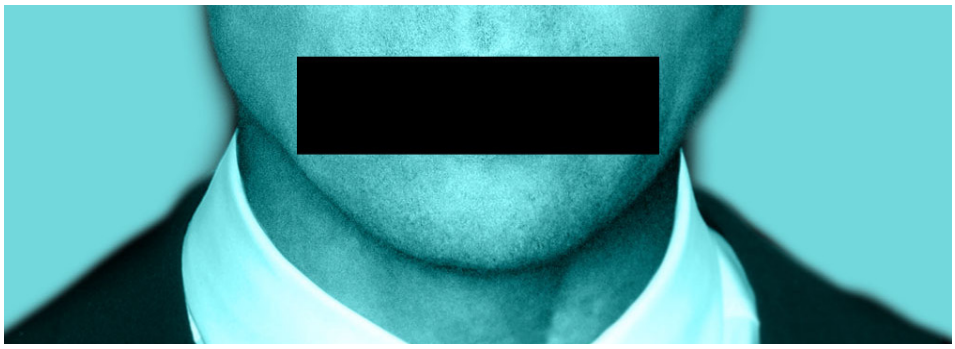
VOLUME 8, ISSUE 40 | DECEMBER 18, 2012

Orthopedics This Week

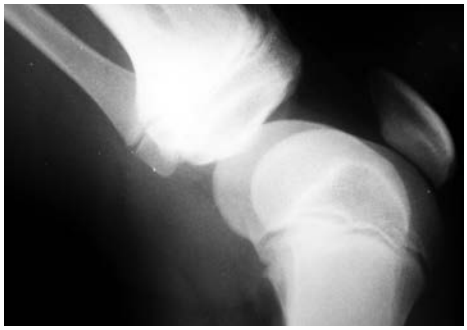
week in review

4 The Re-Boot of Alphatec Spine ♦ After 4 CEOs, maybe its time for a reboot at Alphatec. With the lowest price to sales in orthopedics, Alphatec has very little support on Wall Street. So, why would Cross, the former CEO of DJO, step into Alphatec? The answer is fascinating. Call it déjà vu all over again.



7 Off-Label Prohibition, An Inconvenient Lie ♦ Sales rep off-label discussion protected by the First Amendment? Most definitely say federal appeals court judges. But will the Supremes make this settled law of the land? They will get their chance to review but in the meantime possibilities for medical product education and innovation just got brighter.

11 Barrack V. Stulberg: Head to Head Over Cutting Blocks ♦ Patient specific cutting blocks… "Radiographically we couldn't prove a benefit," says Robert Barrack. "We were slightly better with standard instruments than with the patient specific instrumentation (PSI)." David Stulberg says, "PSI deserves a careful look because there is a clinical advantage."



15 Socio-economics Trumps Design in TKA Outcomes ♦ Socio-economics Trump Design in TKA Outcomes…50% Infection Jump From Embolizing Veins…Placebo Beat HA in Thumb Arthritis Study

breaking news

18 Breakthrough in **Arthritis Research**

Sales Leadership Changes at **NuVasive**

New Robotic Knee Surgery Device Hits Market

SI-BONE Hits 5,000 Patient **Milestone**

UnitedHealthcare Executive Bolsters **Zimmer's Board**

Nawana Lands COO Role at **Alere, Inc.**

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: All in all, the last 30 days have been good for orthopedic equities with the average price up 3%. Some companies, like SMA, ATEC and NUVA rose at solid double-digit rates. Excellent way to end the year. Readers sometimes ask: What does it take to make the Power Rankings? Answer; low valuations, solid earnings and market support due to innovation and sales growth prospects.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Symmetry Medical	5.63%	15.36%	Symmetry, by most analysts' accounts, ended 2012 with a 15% sales increase and an EPS of $0.18 vs. $0.01 last year.
2	5	Integra LifeSciences	13.73	5.55	Integra, say the analysts who know it best, grew sales about 7%. Earnings, says Wall Street, probably rose by the same %.
3	2	Conmed	10.39	4.16	The fourth quarter, say Wall Street's analysts, was CNMD's best of the year with sales rising almost 8% YOY.
4	4	Zimmer	26.37	4.54	Goldman Sachs upgraded ZMH last week. Organic growth is essentially non-existent. Time to grow by strategic acquisitions.
5	3	Stryker	23.68	6.61	Goldman also upgraded SYK last week. Same story. Time to use the cash on the balance sheet to create strategic growth opportunities.
6	6	NuVasive	7.08	10.23	Great news from Japan...new regulatory approvals on the way. Upgrades sales management. Need to get growth revved up again.
7	9	Exactech	8.64	1.42	Exactech, say the analysts, will report 8% sales growth and 40% earnings growth to end the year.
8	8	Johnson & Johnson	25.58	2.05	Barclay's analyst says that growth is improving in all three of JNJ's businesses—including, interestingly enough, DePuy.
9	10	ArthroCare	18.04	5.58	Pretty meager growth and an earnings drop expected for Q4. Now that ARTC is stable, time to find growth opportunities.
10	7	Medtronic	28.65	2.67	2% sales growth to end the year; 4% earnings growth. Hopefully 2013 will mark the beginning of a higher growth global MDT.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$1.26	$116	23.97%
2	MiMedx Group	MDXG	$3.26	$283	22.56%
3	Alphatec Holdings	ATEC	$1.84	$167	22.26%
4	Symmetry Medical	SMA	$9.54	$351	15.36%
5	Bacterin Intl Holdings	BONE	$1.29	$55	10.26%
6	NuVasive	NUVA	$14.66	$638	10.23%
7	CryoLife	CRY	$6.08	$167	7.42%
8	Stryker	SYK	$55.78	$21,208	6.61%
9	TranS1	TSON	$2.74	$75	5.79%
10	ArthroCare	ARTC	$33.10	$923	5.58%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Globus Medical	GMED	$11.76	$1,072	-13.78%
2	MAKO Surgical	MAKO	$12.46	$572	-6.39%
3	RTI Biologics Inc	RTIX	$4.26	$238	0.24%
4	Orthofix	OFIX	$36.83	$712	0.99%
5	Exactech	EXAC	$16.38	$218	1.42%
6	Johnson & Johnson	JNJ	$70.69	$195,900	2.05%
7	Tornier N.V.	TRNX	$16.80	$701	2.13%
8	Medtronic	MDT	$41.86	$42,335	2.67%
9	Wright Medical	WMGI	$20.47	$812	2.86%
10	Conmed	CNMD	$27.06	$771	4.16%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$36.83	$712	12.24
2	Medtronic	MDT	$41.86	$42,335	12.28
3	Zimmer Holdings	ZMH	$67.26	$11,670	12.98
4	Johnson & Johnson	JNJ	$70.69	$195,900	14.00
5	Stryker	SYK	$55.78	$21,208	14.09

