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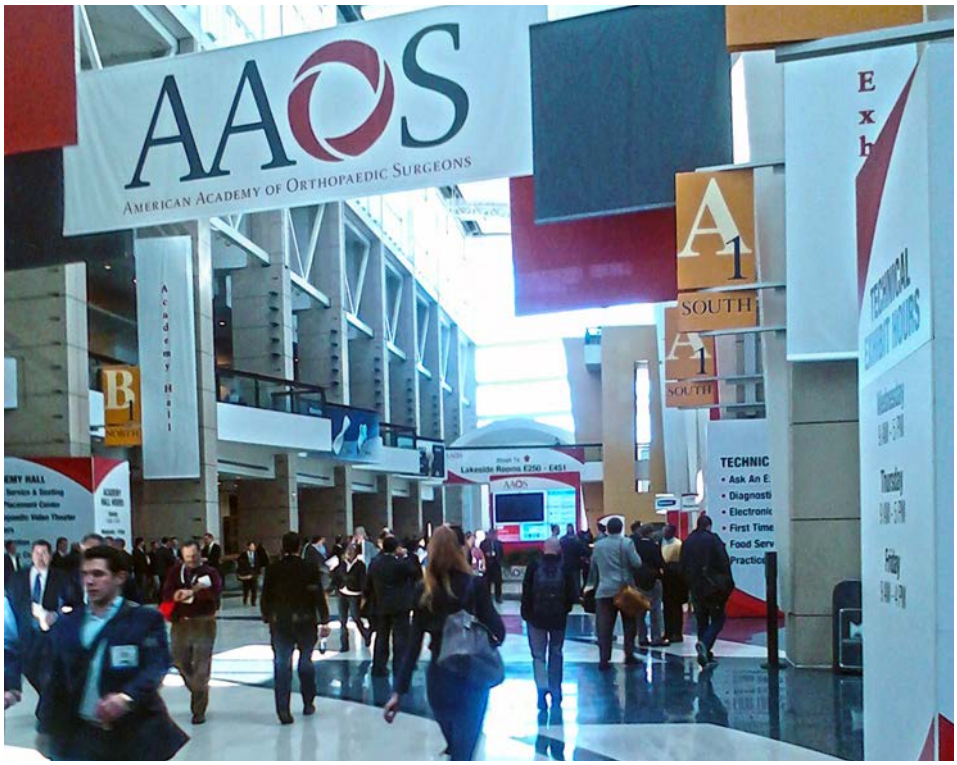
Orthopedics This Week

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: Plenty of moving parts this week. PODs received the long anticipated OIG slam down. Is anyone really surprised? AAOS was crowded and most expect steadily rising procedural volumes, but pricing is tough. No doubt we will all make it up in volume. The real story? New managements. Watch this new class of CEOs; there are a couple true gems here.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	NuVasive	7.08%	16.83%	OIG's fraud alert regarding PODs positive for NUVA. Never went there and now it pays off.
2	2	Alphatec	(4.29)	24.85	Digging into ATEC's inventory management shows that demand may well be accelerating for finished goods.
3	3	Conmed	10.51	10.87	First quarter results are due in about 3 weeks. Despite modest expectations, buyers are stepping in.
4	4	Stryker	23.68	2.48	The updated view on Wall Street is that ACA will put a wind at the back of large ortho. SYK should disproportionately benefit.
5	8	Exactech	8.64	9.01	Strong AAOS with Equinox generating good reviews. We expect upward pressure on overall Q1 sales growth (around 5-6%).
6	7	Johnson & Johnson	25.58	6.83	Believe it or not, the Street thinks that JNJ will add a whopping $1.3 billion in YOY new sales in Q1.
7	6	Globus Medical	28.9	6.22	Patience required. But as the quarters roll by and GMED puts up the numbers, those profit figures should pay off.
8	5	Orthofix	19.68	(0.91)	Same story. Patience. Let management do its thing and, if history is any guide, Brad Mason will deliver nicely.
9	10	Medtronic	28.65	5.43	What's MDT going to buy next? That's the popular guessing game—$4 billion in free cash opens plenty of doors.
10	NR	Symmetry Medical	8.26	9.99	Appears as though SMA is freeing up cash with some smart working capital management. Buyers have noticed.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$2.11	$204	24.85%
2	NuVasive	NUVA	$21.31	$938	16.83%
3	Conmed	CNMD	$34.06	$956	10.87%
4	Symmetry Medical	SMA	$11.45	$427	9.99%
5	MiMedx Group	MDXG	$5.09	$477	9.94%
6	Tornier N.V.	TRNX	$18.85	$787	9.34%
7	Exactech	EXAC	$20.69	$277	9.01%
8	RTI Biologics Inc	RTIX	$3.93	$220	7.97%
9	Smith & Nephew	SNN	$57.73	$10,467	7.81%
10	Johnson & Johnson	JNJ	$81.53	$227,902	6.83%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$11.15	$526	-7.78%
2	Bacterin Intl Holdings	BONE	$0.83	$35	-7.57%
3	Integra LifeSciences	IART	$39.01	$1,092	-2.50%
4	TranS1	TSON	$2.24	$61	-1.32%
5	TiGenix	TIG.BR	$1.14	$114	-1.00%
6	CryoLife	CRY	$6.01	$165	-0.99%
7	Orthofix	OFIX	$35.87	$697	-0.91%
8	ArthroCare	ARTC	$34.76	$975	-0.23%
9	Zimmer Holdings	ZMH	$75.22	$12,739	1.03%
10	Wright Medical	WMGI	$23.81	$1,090	2.41%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$35.87	$697	11.84
2	Medtronic	MDT	$46.96	$47,608	13.04
3	Zimmer Holdings	ZMH	$75.22	$12,739	14.14
4	Smith & Nephew	SNN	$57.73	$10,467	14.36
5	Johnson & Johnson	JNJ	$81.53	$227,902	15.92

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$23.81	$1,090	216.45
2	NuVasive	NUVA	$21.31	$938	62.68
3	Symmetry Medical	SMA	$11.45	$427	34.70
4	ArthroCare	ARTC	$34.76	$975	22.72
5	RTI Biologics Inc	RTIX	$3.93	$220	21.83

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$35.87	$697	0.95
2	Globus Medical	GMED	$14.68	$1,348	1.22
3	Zimmer Holdings	ZMH	$75.22	$12,739	1.42
4	Conmed	CNMD	$34.06	$956	1.44
5	RTI Biologics Inc	RTIX	$3.93	$220	1.46

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$23.81	$1,090	19.68
2	NuVasive	NUVA	$21.31	$938	5.10
3	CryoLife	CRY	$6.01	$165	5.01
4	Symmetry Medical	SMA	$11.45	$427	2.89
5	Johnson & Johnson	JNJ	$81.53	$227,902	2.42

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$2.11	$204	1.04
2	Symmetry Medical	SMA	$11.45	$427	1.04
3	Bacterin Intl Holdings	BONE	$0.83	$35	1.07
4	Exactech	EXAC	$20.69	$277	1.23
5	RTI Biologics Inc	RTIX	$3.93	$220	1.24

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.14	$114	28.02
2	MiMedx Group	MDXG	$5.09	$477	17.64
3	MAKO Surgical	MAKO	$11.15	$526	5.13
4	TranS1	TSON	$2.24	$61	4.20
5	Globus Medical	GMED	$14.68	$1,348	3.49

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

AAOS 2013: New Technology Plus Old Time Religion

By Walter Eisner

Over 31,000 surgeons and health care providers, device reps, manufacturers, analysts, engineers and reporters blew into Chicago the week of March 19 to participate in the world's premier orthopedic bazaar and scientific meeting, the 81st gathering of the American Academy of Orthopaedic Surgeons (AAOS).

Three of the biggest device makers and supporting businesses from the "Orthopedic Capital of the World" (Warsaw, Indiana) are just 100 miles up the road and an optimistic hometown surgeon took his place as the 81st president of the Academy. This year's gathering was generally more upbeat than past meetings.

Famed device engineer and Biomet, Inc. founder Dane Miller told us that he has attended over 40 annual AAOS meetings and this one had good energy. Indeed, with over 600 exhibitors, of which 213 were first-timers, the meeting blew the roof off last year's 517 exhibitors.

After surviving the Age of (Christopher) Christie and deferred prosecution agreements, years of incremental technology advancements, Obamacare, metal-on-metal hip failures and a pinched public purse, incoming Prez Josh Jacobs, M.D., welcomed the profession and industry with a new emphasis on the value orthopedic therapies brings to society.

