VOLUME 8, ISSUE 4 | JANUARY 31, 2012

Orthopedics This Week

week in review

breaking news

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Orthopedic equities have just had the best January in years. In the last 30 days, for example, TranS1 is up 63%, MAKO is up 42%, NuVasive is up 29%, Tornier is up 19% and Conmed and Orthofix are both up 15%. Clearly stock pickers were digging in the bargain bins and finding some very attractive ortho stocks.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.75%	13.81%	The analyst upgrades are piling up. Latest is Piper Jaffray. Even trading 14% higher than last month, ZMH still 2nd cheapest ortho stock.
2	3	Orthofix	14.72	15.06	Expanding biologics footprint with MTF. Earnings expectations just took another ratchet up.
3	2	Stryker	25.23	11.34	Fourth quarter earnings surged because SYK's portfolio of medurg plus ortho is a great combination.
4	5	NuVasive	7.26	29.15	Up 29% in a single month, clearly NUVA hit a long-term bottom and was way oversold a month ago.
5	10	Conmed	9.65	15.94	Analysts looking for zero sales growth in Q4, but rising margins. Deal with MTF was very creative. New growth?
6	4	Medtronic	28.63	5.60	MDT's period of decline is over in spine. We think that overall spine product revenues will be higher in 2012 than in 2011.
7	7	Symmetry	6.45	(4.84)	SMA had its moment in the sun but now returns to the bargain bin of ortho stocks.
8	8	Smith & Nephew	22.80	3.47	Analysts are pretty down on SNN. Flat to down earnings on, surprise, a 6% rise in sales. SNN is not getting respect.
9	6	Exactech	7.69	6.95	Zimmer, Stryker and Biomet all had good news to end the year. Will EXAC follow suit?
10	9	Johnson & Johnson	26.33	0.17	Demand for ortho equities coming from growth stock buyers and stock pickers. JNJ, unfortunately, doesn't fit that critieria.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	$3.05	$83	63.10%
2	MAKO Surgical	MAKO	$37.05	$1,543	42.50%
3	NuVasive	NUVA	$15.73	$664	29.15%
4	Tornier N.V.	TRNX	$20.91	$821	18.74%
5	Conmed	CNMD	$29.45	$822	15.94%
6	Orthofix	OFIX	$40.10	$738	15.06%
7	Zimmer Holdings	ZMH	$60.50	$10,840	13.81%
8	Kensey Nash	KNSY	$21.99	$190	13.04%
9	CryoLife	CRY	$5.30	$149	12.05%
10	Stryker	SYK	$54.90	$21,009	11.34%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	$4.00	$221	-11.50%
2	Integra LifeSciences	IART	$29.22	$784	-5.56%
3	Symmetry Medical	SMA	$7.66	$278	-4.84%
4	ArthroCare	ARTC	$31.06	$855	-0.45%
5	Johnson & Johnson	JNJ	$65.56	$179,034	0.17%
6	Synthes	SYST.VX	$170.67	$20,272	2.17%
7	TiGenix	TIG.BR	$0.92	$84	3.30%
8	Smith & Nephew	SNN	$48.26	$8,626	3.47%
9	Alphatec Holdings	ATEC	$1.85	$165	4.52%
10	Medtronic	MDT	$39.28	$41,454	5.60%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$39.28	$41,454	11.80
2	Integra LifeSciences	IART	$29.22	$784	12.07
3	Zimmer Holdings	ZMH	$60.50	$10,840	12.58
4	Johnson & Johnson	JNJ	$65.56	$179,034	13.11
5	Smith & Nephew	SNN	$48.26	$8,626	14.03

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$17.35	$682	36.91
2	RTI Biologics Inc	RTIX	$4.00	$221	25.00
3	NuVasive	NUVA	$15.73	$664	23.48
4	ArthroCare	ARTC	$31.06	$855	21.72
5	Synthes	SYST.VX	$170.67	$20,272	21.60

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Integra LifeSciences	IART	$29.22	$784	0.48
2	Orthofix	OFIX	$40.10	$738	0.88
3	RTI Biologics Inc	RTIX	$4.00	$221	0.88
4	Zimmer Holdings	ZMH	$60.50	$10,840	1.37
5	Stryker	SYK	$54.90	$21,009	1.39

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$17.35	$682	3.76
2	NuVasive	NUVA	$15.73	$664	3.34
3	Kensey Nash	KNSY	$21.99	$190	2.60
4	CryoLife	CRY	$5.30	$149	2.23
5	Johnson & Johnson	JNJ	$65.56	$179,034	2.12

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$7.66	$278	0.77
2	Alphatec Holdings	ATEC	$1.85	$165	0.96
3	Integra LifeSciences	IART	$29.22	$784	1.07
4	Exactech	EXAC	$16.46	$216	1.14
5	Conmed	CNMD	$29.45	$822	1.15

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.92	$84	135.32
2	MAKO Surgical	MAKO	$37.05	$1,543	34.84
3	Synthes	SYST.VX	$170.67	$20,272	5.50
4	Bacterin Intl Holdings	BONE	$2.73	$111	4.21
5	Tornier N.V.	TRNX	$20.91	$821	3.61

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Racing With the Amputee

By Biloine W. Young

Amputee Bryn Byers is ready to race; Source: Prosthetic Laboratories

Thirteen-year-old Bryn Byers was one of a group of teen-agers, including her brother and friends, who were enjoying a particularly beautiful, 60 degree Labor Day weekend in 2003. They were riding their 4-wheelers across the rolling farm land of rural Wisconsin and celebrating the last days of summer before school started.

At an unmarked country intersection the machine Bryn was on collided with another—pinning Bryn between them. She was about to join the 1.6 million people in the United States who live with the loss of a limb. That Sunday in August was the last day she would walk without a prosthesis.

At first Bryn did not seem badly hurt—there was only a small hairline fracture in her left ankle. Hospitalized at the University of Wisconsin Hospital in Madison, she developed an infection that attacked her muscles. In an attempt to control the infection, doctors transferred her by ambulance to Children's Hospital in Milwaukee and when that effort failed they amputated her left leg six inches below the knee. Bryn's was one of the more than 185,000 amputations performed that year.

Bryn's next stop was the Madison, Wisconsin, branch of Prosthetic Laboratories, an ABC (American Board for Certification in Orthotics, Prosthetics and Pedorthics) provider of prosthetics and orthotics.

Based in Rochester, Minnesota, Prosthetic Laboratories is an institution that is totally independent of other medical institutions yet works so closely with orthopedic surgeons, physical medicine/rehabilitation departments ampu-

Left to right: Korean War Veteran Norm Gerber, Iraq War Veteran BJ Ganem and Vietnam War Veteran Dave Harvey

tee clinics, that patient receive a seamless experience while being fitted for their prostheses.

Mike Gozola, one of Prosthetic Laboratories two company founders and a certified prosthetist, said that members of the staff are called to pre-amputation consultations and are sometimes even in the operating theater after the OR team closes the amputation wound. Gozola credits this unique multidisciplinary approach for the fact that their services are sought-out by patients throughout the country.

"We do what is best for the patient," he said." Do that and everything else will work out. That is what directs our existence. There are three departments but we all work together. The team is the orthopedic department, the physical medicine and rehabilitation department and our company.

"It is like a relay race," he said. "Once the patient is handed off by the orthopedic department to the physical medicine department, a whole new set of things start to happen. We are the linchpin. We are involved at each step of the treatment process. Patients see us with the doctors when they are undergoing surgery, then with the folks doing their rehabilitation. In this post-op management period we see the patient three to five times before they even hit the amputee clinic. We help give them an idea of what the care continuum is. We educate them about it from the beginning.

"I have been asked by many people, 'Aren't these patients emotionally overwhelmed and bummed out by what is happening to them?' And I reply, 'No, not in this practice because we have this multi-disciplinary approach that is so patient centered.'"

Gozola said it is important to work with "prosthetically aware" physicians. The success of a prosthesis depends in part, he says, on how prosthetically aware the surgeon is. By this he means that the manner in which the surgeon stitches the skin at the end of the residual limb affects the way the future prosthesis will function for the patient.

"How the tissues are treated, how the residual limb is fashioned by the surgeon makes a huge difference. Not just anybody can close. It is kind of like a plastic surgery," he said. Gozola hastens to add that while local staff surgeons are all prosthetically aware, he participates in the education of surgical residents to pass on the principles of the care model.

When the surgeon finishes his work and the wound is healed—after about six to eight weeks—the rehab team writes a prescription for a prosthetic device and sends the patient to Prosthetic Laboratories with an elastic bandage wrapped around the residual limb. The immediate task of the prosthetist is to remove the pressure bandage and make a cast of the limb before it swells up.