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$20.47	$812	63.97
2	NuVasive	NUVA	$14.66	$638	52.36
3	Symmetry Medical	SMA	$9.54	$351	41.48
4	CryoLife	CRY	$6.08	$167	21.71
5	RTI Biologics Inc	RTIX	$4.26	$238	20.29

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$36.83	$712	0.87
2	Globus Medical	GMED	$11.76	$1,072	1.24
3	Conmed	CNMD	$27.06	$771	1.25
4	Exactech	EXAC	$16.38	$218	1.38
5	Zimmer Holdings	ZMH	$67.26	$11,670	1.39

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$20.47	$812	6.31
2	NuVasive	NUVA	$14.66	$638	5.64
3	CryoLife	CRY	$6.08	$167	5.43
4	Symmetry Medical	SMA	$9.54	$351	3.46
5	Smith & Nephew	SNN	$53.98	$9,744	3.12

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.84	$167	0.84
2	Symmetry Medical	SMA	$9.54	$351	0.98
3	Exactech	EXAC	$16.38	$218	1.06
4	Conmed	CNMD	$27.06	$771	1.06
5	NuVasive	NUVA	$14.66	$638	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.26	$116	101.11
2	MiMedx Group	MDXG	$3.26	$283	36.44
3	MAKO Surgical	MAKO	$12.46	$572	6.77
4	TranS1	TSON	$2.74	$75	3.90
5	Globus Medical	GMED	$11.76	$1,072	3.23

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

The Re-Boot of Alphatec Spine

By Robin Young

Wikimedia Commons and Aeknier/RRY Publicaitons

Somewhere near the bottom of the valuation pile lays Carlsbad, California, spinal implant manufacturer Alphatec Spine, Inc.. By nearly every measure of a company's value, Alphatec is a dusty bargain bin asset that has been so cheap for so long, buyers can't imagine that it would ever be anything else.

Sales this year will come in somewhere around $192 million. The products that generate those sales include the Trestle Luxe anterior cervical plate, MIS products like the ILLICO fusion system and a pretty full line of biologic products like PureGen, AlphaGRAFT and Ahphatec NEXoss.

Other public spine companies, NuVasive, Inc. or Globus Medical, Inc. for example, report profit margins of between 2% and 17% of sales. Alphatec, on the other hand, lost $2.5 million on $47 million in sales last quarter for a minus 5.3% of sales profit margin.

The stock market could not be any clearer in its assessment of Alphatec. At a market capitalization of $156 million, the company is valued at around 0.79 times revenues. Stock market buyers, in other words, are only offering 79 cents for every dollar of Alphatec sales.

By contrast, the average orthopedic company is attracting $2.79 for every sales dollar. Why the difference? Earnings. One Alphatec sales dollar loses about 5 cents. One average orthopedic company sales dollar makes 20 cents. Without earnings, Alphatec's sales are just not that valuable.

The Silk Sow

There is an old saying. If you want to make a silk purse out of a sow's ear, start with a silk sow. Les Cross, the fellow who is largely credited with taking DJ Orthopedics, a bracing company, from stock market obscurity as a division of Smith & Nephew to the darling of Wall Street in two years, decided to take over day-to-day operations of Alphatec Spine.

When Les looked at Alphatec, did he see a silk sow? "Alphatec has always been an innovation expert and when I looked at the company I saw several key products that can drive revenue," said Cross.

Les Cross

Les is now 61years old. For 40 years he has labored in the orthopedic trenches and has certainly earned the privilege of enjoying his boat off the San Diego coast or wherever breezes are soft and the putting greens well manicured. "It's true. I was happy sailing my boat in Cabo after my retire-

ment from DJO." So why jump in at Alphatec? "The similarities between DJO and Alphatec convinced me that I could change the direction of the company by applying lessons learned from my DJO days," said Cross.

A Snake-Bit Company

Since entering the public market, Alphatec Spine has been at the receiving end of a string of unfortunate events. Its June 2006 IPO, for example, was snake bit from the start. Originally HealthpointCapital, the private equity firm which owned Alphatec, hoped to sell shares for $13 to $15 each. Then the company's underwriters, Deustche Bank Securities and First Albany Capital, strong armed Healthpoint to lower the price to $11 to $12 per share. Literally on the effective date, the final price was set at $9. Even that price didn't hold.

At the closing bell on its first day of trading, June 12, 2006, Alphatec's stock landed uncertainly at $8.60 per share. For the next two and half years sellers dominated ATEC's trading and the stock slid to a previously unimaginable $1.25 per share. Bottom for Alphatec came in early 2009.

With a kind of morbid fascination, analysts who weren't in the underwriting group watched ATEC try to find purchase on that slippery slope. By early 2009, most investors had given up on ATEC. For Alphatec's employees, who got up every day to do the essential work of a spinal implant supplier, those two years were gut-wrenching. Two CEOs came and went.

It seemed at the time as if the orthopedic market was witnessing a particularly rare event in ATEC's collapse. But, point in fact, one other orthopedic company had endured an equally remarkable and ignominious birth as a public stock.

Les Cross

That company was DJO. And its CEO was Les Cross.

Déjà Vu All Over Again

DJO (formerly Smith & Nephew's Don Joy Orthopedics) came public four years before Alphatec's own stumbling attempt. DJO's IPO price was $17 per share—remarkably close to Alphatec's proposed price of $15 per share. DJO's sales that year (2002) were $183 million (Alphatec's sales this year will be about $190 million). DJO lost $15 million that year (Alphatec is expected to lose between $10 to $15 million this year).