AAOS/RRY Publicaitons LLC

A Tale of Two Meetings

There were two meetings really. One in the Exhibition Hall, which was actually chock full of new stuff and ever solicitous sales reps. The other one could be found in the meeting rooms where surgeons faced up to the new realities of American healthcare system—and how their practices, work and patients may well change as a result.

In packed ballrooms, surgeons heard what to do about metal-on-metal hips, re-hashed debates over the safety of BMP's (bone morphogenetic protein) and had to think about shifting economic sands as payers and other economic imperatives appear to be herding them to the large hospital system corral.

Fight Over Knees

The Exhibition Hall was buzzing over the biggest or at least most expensive new product launch, perhaps ever.

AAOS/RRY Publications LLC

AAOS in 2013 was the coming out party for Zimmer's Persona fixed-bearing total knee system. The production quality of Persona's party was enough to make Hollywood/Disney envious. Persona gives surgeons about twice as many implant sizes and, for the hospital purchasing manager, a lot fewer instrument trays.

But wait…across the hall…DePuySynthes was simultaneously launching the Attune and Smith & Nephew was also presenting its new baby—Journey II. But, truth be told, Persona took the prize in terms of glitz and pomp and circumstance.

It didn't take too long for competitors to take a shot at the new knees.

"Variance in sizes is not patient-specific—it's inventory," wrote ConforMIS CEO Philipp Lang in a reader comment in *OTW*.

"Off-the-shelf implant shapes that do not match the patient's anatomy result in residual pain, functional limitations and a knee that does not feel natural. While Zimmer and DePuySynthes may claim to have introduced personalized implants, patients will only receive more generic size options versus a knee that is personalized to their anatomies," added Lang.

During a tour of the Persona exhibit, device developer Bob Booth, M.D., said in response to Lang's critique that he considers knee replacement a soft tissue operation and wants as many options as possible during surgery instead of a single implant created pre-operatively.

Robotics Collide

Humans are clearly intrigued with robots—especially the orthopedic surgeon variety—who we suspect may well be frustrated engineers. MAKO Surgical Corp. and upstart competitor Blue Belt Technologies, Inc. had very popular booths. Competition between the two firms recently heated up as MAKO and Stryker Corp. filed lawsuits against Blue Belt and former employees who had the temerity to join the upstart. Their claims? Stolen secrets and tortious interference. All we know for sure is that the court filings will make for interesting reading.

In what must surely be a first, a federal judge sided with Stryker in barring a new Blue Belt hire, ex-Stryker marketing director James Bruty, from attending the meeting. Stryker said Bruty lied about where he was going to work after leaving Stryker.

A Young Surgeon's Anxiety

Something about AAOS is refreshing. It's that splash of new technology combined with old school religion—you know, how orthopedic surgeries and implants return literally hundreds of thousands of long suffering arthritic patients to normalcy. But then seeping in around the edges of the good news were the fingers of reimbursement and healthcare economics anxiety.

"I'm 40 years old. My fellow surgeons and I are still young enough to switch careers," said a young surgeon to Richard Rothman, M.D., founder of the Rothman Institute, during a session

on the future of surgeon practices after hearing about loss of control, the rise of the administrator and payer and surgeon shortages.

A retired surgeon in the audience stood up and spoke to the young man and calmly reminded him that when he was young, he too thought his elders had just gone through the golden age of orthopedics and change was daunted. But he added that the higher demand for his services and fewer surgeons coming into the field, only made him more valuable.

Dr. Jacobs told us that he would have told the young surgeon that there's no better area in medicine where you improve patients so quickly and dramatically. "Don't lose sight that you really help people. It's a great job."

The Rise of the Payer

Roger Strode, an attorney with Foley & Lardner told surgeons that various experts suggest the successful hospital enterprise must reach at least $2 billion in annual revenues to absorb the administrative, compliance, technology, and risk-taking characteristics of long term sustainability. Those economics are driving surgeon practices under the hospital's umbrella.

He said limits on health insurer premium profits under the new health care law are shifting their focus to provider business and reconfiguring the insurer's landscape to control risk dollars. He cited examples of insurers now buying hospitals.

Jacobs the Optimist

Dr. Jacobs addressed this new environment in his Presidential remarks to the Academy and in an interview with *OTW* on March 27.

"PPACA [Obamacare] is the law of the land; it is time to move forward," Jacobs said. The Academy needs to now clearly demonstrate how orthopedic surgeons are part of the solution to the nation's health care crisis clearly spelled out by a keynote presentation by former Wyoming Senator Alan Simpson and former Clinton White House Chief of Staff, Erskine Bowles

New Era of Surgeon/Industry Relations

"Orthopedic surgery has been a particular target of the government, in part due to the cost of implants and the creative history of orthopedic surgeons as innovators and inventors as they established relationships with manufacturers. These relationships attracted the attention of the Department of Justice. The reverberations from the subsequent investigation and settlements are still being felt," said Jacobs.

Josh Jacobs, M.D.

Jacobs told us interactions with industry in the post-DPA (deferred-prosecution agreements) world are scrutinized much closer and planned and implemented in a more formal fashion. "Companies are committed to following the new rules." His own experience in research is that the interaction with industry is far more complex now. He added that surgeons need to interact with manufacturers to design patient- and surgeon-friendly implants and track the outcomes of the procedures that are performed with these implants.

Zimmer President and CEO Dave Dvorak told us the same thing at the meeting. Dvorak pointed to the development of the Persona knee in a new era of surgeon/industry relationships. "Almost all innovative ideas originate from surgeons," said Dvorak. Those ideas are brought to fruition by industry engineers.

As an example he noted Zimmer's program of separating sales and marketing activities from consulting, medical education and other appropriate financial arrangements with healthcare professionals.

Dvorak said the DPA process certainly changed the manner of the engagement, but did not change the need for collaboration. "The Persona is the biggest product development project the company has undertaken, and it provides a strong example of how appropriate, transparent collaboration can facilitate major breakthroughs in the standard of orthopedic care."

Orthopedic Value to Society

Hip and knee replacement procedure together comprise the highest expenditure of Medicare dollars, Jacobs said, and as a result procedure utilization rates have come under increased government scrutiny. Recovery auditors (RACs) have tried to claim that many surgeries were unnecessary and some payers have classified certain elective orthopedic services as so-called "additional cost tier procedures." This has resulted, for example, in patients having to pay a $500 surcharge in one

state-run system. "That's a significant disincentive to obtaining a needed and effective healthcare intervention."

Well, yeah.

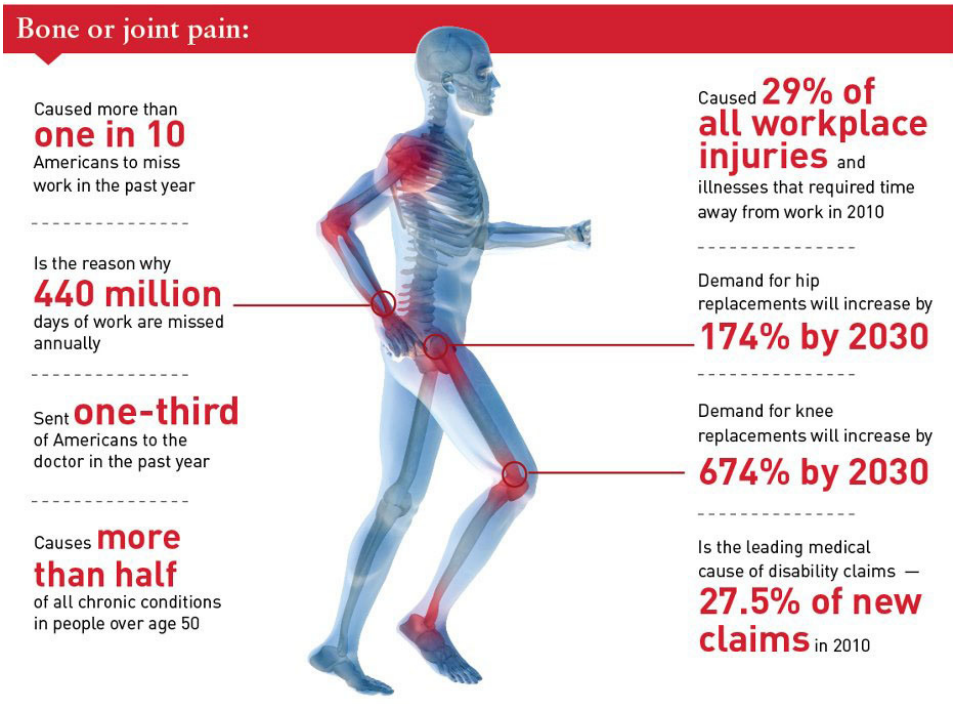
"We are collecting the data to make the case that we're helping keep citizens productive," Jacobs told us. He noted the focus has been on costs, not the downstream value to society, which leads to mistaken conclusions. "We restore workers to gainful employment and keep people mobile and healthy so they stay out of the health care system…we shouldn't reduce access to procedures that are overall cost savers to society."