Moving quickly the prosthetist takes measurements and, using plaster of Paris, makes a cast of the residual limb. In the laboratory the cast is filled with more plaster to make an exact copy of

the patient's leg. From this is fashioned the "socket," the device that will fit over the end of the residual limb and to which will be attached the mechanics of the leg or the arm prosthesis.

It is the fitting of the socket that is the most difficult and painstaking. Steve Amundson, the other founding partner, explained, "There are two parts to it, a soft interface that goes inside and the rigid core structure. We need something solid that is going to transfer the weight between the socket and the foot. This part is made of plastic, heated and molded over the plaster model.

"The interface goes on the residual leg first, followed by one or more prosthetic socks that fill up the space created by the fact the patient's leg is shrinking in size—the body is changing and muscles are atrophying. They are not attached as they used to be."

Fitting the socket on the patient is a painstaking process. As Amundson said, "A lot depends on where they are in the rehab process, and the length of time they have been an amputee. We will make a lot of changes to the inside of the socket to make it fit. Getting the socket to fit is tremendously important. It only takes minutes, when things are not fitting properly, for the skin to become damaged and then the patient has to wait for it to heal."

Amundson assures his patients that, though it is a long process, they *will* be able to walk and chew gum at the same time. But in the meantime they have a lot to learn: balance, proper shifting of their weight, adjusting to having no sensation in their foot, controlling a prosthetic knee as they are walking. "Some adjust faster than others," says Amundson. "Balance is a key issue as is trusting the prosthesis." The average prosthesis, meaning the socket that attaches to the residual limb of the patient, lasts from three to five years.

Amundson says that they may have to change the socket on a new amputee several times during those initial three years. Though the components on the bottom of the prosthesis are still working, patients often need more motion as they become skilled using their prosthesis. "We recommend that patients use a basic foot as the first prosthesis, but after six months or a year, the patient may need more advanced components with more movement, more give. We don't want to hold patients back with the prosthesis. The first year or two are very important for the rehabilitation of the patient," he said.

According to Gozola, diabetes drives their business, afflicting over 50% of their patients. When vascular ailments

Cathy and EJ Skaiffe sustained serious injuries in a motorcycle truck collision. They have not lost their enthusiasm for cycling and frequently speak to driver's ed classes about safe driving practices."

are added in, 70% of their patients' amputations are caused by diabetes and related vascular disorders. Cancer accounts for the third highest patient count with trauma a distant fourth. Patients range in age from young children to patients in their 90's. "The key is mental capacity. If patients cannot remember the proper sequence, how the prosthesis goes on, and then it is going to be very difficult to manage," Amundson said.

Where is the science of prosthetics going? Knees can now be fitted with microprocessors that, when connected to a computer, can program the patient's walking ability. The knee becomes capable of independent thought; learning how the amputee walks, recognizing and responding immediately to changes in speed, load and terrain.

And then there is the Michelangelo Hand, a prosthetic hand with the electronic opposable thumb. Produced by Otto Bock, the hand alone sells for about $85,000. Looking to the future, researchers like Dr. Todd Kuiken, an engineer and physiatrist, are working on prosthetic arms that connect to the user's nervous system. Instead of learning how to move certain muscle groups in the upper body to control the prosthesis, the amputee thinks about moving his missing hand or elbow. Electrodes on the patient's chest sense the muscle contractions triggered by nerves and send messages to the computerized mechanical arm to execute the command.

Active in athletics before her amputation, shortly after receiving her prosthesis Bryn Byers was once again participating in her favorite competitive sports—softball, basketball, downhill skiing. Today she is a college student and, since 2003, has been a camp counselor with the Amputee Coalition of America—helping both children and adults adjust to the loss of a limb.

It has been 28 years since Mike Gozola and Steve Amundson founded Prosthetic Laboratories in one of their garages. The company now employs more than 80 people, has 13 locations in three states, and houses a spacious patient care area and a central fabrication facility in a 21,000 square foot headquarters building.

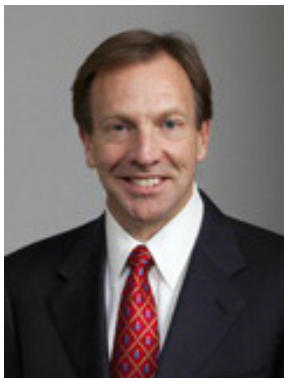
Clearly, in the race with the amputee, Gozola and Amundson have found a way to make everyone in the process a winner. For more information visit http://www.plor.net. ♦

Will Baby Boomers Pull Orthopedics Out of Recession?

By Walter Eisner

Wikimedia Commons and Mila Zinkova

We're getting close to the bottom of the orthopedic market recession and demographics are in favor of healthcare. That's what the CEO's of two of the largest companies in orthopedics say.



Stephen MacMillan/Stryker Corporation

Stephen MacMillan and Bill Weldon, the respective heads of Stryker Corporation and Johnson & Johnson, Inc. (parent of DePuy Orthopaedics, Inc.), recently spoke to analysts and investors about the state of their companies, healthcare and orthopedics in general and their companies in particular.

"Demographics Favor Healthcare"

Their messages were the same. Procedure volumes will not increase until Americans get their jobs back with insurance coverage and those with jobs decide that getting rid of the pain in their joints is more important than taking time off to recover from surgery.

MacMillan and Weldon also say that the progression of orthopedic diseases means untreated pain gets worse and patients who have been putting off the "discretionary" procedures will eventually have to come and get treatment. And then there are those pleasure seeking baby boomers who want to remain active in their old age and will serve as a huge tailwind for the orthopedic industry.

"Demographics are in favor of healthcare," Weldon told analysts during a quarterly conference call on January 24.

Slow Growth

The most recent fourth quarter results for the two companies support their point that procedure volume growth rates have declined due to the recession. Stryker's Recon business was up by only

Bill Weldon/Johnson & Johnson

1.3% and it was Stryker's fast growing Medical Surgical business that pulled overall sales up to a reported $2.2 billion, +11%. DePuy's revenue of $1.45 billion was also flat. DePuy's results also do not yet include quarterly results from Synthes. The two companies expect to complete a merger this year and make the combination the biggest orthopedic company in the world. Synthes will report fourth quarter results in February.

Keeping in step with the market's low procedure volume growth, both companies reported that hips sales increase by only 1%, while knees fell 2% for Stryker and 3% at DePuy.

But back to the big picture.

According to Weldon, there are 3 major forces that are shaping the healthcare environment:

- Macroeconomic conditions
- Government payers and regulators
- Industry trends.

Macroeconomic Conditions

Weldon said macroeconomic conditions have been incredibly challenging the last several years, but opportunities remain. "Slowing economic growth, the uncertainty in financial markets, high unemployment and pressure in healthcare costs have all contributed to constraints on healthcare spending, and the volatility of currency exchange rates continues to be an issue."

However, he said these economic dynamics are balanced by positive demographic trends creating demand. "Populations in the developed world are aging rapidly and we consume more healthcare as we grow older. In fact, those over the age of 65 consume an average of 7x more healthcare per year than those under that age."

Global expansion and growth, even at less explosive rates than a few years ago, also leads to growing demand for healthcare, especially in emerging markets where access has been its historically low. Weldon says JNJ's investments continue to be in line with these market opportunities.

Government Payers and Regulators

"Government payers are requiring more cost-effective solutions…and that impacts the pricing of healthcare products and services." He says the company recognizes these priorities and is making investments in new and productive areas such as personalized medicine and companion diagnostics.

Weldon also pointed to a regulatory environment that has become "much more intense" in its scrutiny of new products. Weldon says he supports strong regulatory environments that ensure patient safety, while also ensuring that the fast and efficient approval

of potentially life-saving medicines and treatments.

Industry Trends

Weldon said the company has always looked to complement organic development with acquisitions and collaborations that help gain new capabilities or provide access to technology, products and compounds that can accelerate products to the market. He also noted that over the past five years, the global healthcare market has had compounded annual growth of nearly 7%, and it should continue to see strong mid single-digit growth over the next five years. And growth in the emerging markets will be double-digits as those economies continue expanding."

Utilization Trends – "Getting Close to the Bottom of the Trough"

In addressing a question from analysts about utilization trends, Weldon said the big area is in elective surgery where the industry is seeing the slope of the line and the decline [of procedures] to starting to smooth out "a little bit."

"The last time I looked at [procedure volume], it was about a 0.5% drop in elective surgery. So we think we're getting close to the bottom of the trough… You can only put these procedures off for so long. And there's going to be a bolus of people that will come back in the market over time. Now I don't know if it's going to be in 2012 or 2013, but I don't think the market is going to decline as precipitously as it had previously."

Weldon added that there is a huge resource. "By that, I'm talking about resources that the government is willing to spend for patients coming into the market. So I think when you look at it, that there's an opportunity.