While Alphatec's post-IPO swan dive was larger in dollar terms—$490 million in lost shareholder value that first year as a public company versus DJO's $250 million—the pain index for shareholders and employees was at the same level of public company hell.

For Les Cross, Alphatec has an eerie sense of déjà vu.

"Both Alphatec and DJO have always had competitive product lines that are capable of driving consistent growth. That is one similarity. But another similarity is that both companies have faced challenging times when they were not executing on all cylinders and their growth waned as a result," comments Cross today.

At DJO of 2002, Cross used a two pronged strategy to turn the company around:

1. Squeeze costs out of the operations and turn a profit as soon as possible
2. Bolt on interesting **and accretive** technology companies.

Roughly two quarters after Cross and his team went to work, the company reported a profit and Wall Street buyers began returning to DJO. Twelve months after Cross took on DJO's CEO job, his company's stock hit the strato-

sphere—$29.00 per share—which represented a 10-fold increase in a single year.

In 2002 Cross reported a $15 million loss on $183 million in revenues. In 2003 he reported a profit of $12 million on sales of $198 million. Three years after ***that***, private equity powerhouse Blackstone Capital paid $1.6 billion or $50.25 per share for his company.

$1.6 billion for a bracing company… whose average medical device product sells for $70. "Compared to DJO, Alphatec's products are much more expensive. We can ring the cash register a lot easier here," say Cross.

Les Cross' Reboot of Alphatec

To Cross, Alphatec has more innovative products which sell at higher profit margins than DJO during his tenure there. He specifically points to Alphatec's commitment to biologics products and such creative implants as the Osseoscrew and the ILLICO MIS system. Cross also notes that Alphatec's product gross profit margins are 60% of sales versus DJO's 56%.

"I believe Wall Street gets excited about consistent growth regardless of the business that drives that growth. When I joined Alphatec as CEO, the company was in the middle of a very difficult spine market that is well characterized today. The first thing we needed to do was to ensure that everyone operated with a sense of urgency and felt accountable for their performance contributions," remembers Cross. "We made several changes in this regard and I think we have a much more aligned culture today."

Pulling a page from his DJO experience, Cross said "At Alphatec we've looked at the company's processes across the organization, starting with our process for developing new products internally. It was clear that we have a very talented R&D group, but that they were working on too many projects simultaneously. So we focused the R&D resourcing to those few projects that would have greater chances for near-term commercial success."

Within one year of taking DJO public in 2002, Cross bought his first company—Orthologic, a supplier of bone stimulation products. Over the next four years Cross and his team at DJO would bolt on another four companies—all of which were accretive to earnings.

Similarly at Alphatec, within months of taking over as CEO, Cross purchased Phygen LLC, a small spinal implant manufacturer in southern California. "It's no secret that if you want to grow your spine business, we need to add more spine surgeon customers and the Phygen acquisition fits this strategy nicely," said Cross when asked about Phygen.

But, at the end of the day, Cross's legacy at DJO was finding that delicate balance between aggressive streamlining operations/driving efficiencies and accelerating sales.

Already, Cross is pointing to some changes at Alphatec. "On the operational side of our business, we made significant progress in 2012 to drive lean practices throughout our U.S. supply chain and in doing so achieved our $2 million annualized savings goal that we set at the beginning of the year."

The Future

"Our focus, as it was at DJO, is on lean operations. The secret to our success at DJO was the experts we brought into the company. Like our CFO, Vicki Capps. And Luke Faulstick, our VP of Operations at DJO. I put Luke on Alphatec's board."

By his second public year at DJO, Cross and his team posted a 6% profit margin. If he pulls the same rabbit out of a hat at Alphatec, his company will be the second most profitable public spinal implant company.

And if Wall Street responds to Cross' efforts at Alphatec as it did to the very same plan at DJO nearly a decade ago, then Alphatec is no longer a bargain bin asset. It is a diamond in the rough. ♦

Orthopedics This Week

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Off-Label Prohibition, An Inconvenient Lie

By Walter Eisner

RRY Publications LLC

The government can't make a criminal out of a medical sales rep for speaking truthfully about his or her product.

That's the 2-1 split panel verdict of a U.S. Court of Appeals in the case of U.S. v. Caronia and seriously questions the basis for prohibiting off-label marketing of medical products. *(See image on next page)*

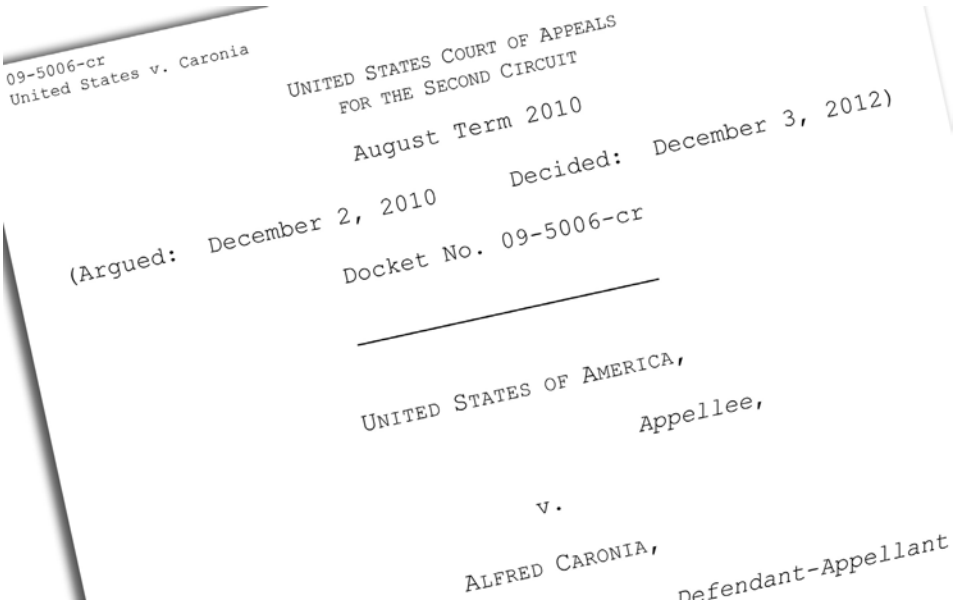
This all began in 2005 when a government sting operation caught Alfred Caronia discussing an unapproved uses of a drug with a doctor. On November 30, 2009, he was convicted for conspiring to "introduce a misbranded drug into interstate commerce."