He credited his predecessor, John Tongue, M.D., with leading an exhaustive Academy-sponsored economic analysis called, "Modeling the Indirect Economic Implications of Musculoskeletal Disorders and Treatment" which demonstrates the societal value of orthopedic procedures.

The research suggests that physical impairments associated with musculoskeletal (MSK)-related disorders reduce household income and the likelihood of employment, and increase missed work days and disability pay for those who are employed. Appropriate treatment of MSK disorders has the potential to significantly reduce indirect costs and is associated with net economic benefits to society.

"Regulatory Advocacy"

To make this case to public payers, Jacobs said the Academy is augmenting its legislative advocacy efforts to repeal the independent payment advisory board (IPAB) and replacing the sustainable growth rate formula by engaging in "regulatory advocacy." In effect, educating those in the executive branch of government who are writing the rules to implement the goals of the new health care law.



American Academy of Orthopaedic Surgeons

"The advocacy message is presented in terms of our quality programs (e.g., clinical practice guidelines and appropriate use criteria) which represent a potential solution to the current healthcare crisis, not just demand for fair reimbursement. We have a golden opportunity to demonstrate the value we provide to society and to each and every citizen of our country."

We don't know what happened to that 40-year-old surgeon. If he wants to make a lot of money, he's probably preparing his MBA or law school application. If he follows the advice of his new optimistic Academy president he's probably figuring out how to fit into a new health care landscape. ♦

The Top 25 U.S. Hospitals for ACL Surgery

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

RRY Publications LLC

Got a pesky knee that's buckling on a regular basis? To whom should you entrust that important ligament, the anterior cruciate ligament (ACL) surgery? Here is list to choose from.

Unlike many of our other top 25 lists, there is a fairly even geographic distribution for these top-performing hospitals. And wherever you go, it looks like you will be in and out in one day…and chances are that you won't have any complications.

And what do these hospitals have in common?

- High volumes—these 25 hospitals average 337 ACL procedures per year, whereas the U.S. average is 135.
- Such low complication rates that they don't even register statistically. Complications searched for include, cardiac, respiratory, peripheral vascular, central nervous system, complications of hematomas, complications of accidental cut, puncture or hemorrhage, complication of operative wound, postoperative infection, cerebrospinal fluid leak, deep vein thrombosis, mechanical complication of implant or graft, death, other.
- Low prices: the average charge was $1,927, compared to the national average of $7,008.

(See table on page 9.)

Two of the top ranked facilities were willing to share how they are able to deliver such high rates of care at such reasonable prices. With ACL tears being rampant, it's especially important to know how the best do what they do.

Provider Name	State	Average Charge	Complication Rate
AHS Hillcrest Medical Center, LLC – Hillcrest Medical Center	OK	$1,720.25	0.0%
Altoona Regional Health System	PA	$2,458.33	0.0%
Bay Regional Medical Center – Bay Medical Center	MI	$1,549.00	0.0%
Baystate Medical Center Inc.	MA	$1,848.50	0.0%
Beth Israel Medical Center	NY	$1,237.43	0.0%
Henry County General Hospital – Henry County Medical Center	TN	$1,883.67	0.0%
IHC Health Services Inc. – Park City Medical Center	UT	$2,229.00	0.0%
IHC Health Services Inc. – The Orthopedic Specialty Hospital	UT	$2,673.50	0.0%
Ingham Regional Medical Center	MI	$2,408.00	0.0%
Mercy Health System Inc. – Mercy Medical Center	TN	$2,480.75	0.0%
Mercy Health System Corporation – Mercy Walworth Hospital And Medical Center	WI	$495.50	0.0%
NY Community Hospital of Brooklyn Inc. – NY Community Hospital	NY	$1,000.80	0.0%
Ohiohealth Corporation-Doctors Hospital Nelsonville	OH	$650.50	0.0%
Peacehealth-Peace Harbor Hospital	OR	$873.33	0.0%
Putnam Community Medical Center LLC – Putnam Community Medical Center	FL	$2,330.25	0.0%
Rowan Regional Medical Center Inc.	NC	$2,902.50	0.0%
Scott & White Memorial Hospital – Scott & White Hospital	TX	$3,308.00	0.0%
Seton Medical Center	CA	$2,144.33	0.0%
St. Bernard's Hospital Inc. – St. Bernard's Medical Center	AR	$966.00	0.0%
St. John Macomb Oakland Hospital – St. John Macomb Oakland Hospital Macomb Center	MI	$2,412.00	0.0%
St. Mary Mercy Hospital	MI	$2,497.80	0.0%
Taos Health Systems Inc Holy Cross – Holy Cross Hospital	NM	$2,998.00	0.0%
Teton Valley Hospital & Surgicenter	ID	$848.50	0.0%
The Memorial Hospital-Memorial Hospital	NH	$2,303.33	0.0%
Waldo County General Hospital – Waldo County General Hospital	ME	$2,491.25	0.0%

Source: PearlDiver Data Technologies, Inc.

Beth Israel Medical Center

Asked why he thought his facility was ranked amongst the top 25 in the U.S., Peter D. McCann, M.D., chairman of the Department of Orthopedic Surgery at Beth Israel Medical Center, told *OTW*, "We are able to provide excellent clinical outcomes due to the skill of our surgeons. In addition, the operative facility offers comprehensive and efficient ancillary care. And I should mention our low complication rate as well." Regarding his facility's average charge for this surgery—$1,237—Dr. McCann stated, "We achieve this through the efficient use of operative time, as well as competitive pricing of implants used in the surgery."

When it comes to getting patients discharged as soon and as safely as possible, Dr. McCann gives credit to the team: "Not only do we have skilled surgeons, but we have expert anesthesiologists who provide excellent, but minimal, anesthesia so that patients are not overly sedated."

Park City Medical Center

Si Hutt, an administrator at Park City Medical Center, told *OTW*: "Being located in an active mountain community, the incidents of ACL tears are much higher. But people come to Park City Medical Center (instead of going 30 miles away to larger hospitals in SLC [Salt Lake City]) because of the reputation of our surgeons and our hospital. We have orthopedic surgeons who are nationally recognized for their skill and quality and who have worked on

some very notable athletes. The hospital is part of Intermountain Healthcare, which also has a great reputation nationally, and Park City Medical Center itself has been recognized as a leader in quality outcomes and patient satisfaction. We focus on providing value, and our staff is truly committed to working with patients so that a challenging circumstance becomes a positive, healing experience. When you combine that with lower costs, an amazing new facility, and beautiful surroundings, why would you go anywhere else?"

When asked about their average charge for this surgery—$2,229—Hutt commented, "The Intermountain Healthcare system has a national reputation for providing high-quality care at a below average cost. In fact, that's our mission in everything we do and we are committed to it. We believe that quality care is actually less expensive and we strive to work in a setting of shared accountability for health—including the physician, the hospital, other health care services AND the patient. A recent study out of Dartmouth Medical School found that if all doctors practiced to the standard of Intermountain Healthcare, Medicare would cost 40% less."

Concerning how they manage to get patients discharged early and safely, Hutt noted, "A concerted, collaborative effort between physicians, nurses, physical therapists and our patients is key to our success. Consistency in utilizing evidence-based practice standards, setting realistic and measurable individualized patient goals, and providing education to our patients before and after surgery helps improve outcomes as well. At the appropriate time in the OR, the patient is given safe and therapeutic medications by the anesthesiologist to avoid such things as nausea, vomiting and pain, which can prolong the length of stay. RNs, PTs, and techs are actively engaged in the discharge process, understanding that the patient must be ready mentally and physically to be released to go home. Our pre-op, post-op and recovery process is very streamlined, but flexible enough to conform to the specific needs of each patient. Patient safety and satisfaction is at the top of each caregiver's priorities—our patients can sense the individual care they receive and feel positive about their experience, and are confident to return home."

