity all can contribute to poorer overall outcomes and subsequent health problems.

To counter these issues, Ivankovich works with hospital social workers and rehab therapists who are, like him, working with the Medicaid population. A silver lining for surgeons is that there is plenty of real medicine to do and the competition is low. In terms of market opportunity, the Medicaid field is wide open for the right surgeon.

And the Bone Squad Is Born

“Dr. Vietta Johnson and I worked together for the Cook County Bureau of Health at Provident Hospital. It’s always been a multi-cultural group of health care providers: African-American, Caucasian, Hispanic, Indian, Slavic, etc. We wanted to be perceived as cool and contemporary doing positive things.

“We wanted to be like a modern day Mod-Squad for musculoskeletal medicine.”
With two-year-long waiting lists for back, knee and hip pain and an average of a five-year wait for a joint replacement, Ivankovich and his colleagues realized this was unacceptable and began to recruit other surgeons to join their pain-busting team. Today the roster, aside from Ivankovich and Johnson includes five other core members: Randon Johnson M.D., Mark Sokolowski M.D., Samuel Cordova, P.A., Thomas Rosen P.A., and Kathy Gillin, RTRM. But there is also a rotating list of string players as well.

“He’s the Really Tall Dude that Plays the Guitar”

That’s how many of Ivankovich’s patients know him, his name might be tough to pronounce for them, but his image is perhaps unforgettable. At six feet, ten inches tall, dressed in motorcycle leather and a cowboy hat, Ivankovich doesn’t look like your run of the mill surgeon. And his schedule isn’t standard by any means either.

Performing around 800 surgeries a year (which is double the rate of most surgeons according to Bone Squad stats) Ivankovich bounces between a dozen hospitals in the Chicago area, with around a third of the cases being uninsured patients. That ratio amounts to Ivankovich working twice as hard for around half the pay that most orthopedic surgeons would be netting. “Charity and regular practice is seamless for me I have no idea which patient has or doesn’t have insurance.”

But it appears Ivankovich wouldn’t have it any other way. Rolling between hospitals, through the Chicago inner-city in his supped up black Dodge Magnum (with its custom seating, oh and undercar lighting) known as the Bone Mobile, the doctor says it’s easy to overlook the population he serves, of “gangbangers, frail old ladies and people who do dangerous work. Healthcare is all about freedom. But how do you just walk and keep going when you see a need?”

It’s on these same streets that Ivankovich’s music can be heard. The Northwestern-trained surgeon who completed his residency at Rush University and is fellowship-trained in Adult Joint Reconstruction, Reconstructive Spine and Traumatology is also a blues guitarist and vocalist whose shared the stage.
with Bo Diddley and Eddie Taylor. But even his musical career is intertwined with his passion for altruistic orthopedics. His band mates in the Chicago Blues All-Stars were not immune, with Ivankovich operating on the lead singer and giving the uninsured drummer a hip replacement.

The One Patient Philosophy

Ivankovich isn’t trying to change the system, just each patient one at a time.

One of Ivankovich’s patients, Felicia Thomas, is a good example. The Harvey, Illinois 53 year old suffered a hyperextended knee while gardening. Lack of proper care led to a progressive degenerative change in her knee to the point where she was unable to walk without a walker and had to hop around in what she described as excruciating pain. She couldn’t work or stand for more than a half hour at a time. Ivankovich diagnosed arthritis. “Nobody wanted to do what was necessary,” he says, “and that was a total knee replacement.” After the surgery and several months of physical therapy Thomas reports that she’s gotten her “Mobility, freedom and life back.”

The Bone Squad went beyond the Chicago city limits to give Reading, Pennsylvania resident Jeffrey Jackson a hip replacement. After paying insurance premiums for two decades the senior couldn’t afford the $1,600 a month and was left waiting for Medicare to set in, until doctors told him that his hip replacement was needed before then. All it took was an email from Jackson’s daughter to the team to set the surgery into motion.

Beyond Chi-town

But Reading is nothing compared to the other spots the team has ventured. “I’ve been referred to land-mine victims from the former Yugoslavia (my country of birth) and we remain quite connected with the work we did in Haiti after the earthquake,” says Ivankovich.

Future plans for the team include developing into a full-scale 501(c)(3) not-for-profit to encourage donations and spreading the word to the next generation of surgeons.

“We have a great opportunity to take this work to new graduates and show them how they can profoundly impact people’s lives by bringing quality orthopedic care into the mix. I’d like to get to the point where every safety-net hospitals could have orthopedic surgeons based there.” 

◆
Getting Real About Surgeon Disclosures  
By Robin Young

Last week Columbia University Professor and consultant to the North American Spine Society (NASS) Dr. David J. Rothman released a study that tracked researcher financial disclosures in The Journal of Bone and Joint Surgery (JBJS) and 25 other orthopedic peer review journals. The study reported that the journals and authors usually (55% of the time) failed to fully disclose payments made by manufacturers. It also reported that, of the major orthopedic manufacturers provided royalty or consulting payments, Biomet or Stryker’s recipients were most likely to disclose (71% and 75%, respectively) while researchers who’d received payments from Zimmer were least likely (26%).

Rothman’s conclusions:

1. There is a “massive, dramatic system failure” in the reporting system at major orthopedic journals

2. There is an urgent need for stricter orthopedic scientific journal disclosure policies, including precise amounts of consulting payments to authors

3. Journal readers need complete financial information to consider the potential for bias in the article

The study, “From Disclosure to Transparency” by Susan Chimonas, Ph.D., Zachary Frosch, BA and David J. Rothman, Ph.D. was published online September 13, 2010, and is available from the Archives of Internal Medicine website at http://archinte.ama-assn.org.