By December 3, 2012, the U.S. Appeals Court panel in New York overturned his conviction. The panel's decision came as either a shock or relief, depending on where you sit and, according to the dissenting judge, "calls into question the very foundations of our century-old system of drug regulation."

Caronia's lawyer, Jennifer McCann, told *OTW* that she believes the panel's ruling also applies to medical device companies.

Off-Label Costs

The specter of off-label communications informs every interaction between physicians and medical device and drug makers. FDA staffers comb the aisles of every major device and drug meeting looking for off-label violations. Companies are frequently sent warning letters about misbranding products.


09-5006-cr
United States v. Caronia

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2010

(Argued: December 2, 2010 Decided: December 3, 2012)

Docket No. 09-5006-cr

UNITED STATES OF AMERICA,

Appellee,

v.

ALFRED CARONIA,

nefendant-Appellant

Caronia 2d Circuit Slip Opinion

Industry spends significant resources to comply with FDA rules related to off-label marketing. The government goes to great lengths to assure drugs and devices are only marketed for the indications on the labels and the plaintiff's bar uses the off-label use of a product in lawsuits against physicians and companies. Insurers have denied payments for off-label use and the Justice Department has used off-label use in pursuing false claims cases.

The restrictions are there to fulfill the government's role of protecting the public from unproven and unsafe products.

However, off-label use by physicians is not prohibited by law because it's considered the practice of medicine. Only manufacturers and their employees are prohibited from speaking about off-label uses.

"The Sting"

The Caronia "sting operation" involved the government wiring up an informant and physician named Stephen Charno, M.D. to catch Caronia telling him about legal and truthful off-label uses of his company's product.

Think about that for a minute. The government went through the time and expense to wire up a physician to catch a drug rep providing truthful information about his product.

Caronia was not convicted for off-label marketing. He was convicted for saying something (truthful) about his product that was not specifically noted on the product's label. Thus, misbranding. The government said it wasn't prosecuting Caronia for his speech, but that the speech demonstrated intent to cause the misbranding. The Court didn't buy that.

Violation of Free Speech

Caronia asked "Why me?" Why can everyone, except a company and rep speak truthfully about a product?

The Appeals Court panel answered, there was no good reason and prohibiting only Caronia from speaking was a violation of his First Amendment right to free speech and actually got in the way of public health.

Here's what the Court had to say:

> *As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs.*
>
> *Second, prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use "paternalistically" interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions.*
>
> *In fact, in granting safe harbor to manufacturers by permitting the dissemination of off-label information through scientific journals, the FDA itself "recognizes that public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses" of approved drugs.*

FDA Fears

Washington insider Steven Grossman writes on *fdamatters.com* on December 12 that if doctors can legally prescribe a particular drug for a specific use (albeit off-label), then companies ought to be able to provide "truthful and not misleading" information that they possess. "Arguably, they can do so now (via reprints of scientific articles), but only in response to a physician's request. This is a very limited means of disseminating information."

It is in the public interest for off-label uses to become on-label indications and, says Grossman, the FDA would like to see every off-label use get the scrutiny necessary to assure it is safe and effective.

Grossman writes that one of FDA's great fears is that off-label prescribing will become dominant in clinical medicine. "FDA is concerned that companies will receive approval for a first use, then (directly or subtly) encourage doctors to prescribe off-label. If this strategy is profitable, FDA worries that fewer and fewer companies will commit the time and money to gain approval for additional indications. If a company can't promote off-label, then it is more likely to invest in clinical trials to gain approval of the additional indications."

He added, "Unrestricted promotion of off-label use would definitely undercut FDA. In such an environment, I believe that many companies will 'game' the system by finding a comparatively easier first use for approval, then let sales for other uses build off-label. Nor do I think companies are universally concerned about 'litigation commenced under states' product liability laws for ineffective products and the resulting reputational harm from such lawsuits.'"

Now What?

So what happens now? What if the full Appeals Court affirms the panel's decision and ultimately, the U.S. Supreme Court decides to hear the case and upholds the decision?

New Clinical Data

Jason Hannon is the executive vice president and general counsel for NuVasive, Inc. Hannon said companies spend significant time and money on protocols to assure that all company communi-

cations comply with existing labeling requirements. Most of that effort takes place at the commercial point of contact with surgeon customers. All literature has to be scrubbed and nothing can be sent without a review process.

How much a company could save in reduced compliance costs isn't known, but Hannon says the real costs is to physicians and patients who lose potential communications about legal, off-label uses. "Upholding the free speech argument would likely cause new interest in generating clinical data related to off-label use.

Companies should think about the possibilities if this ruling becomes the law of the land, says Hannon. But cautions, "Nobody should be meaningfully changing their practices right now."

Paul Anderson: A Surgeon's Perspective

Paul Anderson, M.D., professor of orthopedic surgery at the University of Wisconsin talked to *OTW* about those possibilities and what it would mean for the advancement of science in orthopedics.

Paul Anderson, M.D.

Anderson says current off-label rules stifle innovation. For example, he says he can't get devices from companies for unapproved uses for studies or CME approved courses. As an example, he noted the recent meeting of the FDA's orthopedic panel to reclassify pedicle screws for use in the cervical spine. The screws were not specifically approved for that use. However, the standard of care had long moved past the antiquated wire and hook method for stabilizing the spine and screws were being used successfully. Anderson could only train surgeons one at a time while he was performing an actual procedure on a patient.

He also said IRBs (Institutional Review Boards) are less likely to approve studies if off-label use is required. He noted his difficulty in trying to do studies with BMP-2 products.