This information is based on outpatient procedures within these facilities. The research was performed by PearlDiver Data Technologies, Inc., a company with a proprietary database that includes more than one billion patient records and includes Medicare (de-identified) and private payer data as well as specific industry data as compiled by PearlDiver's team of analysts. (PearlDiver is affiliated with *Orthopedics This Week*). ♦

Spine's Passion Play

By Jeff White

The Redemption of TranS1

TranS1, Inc. (TSON) CEO Ken Reali's proposed acquisition of Baxano, Inc. which was announced on March 4 is but the latest in his steps to resurrect TranS1 from the purgatory that is today's reimbursement confusion…and the revenue and market cap Hell that come with it.

Gaining a Religious Following Until Struck Down by Authorities

Following years of development and refinement, TranS1 launched AxiaLIF in 2006 for "…anterior supplemental fixation of the lumbar spine at L5 – S1 in conjunction with legally marketed facet and pedicle screws." Spine surgeons were increasingly committed to the benefits of minimally invasive techniques and NuVasive's XLIF launched a few years earlier was unable to treat L5 – S1, leaving no truly MIS (minimally invasive surgery) technique for as many as 40% of lumbar fusions. AxiaLIF's pre-sacral approach to L5 – S1 appealed to MIS surgeons.

Between 2006 and 2008, successful serial entrepreneur Rick Randall, then TranS1's CEO, converted an ever growing flock of AxiaLIF surgeons. Sales almost tripled in 2007 to $16.5 million with 81% gross profit margins and the company netted $86.7 million in the rare med device IPO. By the end of 2008, Randall and his team beefed up their product offering with AxiaLIF 2L for L4 – S1 fusion and facet screws for posterior fixation and reached an annual revenue run rate of $38 million.

Wikimedia Commons and Antonio Balestra

NASDAQ-listed TranS1 was the story most private spine companies wanted to be.

But by mid-2008 there was grumbling in the halls of power. Reigning AMA (American Medical Association), NASS (North American Spine Society) and payer executives were threatened by this new upstart who preached a less invasive, different way.

While TranS1 taught that AxiaLIF was but another approach to the spine for fusion reimbursable under existing CPT codes, payers found a loophole to deny coverage for what they deemed a "new procedure."

On New Year's Day 2009, AMA assigned new Category lll or "T" codes to AxiaLIF procedures…potentially a death sentence for this one-trick pony. Con-

fusion among TranS1's surgeons, staff and sales reps reigned in what truly was reimbursement purgatory: was AxiaLIF and its payment headed up….or down to what could be TranS1's eternal demise? What about the "legally marketed facet and pedicle screws" which AxiaLIF "supplemented"? How to bill them?

Indeed, TranS1's guidance to its sales reps included this: "*Effective January 1, 2009, the AMA implemented a Category III code which may describe the work involved in treating some AxiaLIF patients.*"

As payer denials and denying payers mounted, sales and market cap fell. From an opening day close of $25.40, TSON shares were down to $8.45 a year later, and below $4.00 by the time Ken arrived as President and CEO-apparent on January 2010. (Share price for the Baxano deal was $2.28; TranS1's fiscal recovery is yet incomplete.)

Ken Reali Takes Over

Ken arrived at TranS1 to find one leg of the company's strategy for revival almost in place: in January TranS1 signed a deal to distribute Life Spine, Inc.'s Avatar MIS pedicle screw system, ending the dependency on one technique, broadening the potential procedure base and potentially keeping competitive reps out of AxiaLIF cases.

But falling revenues demanded more radical action. Ken brought in a new CFO, Joe Slattery, from the TranS1 board and other management shakeups followed. Determining that it would "take a while" to straighten out reimbursement, he next slashed operating expenses by $10 million, which necessarily included cutting TranS1's direct sales force and terminating its futuristic nucleus programs. Dealing with payer backlash was the **only** priority.

Reali almost had a great year in 2011. It started with the terrific news that Humana had decided to cover AxiaLIF, driving an uptick in the share price and suggesting that the payer strategy coupled with new peer-reviewed papers was working. The company's discussions with Medicare Administrative Contractors and private payers were going well and VEO, TranS1's lateral access system, was about to launch. Finally the company's secondary public offering was priced and closed in September, netting the company more than $18 million.

I'm From the Government…(or, arrival of the Romans with the Sanhedrin)

As 2011 was nearing the finish line, on October 17, Reali and his team disclosed to Wall Street that Health and Human Service and its OIG (Office of Inspector General) arm had issued a subpoena under the federal healthcare fraud and false claims statutes, seeking TranS1 records from January 2008 to

Wikimedia Commons and David Friel

October 6 2011. Despite the company's best efforts to navigate the reimbursement maze that would result in its first local coverage decision (LCD) by a Medicare contractor by year's end, had TranS1 possibly run afoul of federal laws? Sellers dumped TranS1 shares the next day and the value of the company fell 44%. In January 2012 shareholders, surgeons and employees learned of the inevitable class action shareholders' suit. Surely, investors' shares were unduly devalued in all of this.

The only way forward was to bear this latest cross with the rest and continue with strategies that could redeem TranS1 among its many stakeholders: create AxiaLIF credibility, diversify, and halt the skid. All the while losing money.

2012: Progress Despite Record Losses

Head down under the heavy load, Ken and his team plowed through the obstacles in 2012. TranS1 opened its new training facility in February and in March AMA created a new CPT code just for pre-sacral interbody fusion where AxiaLIF is used, and would be effective January 1, 2013. The company completed its first prospective studies comparing AxiaLIF to other LIFs in August. In October it signed Beijing Jiade Sunshine as its Chinese distributor, complete with a stocking order big enough to negatively impact fourth quarter COGs (cost of goods) but also to help generate TranS1's first year-over-year (YOY) quarterly increase in years. And the good news kept coming.In December TranS1 announced a tentative agreement in principle to resolve the OIG investigation with no charges or implication of guilt and AMA announced the value for the Category 1 code for pre-sacral interbody fusion and revised certain related codes, effective 1/1/2013.

A new life, right?

Not yet. Confounded by the steepest decline in TranS1 sales yet AND $6.6 million in charges associated with resolving the OIG/DOJ (Department of Justice) investigation, TranS1 closed 2012 with a whopping $12 million fourth quarter loss and a record annual loss. At this rate, it would be bankrupt in a year. What else could be done to revive the company?

Baxano: Spending like Crazy

Ken Reali had been talking with Tony Recupero, Baxano's spine commercialization expert CEO since late 2010. Founded in the heart of Silicon Valley in 2005 when spine times were still good, Baxano launched iO-Flex in 2009 as an MIS facet-sparing decompression instrument for patients with stenosis. By then, reimbursers had already started twisting the payment screws. Reminiscent of TranS1's experience with AxiaLIF, iO-Flex received FDA permission to market via 510(k) but was handicapped by a lack of Level 1 randomized prospective data. Baxano spent heavily on several lower-level clinical studies but payers, in 2009, were beginning to demand higher levels of clinical evidence in order to pay for new technology. The fact of life in today's tight payer environment is that big companies can rely on momentum for a while, but little ones need data which means they need cash.

Despite raising $50 million in rounds B (September 2008) and C (June 2010) from A-list venture capital (VC) investors, Baxano found itself continually short of cash. Recupero and his team could not generate enough sales to reach critical volume cost-of-goods reductions fast enough to pay for their expensive marketing campaigns. (As all thirsting spine companies know, the DRGs for high volume decompression and laminectomies leave little or no room to bear and bury even mod-

erately-priced disposables). In July, the company laid off 20% of its workforce and reportedly would run out of money in 2Q 2013; break-even was never in sight.

With TranS1's biggest problems behind them and Baxano on fumes, Baxano's board of directors took the only deal that landed on their table—a crew-cut being better than the guillotine.

You can't exit if you're dead and in this case misery really did love company.

A Good Deal?

TSON shares have not moved since the deal was announced. This is, however, a great deal for both firms, *under the circumstances*. Baxano shares are worth more than zero and TranS1 shares, while diluted, have a much better chance for real growth.

The deal rescues Baxano investors from a total loss….the only upside they had left. In one of the most imaginative (some would say, desperate) deals in recent years, Baxano investors agreed to invest $15.3 million of a new $17.2 million TranS1 PIPE while surrendering Baxano for TranS1 stock currently worth ~$23 million, plus $550,000 cash. Baxano's investors are now in for ~$63 million net, but they will hold at closing a lot of TranS1 shares that are worth…well, a lot less than that but that have more chance of appreciating (let alone surviving) than Baxano shares. After the PIPE, they will hold more than a third of TSON shares. A 50% increase in TSON share price, more or less, will get their latest $15.3 million back, but to realize a "VC 5X return" on their total investment however, Baxano investors will need to seeTranS1's market cap exceed $1 billion.