Rothman’s study was not, however, without its own missing pieces. The study’s authors did not check to see if the articles in question actually addressed products from the companies providing payments. So, for example, an author receiving royalty payments for a hip or knee invention from Zimmer may have written about a product from DePuy. Additionally, the study’s authors did not measure whether the content of the article was favorable or unfavorable to products from the paying company or whether the articles were Level 1, 2 or 3 studies or case reports or literature reviews or what. Finally, the authors did not explore the peer review mechanism to see if it was in place and whether each author’s work had been subjected to a blinded review.

In short, the authors found what appears to be a priori (independent of experience) evidence of bias but not, as some observers are claiming a posteriori (after experience or empirical knowledge) evidence of bias.

From Disclosure to Transparency

In the study, Rothman and his colleagues compared payment disclosures from the web sites of Biomet, DePuy, Smith & Nephew, Stryker, and Zimmer to disclosures in the acknowledgments.
section, conflict of interest statements, and financial disclosures of recipients’ articles published in JBJS and 25 other orthopedic journals. The researchers specifically chose to examine “consultant” payments in 2007. “Consultants” included individuals, as well as hospitals, academic medical centers, professional medical associations, foundations, and corporations who received payments for “services relating to hip and knee reconstruction and replacement.”

Then, to narrow the focus further, the study’s researchers selected recipients who’d received $1 million or more in direct payments from a single manufacturer. Finally, the researchers looked at articles from January 1, 2008 to January 15, 2009, to ensure that the authors had received the 2007 payment of $1 million or more by the time the article appeared in print.

The Results

Overall, less than half (45%) of the articles disclosed the name of the company providing payments. Only 8% of the articles stated that the payments “Exceeds $10,000.”

Background

Professor David J. Rothman, who is a non-compensated advisor to NASS, has been studying and writing about medical ethics for more than a quarter century. In 1983, he formally started to examine and understand the unique ethical and moral problems that occur in medicine.

In 1991, Dr. Rothman put much of what he’d learned into an historical perspective in “Strangers at the Bedside, a History of How Law and Bioethics Transformed Medicine”.

When he started looking into medical ethics, he found himself in a most unfamiliar world. As he spent time with physicians, he said that he felt a bit like an anthropologist exploring a new tribe. “I was a throwback to the anthropologists of the 1920s, an explorer of foreign parts, as though 168th Street in northern Manhattan was at one with the South Seas.”

But over time, he formed some opinions about physicians and their approach to patient ethics. Rather than, as he was accustomed, to taking general principles and applying them to the patient or situation, physicians, Dr. Rothman learned, were more apt to adopt what he referred to as “bedside ethics.”

“Physicians, as I have learned, frequently bring a case-by-case approach into the consideration of social and ethical issues. Offer a principle to consider (for example, that patients have the right to know their diagnosis), and they will often come up with a case (from their own experience) that they believe undercuts...”

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### Number of Publications and Disclosures of Payment of $1 Million or More per Company

<table>
<thead>
<tr>
<th>Company</th>
<th>Number of Articles in Sample Written by Payment Recipients</th>
<th>Number (%) of Articles in Sample Identifying Company Name</th>
<th>Number (%) of Articles in Sample Disclosing Payment “Exceeds $10,000”</th>
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<tr>
<td>Biomet</td>
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<tr>
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<td>4 (21%)</td>
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<tr>
<td>Smith &amp; Nephew</td>
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<td>Stryker</td>
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<td>2 (5%)</td>
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<td>Total</td>
<td>91</td>
<td>41 (45%)</td>
<td>7 (8%)</td>
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Source: “From Disclosure to Transparency” by Susan Chimonas, Ph.D., Zachary Frosch, BA and David J. Rothman, Ph.D. published online September 13, 2010, in the Archives of Internal Medicine
or thereby negates the principle (for instance, the seeming inappropriateness of informing a seventy-five-year-old woman about to go off to her grandchild’s wedding that she has an inoperable and slow-growing brain tumor.” This suggests “how alien rules are to medical decision making and how dogged and persistent an effort to alter this orientation would have to be.”

Transparency for Its Own Sake?

“What we were interested in was disclosure practices, not evidence of bias. Our goal in doing this study was to follow the money.” Said Dr. Rothman to OTW. And why is that important? “There is a significant amount of study in the literature which shows that gifts invoke reciprocity. I think that the potential for bias in cases like this is self evident.”

Going alphabetically, the first million dollar recipient we found was Dr. Peter Bonutti. He received $2.5 million in 2010 in the form of royalty income from inventions and intellectual property. Stryker was good enough to list his patents—it is a long list. We continued searching and spent about 30 minutes looking at approximately a dozen other surgeon consultants on the Stryker site and they received between $25,000 and $150,000 for out of practice consulting with $25,000 being by far the most frequent amount paid.

The only million dollar payment to a surgeon we found from our short search was for royalty income for inventions. Dr. Rothman and his colleagues also searched and they found 41 members of the million dollar club. The millionaire we found earned his royalties fair and square. It was not a gift, in other words.

We did not find million dollar payments to surgeons for either using Stryker’s products or teaching other surgeons to use Stryker products or giving talks about Stryker products or writing peer-reviewed articles about Stryker products.

So, if, as Dr. Rothman mentioned, that gifts invoke reciprocity what do royalty payments invoke? We suspect it is like any other business relationship—a fair price for a valued product or service. Can Dr. Bonutti write objectively about his own products? Who knows—but that is why the blinded peer review process is in place at JBJS and other journals. Can Dr. Bonutti write objectively about hip and knee surgery and treatment? I’ll bet he can and absolutely does.

Without searching for actual evidence of bias—like a statistical tendency to reach favorable conclusions regarding the products of the company providing payments—this study appears to be implying that transparency is valuable simply for its own sake. We don’t think it is. Transparency, in our view, must serve some greater good—otherwise it can become intrusive and oppressive.
Bias, whether explicit or implicit, is always an issue in scientific studies. This has been known and fought over since the beginning of the scientific method. Strict disclosures, a blinded peer review process, categorization of studies into Level 1 or 2 or 3 or case reports, etc. are critical tools to ensure that bias is reduced, potentially eliminated.