"We need company involvement in these studies," said Anderson. The companies are needed because their instrumentation is required for surgeons to be able to perform "hands-on" procedures during training. "We're holding back education and innovation."

Protecting Patients

Anderson is quick to point out that we need rules to protect patients from ineffective or unproven devices.

Here is how the appeals panel addressed that issue:

> *The government could pursue several alternatives without excessive First Amendment restrictions.*
>
> *The government could develop its warning or disclaimer systems, or develop safety tiers within the off-label market, to distinguish between drugs.*
>
> *The government could require pharmaceutical manufacturers to list all applicable or intended indications when they first apply for FDA approval, enabling physicians, the government, and patients to track a drug's development. To minimize off-label use, or manufacturer evasion of the approval process for such use, the government could create other limits, including ceilings or caps on off-label prescriptions.*

AAOS: Nothing Changes

The American Academy of Orthopaedic Surgeons' (AAOS) outside counsel Katie McDermott told us that this decision will likely not change the legal relationship between surgeons and device companies. "Surgeons always want truthful information," said McDermott.

She also noted that this was only a three judge panel with a 2-1 split in one court district in New York. There is no telling how the entire Appeals Court bench will rule. "Nothing here changes the AAOS' position on off-label use."

McDermott also said there are over 700 sealed whistleblower cases pending against drug and device makers for False Claims and the Justice Department is not likely to back off because of a change in off-label rules. This case deals with criminal activity while the whistleblower cases are civil.

Neither the FDA, AdvaMed nor the Medical Device Manufacturers Association would comment on the case.

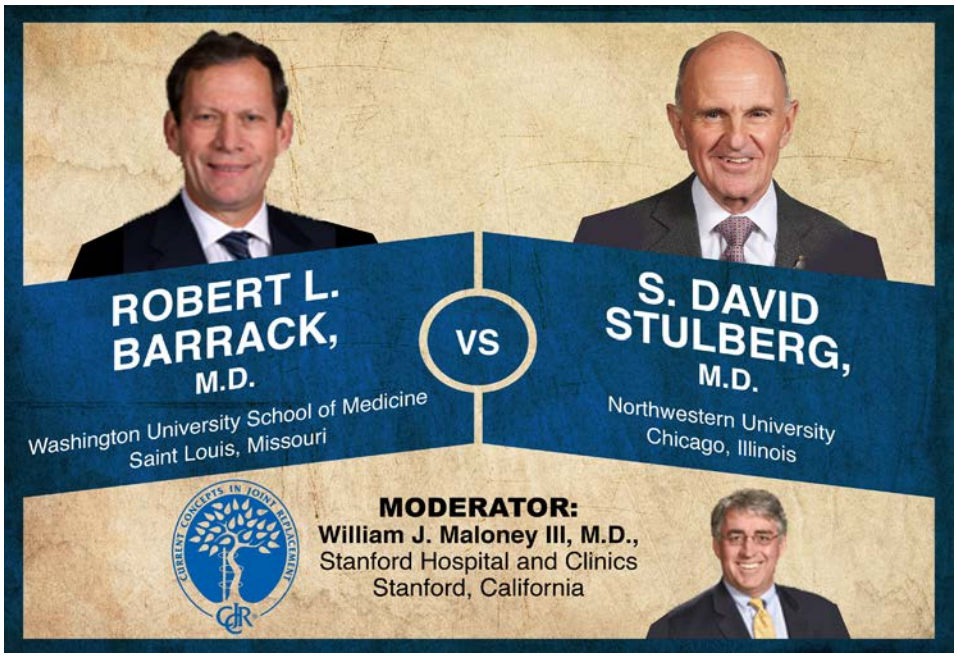
We don't know yet what the FDA will do. We learned that the agency has filed for a 30-day extension to consider appealing the decision. ♦

Barrack V. Stulberg: Head to Head Over Cutting Blocks

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

When it comes to patient specific cutting blocks "Radiographically we could not prove a benefit," says Robert Barrack. In fact, "we were slightly better with standard instruments than with the custom specific, patient specific instrumentation (PSI)". The epidemiology of revisions is troublesome, says David Stulberg, so "PSI deserves a careful look because there is a clinical advantage. The costs will come down."

This week's Orthopaedic Crossfire® debate is "Patient Specific Cutting Blocks: No Added Value." For the proposition was Robert L. Barrack, M.D. from the Washington University School of Medicine in St. Louis. Against the proposition was S. David Stulberg, M.D. of Northwestern University in Chicago. Moderating was William J. Maloney III, M.D. from Stanford Hospital and Clinics.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Barrack: "Variability in component alignment continues to be a major issue in total knee arthroplasty (TKA). In the short term it can cause persistent pain and dissatisfaction. In the longer term, it can contribute to every mode of failure. After a decade of clinical use I think that navigation isn't going to be the answer."

"A new approach: patient specific guides in which you do an MRI or CT and generate a model for each patient's lower limb to produce the patient specific instrumentation [PSI]. Almost every company has some version of this. I'll speak about the Biomet Signature."

"The goals of the patient specific approach are to increase accuracy, to customize instruments for the patient, and to eliminate outliers. Secondarily, we want to get more efficient and lower the total operative time and cost. We did a series of studies—about 114 cemented cruciate-retaining knees, and we used coronal alignment assessment with a scout CT."

"We have 57 in each group who successfully completed the scout CT and had analysis. The femoral component has a posterior flange that has wedge holes that allow you to reference so you can accurately locate the limb to get reproducible alignment."

"We did a careful assessment of coronal alignment: femorotibial angle, Hip Knee Ankle Axis, the Zone of the Mechanical Axis, and the mechanical axis deviation. The femorotibial axis is typically between two and seven degrees. A long film is utilized to measure the Hip Knee Ankle Axis—center of the hip to the center of the knee through the center of the ankle. In a perfect case it's zero degrees."

"The Zone of the Mechanical Axis is where that line crosses the center of the component, and it should be in the central zone if you divide the tibia into five zones. We also measured the number of millimeters that we deviated from achieving this central zone. We determined the total tourniquet time and the total time in room between groups. All steps in instrument processing were timed utilizing industrial efficiency methodology. These times were converted to cost of materials, personnel, and fixed hospital overhead, including the time in the operating room."