Stryker's Cash Machine

MacMillan said looking back on the company's 2011 financial results he was encouraged while remaining cognizant of the current economic environment.

"We completed 2011 with over $8.3 billion in sales, up 11% on a reported basis and reflecting mid-single digit organic growth, augmented by the benefit from a series of key strategic acquisitions as well as a currency tailwind."

"We head into 2012 with strong momentum, a compelling lineup of new products and a high degree of conviction regarding our ability to continue to deliver strong growth in these businesses."

Not to mention a boatload of cash. "We enter 2012 with a net cash position of over $1.6 billion, so our balance sheet remains an important competitive strength for 2012 and beyond.

Stryker 4Q11	Sales $ in million	% Change
Total Reported Sales	**$2,215**	**11.0%**
Reconstructive	$981	1.3%
Hips	$314	1.0%
Knees	$341	down 2%
Trauma/Extremities	$253.00	9.1%
Med Surg	$857	11.2%
Neurotech/Spine	$377	47.3%
Spine	$178.0	6.0%

Source: Stryker Corp.

Reconstructive Slowdown

Although Stryker's Reconstructive implant growth slowed sequentially, MacMillan said he was encouraged by the ramp up of the company's MDM large head hip offering as well as the traction that their customized cutting guides are now seeing within knees.

"While we conservatively assume no improvement in elective procedure trends in 2012, we believe that share gains in hips and knees are achievable. And if the economic environment and/or the degenerative nature of osteoarthritis results in a stronger rebounding of implant procedures, we are well positioned to capitalize on the volumes."

The company is committed to delivering organic sales growth at a minimum of 2% to 5% in 2012, which atop the contribution from acquisitions, posi-

tions the company to post a rate of constant currency revenue growth in the 3.5% to 6.5% range.

DePuy – Waiting and Recovering

The story for DePuy is all about waiting for Synthes and recovering from the ASR metal-on-metal hip recall and lawsuit settlements. The company still expects to close on the Synthes acquisition later this year and disclosed that it has set aside over $3 billion to deal with various recalls and settlements.

DePuy reported that sales grew 0.3% to $1.453 billion for the fourth quarter of 2011. Strong sales in sports medicine were partially offset by lower sales for knee and spine products. Results, according to the company, continue to be affected by low single-digit price erosion, partially offset by positive mix.

DePuy4Q11	Sales $ in million	% Change
Total Reported Sales	**1,453**	**0%**
Knees	355	down 3%
Hips	295	1%
Spine	236	down 2%
Bone Cement/Codman	249	down 1%
Sports Medicine/Mitek	167	8%
Trauma	81	5%

Source: Larry Biegelsen, Wells Fargo Securities

Reported hip sales were up 1%, driven by 3% growth outside the U.S. In the U.S., hips were essentially flat. Globally, sales of knee implants declined 3%, with U.S. shipments declining 5% due to increased competition and a softer market. Sales outside U.S. were flat.

In management's estimation, overall demand for orthopedic products declined modestly in the third quarter with U.S. showing the most decline (down 3%) and the OUS market slipping 1%. That softness continued into the fourth quarter. Spine was down 3%, with the U.S. down 7%, primarily due to continued pressure on price. Sales outside the U.S. actually rose 4%.

The Cost of Metal-on-Metal

In setting aside more cash for product liability costs primarily related to the DePuy ASR Hip recall, JNJ's executives said they have recently completed an analysis of new information, including recently updated revision rates for the recalled products, and have updated estimates with respect to potential costs associated with the recall.

JNJ's CFO Dominic Caruso told analysts that that over the past two years the company's hip recall program costs have cost about $800 million.

Medical Device and Diagnostics

Outside the U.S. sales of JNJ's MD&D products showed strong double-digit growth in 2011. Management also announced in its call with analysts that they had increased investments in emerging markets with recently opened innovation centers in India and China, while continuing to support dozens of training institutes around the world.

"With these actions and others, MD&D has been able to sustain #1 or #2 leadership positions in 80% of our key platforms, while growing or maintaining share in the majority of these markets." Weldon reported that to better serve a market that has been undergoing dramatic change, the MD&D segment began reorganizing into three more integrated and agile businesses at the end of November. The business groups consists of the Global Surgery Group, the Global Medical Solutions Group, and the Global Orthopedics Group.

Preparing for 2012

Both leaders made it clear that while top line growth is not expected to recover to pre-Great Recession levels just yet, they do see the potential for a wave of new patients who are making appointments to treat their orthopedic unmeet needs. In the meantime, both management teams are reassuring investors that pre-Great Recession earnings growth rates are still possible by throwing their substantial cash into high growth areas and continually reorganizing and improving operating efficiencies.

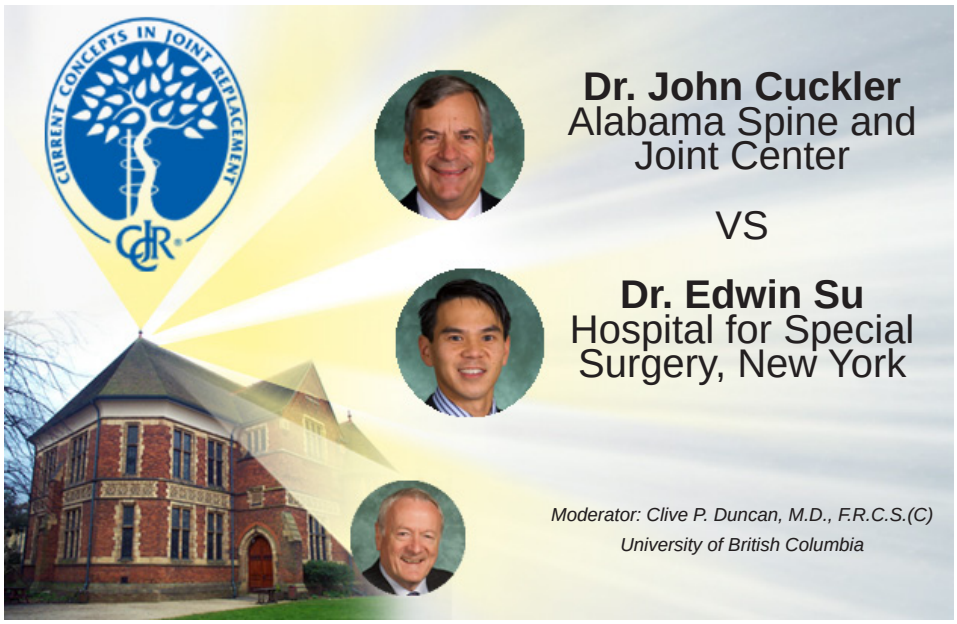
In short, they think they see a rise in unit demand and are preparing for it. ♦

Cuckler Debates Su Over Metal-Metal Resurfacing

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

Rumors about the effects of resurfacing are "a load of crap" says Dr. Edwin Su. Dr. John Cuckler disagrees and asserts that surgeons should "rethink resurfacing."

This week's Orthopaedic Crossfire® debate is titled "Metal-Metal Surface Replacement: A Triumph of Hope Over Reason." For the proposition was Dr. John Cuckler of the Alabama Spine and Joint Center. Against the proposition was Dr. Edwin Su of the Hospital for Special Surgery in New York, and moderating is Clive P. Duncan, M.D., F.R.C.S.(C) of the University of British Columbia. Let the fireworks begin.



Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Cuckler: "This should be easy. Ed, I've watched you operate and I admire your technical skill. Ten years ago I was very enthused about surface replacements. I occasionally do some for situations such as a man with extreme metaphyseal deformity. But the short and intermediate term data aren't reassuring, and for that reason I've changed my stance, and changed my mind about metal-on-metal articular couples in general. So, Ed…just push the 'easy' button for your patients…let's go to a conventional total hip and be safe and effective."

"There are some advantages—such as conservation of femoral bone stock—to the resurfacing concept. But the disadvantages far outweigh the advantages: things like the risk of femoral fracture; acetabular bone stock removal, which is greater than with conventional hip arthroplasty; significant anatomic limits, which affect the younger patients who need total hip arthroplasty, such as large cysts associated with avascular necrosis, severe head/neck deformities, small sockets…the biomechanics are somewhat constraining with regard to restoring offset and leg length."

"So, what are the short- and long-term results compared with total hip replacement with regard to pain relief, function, and patient satisfaction? The outcome of revisions is equally important…and you're all aware of the process of pseudotumors that have been reported from the Oxford Group which significantly compromise the results of revision in some cases."

"Look at the early data. You might say, 'Well, it is old and not relevant.' But consider the wide discrepancy in revision rates that occur even in the hands of extremely experienced resurfacing surgeons such as Derek McMinn. Even in experienced hands, the results of resurfacing are still not as good as conventional total hip; and there is a steep learning curve."