Because Rothman and his research colleagues decided to look only at authors who’d received $1 million or more they sent a clear message that money matters. One person who heard the message was Dr. Marcia Angell, a former editor of The New England Journal of Medicine. This is her quote from The New York Times article about Rothman’s study “It is one more indication of the widespread corruption of the medical profession by industry money.”

In fact, Rothman’s study offered no evidence of corruption.

What do surgeons want from scientific papers in medical journals? Clinically relevant and robust studies that are strong enough for practices to lean on, we think. Did Rothman’s study further that cause? If it prompts journals to provide fuller disclosure, then ‘yes’. If, as is happening, the focus on million dollar payments (which we suspect are all royalty payments) fuels charges of surgeon corruption and bias then, we think, it sets the cause of better studies back. Our conclusion, the editors should have sent Rothman’s study back for more work.

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Finding the beautiful evidence in orthopedic literature today is sort of like standing on a corner in midtown Manhattan and trying to hear the flapping of butterfly wings. It requires training and an exceptional attention to detail. When is even a randomized controlled trial not good enough? How can a failure to understand statistics impact your practice? When should you question a surgical procedure shown on YouTube?

Dr. Edward Akelman, Chairman of the AAOS (American Academy of Orthopaedic Surgeons) Council on Education, has a view from the top that emanates from his work “on the ground.” As Director of the Warren Alpert Medical School of Brown University Hand Surgery Fellowship, he interacts daily with young surgeons who are struggling to make their way through the cacophony of materials available coming at them from all directions. He says, “This is the YouTube generation. So many papers are available online, in addition to videos that demonstrate how procedures are done. The most challenging thing is to ensure that young surgeons understand that everything out there is not peer reviewed or evidence based.”

The overarching goal, says Dr. Akelman, is that when young surgeons read an article that they see the process behind the words...that they understand what steps the researcher went through to arrive at his or her conclusions. “Journal clubs remain an appropriate venue for teaching these skills because they invite a back and forth discussion. One usually begins by asking, ‘What is the hypothesis of the article?’ Then you examine the methodology section to determine if the study was set up appropriately such that it will answer the hypothesis/study question. Let’s say a study’s goal is to determine the outcomes of the surgical treatment of distal radius fractures. If you read the methodology section and see that there were 60 patients in the study, but that some had elbow, as opposed to distal radius fractures, then you know that the exclusion criteria were not appropriate. This is a huge red flag as it results in bias. If the two groups are not equivalent in terms of how the study was set up then the conclusions you draw may be off the mark.”

Dr. Akelman, who says that many of the best literature mentors are those who have served on editorial boards, adds, “You also want to see that the discussion includes sufficient referencing of...”
previous work in the same area so that younger surgeons have some perspective on what was done in the past and how effective it was. Fundamentally, much of this evaluation process is the same as it was 30 years ago. The difference today is with regard to online texts and video. Even though a technique is on YouTube that is not some automatic stamp of approval; you must verify that there is peer reviewed literature to support it.

Just as one should never make grand assumptions in the research arena, one should not jump to conclusions about people. In his role with AAOS, Dr. Akelman tries to put the brakes on some runaway assumptions about the younger generation of orthopedists. “I often encounter people who think that the new generation of orthopedists are just hurriedly perusing the literature and not thinking through whether the technique or technology involved actually works. I think these younger surgeons are more sophisticated than that, however, and it is only the way they approach things that differs. They are increasingly pressed for time, and have more and more to learn…all the more reason to not waste time with literature that leads them down the wrong path.”

Dr. Michael Schafer, Chairman and Professor of the department of orthopedic surgery at the Northwestern University Feinberg School of Medicine, has trained nearly 300 individuals in the art of reading the literature. He states, “My primary method of teaching this skill to residents is via our journal club. The purpose is not to have residents memorize the article, but to have them critically evaluate the methodology and discussion sections. The goal is that someone will be able to read an article, analyze it, and make the right decision as far as whether to incorporate the contents of the piece into their practice.”

Putting a magnifying glass to his process, Dr. Schafer explains, “First, I ask the residents or fellows to describe the article and select the most relevant points. I have seen that some people—in an effort to save time—are tempted to jump to the discussion section without looking at the methodology. After I slow them down, I ask them to discuss whether it is a randomized controlled study (RCT), if it is blinded, if it is retrospective, etc. I then go over the importance of levels of evidence.”

Aside from relying on respected publications and authors, Dr. Schafer recommends that readers have a strong understanding of the methodology sec-
When training people on the literature I strongly emphasize the difference between results that are statistically significant and those that are clinically important.

He continues, “After they look at the methodology section I have the students review the discussion section and see what has been presented in the past on this topic. Is it new and relevant? Does it expand on prior work or just validate what was already in existence? Finally, will the study result in a clinically relevant change in the way they approach patients? Questions are the fundamental tools of the researcher—as well as the reviewer.”

As the Associate Editor of the Journal of Bone and Joint Surgery (JBJS), Dr. Robert Bucholz, has the inside track on what constitutes stellar literature. Dr. Bucholz, also a former President of AAOS, states, “Peer reviewed literature is the central feature of continuing education, hence surgeons must know how to read it critically. Such literature has changed dramatically in the last 20 years. Whereas the mainstay used to be retrospective or case series, we see few of those now. Currently, there are three types of peer-reviewed studies that are widely used. The first is the RCT; the authors of these studies tend to follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines that outline acceptable ways to design and conduct the trials. Then there are systematic reviews, which attempt to synthesize the data from several high level studies. Finally, there are epidemiological studies based on databases that arise from sources such as Medicare, hospitals, etc. Even though the studies are often flawed because they don’t contain all of the information you want, the sheer numbers give these studies a lot of weight.”