"Customized knees have about half the number of trays, and every step of the process was much quicker, so you do save money on the sterile processing cycle. But when you do this in large volumes, the cost saving is not as much as we had thought. It was only about $26 per case in fixed overhead for the hospital; the bigger savings was about $300 in saved time in the OR per case."

"Radiographically we could not prove a benefit. We were just as good with standard instrumentation; in fact with the Hip Knee Ankle measurement we were slightly better with standard instruments than with the custom specific, patient specific instrumentation. So we couldn't prove an advantage in a coronal alignment."

"There are limitations. We didn't measure the lateral view, rotational alignment was not assessed, clinical result and patient satisfaction were not measured; we have a randomized clinical trial underway to see if the patients do better because of more accurate and consistent rotational alignment, and possibly lateral alignment."

"The cost-utility analysis—although we saved $300 per case the guide itself costs anywhere between $500-$1,000…and then there's the imaging cost. I will say that there's a high acceptance among patients, the OR staff, the processing personnel. But right now, the cost benefit is hard to justify in the absence of demonstrated radiographic or clinical advantage."

Dr. Stulberg: "The number and cost of revision TKA are increasing in the U.S., and the epidemiology of revisions is troublesome. Many of them occur very early, often within the first two years; a very high proportion of these are a result of inadequate surgical technique. The goals of navigation are to emphasize the importance of accuracy in attempting to deal with this issue. While navigation is focused on an alignment in the coronal plane and reducing outliers, its biggest goal was to reduce the number of inaccuracies in each step of the operation."

"Navigation has not been very helpful for inexperienced/nonarthroplasty surgeons. It's too expensive, it requires clear understanding of total knees, it requires a significant learning curve, and it uses cumbersome instrumentation."

"My interest in this emanated from the idea that if PSI technology increased the accuracy and reduced the outliers for surgeons who weren't arthroplasty surgeons, that maybe the reduction in cost associated with that improved accuracy—in association with the improved efficiencies that go with this technology—might offset the increased cost. The question is, 'How accurate is this technology?'"

"Navigation is an accurate measurement tool that could be used to look at this technology. We tried to look at each step of the operation to see how accurate this technology was…because there is very little data on it. My arthroplasty partner, Raj Ghate, and I looked at our first 111 total knees using this technology…the first 31 of which I did I used computer assisted technology. We also looked at how accurate PSI planning program was in predicting the size of the femoral component, and comparing that to the accuracy of computer assisted surgery in predicting femoral component size. We also measured all of our bone resection to see whether it matched the preoperative plan. We looked at the positioning of the femoral component, both with regard to anterior/posterior positioning, as well as rotation."

"The results: the coronal alignment is 'on'…and if this were the reason you were using PSI technology I'd suggest it isn't worth it because you can achieve this without really going to PSI technology. The PSI technology gives very accurate coronal and sagittal alignment—even on the tibia, which is harder to use when you're starting this, and which we would recommend using an external guide when you're placing that initial PSI guide."

"Still, it was extremely accurate in the frontal and sagittal plane. But the money is here: the PSI predicted femoral component size virtually every time (92% of the time versus 43% with computer assisted technology. Moreover, the PSI technology tends to place a component dead-on in the anterior/posterior (A/P) plane…and it positions it very accurately in rotation as a result of the preop plan using accurate anatomic landmarks. So if you've got a precise femoral size and you have precise A/P placement and precise rotation then you have the makings of a very accurate flexion gap."

"PSI deserves a careful look because there is a clinical advantage. The costs will come down. The PSI technology focuses our attention on making TKA more efficient and cost effective. The financial benefits of reducing revision rates must be included in any cost analysis."

Moderator Maloney: "Robert, a minute to rebut."

Dr. Barrack: "The buzz words we'll be hearing are value-based purchasing and comparative effectiveness. And when we introduce an expensive new technology we must be able to produce data showing that it accomplishes something. We're still dealing with early generations. We are arthroplasty specialists, so this may do better in the hands of less experienced surgeons. But you don't want people to become totally dependent on this because if they don't get a great fit with their cutting block then they won't have the experience to bail themselves out."

Moderator Maloney: "David?"

Dr. Stulberg: "We're just beginning to understand the impact of this kind of technology. There are other ways of achieving fewer instruments in the room and faster turnover. The kind of efficiency embodied in this first generation is going to be the way we go; add that to an accurate technology that's user friendly and efficient, then you've got a winner."

Moderator Maloney: "Robert—sources of error…one of them is that the surgeon must approve the preoperative prescription. How cumbersome is that?"

Dr. Barrack: "It adds 10/20 minutes. You look at the cut plan and see if it makes sense."

Moderator Maloney: "You said the overall time savings was in the OR, but what about when you add the preoperative planning phase? Does that make the time a wash?"

Dr. Barrack: "No, because it's web based…you can go online anywhere in the world and make sure it makes sense."

Moderator Maloney: "What's the time lag from the time you get the scan to the time can actually get the implants?"

Dr. Barrack: "Four weeks."

Moderator Maloney: "David, is computer assisted total knee arthroplasty a dead horse?"

Dr. Stulberg: "No, it's not dead."

Moderator Maloney: "Is it on life support?"

Dr. Stulberg: "It's relegated to a small volume of what we do."

Moderator Maloney: "Robert, as for the cost, you're adding on somewhere between $1,000 and $2,000 for the scan. I suspect the system/Medicare won't look upon that positively."

Dr. Barrack: "The cost of the plastic itself—I think it will come way down. Although there is some software planning—a technician has to review and generate…"

Moderator Maloney: "When you send a patient for an MRI for a total knee replacement, what do you use as a preop diagnosis? Osteoarthritis isn't something typically that they'll accept as a reason to get an MRI or a CT."

Dr. Barrack: "You'd be surprised. They will."

Moderator Maloney: "They must not be looking at this very carefully yet. David?"