That would be worth writing about.

Is TranS1 Back From the Abyss?

"Not really", says the Street, which has slightly devalued TSON shares since the announcement.

The deal does offer potential synergies that have all been reported and discussed and, let's face it, how bad a deal can it be for TranS1 who now has more products in the bag and more cash in the bank. But the dilution hurts and the numbers need a lot of improvement; TranS1 is hardly in great shape and will even be looking for more cash at this time next year.

Reali points out that the circumstances are ripe for improvement in the numbers. Both firms field hybrid U.S. sales organizations augmented by distributors. "We will have 34 directs for TranS1

and 24 from Baxano plus ~130 "accredited" (able to cover their own cases) Baxano distributors reps and "40-50" TranS1 distributors. Altogether, a pretty good footprint" says Reali. Few would disagree but the question as before is, how quickly can those directs exploit the bigger bag to pay for themselves? "With the continuing trend to MIS, the broader base of spine surgeons who are now customers (Baxano has about 150 spine surgeons using 300 iO-Flex systems per month), more procedures covered by our products and clear AxiaLIF reimbursement, we are in great shape going ahead. We are the only pure play spine MIS firm and we address $3.9 billion of the spine market." says the reason-to-be upbeat Reali.

TranS1 has a lot to do to hit or exceed the $28-32 million guidance that was recently offered, but at least everything is now in their own hands: Cross-selling to committed MIS surgeons, key evidence for the podium/publication strategy; effectively relaunching AxiaLIF; maintaining or increasing iO-Flex sales growth, becoming an important MIS player. Perhaps iO-Tome when fully launched will bring a novel MIS or mini-open facetectomy to mainstream TLIF's.

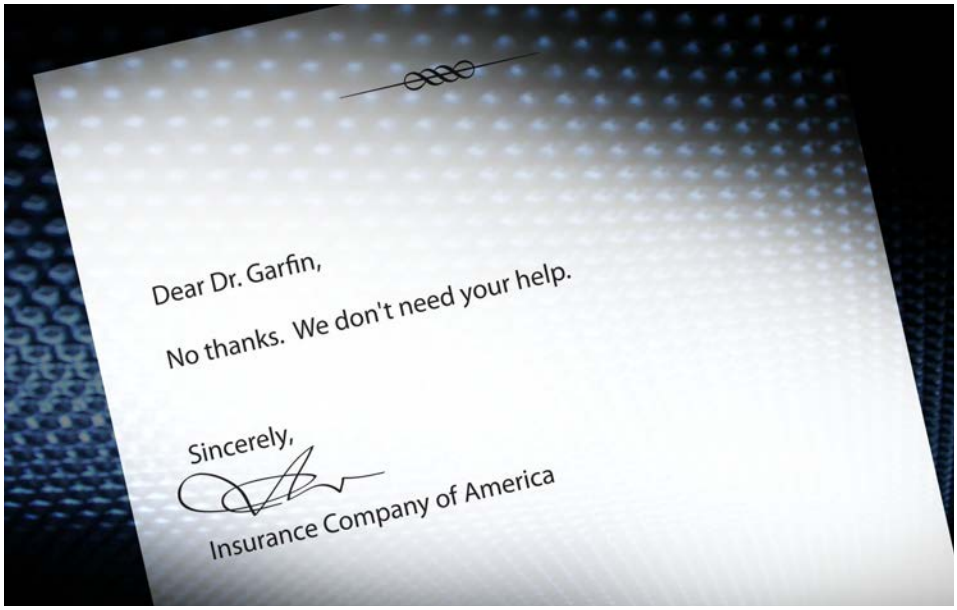
"We expect to be fully integrated and cross trained by the end of the year", says Reali "and while we have grown AxiaLIF coverage from 15 million to 100 million covered lives in the last year, there is still a lot of upside". But hopefully, no repeat of past reimbursement challenges. To that end, Reali has made it clear to anyone that will listen that, "…iO-Flex is NOT a new decompression procedure, it is a minimally invasive instrument to perform standard direct decompression."

Having shown his mettle as a CEO turnaround specialist, Reali can move into the upper echelon of spine CEO ranks if he can grow TranS1's sales and market cap, truly completing its redemption. ♦

Major Insurer Rebuffs Top Spine Surgeon… New Study Confirms—Again—Fusion Works!

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

President of Insurance Company to Steve Garfin, M.D.: We Don't Need Your Help Steven Garfin, M.D. is professor and chair of the Department of Orthopaedic Surgery at the University of California, San Diego. He is also president of the International Society for the Advancement of Spine Surgery (ISASS). These days, Dr. Garfin is hearing a lot of angst about the fact that doctors are less in charge of patient care. And to top it off, he says, surgeons' efforts to work with insurers are being rebuffed. Dr. Garfin, who is very involved in spine politics, tells *OTW*, "I was frustrated with these large, random swaths of denials, and I penned a letter to the president of one of the top five insurers in the country. In it, I offered to help form an advisory panel of ISASS surgeons. In return I received a letter saying, basically, 'We don't need your help. We have our own panel.' I have no idea if there are doctors on that panel. Is it really too much to ask for more transparency and doctor participation?"



RRY Publications LLC

Why to Advocate for Orthopedics and How "But I didn't go to medical school to become a politico," you say. Manish Sethi, M.D., assistant professor of orthopedics and rehabilitation at Vanderbilt University Medical Center, says, 'Wake up. It's time we face the fact that patient care is on the line. We must advocate for our patients.' Dr. Sethi, founder of the Vanderbilt Orthopaedic Institute Center for Health Policy, tells *OTW*, "I've just published a paper entitled, 'The Evolution of Advocacy and Orthopaedic Surgery.' In it my colleagues and I define the role of advocacy in medicine, specifically within orthopaedic surgery, explore the history of physician advocacy and its evolution, examine the various avenues of involvement for orthopaedic surgeons interested in advocacy, reflect on the impact of such activities on the future of orthopaedic surgery as it relates to hospital-physician alignment."

"There have always been disputes of patient care. From the 1500s to the 1800s there was a substantial debate over the role of doctors, and many people felt that physicians should be involved in all spheres of a patient's life. Political involvement on the part of physicians is not new…a doctor signed the Declaration of Independence, one of the first governors of New Hampshire was doctor, etc. It's time again for us to reach beyond the bedside and leave our tunnel vision behind."

"As a society we have come to believe that big government is going to solve our problems, resulting in an 'I don't need to get involved' attitude. For many years we have served patients well at the bedside, but in focusing too narrowly on this we created a vacuum where policy makers who have no idea what they are doing are running the show."

"What motivated my interest in advocacy? I come from a long generation of doctors. When I was a third year medical student my father was diagnosed with liver cancer. My dad had dedicated his entire life to medicine, often going so far as to go pick patients up and bring them to the hospital. During this horribly difficult time he was hit with a lawsuit. Although the suit was ultimately dismissed, it struck me that if such a thing can happen to my dedicated father, it can happen to anyone. It was then I knew that we had lost control of our profession. For me, advocacy is synonym of being a citizen of this country. Truly, who is going to solve this problem…those of us on the frontlines or the bureaucrats?"

"There are easy ways get involved: join your medical society, get to know your congressman or congresswoman, host or attend events. If possible, make financial donations or even run for office. We can do this! Remember that we have more of the nation's trust than the lawmakers do. Five years ago when I talking about this people thought I was crazy. Now I think the light has come on and more and more we are realizing that there's no way around getting involved."

Green Light: Lumbar Fusion for Low Back Pain What does the existing research—randomized controlled trials, prospective and retrospective nonrandomized trials, etc.—say about the efficacy of lumbar fusion surgery for chronic low back pain? Frank Phillips, M.D. and colleagues have found out. Dr. Phillips is with Midwest Orthopaedics at Rush, and is Professor of Orthopaedic Surgery and Director of Minimally Invasive Spine Surgery at Rush University Medical Center. He tells *OTW*, "This work, which was just published yesterday in *Spine*, was an attempt to provide a transparent and validated review of the literature to determine the value in what we do. We undertook an up to date systematic review of the literature regarding outcomes for spinal fusion for a diagnosis of low back pain with disc degeneration, arguably the most contentious diagnosis in terms of insurance reimbursement. Most previous studies relied on by the insurance industry are dated and include older fusion techniques or exclusively rely on Level 1 studies. Our study included more than 3,000 patients using strict inclusion/exclusion criteria. Surgical fusion was confirmed as an effective treatment strategy in this patient population."