The RCT, given a lot of credence in the world of research, must be explored with care. Dr. Bucholz: “Those reading a RCT must understand all of the potential biases, such as attrition and selection bias. For example, with regard to the latter, you can end up selecting patients that aren’t representative of the entire population, meaning that your conclusions cannot be generalized.”

“Systematic reviews, which can include retrospective case studies, can be helpful if they are well structured and unbiased. The problem with them, however, is that at the end of the day you may not learn anything new. Let’s say you have...”
Dr. Bucholz, Chair of the University of Texas Southwestern Medical School, sheds light on his own approach to teaching the literature. “We begin by having the junior residents review the manuscript at hand, giving their opinions on the strengths and weaknesses. Then the senior residents come forward with an historical perspective and discuss how this specific study fits into the overall literature. The most difficult thing to teach is the statistics. Generally speaking, orthopedists aren’t well trained in statistics…and the statistics involved in peer reviewed literature are complex. JBJS has actually hired three deputy editors for statistics and methodology to serve as screeners. The most talented and prolific authors are those who have degrees in epidemiology, have taken specific courses, or have studied under people who are extremely good in methodology. Unfortunately, most residents and fellows aren’t learning statistics in a formalized way.”

At the end of the day, if a research question isn’t helping patients live healthier lives, then it is best left in the mind of the researcher. Dr. Bucholz states, “When training people on the literature I strongly emphasize the difference between results that are statistically significant and those that are clinically important. Let’s say you are reviewing a study on minimally invasive (MI) total hip surgery. The results of the gait analysis show that while at three months there is no difference between a conventional and a minimally invasive approach to the hip, at six weeks there was a statistically significant difference in hip flexion contracture in the MI group. Those inexperienced in the literature realm would say, ‘Oh, the p-value is less than .05 so that means they are more likely to have a faster rehabilitation.’ The fact, however, is that this statistical difference may be of no clinical significance in terms of their ability to go about their daily lives.”

Fortunately, when it comes to spotting the beautiful evidence, the butterfly, amidst today’s crowded stream of orthopedic resources, the best technique is one used by orthopedic surgeons every day…a methodical approach.◆
New Direction for HydroCision

Donnelly referred to a “new strategic direction” for the company and plans to invest in U.S.-based research projects to further validate the clinical and economic value of HydroCision products.

“We believe a stronger medico-economic justification for the use of our products will afford us the platform we need to scale adoption in the U.S. and OUS markets,” added Donnelly.

Paul Kowalski, the company’s VP for Sales and Marketing, added some detail in comments to OTW, including:

• Sales force expansion in the U.S. using independent reps that meet the company’s target profile; selective continued OUS expansion in China, Middle East, Brazil, and Europe
• Clinical research guided by a reimbursement consultant recently hired by the company
• Comparative effectiveness research of the company’s discectomy technology used in outpatient settings vs. inpatient and resulting clinical and economic advantages for patients and payers
• Comparative effectiveness of manual instrumentation for interbody fusion with endpoints (demonstrating) time savings and resulting OR efficiencies, disc prep effectiveness and resulting fusion success rates.

In a question about the departure of the previous CEO, Kowalski told us the new investors decided to bring in new leadership.

Since its introduction in 2005, the SpineJet system has been used in more than 45,000 spinal, arthroscopic and wound debridement procedures.

—WE (September 17, 2010)

Another Investor for TiGenix’s Acarios

EUR 4.1…now that a lot of seeds. TiGenix is on the move. Along with the recent announcement about the first closing of a seed-financing round for Acarios, a spinout established jointly with Netherlands-based Therosteon, they are now announcing that LRM has joined the original group of investors to bring the total funds raised to EUR 4.1 million. The seed financing round was led by BioGeneration Ventures. Other investors include Erasmus MC Biomedical Fund, Gemma Frisius Fund, CD3, Baekeland Fund II, Credit Agricole and VINNOF.

TiGenix has a significant equity stake in Arcarios (below the consolidation threshold) and is the largest shareholder of the company. TiGenix also retains certain rights to drug candidates developed by Arcarios for ex vivo applications and the local treatment of arthritic diseases. Based in the Netherlands and Belgium, Arcarios is a drug development company dedicated to the discovery and development of innovative products that

HydroCision Inc., developer of the SpineJet system has new venture capital owners, a new leader and is moving in a new direction.

The company announced on September 15 that Howard Donnelly has replaced Doug Daniels as President and CEO. The company also announced that new investors including Volcano Capital, Bioventures and Omega Funds have acquired the majority of the company. No purchase price was noted.

New CEO: Howard Donnelly

According to the company announcement, Donnelly has more than 20 years of senior-level experience in the medical device industry. He previously served as president of Level 1, a medical device subsidiary of Smiths Group.

HydroCision has been challenged with reimbursement issues and providers have needed additional proof of the cost effectiveness of the company’s Fluidjet surgical technology which is used in discectomy and interbody fusion procedures.
target bone and joint diseases, indications of unmet medical need and significant commercial potential.

TiGenix CEO Gil Beyen told OTW, “I’m pleased with the strong scientific and investor syndicate that has been formed to support Arcarios. It’s the ideal consortium to support this truly innovative and powerful new drug development company. The EUR 4.1 million committed in this seed financing round should allow the company to bring its lead programs to a proof-of-concept stage in man. For TiGenix, the creation of this new venture provides an excellent opportunity to maximize the value of our assets and expertise outside our core competence without deviating any resources from our cell therapy activities.”

He also commented to OTW, “TiGenix is pursuing a number of options to enforce its financial position. Our primary focus is on 1) increasing our capital base through a private placement; 2) partnering with ChondroCelect outside Europe (U.S., Asia and Middle East); 3) leveraging our commercial infrastructure by adding additional products to our product pipeline. The funds will be used to support the commercialization of our lead products and for the development of new products based on our (stem) cell- and biomaterials platforms.”