Dr. Stulberg: "If you put down 'preoperative planning,' that will be the catch word—at least for United Health. My view on it is that most surgeons don't do very good preoperative planning anyway…and they do it on a technology—X-rays—that is highly inaccurate. Now we have a very accurate imaging tool and the preop plan that you get back is probably much better than most of us would do."

Moderator Maloney: "I would agree. David, you stated that the rotation alignment was significantly better with the PSI, but there was no data up there. Did you measure that or was that a hypothesis?"

Dr. Stulberg: "CT would be one way to look at it. We looked at it with Whiteside's line as our preoperative alignment guide and we matched that with an intraoperative assessment."

Dr. Maloney: "So that was a guesstimate in the OR. Robert, how do we measure rotational alignment and should we?"

Dr. Barrack: "We're doing it clinically. Patients don't care if their components parallel the epicondylar axis…they care if they have stiffness or pain. The corollary is that if you're right on with the position then they should get their motion back quicker, and they should have less residual symptoms."

Dr. Maloney: "So you're not objectifying that with a CT scan to look at the rotational axis?"

Dr. Barrack: "No. We all know that the secret among arthroplasty surgeons is that 20-30% of patients aren't crazy about their knee—and I think that they are most likely malpositioned."

Dr. Stulberg: "Intraoperative assessment: one way is by seeing whether the measured cuts are actually what was predicted because that will tell you whether you're close. The other is to use an intraoperative sensor to see whether you're balanced."

Dr. Maloney: "That doesn't tell you whether you're actually matching the rotational axis that you were shooting for. Thank you to both debaters." ♦

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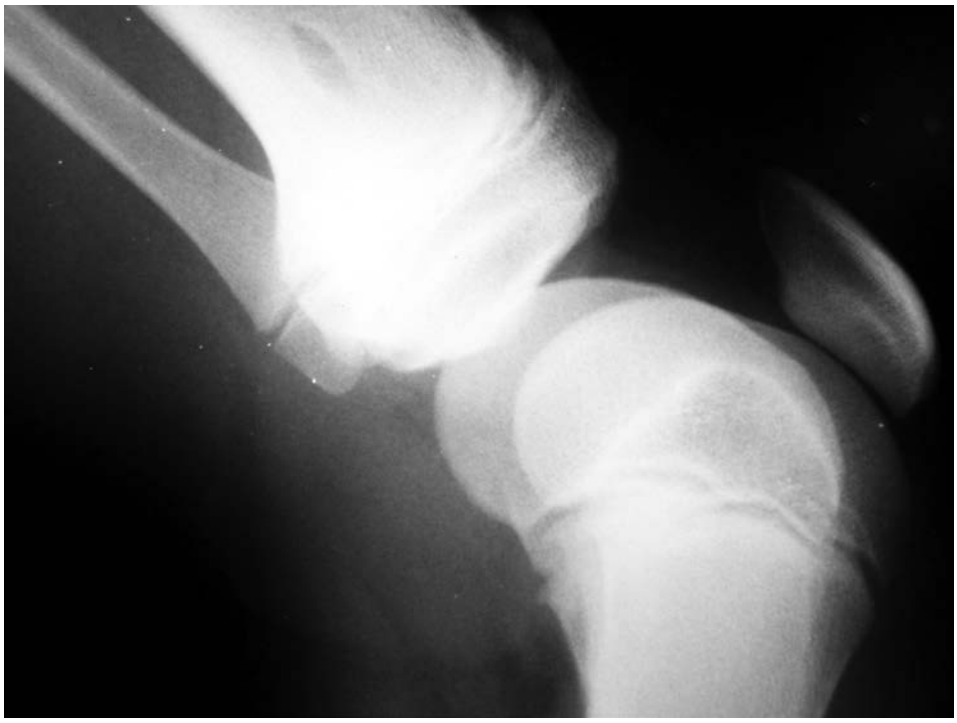
Socio-economics Trumps Design in TKA Outcomes

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

Socio-economics Trump Design in TKA Outcomes Ryan Nunley, M.D. is assistant professor of orthopedics at Washington University in St. Louis. He has recently done research on the impact of socio-economic factors on results of total knee arthroplasty. Dr. Nunley tells *OTW*, "All implant companies have different designs and different types, whether fixed bearing or mobile, gender specific or not. When you compare total hips to total knees, it has been established that total hips perform better as far as pain relief. (90-95% versus 80-85% for patient overall satisfaction after surgery) So we wanted to know how we could create better options for knees. We found that when we compared implant types via multivariate analysis the only thing that bore out were the secondary factors (socio-economic, education level, etc.). That means that it might not matter as much about the implant design as previously debated, because the knee implant isn't the predominant factor. We were very surprised by our findings. In the literature various articles talk about one implant being superior to another; the fact is that most peer reviewed articles don't report socio-economic factors… so we are going back and examining these studies. This is important work, and I am pleased that it has been nominated for several awards. What I don't want to happen, however, is that we start avoiding arthritis patients who are less educated, poor or who are minorities because we think they might have a poor outcome."



Morguefile and clarita

Watch This Space – PTOA Clues for Osteoarthritis Commander Matthew T. Provencher, M.D., M.C., U.S.N. is Director of Orthopaedic Shoulder, Knee, and Sports Surgery at the Naval Medical Center San Diego Department of Orthopaedic Surgery. He is also Professor of Surgery and Orthopaedics at the Uniformed Services University of Health Sciences. Dr. Provencher tells *OTW*, "My colleagues and I are very excited about the progress we're making with post traumatic osteoarthritis (PTOA). This is not just a condition related to major trauma, but it results from athletic injuries throughout high school, college, and thereafter. Research in this area is increasingly focused on preventing PTOA—and its basic science, cartilage work, metabolism research, as well as translational and clinical trials. Many researchers have been making progress with the prevention of PTOA in animal models; the next phase is look at the disease modifying trials. We must concurrently look at the animal, the basic science, and the natural history perspective to truly see our future impact."

"Our group is looking at longitudinal studies (at what happens after sports trauma). But the real key is to have multi center trials and established multi center networks that can look at aggregated data and see where we can have an impact and also determine what agents will be highest impact and at which point in the disease. For example, although preliminary, we did find that the longer patients have shoulder instability, the more cartilage and soft tissue injuries they present with. We need to find ways in which to modify this progression and we hope that in a

year from now we will have a lot more historical data and we will be much close to disease modification."