"We included patients who had a primary diagnosis of back pain, and we used patient centered outcome measures such as the Oswestry Disability

Index and SF-36 and we required at least one year of follow up. Traditionally, payers have considered only Level 1 studies of nonsurgical versus surgical treatments. This is a flawed paradigm as in real world medicine, surgery is generally recommended only in patients that have failed conservative treatment. These should not be viewed as competitive treatments. Comparing these two groups doesn't make clinical sense and as in other surgical trials using patients as their own controls is a reasonable research approach."

"After reviewing over 1,000 papers, we found that 26 met inclusion criteria; we graded them by level of evidence. The clinical outcomes did not vary by level of evidence, confirming that the entire body of literature and not only Level 1 studies add to our evidence base. With this work we have shown that the literature as a whole is in support of fusion surgery as a viable treatment for reducing pain and improving function in selected patients with chronic lower back pain. Now we have to get insurers to pay attention to these results and provide similar levels of evidence and transparency to support their position on spinal fusion to ensure optimal patient care."

High-Grade Open Fractures Plaguing Developing Countries There is an ever-increasing problem of serious fractures in some countries…and it is compounded by the fact that delayed care results in high mortality and complication rates. And while the World Health Organization has acknowledged this as one of the most important global priorities there is insufficient data from low and middle-income countries that could help determine the exact level of the problem…and that could help focus research and treatment. Mohit Bhandari, M.D., professor and research chair in Orthopaedic Surgery at McMaster University in Canada, is helping to solve the problem. "My colleagues and I have undertaken a large, prospective cohort study that involves over 4,500 patients in India (our sample size will increase to 10,000). We are going with a low cost, fairly low technology, 'minimal dataset' approach to decrease the burden of data collection to only those critical questions about factors associated with major outcomes in fractures. Our primary outcome is death and major complications. We aim to determine whether patients who arrived at a hospital with a fracture across several public and private hospitals in India were alive or dead within 30 days (or suffered a major complication such as a reoperation or major infection). Our team presented the preliminary findings at the Orthopaedic Trauma Association meeting this year."

"The most significant obstacles we have encountered in our ongoing large cohort study are the assurance of accurate data, the lack of existing knowledge and infrastructure about research in many developing nations, and lack of large scale funders for this type of research. But we are progressing, however, and a year from now we expect to be recruiting actively in Nepal, India, Africa and South America towards our sample size goal of 50,000 patients."

"Thus far we have found that the number of nonorthopaedic injuries, fractures, open fracture, time to stabilization, and hospital type were significant predictors of mortality, reoperation, and infection; open fractures were the strongest predictor of early mortality. In sum, we must have consistent orthopaedic trauma protocols in order to improve the timing of care for severely injured patients in these countries." ♦

company

Orthofix's Plating System Addresses Vascularity Damage

Newly-minted Orthofix International N.V. President and CEO Brad Mason got to announce his first new product launch on March 20, 2013.

The Countours PHP (Proximal Humeral Plate) is being released through the company's international distribution network. The plating system, for the treatment of the proximal humeral fractures, consists of anatomically contoured left and right plates with a low head profile and is designed to decrease the risk of impingement, while providing minimal invasiveness of metal content in the humeral head.

"Since avascular necrosis is initiated by the fracture pattern, that almost unavoidably damages the delicate blood supply of the humeral head, Contours PHP has been designed to decrease the invasiveness in terms of metallic content in the humeral head and reduce further damages to its vascularity," stated in the company press release.

Mason said the launch of the system highlights the company's commitment to the trauma market. "With this internal fixation device, Orthofix now has a complete hardware offering, including a nail, plate, and external fixation system, for the repair of proximal humeral fractures."

According to the company, the device "provides enhanced stability through triangular configuration of the proximal screws, consisting of a Main Locking Screw and angulated Fine Threaded Screws." The system requires fewer and smaller diameter screws to be inserted in the humeral head, thereby reducing the amount of bone stock required to be removed and thus decreasing the risk of further vascularity damage. "Contours PHP can be easily applied as well as removed," continued the statement. The product launch is currently being rolled out in certain markets in Europe, the Middle East, and Africa.

The company says an additional benefit is that the system allows for easy application due to simple instrumentation and a straightforward operative technique. Many instruments are quick coupling for a very fast and handy usage with the power drill or the soft touch handle.

To see an animation of the device at work, click here: www.contoursphp.com.

—*WE (March 26, 2013)*

Orthofix/Countours PHP System

Invibio: New Regulatory Milestones

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Invibio Biomaterial Solutions' PEEK-OPTIMA family of biomaterials has achieved considerable regional regulatory milestones says Invibio's director of Regulatory Affairs, Craig Valentine. As of February 2013, the number of implantable medical devices manufactured from PEEK-OPTIMA and cleared for market in the U.S. reached 500, with more than 80 approved for market in China.

"The regulatory environment globally is more challenging than ever. Support of data and knowledge through the process can help device companies overcome regulatory barriers. We are committed to continuing our investments in resources to support medical device companies' regulatory submissions across global markets. Invibio maintains a Drug & Device Master file data at the U.S. Food and Drug Administration (FDA) and has specific test data required for both China and Japan available to customers on file. This data is utilized by the regulatory authorities and provides the verification of PEEK-OPTIMA's biocompatibility and biostability, which is supported by a dedicated global regulatory team," said Valentine in a March 14, 2013 news release.

"As demonstrated by these global regulatory milestones, PEEK-OPTIMA continues to set an industry standard for biomaterials biocompatibility and quality. Invibio's commitment to advancing medical device design innovation does not stop at our biomaterial capabilities. Our strong strategic alliances within the research and surgical community and across the global medical device industry, combined with our depth and breadth of biomaterials, and manufacturing capabilities enable Invibio to partner with our customers to access and accelerate their time to market in a challenging environment," said Valentine.

Asked where they go from here, Valentine told *OTW*, "PEEK-OPTIMA is already a truly global product, so that we are now supporting our clients with registrations in all of the BRIC emerging markets in addition to the established markets of North America, Europe and Japan."

Regarding their global regulatory team, Valentine commented to *OTW*, "In order to deliver regulatory support in all the key regions its necessary to put a team in place that is highly skilled, with a wealth of experience of the local regulatory requirements, and a proven track record of managing the regulatory challenges. This team is also supported by a network of local regulatory consultants who can supplement our internal knowledge when required. The major challenge remains the diversity of process, and the continual evolution of regulations that ensures we must work constantly to ensure our customers have sufficient support to progress with device registrations, particularly in the emerging markets. This, coupled with the increasing focus on the materials from a quality, regulatory and risk perspective resulting from the highly publicized PIP issue, will mean that the regulatory landscape for medical device manufacturers will continue to evolve. The Invibio regulatory team will continue to work with regulatory authorities in all the key markets to ensure we clearly understand new requirements from a material perspective, which will keep the pathway to market open for our customers irrespective of the strengthening of regulations."

—EH (March 26, 2013)

Zimmer's $150 Million Defense Department Order

Zimmer Holdings, Inc. has been awarded a $69.2 million contract to supply the Department of Defense with orthopedic products.

The award was a modification of the second option year of an existing contract and is a fixed-price with economic-price-adjustment. The contract is an indefinite-delivery/indefinite-quantity contract capped at $69.2 million for hips, knees, spine, and extremity "procedural packages, instrumentation sets and auxiliary products needed for implantation." The completion date is March 24, 2014.

Fool.com reported that the award "illustrates the high but hidden cost of America's wars in Iraq and Afghanistan" in that the Zimmer award was the second highest contract out of 18 contracts awarded on March 18, 2013.

The contract was issued through Defense Logistics Agency Troop Support, Philadelphia, Pennsylvania.

The instant contract is the second of four potential one-year "options" exercisable after the expiration of an initial one-year supply contract for the devices. That original contract, awarded in March 2011, was for $13.5 million. The first-year option, awarded last year, added $71.2 million in payments for Zimmer. The current award brings the total to just under $154 million with two option years to go.

Surprisingly, there was originally one proposal solicited with one response, according to the Defense Department.

—WE (March 25, 2013)

Wikimedia Commons and U.S. Navy photo by Mass Communication Specialist 2nd Class Gina Wollman

legal

OIG Warns PODs

The Office of Inspector General (OIG) fired a "Warning Shot" on March 26, 2013, for physician-owned distributors (PODs) that don't follow appropriate investor guidelines.