—EH (September 17, 2010) ◆

Company Assets

Here, in part, are some assets the company believes are valuable to a buyer:

- The Stabilimax System, upon successful completion of a clinical trial and FDA approval, will compete in a $250 million U.S. market. The current inventory of implants, pedicle screws, implant components and instruments is valued at approximately $2.7 million.

- The Stabilimax design, with its proprietary combination of springs and articulating junctures, utilizes pedicle screws and a posterior surgical approach, which appeals to surgeons due to a low (or no) learning curve.

- Class I data that validates the design rationale and offers proof of near normal kinematic motion.

- Eight issued U.S. patents including method patents of use of a dual spring dynamic stabilization device as well as apparatus patents covering the dual spring, specific travel and stiffness ranges for the dual spring, and the articulating spheres connection to the pedicle screw that enable intraoperative assembly.

- The company says it has become the “last man standing,” and claims the only true PMA/IDE (Premarket Application/Investigational Device Exemption) product in the market after Zimmer’s Dynesys was denied a PMA recommendation by the FDA’s Orthopedic Panel. All other devices such as N-Hance (Synthes), and Transition (Globus) are caught under the FDA’s 522 order and are exposed to labeling issues.

Applied Spine Assets for Sale

Applied Spine Technologies, Inc.’s (AST) assets are for sale. Has FDA uncertainty claimed the scalp of another spine device company to go along with Disc Dynamics?

The news of the sale came on September 13 with the announcement that the company has retained a broker to “solicit interest” for the acquisition of the company’s assets.

Applied Spine commercialized the Stabilimax System; a pedicle screw based dynamic stabilization system. The company’s intellectual property was developed from over 30 years of research conducted famed spine scientist, Dr. Manohar Panjabi of Yale University.

FDA Uncertainty

An FDA 522 Order in the last year required the company, and all other companies with dynamic screw systems on the market, to conduct post-market studies. The company was unable to see eye-to-eye with the FDA and the uncertainty of the regulatory environment contributed to the company’s board of directors’ decision to take the company’s remaining cash off the table and sell the assets.

Founded in 2004, the company has been financed with $47 million over three venture rounds. Investors include: Oxford Bioscience Partners, BioVentures Investors, Interwest Partners, DeNovo Ventures, Investor Growth Capital and MB Venture Partners.

Company Assets

Here, in part, are some assets the company believes are valuable to a buyer:

- The Stabilimax System, upon successful completion of a clinical trial and FDA approval, will compete in a $250 million U.S. market. The current inventory of implants, pedicle screws, implant components and instruments is valued at approximately $2.7 million.

- The Stabilimax design, with its proprietary combination of springs and articulating junctures, utilizes pedicle screws and a posterior surgical approach, which appeals to surgeons due to a low (or no) learning curve.

- Class I data that validates the design rationale and offers proof of near normal kinematic motion.

- Eight issued U.S. patents including method patents of use of a dual spring dynamic stabilization device as well as apparatus patents covering the dual spring, specific travel and stiffness ranges for the dual spring, and the articulating spheres connection to the pedicle screw that enable intraoperative assembly.

- The company says it has become the “last man standing,” and claims the only true PMA/IDE (Premarket Application/Investigational Device Exemption) product in the market after Zimmer’s Dynesys was denied a PMA recommendation by the FDA’s Orthopedic Panel. All other devices such as N-Hance (Synthes), and Transition (Globus) are caught under the FDA’s 522 order and are exposed to labeling issues.
Bidding Information

Interested parties will be invited to participate with a sealed bid. Bids must be received by Gerbsman Partners no later than Friday, October 15, 2010, at 3:00 p.m. CST at Applied Spine Technologies’ office, located at 30 Cold Spring Rd, Rocky Hill, CT 06067. Interested parties are asked to email steve@gerbsmanpartners.com with any bid and will be required to close within seven days.

—WE (September 17, 2010)

K2M’s Chesapeake Cleared

K2M has received 501(k) clearance from the FDA to market the company’s Chesapeake Anterior-Lumbar Stabilization System.

The company announced on September 7, that the product is a “unique interbody device designed for stabilization of the spine through an anterior approach.” The system provides screw fixation through the company’s tifix locking technology, whereby each screw head forms an autogenic lock to the implant upon insertion.

The Chesapeake is manufactured from biocompatible PEEK polymer and allows for anterior stabilization and fixation with a zero-profile design.

Amiel Bether, M.D., Division Head, Department of Surgery at Greater Baltimore Medical Center, said the device “is the perfect offering for low-profile interbody instrumentation and, in my opinion, is the future of vertebral arthrodesis.”

John I. Williams, M.D., an orthopedic surgeon at Ortho Northeast, said the system, “gives an element of variability in terms of screw angulation into the vertebral body.

A company spokesperson told OTW the product is currently in alpha evaluation and will be one of the featured products at the company’s NASS booth.

K2M’s Chief Medical Officer, Chairman and co-founder, John Kostuik, M.D., is the former Chief of Spine Surgery at The Johns Hopkins University School of Medicine. The company was acquired by Welsh Carson in August.

—WE (September 14, 2010)

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Court Trims Synthes’ Medtronic Award

Synthes sued Medtronic in 2007, claiming that Medtronic’s Maverick, A-Maverick and O-Maverick spinal implants infringed on Synthes’ 2005 U.S. Patent No. 6,936,071. The patent related to an implant used to replace degenerative or diseased spinal discs.


On September 9, the U.S. Court of Appeals for the Federal Circuit in Washington upheld findings that two Medtronic spinal implants infringed Synthes’ patent. The court ruled that a third device did not infringe.