"Looking at the results of the Australian Joint Registry from 2010…the cumulative revision rate at nine years was around 8%, and this is almost regardless of age. It gets worse when you segregate the data according to gender and head size. Females and males with small sockets do far worse than those with more conventional anatomy. Older females do even worse, approaching a 14% failure rate at nine years. This is not acceptable, Ed."

"How do surface replacement arthroplasties compare with metal-on-metal conventional total hips? About the

same. Which tells you that there may be something that we don't yet understand about metal-on-metal articular couples. In a comparison of metal on metal versus metal/polyethylene articular couples from Australia, at eight years the failure rate is approaching 4% for metal-metal, compared with about 2% for metal/polyethylene. How can we justify that…that significant difference between these couples, given this data?"

"How do you choose a patient for surface replacement arthroplasty? Paul Beaulé, an expert in this field, developed a surface arthroplasty risk index in 2004 and it's still valid. If you add up to more than three—[wherein previous surgery=1; weight=2 if <180lbs; femoral cyst>1cm=2; activity level=1]—you have a twelve times increase in your failure rate."

"Do these conserve bone stock? No, in fact you have to ream a little more acetabular bone in order to accommodate the diameter of the femoral head. There is a higher metal ion release with any metal-metal articular couple. Pseudotumors: probably related to component malposition and high socket angles leading to advanced wear."

"So Ed, let's just push the 'Easy-THR' button…not this one: 'Bullshit-SRA"… and do the right thing for our patients."

Dr. Su: "Thank you, John, for an eloquent opening salvo. This video shows how I think this debate may go: *Dr. Su:* 'I will convince you through scientific argument that there is still a role for hip resurfacing. *Dr. Cuckler:* They say that if you have a hip resurfacing you will lose your hearing, your kidneys will fail, and your pecker will fall off. *Dr. Su:* That is a load of crap.'"

"Fact #1: Hip resurfacing preserves bone. It is indisputable that it does this on the femoral side. It is, however, a possibility that it does so at the expense of acetabular bone…we investigated this. We performed hip resurfacing and hip replacement on 10 cadaveric specimens—matched for size. In all cases the femoral bone was preserved with the hip resurfacing, and we found no difference in the amount of acetabular bone removed. Then we did a clinical prospective study, matching for native femoral hip size…and we found a greater tendency to upsize the acetabular component in a hip replacement due to the desire for a larger head size."

"Fact #2: Not all implants are created equal. We've heard a lot about the Durom and the ASR [Articular Surface Replacement], and that's because these implants had design flaws that led to problems and early failures. The Durom had problems with acetabular fixation, and the ASR had a small arc of coverage and tight clearances that have led to a high failure rate. Looking at that Australian registry…from their revision curves you can see that they were failing at higher [rates] than the other cohort of hip resurfacing implants. But my point is that these two implants are not representative of the whole class of resurfacing implants."

"Fact #3: Most problems with hip resurfacing can be avoided by good surgical technique and a good implant. We know that hard-on-hard bearings are more sensitive to malposition; a ceramic-on-ceramic bearing, that probably leads to squeaking and stripe wear. With a metal-on-metal bearing, edge loading will lead to metal ion debris and possibly metal reactivity. In a hip resurfacing socket positioning is more difficult due to the difficulty of exposure and the lack of screw fixation. This may lead one to put the cup in a position that is sub-optimal just to gain stability of

fixation. This is further compounded by the smaller arc of coverage in which there is less room for error."

"Fact #4: "Metal-on-metal resurfacing performs better in certain subgroups. The Australian registry: women are failing at about twice the rate of men. However, if we look at those men and break them down by age, we find that at seven years the revision rate is about 3.6%. With a hip replacement, men at the 7/8 year mark are failing at around the same rate, 3 to 4%; women also are failing at a higher rate with a hip replacement."

"I will use my opponent's own words to make my point: hip resurfacing, in the hands of a surgeon with sufficient experience, appears to produce results at intermediate follow-up comparable to a conventional metal-metal total hip replacement. Many of the reasons not to perform hip resurfacing are based on FEAR…fear of fracture, fear of difficulty of the technique, fear of metal reactivity and sensitivity. We should not allow fear to triumph over reason."

Moderator Duncan: "Can each speaker give us data that will convince this audience that a surface replacement will outperform a well done hip joint replacement today. Ed?"

Dr. Su: "The best study is the randomized controlled study coming from Canada. They did two sets of experiments where they compared a metal-metal total hip with smaller head size, compared to resurfacing and looking at gait studies and activity levels they found that these studies were improved with the resurfacing group at one year. When they further did a study controlling for head size there was no difference."

Moderator Duncan: "So if you have a larger head size that will equalize the results?"

Dr. Su: "Correct."

Moderator Duncan: "John? Any data that will convince us that surface replacement will outperform a total hip replacement with a larger head in conventional practice?"

Dr. Cuckler: "In one word…no. We must remember that the three of us on the podium have had the luxury of being highly specialized surgeons who do a lot of arthroplasty. Our job is to look at the performance of articular couples and implants, not for the highly specialized surgeon, but for the community surgeon who may do less than 60 or so hip arthroplasties a year. Resurfacings have had a great loss of enthusiasm in Australia over the last five years because the community is aware of the problems of this design. I'm not saying it doesn't work in Ed's hands."

Moderator Duncan: "A second question: are you convinced—each of you—that the outcome measures we use are sensitive enough to pick up the increased performance, increased satisfaction that some of the surface replacement patients claim?"

Dr. Su: "I agree that it is not sensitive enough. Most of us use the Harris Hip Score which, I think, has a ceiling effect. We're not picking up the small factors that may separate out the two."

Moderator Duncan: "Studies suggest that even though we go to great pains with patient reported outcome data, that we are still not picking up what potential advantages there may be."

Dr. Cuckler: "I agree…we can't measure these subtle differences, and the vast majority of studies on resurfacing have had huge biases of selection… selecting people who are more active to begin with, less disabled to begin with…you're comparing apples and oranges."

Moderator Duncan: "Tell us what you're doing with your patients on an annual basis when you bring them back."

Dr. Cuckler: "Patients need to be seen every two years, but more importantly you should tell the patient that if they develop new pain you need to see them. I suggest you do an ultrasound of the hip looking for abnormal fluid collection, which can be the first sign of the ALVAL [Aseptic Lymphocytic Vasculitis Associated Lesions] response, or runaway wear, which can occur with malposition…and it's the pseudotumor type reaction."

Dr. Su: "I agree that these metal-on-metal bearings need closer surveillance. I follow them every year with X-rays, clinical exam…and if they have symptoms I send metal ions."

Moderator Duncan: "As far as I'm concerned it's still unresolved how you should deal with these patients who insist on a surface replacement. Please join me in thanking our speakers." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.

On (and Off) the Record

By Elizabeth Hofheinz

Dear *OTW* Reader: "**70% of Stiff Shoulders Have Sugar Issue**" says Dr. John Kelly….**Shortage of Orthopedic Surgeons?** New studies say YES…**Are surgeons being punished for innovation –but rewarded for efficiency? … Mike Zafirovski, John Murphy Join DJO**…and more.

70% of Stiff Shoulders Have Sugar Issue Dr. John Kelly, Associate Professor of Clinical Orthopaedic Surgery at the University of Pennsylvania, has been thinking about diabetes and healing lately. He tells *OTW*, "There is an emerging link between diabetes and shoulder stiffness and diabetes and arthritis. One study showed that of all patients coming in to a clinic with a stiff shoulder, a full 70% had a sugar issue. If a diabetic has a rotator cuff tear it definitely takes longer to heal. Interestingly, recent studies have found that poorly controlled diabetics have no higher risk of infection than those with tighter control; it's almost like you must get the sugars normalized in order to see any real difference. You could call up the analogy that someone is either pregnant or not pregnant…either they have a sugar issue or they don't. We are conducting a study on the role of inflammation, and are finding that diabetics seem to have more generalized inflammation and that's why they take longer to heal. We are cutting rat rotator cuffs and then reattaching them to compare the healing response. The preliminary findings show a significant delay in healing…50-100% longer healing times in rats with diabetes."

Matthew Murphy, Ph.D. Joins SpineSmith The new Senior Scientist at SpineSmith is Matthew Murphy, Ph.D. Dr. Murphy will design and implement new strategies for the isolation and application of autologous stem cells for spine, orthopedics, and cardiovascular therapies. Formerly a senior researcher at Methodist Hospital Research Institute

in Houston, Texas, Dr. Murphy focused on the combination of adult stem cells and biomaterials for regenerative medical applications in orthopedics, spine, pancreatic, and soft tissue repair. He earned a Ph.D. in Bioengineering from Rice University and a B.S. in Chemical Engineering from The University of Texas at Austin. Dr. Murphy also lent his talents to NASA where he designed new spacesuits for travel to the moon and Mars as part of the Constellation Program. He then joined the laboratory of Dr. Paul Simmons at UT Health Science Center at Houston where he investigated adult stem cells harvested from bone marrow, cortical bone, and adipose tissues.