Image created by RRY Publications, LLC / Office of Inspector General

In a "Special Fraud Alert,, the OIG reiterates its longstanding position that it views PODs as "inherently suspect" under the anti-kickback statute. "The opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration," stated the Alert.

Former federal prosecutor Tom Beimers, now in private practice with Faegre Baker Daniel LLP told *OTW*, "It seems to me that that the OIG analysis is a fairly straightforward application of prior

relevant guidance. However, they frame the fraud alert in such a way as to provide a warning shot for PODs with certain characteristics, particularly related to variable ROI (return on investment) based on volume or value. Quite clearly such PODs may now become the subject of enforcement actions or whistleblower False Claims Act lawsuits."

In response to our inquiry, John Steinmann, D.O., founder of one of the first PODs, said members of the American Association of Surgeon Distributors (AASD) recognizes that the POD model "bears risk of abuse." He says his association has advocated for comprehensive legal and ethical standards so that the distributorships are established according to the OIG guidelines. "We are very happy that the OIG is creating clarity in defining characteristics of such distributorships that violate the public trust and are also happy that this alert confirms the appropriateness of the model for which we have long advocated. We look forward to the OIG defining this model through compliance program guidance."

The Alert notes that the OIG is particularly concerned when PODs exhibit any of the following suspect characteristics:

- *The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.*
- *Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.*
- *Physician-owners condition their referrals to hospitals or ASCs (ambulatory surgery centers) on their purchase of the POD's devices through coercion or promises,*
- *Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD.*
- *The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability to refer, recommend, or arrange for the purchase of the POD's devices.*
- *The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.*
- *The POD does not maintain continuous oversight of all distribution functions.*
- *The POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.*

PODs now capture around 10-15% of the U.S. spine market, according to Wells Fargo analyst Larry Biegelsen. Former government officials familiar with the POD model tell us that as long as PODs squeeze out distribution costs for payers and hospitals, their financial incentives will remain aligned with PODs and the model is likely to remain in existence. OIG is expected to issue a detailed report on PODs later this year.

To read the entire Alert, click here: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf

—WE (March 26, 2013)

large joints

Four Million Knee Replacements in U.S.

What percentage of U.S. adults, age 50 and older, are walking around on total knee replacements? Alexander M. Weinstein, of Brigham and Women's Hospital in Boston, and his colleagues utilized the OsteoArthritis Policy Model, combined it with data on the utilization of total knee replacement and came up with an answer.

HealthDay News reports the researchers estimated that the number of U.S. adults currently living with a total knee replacement is four million. This means that about 4.2% of adults, ages 50 years or older, have had a knee replacement. The prevalence of total knee replacement increases with age and is higher among females (4.8%) than males (3.4%). For females and males, the life-

Wikimedia Commons and Tenna Takahashi

time risk of primary total knee replacement from the age of 25 years is 9.5% and 7.0%, respectively. More than half of U.S. adults who have been diagnosed with knee osteoarthritis will undergo total knee replacement.

"While total knee replacement is a remarkably successful treatment for individuals with end-stage knee osteoarthritis, our findings emphasize the large public health burden posed by the millions of adults in the U.S. living with total knee replacement," the authors wrote.

—BY (March 25, 2013)

TKR Surgery No Impediment to Work

This is good news for TKR patients. Ninety-eight percent of those who were working prior to their joint replacement surgery returned to work. And 89% did not just go back to work, they returned to their previous positions. This is the result of a survey conducted by an independent third party of more than 660 TKR patients, ages 18 to 60, from five major medical centers 1-5 years following their surgery.

The investigators found that nearly 75% of patients (493) were employed during the three months prior to their TKR and that 98% returned to work after surgery. Of these patients, 89% successfully returned to the job they had prior to surgery. The return to work rate was 95% among sedentary employees, 91% among those in jobs deemed light; 100% in medium jobs, 98% in heavy jobs, and 97% in very heavy jobs. Men were more likely to have worked during the three months before surgery (83% versus 70%) but of those patients the rates returning to work after surgery were similar (96% of men versus 99% of women).

"When pain and suffering from end-stage degenerative joint disease of the knee compromises a patient's ability to maintain gainful employment, total knee replacement is successful in keeping the patient in the work force," said lead study author and orthopaedic surgeon Adolph V. Lombardi, Jr., M.D.. "Returning patients back to work not only gives the patient a sense of fulfillment, but also is economically beneficial to our society."

In a similar study of TKR patients at a large Swiss hospital researchers found that, prior to surgery, 39% of the patients reported an active lifestyle compared to 55% at five years postoperative. They found that medical comorbidities and the patient's preoperative activity level substantially influenced physical activity five years post surgery. The study authors reported that, in the last decade, the proportion of patients with an active lifestyle before and after THR increased by 10%.

The lead study author Anne Lübbeke-Wolff, M.D., a Swiss orthopaedic surgeon, said, "Surgery substantially and durably improved physical activity levels in men and women of all age categories, but the level remained somewhat lower than just before the onset of osteoarthritis symptoms. In most instances, patients who had previously participated in activities such as bicycling, bowling, golf, mountain hiking or swimming, and who wished to continue them after surgery, were able to return to these activities." The study authors presented their research at the 2013 annual meeting of the American Academy of Orthopaedic Surgeons.

—BY (March 25, 2013)

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Better Sex With THR and TKR

As if arthritis sufferers need another reason to get a hip or knee replaced, research presented to the 2013 annual American Academy of Orthopaedic Surgeons (AAOS) meeting found that joint replacement improved sexual function for 90% of the recipients. For the study 147 patients under the age of 70 who were scheduled for either a hip (THR-total hip arthroplasty) or knee (TKR-total knee arthroplasty) replacement agreed to participate. They filled out three questionnaires—one prior to their surgery, another at six months and a final one a year post surgery. Sixty-five percent of the patients completed all three surveys.

The group of patients included 68 men and 78 women with a mean age of 57.7 years. Prior to their surgery, 67% of the patients reported physical problems with sexual activity. Their problems broke down to 67% pain, 36% stiffness; 49% reduced libido; and 14% inability to attain a proper position. Ninety-one percent of the participating patients reported psychological issues related to their osteoarthritis including 91% diminished general well-being, and 53%, diminished sexual self-image.

Following the surgery, 42% of the patients reported an improvement in libido; 41% reported increased intercourse duration; and 41% reported increased intercourse frequency. Eighty-four percent of the patients reported improvement in their general well-being, and 55% improvement in their sexual self-image.

Sixteen percent of patients reported that their joint replacement surgery adversely affected their sexual function, which was primarily due to a fear of damaging the replaced joint. Overall, 90% of THR and TKR patients reported improved overall sexual function, with a slightly higher rate of improvement after THR than TKR. More females reported improvement after THR than did males.

—BY (March 24, 2013)

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trauma

Amputation Rate—A Racial Issue?

Is it possible that race could be a factor in the decision to amputate a leg? Chris Kaiser, cardiology editor of *MedPage Today*, writes that a recent study found data which indicates that African American patients have greater odds of undergoing amputation than do white patients despite access to high rated hospitals or above average incomes patient income. Tyler S. Durazzo, M.D. and colleagues at the Yale University School of Medicine conducted the study and published it online in the journal *Jama Surgery*.

Wikimedia Commons and Beatrice Murch

Kaiser noted that in hospitals with the greatest capacity to perform revascularizations, African American patients had a 98% higher probability of undergoing amputation for critical lower limb ischemia than did white patients, independent of all other variables. Income seemed to make no difference. While both African American patients and white patients with higher incomes had a better chance of revascularization, even African American patients from the wealthiest ZIP codes were disproportionately more likely to undergo an amputation.

They found that African American and Hispanic patients both had greater odds of undergoing an amputation compared with whites, but Hispanics were less likely to undergo amputation compared with African Americans (34% Whites versus 48% Hispanics versus 56% African Americans). Kaiser reported that the only two variables with more odds of leading to an amputation, than being African American, were having gangrene and needing repair of a previously revascularized artery. "Race independently influenced the treatment decision more than insurance or socioeconomic status," the researchers said.

The study included 774,399 patients with a primary diagnosis of critical lower extremity ischemia from 2002 to 2008. A total of 38% underwent amputation, and 62% had revascularization. The mean age was about 70, and there were more African American women compared with white or Hispanic women.