The 2008 jury award included $5.7 million in 2008 for lost profits. The jury also awarded Synthes an 18% royalty on $9.1 million in sales of the three implants.

No O-Maverick Infringement

According to Bloomberg News, the Court of Appeals said Synthes wasn’t entitled to lost profits because the unit that makes a product that competes directly with Maverick discs wasn’t a party to the case. The appeals court also said O-Maverick doesn’t infringe the patent.

In addition, the court upheld the validity of the patent and said an order Synthes had won to ban sales of products that infringe the patent can’t be applied to overseas sales.

Neither Synthes nor Medtronic spokespeople commented in the Bloomberg story.

Synthes acquired Spine Solutions in 2003 from the Viscogliosi Brothers for $350 million.

—WE (September 15, 2010)

RTI Biologics and Athersys to Collaborate

RTI has licensed Athersys’ technology to isolate and preserve cells from organ and tissue donors, thus enabling RTI to develop and commercialize MAPC technology-based biologic implants exclusively for certain orthopedic applications. This agreement expands RTI’s capabilities for accessing the fastest growing segment of the bone graft substitutes market, while Athersys extends the application of its robust stem cell technology platform to an important segment of the orthopedic market.

“We are very excited about our collaboration with Athersys and the potential to apply its MAPC and related technologies in the orthobiologics market,” said Brian K. Hutchison, RTI’s Chairman and CEO, in the news release. “After significant research into stem cells and the evaluation of multiple technologies, we have determined that the MAPC technology offers the greatest potential to create high quality, innovative implants for our surgeons and their patients. Licensing this technology is an important step in enhancing and further differentiating RTI’s orthobiologics offering, an area of strategic focus for the company.”

“We are enthusiastic about our relationship with RTI and this application of our proprietary stem cell technologies to the orthopedic market,” added William Lehmann, Jr., President and COO of Athersys. “Our primary focus is the development and commercialization of expanded, ‘off-the-shelf’ cell products, such as MultiStem, for the treatment of certain cardiovascular, central nervous system-related, inflammatory and immune system disorders, diseases and conditions. This collaboration allows for the utilization of our already developed stem cell technologies in an additional area. Further, it provides potential near-term revenues from the orthopedic market.”

Hutchison told OTW, “This technology isolates and preserves cells from tissue we are currently recovering, leveraging our strong relationships in the organ and tissue donation community. The new MAPC technology-based implants will strengthen our portfolio, enabling us to provide a broader offering of high quality biologic implants to the orthopedic community. We plan to make MAPC technology-based biologic implants available in the first half of 2012, and will communicate milestones as we go through the development process.”

—EH (September 13, 2010)
large joints

Biomedical Structures Expands Engineering

There are no looms or coffee klatches involved in these weaving activities—just high-end medical equipment. Biomedical Structures LLC (BMS) has announced that it has expanded its textile engineering capabilities with a new purpose-built clean room for high-density weaving and advanced braiding infrastructure for polymer and wire materials. The company is also bringing on board new personnel with talent in the engineering realm.

BMS' newest clean room supports high-density weaving and knitting for biomedical textile production, and houses state-of-the-art warping and twisting equipment for an increased range of very fine and precise solutions for orthopedic, cardiovascular, and general surgery device applications. The facility addition is purpose-built for handling finer PET fibers, DSM Dyneema Purity, and other mono- and multifilament fibers, especially those of lower denier. BMS recently teamed up with fiber manufacturer DSM Dyneema as a proven specialist in processing Dyneema Purity and Dyneema Purity BLUE, the first ever 100% colored implantable grade Ultra High Molecular Weight Polyethylene (UHMWPE) fiber.

Additionally, BMS has expanded its braiding capabilities with multiple new 16-carrier braiding machines, as well as a best-in-class 48-carrier machine for improved production capacity of polymer and wire braiding. In support of this expansion, the company has increased its manufacturing workforce with additional textile technicians, and plans to supplement current employee growth with more sales engineering and project management expertise in the near future.

“BMS has consistently worked to remain at the cutting edge of medical device product development,” said BMS President John Gray in the news release. “Our textile solutions are helping orthopedic and cardiovascular device manufacturers bring the next generation of more lifelike, high performance implantables and instruments to market. These expanded capabilities for more advanced engineering and production of our biomaterials will allow us to further innovate and deliver at the level our customers have come to expect.”

BMS offers expertise in knitting, braiding, weaving, nonwovens, and composites, and utilizes implantable-grade absorbable and permanent fibers in orthopedic, general surgery, tissue engineering, cardiovascular, bariatric, cosmetic surgery, and veterinary applications, including implantable devices, drug delivery technologies, and surgical instrumentation.

John Gray told OTW, “State of-the-art warping and twisting equipment allows for advanced fiber preparation processes that aid in the manufacturing of balanced, consistent fabrics that offer precise apertures and uniform strength for orthopedic reinforcement and replacement applications. Because fabric integrity and consistency are so important to performance, these new capabilities will help orthopedic OEMs more specifically engineer orthopedic devices with highly specialized characteristics for particular applications. Good examples of these biomedical textile applications include ligament and tendon replacements and reinforcement.”

—EH (September 16, 2010)

AAOS CEO to Chair ASAE

Karen L. Hackett, AAOS CEO

An executives’ executive…The American Academy of Orthopaedic Surgeons’ (AAOS) Chief Executive Officer, Karen L. Hackett, CAE, has assumed the role of Chairman of the American Society for Association Executives (ASAE). Hackett is board certified in healthcare management and a Fellow of ACHE, as well as being a Certified Association Executive (CAE). She holds an MBA from Lewis University and a degree from the University of Central Florida.
Concerning how this new position will intersect with the orthopedic world, Hackett told OTW, “My new role as Chair of ASAE will bring me many opportunities to take some of the exceptional expertise of ASAE and bring new ideas and innovation to the AAOS. ASAE has a highly successful annual meeting with motivating opening ceremonies, interesting educational sessions, and new ideas in creating a paperless meeting and using social media techniques to promote the meeting. I am gaining many new ideas that I hope to bring to the Academy, although dancing out onto the stage when I am introduced may not be one of them.”