Not Enough Orthopedic Surgeons An orthopedic surgeon with a significant amount of administrative experience tells *OTW*, "My biggest concern these days is manpower. Studies are showing that in 25 years we will not have trained enough surgeons to care for total joints, much less everything else. But when we try to develop a plan to train more surgeons, we find that the rules involved are so strict, and that it is so expensive that we can't proceed. As usual in a democracy, it will have to be a crisis before things get addressed… All of a sudden—when it's really too late—people will panic and say, 'Oh no, we don't have enough orthopedists.' If you tell me *today* that I can train one orthopedic surgeon, it will be nine years before the first one 'pops out.' My plan would be to examine all orthopedic training programs and see which ones could add more training spots…and then *fund them*. Then, if we have enough spots based on our future needs, great. If not, we have to create new programs."

Tom Boyd Joins Vertebral Technologies Going forward, Tom Boyd will be the one ensuring that thing are running smooth in sales at Vertebral Technologies, Inc. Boyd, who has more than 25 years of experience in the medical device industry, has been hired to oversee the sales and marketing teams. He has managed and advanced sales operations for firms ranging from mid-sized medical device companies to global, multi-billion dollar corporations. And importantly, Boyd has 19 years in senior management positions in the spine market.

Reward Efficiency and Punish Innovation? A concerned spine surgeon tells *OTW*, "Those of us in spine and total joints are being punished for being innovative. We are really far along with instrumentation and approaches, and we are getting patients home quicker with a minimum of complications. *The powers that be, however, are saying, 'Listen, you're working more efficiently and so we don't need to pay you as much to do your procedures anymore.' Talk about disincentivizing people! I mean, we are never reimbursed more for good outcomes!* The result of this is that it is going to incentivize doctors to do simple procedures because they don't want to put hospitals on the hook for lower reimbursements. If a doctor can do a surgery that carries lower infection rates, then why do the big surgeries? This ultimately means that all major surgeries will be done at tertiary centers. Why should surgeons continue to do cadaver training and evolve our skills—so we can best serve our patients—if we are going to get punished for it?"

Mike Zafirovski, John Murphy Join DJO DJO Global, Inc. has elected **Mike S. Zafirovski** as a member of the DJO Global Board and as non-executive Chairman of the Board. Zafirovski is a senior advisor to The Blackstone Group and also serves on the boards of directors of the Boeing Company and Apria Healthcare Services. He was previously Director, President and CEO of Nortel Networks Corporation from November 2005 to August 2009 and held several positions, including Director, President and Chief Operating Officer of Motorola, Inc. from June 2000 to May 2005. Prior to joining Motorola, Mr. Zafirovski spent nearly 25 years with General Electric Company, where he served in management positions, including President and Chief Executive Officer of five GE businesses in the consumer, industrial, and financial services arenas. **John R. Murphy** will now serve as a director of the company and as Chairman of the DJO Global Audit Committee. Murphy currently serves on the Board of Directors, the Governance Committee and as Chairman of the Audit Committee of O'Reilly Automotive, Inc. He was Senior Vice President and Chief Financial Officer of Smurfit-Stone Container Corporation from 2009 to 2010, and prior to that he served in various senior management roles, including Chief Financial Officer and Chief Operating Officer, ending as President and Chief Executive Officer of Accuride Corporation.

Surge of Excitement for Orthopedics in Developing Countries Lew Zirkle, M.D. founder of the Surgical Implant Generation Network (SIGN), is pleased to see more of a focus on orthopedics in the developing world. He tells *OTW*, "We are seeing a real surge of excitement and knowledge from orthopedic surgeons in Africa and other developing countries. It used to be that there were only one or two orthopedic training programs on the entire African continent; now most countries have at least one training program. These programs are sending orthopedists to other places throughout Africa. For example, Kenya used to have one training program, whereas now they have three. In Ethiopia we were just keeping our heads above water, but things are better now that local surgeons there are developing protocols for treating fractures. The SIGN program is expanding, and we have a large number of requests for implants and education. We'll now be starting programs in Zimbabwe, Sudan, and Somaliland. At the same time we are increasing the number of programs in Africa and Afghanistan. A common thread is urbanization. As people move to the cities they acquire vehicles, largely motorcycles. There are not more roads, however, and we are seeing a huge increase in motorcycle accidents. Anyone who wants to know more about our projects can visit www.signfracturecare.org."

OrthoWilmington: Two Major North Carolina Groups Merge Atlantic Orthopedics and Wilmington Orthopaedic Group have joined forces to become OrthoWilmington. All together, the group's resources include 20 board-certified or board-eligible orthopedic and spine specialists, 17 physician assistants and nurse practitioners, plus a team of therapists, technicians and support staff. There are five locations and six subspecialty care centers that focus clinical and diagnostic resources on specific areas. The practice also offers physical and occupational therapy in four locations, advanced imaging with an ACR-accredited MRI, and orthopedic urgent care through AccessOrtho, a walk-in medical clinic that enables patients to be diagnosed and treated immediately. ♦

company

Zimmer Takes Share in 4Q

Italian Risk Board/Wikipedia

Zimmer Holdings, Inc. reported a 2.9% increase in sales during the fourth quarter. Total sales reached $1.167 billion for the quarter with currency adding 0.5%. For the year, reported sales of $4.45 billion rose 5.5%

For the quarter, Zimmer reported reconstructive sales rose 2%. Knees were flat and hips grew by 5%. Extremities and trauma climbed 10% and 12%, respectively, while spine fell 6%.

Zimmer 4Q11	Sales $ in million	% Change
Total Reported Sales	**$1,167**	**2.9%**
Reconstructive	$877	2.0%
Knees	$475	0.0%
Hips	$358	5.0%
Trauma	$77	12.0%
Spine	$56	down 6%
Extremities	$44	10.0%

Source: Zimmer Holdings, Inc.+

Taking Market Share

Mizuho Securities Analyst Mike Matson reported that Zimmer continues to gain share in both hips and knees and that new products, including a knee, may widen the competitive gap this year. He estimates that on a constant currency basis, the recon market was flat in the quarter. Based on actual results from Zimmer's largest competitors, Matson estimates that global knee growth, on a constant currency basis, was down 1% and hips grew by 2%.

Dave Dvorak, Zimmer's president and CEO, said the company achieved a solid finish to 2011, driven by above-market performance in the company's Europe, Middle East and Africa and Asia Pacific businesses, as well as the ongoing positive contribution of innovative and proprietary product introductions across the musculoskeletal portfolio. "We expect to deliver sustained growth in sales, earnings and cash flow in 2012 through continued execution of the company's strategic priorities, including growth initiatives, transformation programs and disciplined capital allocation."

Margins – The Big Squeeze

Like its competitors, Zimmer's margins have been squeezed by pricing. The company expects gross margins to decline to 74-75% in 2012 from 75.1% in 2011. The expected decline, according to the company, is due to pricing pressure, lower manufacturing volumes and further hedging losses. However analysts point out that the company expects to more than offset this with lower SG&A spending which it expects to decline to 39.5-40.5% in 2012 from 41.2% in 2011. The anticipated decline is mainly due to cost-savings realized from Zimmer's restructuring programs.

When asked by analysts during a January 26 conference call about tightening margins, Dvorak said the orthopedics industry did not historically have to be excellent given the environment. "But we've changed," said Dvorak as he described modern quality control programs to improve efficiency.

According to a company statement, Zimmer expects to continue, "global restructuring and transformation initiatives designed to streamline business operations and support functions in 2012." Savings from these initiatives will enable the company to accelerate investments in innovation and commercialization of new products and technologies, expand global sales channels and drive sustained growth in earnings and cash flow.

The programs to be completed in 2012 are expected to generate annualized pre-tax savings of more than $80 million, including $30 million to $40 million to be realized in 2012.

The company also reported that it recorded an additional $108.0 million provision for known and anticipated worldwide claims related to the Durom Acetabular Component during the quarter

2012 Guidance

Guidance for 2012 looks a lot like 2011 as Dvorak offered revenue guidance of 2-4% on a constant currency basis with foreign exchange rates expected to reduce reported revenues by 1%. The guidance is predicated upon hip and knee procedural growth remaining tepid.

—WE (January 27, 2012)

New Coverage for TranS1's AxiaLIF

Rack up another reimbursement victory for TranS1 Inc. and patients who can benefit from the company's pre-sacral approach and AxiaLIF interbody fusion procedure.