Commenting on the study Karl Illig, M.D., the University of South Florida, Tampa, said that while provider bias could not be excluded, he suggested that genetic differences between races could be an explanation Kaiser quotes him as saying, "It is politically dangerous to raise the issue of consistent biologic variability between groups, but such variability unequivocally exists for certain genetically determined entities."

Illig added that if this possibility is ignored, the result may be inferior care because the "true problem" is not fully understood or recognized. The cause of disparity may be provider bias, but the possibility of genetic differences must be investigated "to provide the best possible care for all our patients."

—BY (March 25, 2013)

extremities

Integra Adds New Shoulder Repair System

Integra LifeSciences Holding Corporation has received 510(k) clearance from the FDA to market the latest addition to its shoulder product line, the Proximal Humeral Fracture Plate System. The company plans a controlled release of the product during 2013.

The company release says that the Integra Proximal Humeral Fracture Plate System offers two plate designs to address varying degrees of complex proximal humeral fractures. The designs include a GT Plate and LP Plate in multiple anatomic left and right plate options. Both plate designs allow for varying screw diameters and lengths in locking, non-locking and lag screws options.

"We are very excited to introduce our new Proximal Humeral Fracture Plate System. Not only does the system expand our shoulder product family, but the plate design also has some unique advantages, including a four screw hole option for calcar screws that allows for solid fixation in the calcar neck and provides humeral head support," said Bill Weber, Integra's Vice President and General Manager, Extremity Reconstruction.

The company estimates that approximately 108,000 shoulder fixation procedures will be performed on patients 65 years and older in the U.S. this year. A proximal humeral fracture is the third most common fracture reported in emergency rooms. Over half of all humeral fractures that are surgically treated are corrected using humeral plating systems.

—BY (March 25, 2013)

Integra LifeSciences Holdinc Corporation

reimbursement

No Foolin'—2% Medicare Cuts on April 1

On March 28, 2013, the Centers for Medicare and Medicaid Services (CMS) published the latest directive on mandatory payment reductions in the Medicare FFS program under "Sequestration"

As required by law, President Obama issued a sequestration order on March 1, 2013 requiring across-the-board reductions in federal spending.

In general, Medicare FFS (fee for service) claims with dates-of-service or dates-of-discharge on or after April 1, 2013, will incur a 2% reduction in Medicare payments. Therefore, to prevent making overpayments, interim and pass-through payments related to the Medicare cost report will be reduced by 2%. Beginning April 1, 2013 the 2% reduction will be applied to Periodic Interim Payments (PIP), Critical Access Hospital (CAH) and Cancer Hospital interim payments, and pass-through payments for Graduate Medical Education, Organ Acquisition, and Medicare Bad Debts.

Questions about reimbursement should be directed to your Medicare Administrative Contractor.

—WE (March 29, 2013)

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Device Tax Repeal False Alarm

Device manufacturers got a false alarm in mid-March when the U.S. Senate voted overwhelmingly to repeal the 2.3% medical device tax.

Unfortunately, the vote was meaningless, as the measure was part of a Democratic spending bill that has no chance of passing the Republican-controlled House of Representatives. The byzantine rules of order of Congress don't allow to just simply agree on one thing. The budget resolution is not binding, so even if the Senate resolution is reconciled with a competing House version, *The Hill* reports the device tax would still be in effect.

Senate Finance Committee Chairman Max Baucus of Montana, whose committee controls tax policy, voted "no" on the amendment. The bill was sponsored by Democrat Amy Klobuchar of Minnesota and Republican Orrin Hatch of Utah.

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But the vote wasn't a total waste of time as lawmakers made it clear they don't like the tax and get to go back to home to their constituents and say they voted to repeal the tax.

The Hill reported that Republicans quickly claimed the vote as a partial victory in repealing the health care law. "Today's bipartisan vote to repeal the medical-device tax is an important step in the right direction," Senate Minority Leader Mitch McConnell of Kentucky said in a written statement.

Senators from both parties can't resist offering changes to modify the U.S. health care system through amendments to the proposed budget. About 80 of the roughly 400 proposed amendments pertained to healthcare as of Friday, March 22, with about 30 modifying President Obama's health care law and three curbing abortion rights.

Senate Majority Leader Harry Reid of Nevada said that he would seek to limit debate to between 25 and 35 of the proposals, meaning most will not see floor action

Device companies say the tax, which applies to sales rather than profits, is unfair. Supporters of the law say device companies will get new customers, but device lobbyists argue that most of the patients who need devices are older and already covered by Medicare. Hospitals, meanwhile, have countered that, because they had already agreed to give up $155 billion in the form of Medicare payment cuts over 10 years to help pay for the health law, other sectors should contribute.

It was all for nothing. Just move along. Nothing to see here.

—WE (March 28, 2013)

Study Reveals Outrageous Pricing Variations

How much do spinal implants—the screws, plates and cages used in spinal surgery—cost a hospital? A study, presented at the recent AAOS conference and reported on by Nancy Walsh, staff writer for MedPage Today, found wide differences in what hospitals paid for similar devices. In their study Samuel Bederman, M.D., Ph.D., and Sohrab Pahlavan, M.D., both of the University of California Irvine, examined the hospital purchasing records for a large consortium of academic medical centers across the country. They wanted to find out the differences that exist in the cost of three commonly used spinal implants—pedicle screws, anterior cervical plates and posterior interbody cages.

Walsh reported that, for their study, the two investigators examined 181 records from 45 centers for pedicle screws, 158 records from 41 centers for cervical plates and 102 records from 33 centers for the interbody cages. They discovered that while the mean price of a pedicle screw was $878, the range went from $400 to $1,843. For anterior cervical plates, the mean price per item was $1,068, with a range of $540 to $2,388. And for the interbody cages, the mean was $2,975, with an almost eight-fold variation in cost for the same device, with ranges from $938 to $7,200.

Bederman reported that hospitals and manufacturers negotiate their prices, but that hospitals are handicapped by the fact that they are not permitted to share the prices they have agreed on with other medical centers. "One hospital can't just call up another and ask what they are paying for a specific type of implant in the hope of getting the same price," Bederman wrote.

Walsh quoted Bederman as saying, "What is needed today is more transparency in the system. We're all in this together—hospitals, surgeons, and implant companies. This closed-door policy of no one telling anyone else what implants cost needs to be addressed to reduce some of the variation and to help limit healthcare expenditures overall."

—BY (March 25, 2013)

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spine

It's 10,000 and Counting at Amedica

Amedica Corporation has now implanted 10,000 of its Valeo Interbody Fusion Devices in patients located in ten countries worldwide, according to a company press release. The Valeo Interbody Fusion Device System is made of Amedica's proprietary Silicon Nitride ceramic technology and is used during surgical procedures to treat spinal disorders such as spondylolisthesis, scoliosis, severe disc degeneration, or spinal fractures.

Company officials say that because of the device's record of promoting superior new bone growth and its antibacterial properties, surgeons at leading hospitals worldwide are increasingly relying on it to increase the probability of fusion in their patients. The first time a surgeon used the company's proprietary silicon nitride implant was in May of 2008, according to a company spokesperson.

"In my four years of experience with Silicon Nitride Interbody Fusion Devices, I've seen the material exceed the capabilities of poly-ether-ether-ketone (PEEK) or titanium (Ti), resulting in better fusion, which translates to better results for my patients," said Grant Skidmore, M.D., of Neurosurgical Specialists, Inc., in Norfolk, Va. "As a spinal surgeon, my paramount concern is getting my patients back to their daily activities as soon as possible. Patients who I've treated with Valeo implants have had a quicker recovery time compared to traditional implants."

The Valeo Interbody Fusion Device System includes cervical and lumbar implants designed to participate in the fusion process, optimizing patient outcomes. The implants are semi-radiolucent allowing surgeons to ascertain exact placement intra-operatively and improve post-operative monitoring. Amedica representatives say that Valeo Interbody Fusion Devices do not cause MRI or CT artifacts which can make imaging interpretation difficult.

"The success of the Valeo Interbody Fusion Device System is a testament to the proven safety and effectiveness of our Silicon Nitride technology," said Eric K. Olson, President and Chief Executive Officer of Amedica. "As we continue to work toward a new standard of care for interbody fusion devices, we are pleased to see a continued increase in physician adoption. We are greatly encouraged for the future of this technology."

Amedica, located in Salt Lake City, Utah, is a privately held, private equity backed company founded in 1996 by orthopaedic surgeons and ceramicists. The company is ISO 13485 certified and its spine products are both FDA cleared and CE marked.

—BY (March 25, 2013)

Courtesy of Amedica

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