She continued, “Every association has issues dealing with member communications, finance, demonstrating value, working with volunteers, education, evaluation of success, and staff training and team building. As I bring my expertise and leadership skills to ASAE, I plan to learn from every other association and bring new ideas and innovation back to our Academy. For me, that is what leadership is all about—mutual respect, continuous learning, and being open to new ideas.”

Regarding what her time at the helm of AAOS has taught her, Hackett told OTW, “I take great pride in what our Academy has and continues to achieve in all of our educational endeavors. I have also gained a tremendous appreciation for the very important role of volunteers, whether someone serves on a board of directors, a committee, or helps as a media spokesperson, volunteers are what keep our Academy vital and relevant. I have also had extensive leadership experience in dealing with strategic communications issues, with crisis communications, with association image issues, with media relations, social media, public service campaigns, and with celebrating milestones like our Academy’s 75th Anniversary.”

She added, “One of my most important roles at AAOS is being the leader of a staff over 250 people. The role brings me great pride as I watch my staff succeed, innovate, and demonstrate value to orthopaedic surgeons. I am extremely proud of the staff I have built and I intend to help every association CEO learn the importance of team building and staff/volunteer relationships and mutual respect.”

—EH (September 15, 2010)  

Shedding Light on Those in Need

Orthopedic humanitarian efforts aren’t just about dramatic surgeries. As the F1 HID Portable Surgical Headlight System proves, details matter too.

Egypt: land of the great pyramids and sweeping desert vistas. Here a humanitarian effort recently unfolded that sheds serious light on the need for ancillary medical tool innovation in crisis situations.
Small details like having good lighting can often mean the difference between a successful and failed surgery. So the question then arises: What ancillary equipment is most needed for extreme situations and locations that lack a high-tech medical infrastructure.

Lighting is one piece of the puzzle. That’s where the Xenon arcing bulb-based F1 HID Portable Surgical Headlight Systems from HHW Technologies recently came into play in Egypt. Dr. Ronald Wisneski, Associate Professor and Chief, Division of Spine Surgery at Ohio State University Medical Center, brought the device along on a humanitarian trip to Ismailia Medical Center, where he described it as “invaluable,” noting the comfort and performance in the challenging surgical environment.

Challenging to say the least! According to James Horvath, CEO and Founder of HHW Technologies, “The surgeons had to in a way operate like it was in war conditions. There was a window open because the air conditioning had failed and a cat even strolled through the operating room at one point.” Horvath says that with a failing power supply the cordless feature of the HHW Technologies portable headlight system proved a critical component. “The surgeons had strung LED lights from the ceiling and ended up using the F1 HID Headlamp as their primary lighting.”

These benefits could also translate of course to remote locations. “With a four and a half hour charge, the light can go into locations where the power infrastructure is unreliable and since it meets all the UL standards it works everywhere in the world even with a generator.

The F1 HID Portable Surgical Headlight Systems, from Redlands, California-based HHW Technologies, was introduced last year and a new version will be on display for demonstration at this year’s NASS Annual Meeting. The newest addition in 2010 for HHW is a retro fitted kit that integrates itself into surgical space suits.

Horvath says that surgeons who aren’t in remote locations can benefit from the Xenon HID’s technology. “Here you get the intense light you’d normally find in a plugged in model, but because it’s a self-contained unit, you don’t have to worry about rolling the cord, unplugging when leaving the operating room or burning yourself on the hot tip.”

And as for the light itself, Horvath describes it as “constant clarity” with a columnated beam that does not fade or fuzz, but “provides true daylight color and two to four times the brightness of any battery-powered headlamp on the market today.”

—JR (September 13, 2010)◆
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THE PICTURE OF SUCCESS

Dr. William Mallon

By Elizabeth Hofheinz, M.P.H., M.Ed

When Bill Mallon walked off the PGA Tour in 1979, it was with a heavy heart...he was indeed heading into an uncertain future. In time, he would become Dr. Mallon, a specialist in complex shoulder reconstructions and the esteemed Editor-In-Chief of the Journal of Shoulder and Elbow Surgery. Dr. Mallon, who was awarded the Olympic Order in 2001 for his service to the Olympic Games, credits his success to his intense focus and to the fact that he always finds some good in any situation or person.

Those of us raised by parents who endured the Great Depression do learn focus...and the focus is on education. Growing up in Framingham, Massachusetts, Bill Mallon would become the second person in his family to attend college. And he would do it via his first love—golf. Dr. Mallon: “I vividly remember the day that I knew my path was set. I was 14, and had just hit my 400th ball of the day when I thought, ‘This is not going to make me great. But if I do this every day I will be great.’ I ended up attending Duke University on a golf scholarship. I joined the PGA Tour in 1975 and in my five years there gained some tough life lessons.”

One of those lessons was driven home with every drive. “Focus is everything, both in golf and surgery,” says Dr. Mallon. “If you make a bogey you must forget about it in order to have a solid chance at the next hole. When you’re having a problem in surgery, you have to correct it and move on. It can be difficult to put aside your emotions, but if you don’t then it is to the patient’s detriment. Also, I always tell residents and fellows that if they are feeling rushed or worried, then there will be a natural tendency to speed up. But, I tell them, this is the time to slow down because then you are less likely to make a mistake and further complicate the situation.”

So how did someone with “zero” interest in medicine become such a sage of the orthopedic field? Dr. Mallon explains, “I injured my shoulder while playing golf in the ’70s, something that necessitated surgery. I continued on the PGA Tour, but then started to struggle...I could see that I had to find another calling. My interest in medicine was piqued by the surgeon who had treated my shoulder. It was also appealing that I could actually make a living at medicine—I had made almost nothing as a professional golfer in my last two years.”