The company recently announced that it was informed by Health Care Services Corporation, the Blue Cross and Blue Shield provider for Illinois, New Mexico, Oklahoma and Texas, that the insurer had removed its non-coverage policy for AxiaLIF.

The company has confirmed with the insurer that CPT codes 0195T and 0196T, which are the CPT codes associated with the company's AxiaLIF procedure, will be deemed eligible for coverage when the medical necessity fusion criteria are met. Health Care Services serves over 12 million members in these four states.

We have previously reported that there has been a lack of consistent reimbursement for CPT Codes 0195T and 0196T used to describe that fusion surgery. Some physicians have found it hard to get reimbursed for the procedure. It's been an important company initiative to get payers to cover the procedures while working with medical societies to clear up coding issues.

Previous Coverage Decisions

Health Care Services joins other insurers that have come around to cover AxiaLIF. In October Horizon Blue Cross Blue Shield of New Jersey agreed to provide coverage for its 3.6 million members. In January 2010, Humana Inc. agreed to provide coverage.

The company also continues to have clinical papers accepted for peer review and tell us that five more papers have been accepted for publication this coming year. A study published in the September issue of the *SAS Journal* says the AxiaLIF's complication rate compares favorably to open fusion approaches. TranS1 also raised a little over $18 million from investors this past September.

—WE (January 23, 2012)

Image Credit: company logos

legal

OP-1 Prosecutions Down to One

The *Boston Globe* reported on January 20 that prosecutors dropped felony conspiracy and fraud charges against two remaining Stryker Biotech OP-1 sales reps on trial in Boston.

Judge George O'Toole, Jr. of the U.S. District Court for Massachusetts agreed to dismiss all criminal charges against Jeff Whitaker and William Heppner. Charges against a third rep, David Ard, had been dropped earlier during the trial when the company agreed to plead guilty to a minor misdemeanor crime of misbranding a product and paid a $15 million fine.

The company had faced 13 felony charges.

Image Credit: wikimediacommons

Brandy Donini-Melanson, a spokeswoman for the U.S. attorney's office, said in a statement that prosecutors agreed to drop the charges "in the best interests of justice."

"These were fraud charges that never should have been brought," said Robert Ullmann of Boston, who represented Heppner.

The *Globe* reported that defense lawyers and legal observers said they could not offer a single reason why the government ultimately decided to drop the case, only that it was clear that the government could not prove that an intentional fraud occurred.

The dismissal of the charges against the sales reps and the guilty plea by the company only leaves Stryker Biotech's former president, Mark Phillips, still under prosecution. His case was separated from the main case earlier, based on technical legal issues and is set to go to trial next month.

The outcome of this trial is in stark contrast to the recent jail sentences issued in Philadelphia to former Synthes executives charged with conducting a clinical trial without FDA approval. In the OP-1 case, the company did have FDA approval for testing under a Humanitarian Device Exemption. Prosecutors had accused Stryker and the reps of marketing OP-1 in a mixture with Calstrux, a bone void filler, without FDA approval.

—WE (January 25, 2012)

Second Ex-Wright Employee Files Suit

A second former Wright Medical Technology Inc. senior executive has filed a lawsuit against the company for, "breach of contract and retaliatory discharge."

OTW has obtained a copy of the lawsuit filed on January 5 by Cary Hagan, the company's former vice president, commercial operations for Europe, the Middle East and Africa.

Frank Bono, the company's former senior vice president and chief technology filed a similar lawsuit in early January. Both men claim that they were either discharged or forced to resign to demonstrate the company's cooperation with the federal monitor imposed on the company by a deferred prosecution agreement (DPA) with the New Jersey U.S. Attorney.

Hagan alleges that his forced resignation was in retaliation for raising documented concerns at a special board meeting about Lisa Michels, Wright's former chief compliance officer, and her inability to run an efficient and effective compliance department. Wright, unlike other orthopedic companies under similar DPAs, had negotiated a 12-month monitor period. The other companies' monitoring programs lasted 18 months. Wright eventually agreed to extend the DPA for one additional year and Lisa Michels left the company.

According to Hagan, James Tucker, the federal Monitor hired to oversee the company's compliance program, was opposed to paying terminated employees severance pay. He claims, Wright's then CEO, Gary Henley, "attempted to ensure, to no avail," that Wright comply with employee severance agreements, as well as Wright's "general mismanagement" of it's compliance program.


IN THE CHANCERY COURT OF TENNESSEE FOR THE
THIRTIETH JUDICIAL DISTRICT AT MEMPHIS, SHELBY COUNTY
CARY P. HAGAN,
Plaintiff,
v.
WRIGHT MEDICAL TECHNOLOGY, INC.,
Defendant.
Case No. CH-12-0013-3
Jury Demanded
COMPLAINT FOR BREACH OF CONTRACT AND RETALIATORY DISCHARGE
Plaintiff Cary P. Hagan ("Mr. Hagan") makes the following complaint against Defendant Wright Medical Technology, Inc. ("Wright"):
THE PARTIES

Image Credit: Hagan Complaint

As in Bono's lawsuit, Hagen alleges that the company was far more concerned with the appearance of compliance than it was with actually complying with applicable laws and regulations. Bono's complaint also claims he and his coworkers were terminated in an attempt to "shore up stock prices by eliciting positive review from the federal monitor."

We will report on the two Complaints in detail in the next issue of *OTW.*

—WE (January 20, 2012)

Fired Chief Science Officer Sues Wright Medical

The Memphis Daily News reported on Monday, January 16, that Frank Bono is suing Wright Medical Technology Inc. for, "breach of contract, retaliatory discharge, defamation and violations of the Tennessee Public Protection Act."

Bono was the company's senior vice president and chief technology officer during the time of the company's deferred prosecution agreement (DPA) with the U.S. Attorney's Office in New Jersey. He, along with a number of other senior executives, was terminated last spring for failing to "exhibit appropriate regard for the company's ongoing compliance program."

Bono disagrees. According to the news story, Bono alleges the board fired him, "despite positive performance reviews, and also fired other employees who had raised concerns" about the company's compliance program and Chief Compliance Officer Lisa Michels. He claims the company was "far more concerned with the appearance of compliance than it was with actually complying with applicable laws and regulations." The complaint also claims that he and his coworkers were fired in an attempt to "shore up stock prices by eliciting positive review" from the federal monitor.

Unlike other orthopedic device companies which agreed to 18-month DPA periods, Wright negotiated a 12-month period. When the company self-reported problems with its compliance program and removed senior company leaders, the DPA was extended in September 2011 by at least a year. The month before the extension, Michels was terminated, according to the complaint, because the company, "knew that its gambit of blindly supporting Michels in an effort to avoid extension of the DPA had failed."

Bono wants compensatory damages in an amount to be determined at trial, in addition to punitive damages, front pay, back pay, interest, expenses and attorney's fees.

Wikimedia Commons; Aliiolanihale-courtroom

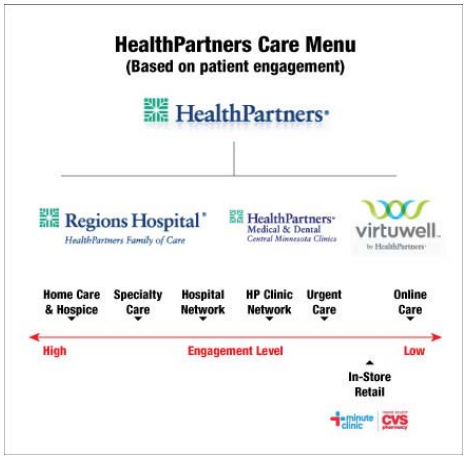
We will report on the full Complaint in the next edition of *OTW.*

—WE (January 17, 2012)

New Rules Aim to Reduce Spine Surgery

HealthPartners, the largest consumer-governed, nonprofit health care organization in the United States, has notified its members who are considering back surgery that they must first be evaluated by a physician who will focus on nonsurgical options before they can see a surgeon.

In a story first reported by the *Minneapolis Star Tribune* writer Jackie Crosby on January 5, Health \Partners officials said the change in policy came about because of growing evidence that aggressive treatments may not always be the most effective treatment for low-back pain. They project that patients



Source: Courtesy of HealthPartners

will be willing to choose treatments, other than surgery, once they receive information about the options available to them.

HealthPartners has identified 102 sites in Minnesota and Wisconsin where patients with back pain can meet with specialists in rehabilitation, occupational medicine and sports medicine.

"They are not the gatekeepers," insisted Dr. Thomas Marr, HealthPartners' medical director of clinical relations, who was quoted in the newspaper story. "Patients can still see a surgeon if they wish. But after this visit, they'll be better informed about all of their options, and can make decisions more aligned with their own values."