Despite seeing a way forward, leaving behind the clubs and the Leaderboard would be anything but easy for Bill Mallon. “I had been a math and physics major, but I had to do additional coursework to get into medical school. All during this planning process my heart was churning...my childhood dream was gone. I recall sitting in a laundromat crying my eyes out because I realized that my life as a professional golfer was over. It was also surreal when a few months later someone said to me, ‘Didn’t you used to be Bill Mallon?’”

“One door closes,” Dr. Mallon is fond of saying, “and another one opens.” The doors of medical school opened easily for him. “I got into Duke University School of Medicine on my first try, probably because of my unusual story. I
Many of the surgeries I do are in the subspecialty realm; I am a final referral point in North Carolina for complex revision shoulder replacements and rotator cuff repairs. The most exciting thing is that I help make a lot of people feel better.

was concerned because I lacked a premed background; I studied so hard that my friends said, ‘Bill, you’re overdoing it.’”

As hard work usually does, however, Dr. Mallon’s dedication paid off. He would go on to become the first fellowship trained shoulder specialist in North Carolina. “I matched in ophthalmology at Michigan, but also did an orthopedics rotation and really enjoyed the tie-in with sports. Time was running out, but I went to the Chief of Orthopedics at Duke and, because someone had dropped out of the match, I was given his residency spot. I remember talking to an attending about my becoming a shoulder specialist. He said, ‘You can’t do that. There are only three or four guys in the country who do that.’”

Reflecting on what has surprised him over the years, Dr. Mallon states, “I was so naive that I thought that after graduating from medical school that I would be a full-fledged doctor. I remember telling someone, ‘Really? I’ve gotta do another five years?’ I was undeterred, however, and pressed on.”

An unqualified success, Dr. Mallon has worked at it— not only on the intellectual side of things, but on the attitudinal aspects as well. “My last two years on the PGA Tour were especially difficult. In that world your value is determined by your pecking order; if you’re not making the cut other players won’t even practice with you. I often drew up the wisdom of luminaries such as Vince Lombardi, who said, ‘...But I firmly believe that any man’s finest hour—his greatest fulfillment to all he holds dear—is that moment when he has worked his heart out in a good cause and lies exhausted on the field of battle, victorious.’”

In the hours that are his less-than-finest, Dr. Mallon can walk down the hall and look at a photo of his treasured mentor. “Bill Strausbaugh, a golf instructor, became my mentor during my PGA years. Whenever I have a bad day I remember some of the things he taught me. One of the most valuable lessons was that people do much better when you tell them what they are doing well instead of always pointing out their mistakes.”

This focus on the positive has served Dr. Mallon well in the professional realm. Now Editor-In-Chief of the Journal of Shoulder and Elbow Surgery, Dr. Mallon says, “In 2004 I was asked to become an Associate Editor. In 2007 when Dr. Bob Neviaser stepped down, I was selected to be the next Editor-in-Chief. I think that I was chosen in part because I have never been a hypercriti-
cal reviewer, and I try to find something good in nearly any manuscript.”

“Welcome aboard…now, to your first set of problems.” Dr. Mallon recalls, “One editor was angry because we rejected a paper that he had approved. Also, we had accepted an article with one of the authors saying he had no conflicts of interest, when in fact there were significant conflicts. Fortunately, I’m finding that the quality of research is improving, actually to the extent that it is increasingly difficult to reject papers.”

When not giving positive feedback to researchers, Dr. Mallon is performing surgeries that others turn away. “Many of the surgeries I do are in the subspecialty realm; I am a final referral point in North Carolina for complex revision shoulder replacements and rotator cuff repairs. The most exciting thing is that I help make a lot of people feel better.”

And just like any thoughtful physician, Dr. Mallon knows there is more to learn. “Because it is difficult to know who to operate on and when, I think I can learn more in the patient selection arena. I am better at it than in the past, but it takes years to learn, and involves much more than reading MRIs and X-rays.”

As for what ‘Shoulder and Elbow’ needs to learn, Dr. Mallon says that there are some ‘play nice in the sandbox’ issues arising. “The hand surgeons say, ‘The shoulder doesn’t do anything.’ The shoulder surgeons say, ‘If the shoulder isn’t working then the hand won’t cooperate.’ Increasingly, hand surgeons want to do elbows; also, some hand fellowships are now billing themselves as ‘hand and upper extremity.’ This means they include shoulder as well. These things will have to be sorted out as we go forward.”

In working on these and other issues in the field, perhaps Dr. Mallon can draw upon his knowledge of history. Dr. Mallon, who has written 24 books on the history of the Olympic Games, states, “I have always been fascinated and inspired by those athletes who have reached the pinnacle of athletic competition. Studying the history of the Olympics has been a hobby that has become more than that, but in some ways is my release valve, and keeps me sane.”

But even if the day brings problems that he cannot solve, Dr. Mallon can rest assured that there are those at home who accept him nonetheless. “My wife was a flight attendant and was generous enough to put me through medical school. We have five gregarious dogs who greet me at the door every day and whether or not I’ve had a good or bad day, they are always their wonderful selves.”

Dr. Bill Mallon…focused on the moment, and reaching for the best.
New Study of VCF and Mortality Rates Available

The Study: PearlDiver has just completed an extensive study of the VCF market with particular attention to patients who’ve received either vertebroplasty or Kyphoplasty treatment for vertebral compression fractures. Patients were tracked by age, gender, and select comorbidities. While the study does not attempt to correlate VCF procedures and mortality, it does track subsequent in-hospital mortality over time in these patients. Fully 41,000 VCF patients were tracked between 2006 and 2008 using the PearlDiver database of more than 1 billion patient records.

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