HealthPartners paid out more than $28.3 million on lumbar fusions and other spine surgeries in 2011. Had this new program, of first seeing a specialist for back pain before consulting a surgeon, been in place in 2010, about 8,800 out of the 1.36 million enrolled in HealthPartners insurance plans would have been eligible for the evaluations.

HealthPartners modeled its spine program after one devised by Priority Health of Grand Rapids, Michigan. According to a Priority Health spokeswoman, quoted in the *Tribune* report, Priority Health found that, over the past four years since it instituted its program, surgeries dropped by 26 percent and orders for high-tech radiology fell by 12%. HealthPartners has been examining its treatment costs and patient outcomes associated with low-back pain since 2004.

—BY (January 16, 2012)

biologics

Geron Selling Off Embryonic Stem Cell Technology

After nearly $450 million of equity raised and a record breaking $40 million FDA submission, Geron is throwing in the towel regarding its ground breaking embryonic stem cell therapy to treat nerve damaged patients.

Under the FDA trial, Geron had treated four patients—total.

Roughly a year ago the company fired its long time CEO Thomas Okarma and last week new Geron CEO John Scarlett told industry executives at the J.P. Morgan Healthcare Conference in San Francisco that his company had recruited St. Louis-based broker Stifel Nicolaus to help it sell off its cell therapies, according to a report in *Fierce Biotech*.

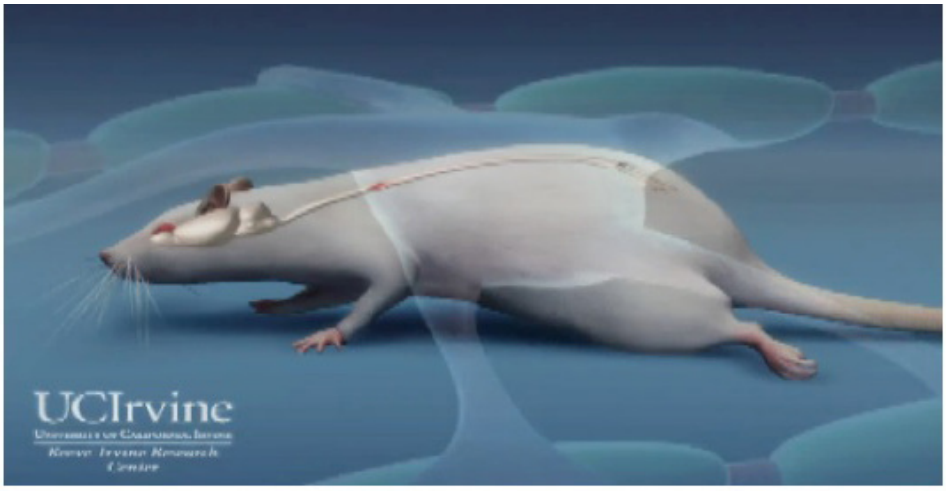
In 2010, Geron officials announced that the firm intended to stop clinical trials in spinal injury patients and sell its embryonic stem cell therapy program.

According to the *Fierce Biotech* writer Suzanne Elvidge on January 12, Geron is in active discussions with potential partners. The stem cell programs are, at the present time, in preclinical and clinical development and include potential therapies for central nervous system disorders, heart disease, diabetes, immunotherapy and cartilage repair.

Geron officials indicated that it will tighten the firm's focus on its cancer therapies. It has two agents in Phase II clinical trials, with results expected in late 2012. If these are successful, Phase II proof-of-concept data will give the company a solid scientific base to seek further partnerships or collaborations.

"Every company has to make decisions about what it can do, not just what it aspires, or would like to do," Scarlett told *Bloomberg*. The official indicated that Geron has enough money to get through the clinical trials this year without seeking further funding, and the sale of the cell therapies could further boost funding.

—BY (January 19, 2012)



Source: Courtesy of Geron Corporation/ Caption: Image from Geron's Video of the use of stem cell therapies in rats

Arthrex to Market Stem Cell Concentrator System

Arthrex, Inc. has agreed to distribute a stem cell concentrator system manufactured by ThermoGenesis Corp., a supplier of products and services that process and store human cell concentrates. The agreement has a five year term to it and under its provisions Arthrex has agreed to use its extensive sales and distribution network to market ThermoGenesis' Res-Q 60 System technology for use in the preparation of autologous platelet rich plasma (PRP) or bone marrow concentrate (BMC)—either one of which results in a concentration of the patient's own supply of adult stem cells.

Based in Naples, Florida, Arthrex is one of the largest suppliers of surgical tools and instruments in the world with more than 5,000 products for arthroscopic and minimally invasive orthopaedic surgical procedures available.

ThermoGenesis's Res-Q technology is a simple filter plus centrifuge system which separates stem cell rich buffy coat from the other components of bone marrow or blood in the operating room. The FDA cleared Res-Q for commercialization in the U.S. in June 2011 for use as a method to prepare autologous PRP from a small sample of blood. According to the company's description of its product, the resulting PRP or BMC can be mixed with autograft and/or allograft bone in the OR and can be used to help fill any bone voids or other defects. Importantly, the system works quickly. OR staff can have concentrated and stem cell rich (greater than 250 million overall cells and greater than 9.5 million CD34+ verified progenitor cells) in about 15 minutes.

Here is a picture of the system.

—BY (January 19, 2012)

Source: Courtesy of Thermogenesis Corp

large joints

Rush Surgeons: Radiostereometric Analysis Milestone

Does your implant have a few too many and go awanderin'? Now there is help. Nip that meandering implant in the bud! Two hip and knee

Rush University

surgeons from Midwest Orthopaedics at Rush (MOR) are the first in the U.S. to implant all compliant patients with radiostereometric analysis (RSA) beads, something which will reveal if there is any wear or movement in the implant. It also provides the world's first RSA registry for implants that allows scientists to collect data on materials and designs used for hip and knee replacement prostheses. The procedure was performed at Central DuPage Hospital.

"RSA will let us track relative motion of different implant materials such as metal, plastic and ceramic and provide us data about the safety and efficacy of these devices," explained Dr. Sporer in the January 18, 2012 news release. "Although research shows that very

few hip and knee replacement patients experience failure (less than 10%), now we have data to determine the success of each patient's implant."

"This groundbreaking RSA technology allows us to identify problematic implants before they fail and develop an individualized course of action for patients depending on the situation," says Dr. Paprosky. "For example, if a patient complains of pain, we compare a recent RSA scan to the original scan. If we notice instability, we can intervene, by possibly performing a surgery to stabilize the implant before more complications develop."

RSA analysis has come to fruition due to the collaboration between the physicians and Halifax Biomedical, a Canadian based biomedical company that developed the stereo radiography technology. Once the beads, or biomarkers, have been inserted into the bone, two or more pairs of stereo x-ray images are taken and sent to Halifax Biomedical. Technicians use visual assessment software to monitor the position of the biomarkers in relation to the implants. If a patient experiences pain, another x-ray of the patient's joint is taken and compared to the original one to determine the relative motion of implants with respect to the bone. This is followed up with a detailed report showing the stability of the implant.

Dr. Sporer told *OTW*, "RSA is an extremely accurate technique to assess component stability following total hip and knee replacement. The ability to utilize this technology on all patients, rather than a select subset of patients enrolled in a clinical trial, will allow the early detection of problematic implants and may provide diagnostic information among symptomatic postsurgical patients. It is the hope that the development of the first RSA registry within the U.S. will lead to improved patient outcomes, minimize the need for revision surgery and ultimately reduce the costs associated with arthroplasty surgery."

—EH (January 23, 2012)

extremities

Studying Injury: Markerless Motion Capture

A new study, published in a recent issue of *Annals of Biomedical Engineering*, may alter how orthopedists work with tennis and orthopedic injuries in general. Researchers studied three types of tennis serves, and identified one in particular, called a "kick" serve, which creates the highest potential for shoulder injury.

"The potential for markerless motion capture in medicine is vast and exciting,


Courtesy of Alison Sheets, Ph.D.

because it can quantify how a person moves without the need to attach electronic markers or other equipment to their body," said Alison Sheets, Ph.D., assistant professor of mechanical engineering at Ohio State University, in the January 17, 2012 news release. "People can move naturally, and in a natural setting outside of a laboratory."

Along with study coauthor Marc Safran, M.D., an expert in shoulder surgery at Stanford, they recruited seven members of the Stanford men's varsity tennis team for the study. The study examined the difference in body positioning for the three serves. The measurements taken suggest that the kick serve generates larger forces on muscles crossing the shoulder joint than the other two serves, which could promote injury.

Dr. Sheets told *OTW*, "This tennis study was performed while I was a postdoctoral researcher at Stanford University with Thomas Andriacchi (Ph.D.). It utilized the markerless motion capture approach that had been previously developed by Stefano Corazza (Ph.D.) and Lars Mundermann (Ph.D.) in Dr. Andriacchi's lab."

"Our most interesting finding was that positions of the players' bodies were very different when they hit the ball during the flat and kick serves. In the kick serve, the shoulder was more extended which placed the racquet behind the head and closer to the center of the body. This could potentially create larger forces on the muscles that stabilize the shoulder, and may increase the risk of injury."

"The work that I am currently pursuing with Dr. Michele Basso uses a different markerless approach to quantitatively evaluate functional movements in mice. This is important because mice and rats are used as models to develop treatments for many debilitating neural and muscular conditions such as Parkinson's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (commonly known as ALS), and Multiple Sclerosis. By developing a more sensitive, repeatable, and time efficient method to evaluate motor performance, researchers will gain access to quantitative measures of animal motion that have never been possible before. We hope that this will lead to advancements in developing treatments for neural and muscular conditions that affect humans."

—EH (January 27, 2012)

Doc's Hospital Employment Soars 32%

Physician employment by hospitals jumped 32% between 2000 and 2010, according to the 2012 edition of *AHA Hospital Statistics*. In 2010 hospitals employed approximately 212,000 physicians, or almost 20% of all doctors.

Hospitals have a variety of relationships with their physicians. Although 55.1% of physicians are not employed by or are under contract with hospitals, the report notes that 20.3% are covered by a group contract, 17.3% are directly employed, and 7.2% have individual contracts.

The number of hospitalists rose from 29.6% in 2003 to 59.8% in 2010, according to the report. Hospitals' employment of intensivists (physicians with advanced critical care board certification who specialize in treating the most seriously ill or injured patients) also increased from 20.7% to 29.7% between 2007 and 2010.

To cope with the anticipated shortage of primary care physicians, the report explored the expected growth of advanced practice registered nurses (APRN). Approximately 32.6% of all APRNs employed by hospitals work in primary care; 26.3% work in another specialty, 22.8% are employed in anesthesia services, 21% work in EDs, 9.3% are employed in patient education and 5.6% work in case management.

Wikimedia Commons and SenatorDF

—BY (January 16, 2012)

trauma

Orthopedic Surgeon on Extreme Makeover

After two tours of duty in Iraq, Dr. Steven Cyr, an orthopedic surgeon, came home and founded the Orthopaedic and Spine Institute in San Antonio, Texas. Now he and his colleagues are going to be putting their efforts toward helping out during a house construction on Extreme Home Makeover Edition (to be aired as a Christmas 2012 special)…a home for a disabled Army veteran.

Dr. Cyr told *OTW*, "We're honored to be selected to be a participant in the ABC-TV show Extreme Makeover: Home Edition! Having served two tours of duty during the Iraqi War, we felt compelled to contribute and to participate with Extreme Makeover: Home Edition (EMHE), United Services Organization (USO), HelpingaHero and Morgan's Wonderland to deliver a mortgage-free home to a deserving Iraqi War Veteran.

He continued, "There is no better cause than to help another in need, and honoring U.S. Army SSgt Harris was just such a cause. SSgt Harris was injured around the same time that another of our surgeons, Dr. Joel B. Nilsson and I were deployed to Iraq. We truly understand and appreciate the sacrifice that our men and women of the Armed Forces make for our great Country. After two deployments to Iraq, treating hundreds of injured soldiers, sailors, marines, and airmen, our heart goes out to heroes like SSgt Harris. Since we've separated from the military, we felt it was important to show our gratitude for their continued contribution and sacrifice."

"These great men and women deserve our respect and support, and it was a real privilege to be part of the effort to recognize SSgt Harris. Our contribution was multifaceted. Our staff and providers contributed refreshments to the more than 2,000 volunteers, 400 vendors and trades, and 75 EMHE workers during the 7-day build. Our massage therapist offered free treatments to any of the workers on site. In addition, we made a cash contribution on behalf of

Dr. Steven Cyr

SSgt Harris and his family to the USO, who purchased mobile entertainment communications and gaming systems (MEGS), and shipped these to Afghanistan. These state-of-the-art units allow our service men and women to communicate with loved ones at home for free, and provide a host of entertainment devices to pass the time (iPads, Kindles, Xbox, PlayStation, Nintendo, etc.). We have never forgotten the family sacrifice, andhow difficult it was to be displaced from home and our loved ones.We hope these units will help our troops stay in touch with their loved ones and pass the time more easily in a difficult situation."

—EH (January 26, 2012)

BMD Screening: Some Can Wait

Get screened now! OK, no later… Yes, it hasn't been exactly clear how often women should be screened for osteoporosis via bone mineral density (BMD) testing. A new study led by Margaret L. Gourlay, M.D., M.P.H. of the University of North Carolina at Chapel Hill School of Medicine has found that women aged 67 years and older with normal bone mineral density scores may not need screening again for 15 years.

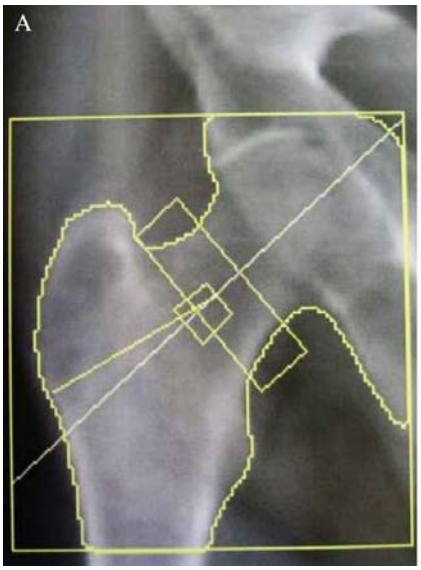
"If a woman's bone density at age 67 is very good, then she doesn't need to be re-screened in two years or three years, because we're not likely to see much change," Dr. Gourlay said in the January 18, 2012 news release. "Our study found it would take about 15 years for 10% of women in the highest bone density ranges to develop osteoporosis."

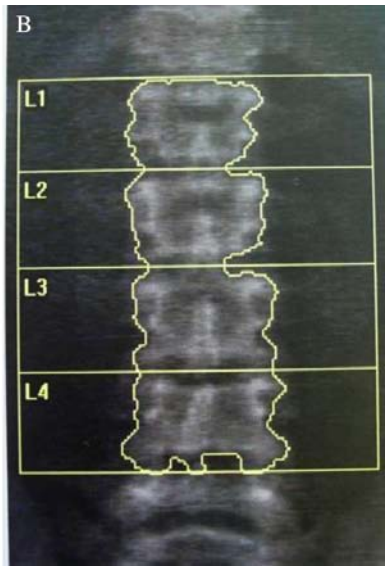
"That was longer than we expected, and it's great news for this group of women," Dr. Gourlay said. Dr. Gourlay, an assistant professor in UNC's Department of Family Medicine, presented these results in a study published in the January 19, 2012 issue of *The New England Journal of Medicine*.

The authors analyzed data from the Study of Osteoporotic Fractures, the longest-running osteoporosis study in the U.S. A total of 4,957 women aged 67 years and older were enrolled in the study from 1986 to 1988 when they were 65 years or older. They had bone mineral density testing starting about two years later. All participants underwent bone mineral density testing at least twice during the study period; some were tested up to five times over a period of 15 years.

The team concluded that baseline BMD is the most important factor for doctors to consider in determining frequency of screening. It also suggests that older postmenopausal women with a T-score -2.0 and below will transition to osteoporosis more rapidly, while women with T-scores higher than -2.0 may not need screening again for 5 to 15 years, Gourlay said. "Doctors may adjust these time intervals for a number of reasons, but our results offer an evidence-based starting point for this clinical decision."

—EH (January 24, 2012)





Wikimedia Commons and Dr. Caroline Lebreton

Rearview Mirror Forecast

+

PearlDiver reports:

- Available in spreadsheet and written report form
- Bottom up analysis starting with diagnostic and procedure codes
- 1.7 Billion patient records in database (HIPPA compliant)
- Every zip code and virtually every hospital covered

PearlDiver co-founder Robin Young has been at the forefront of virtually every major technology trend in orthopedics. He organized PearlDiver's research to give senior marketing executives the most actionable market data possible.

Detailed market analysis (in spreadsheets) from $1,950.

Specific indication analysis (in pdf) from $950.

PearlDiver

unfathomably deep data retrieval

For unfathomablty deep and useful tmedical market research, call the Data Guys at PearlDiver-Scott or Heather at 260-468-3635 or dataguys@pearldverinc.com.

Orthopedics This Week | RRY Publications LLC

Main Contact Information:
RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
Fax: 610-260-6451

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Biloine W. Young
Writer
bgwy@msn.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com