Robert F. LaPrade M.D., Ph.D. Wins OREF Award The American Academy of Orthopaedic Surgeons and the Orthopaedic Research and Education Foundation (OREF), has announced that Dr. Robert LaPrade has been awarded the 2013 OREF Clinical Research Award for his paper, "Improving Outcomes for Posterolateral Knee Injuries." Dr. LaPrade will be presenting his winning paper at the Annual Meetings of the Orthopaedic Research Society and the American Academy of Orthopaedic Surgeons in 2013. In addition to the posterolateral knee for which this award was based, Dr. LaPrade and his team of collaborators have similar ongoing programs in place for the medial knee and MCL, anterior cruciate ligament, and posterior cruciate ligament.

50% Infection Jump From Embolizing Veins? Andrew Pollak, M.D. is chief of the Division of Orthopaedic Traumatology and associate director of Trauma at the R Adams Cowley Shock Trauma Center. He tells *OTW,* "I worked with Ted Manson, M.D. on a recently published article on complications after embolization of pelvic arterial injuries. These patients are bleeding rapidly and in shock—extremis—and in addition to stabilizing their pelvic ring injuries, they are often treated with angiographic embolization of their pelvic arterial system in order to control hemorrhage. Rather than selectively embolize the artery that is bleeding, interventional radiologists will occasionally embolize proximal vessels the one proximal to that, arguing that collateral flow will limit the risk of distal muscle death. Their experience in large numbers of patients is that it is safe. However, our study found that in a subset of patients who underwent surgery later for an associated acetabulum fracture the risk of infection increases—up to 50%. This is a warning to all of us that if a patient has had embolization of the vascular tree, be careful. Surgeons treating these patients during their initial resuscitation should pay particular attention to this…the risk/benefit assessment with regard to later operative treatment of their acetabulum fracture changes considerably."

Placebo Beat HA in Thumb Arthritis Study Lisa Mandl, M.D., MPH is a rheumatologist at Hospital for Special Surgery. She recently led a randomized, double-blind clinical trial which revealed that corticosteroids are more effective than Hylan G-F 20 in providing pain relief to patients with thumb arthritis. The team also found that while both of these treatments provided pain relief, so did a placebo injection. "Our

study is the first large randomized clinical trial in patients with carpometacarpal (CMC) osteoarthritis (thumb arthritis). My interest in this topic started during my fellowship. I had begun to notice a lot of older patients who were looking forward to retiring and being active, but who were severely affected by arthritis at the base of the thumb. It was actually their ruining their lives; their sleep was disturbed, regular activities were painful and/or difficult… yet nothing else was wrong with them. They had tried nonsteroidals, splinting, and steroid injections, but they were still miserable. They didn't want surgery, and I was struck by the fact that there was nothing else out there to help them. I got the idea that perhaps Hylan G-F 20—a product approved by the FDA for knee OA—might be helpful."

"We had 200 patients with thumb arthritis, and they received either bupivacaine, Hylan G-F 20, or triamcinolone. We were very surprised to learn that nothing worked better than placebo; in fact, some patients had phenomenal responses to bupivacaine. Bupivacaine shouldn't do anything… just numb the area and wear off in 20 minutes…but even that was helpful for some patients. It may be that the injection itself is making people feel better."

"This was essentially a negative trial. The take home message here is that if you have exhausted conservative therapies, try steroids first. If the patient is very risk averse you might try bupivacaine. In patients who are miserable and refuse to have surgery, I would still try Hylan G-F 20 as a last resort."

Charles Blitzer, M.D. Given Humanitarian Award Charles Blitzer, M.D. of Seacoast Orthopedics and Sports Medicine in Somersworth has been presented the Humanitarian Award by the New Hampshire Orthopaedic Society, the state organization committed to bringing together orthopedic physicians to work for the benefit of patients and the profession. The N.H. Orthopaedic Society Humanitarian Award recognizes orthopedic surgeons in the state who have distinguished themselves through outstanding musculoskeletal care and community service in New Hampshire and/or abroad. Dr. Blitzer is an orthopedic surgeon, specializing in trauma and fracture care, who has been in practice in New Hampshire for 28 years.

Lowest Infection Rate Winner – Hospital for Special Surgery (HSS)! For the fourth year in a row, HSS is being lauded for having an infection rate that is significantly lower than the New York State average for hip replacement or revision surgeries. Surgeons at Hospital for Special Surgery performed the most hip replacement surgeries in New York State, with nearly 4,200 procedures, which is about 15% of the approximate 27,000 hip replacement or revision procedures in New York State in 2011. Among the 167 hospitals included in the report, Hospital for Special Surgery had a statistically lower surgical site infection rate of 0.4% compared with the state average of 1.12% for total hip replacement or revision hip procedures. How do they do this? First of all, an electronic data monitoring program serves as a "first alert" system for new cultures and organisms that could pose a threat to patient safety. Patients' exposure to contaminants is minimized, because they are isolated from the surgical environment by a specially designed Plexiglas enclosure, which helps to improve air flow and to restrict excess personnel at the surgical field. After surgery, the operating rooms are meticulously cleaned by staff that is regularly monitored for competency by the infection control nurse. ♦

company

New Robotic Knee Surgery Device Hits Market

NavioPFS System/Blue Belt Technologies, Inc.

The orthopedic robotics market grew by one on December 10 as the FDA cleared Blue Belt Technologies, Inc.'s robotic-assisted NavioPFS orthopedic surgical system for unicompartmental knee replacement.

The clearance covers only partial knee replacement, but a Blue Belt press release said the company anticipates expanding further into orthopedic surgery.

Blue Belt received European CE Mark for the system in February and expects to begin commercialization in the U.S. sometime in 2013 and start competing with MAKO Surgical Corp's RIO system.

NavioPFS

NavioPFS consists of a navigation system and an intelligent, handheld, computer-assisted bone-cutting tool. The system limits bone cuts to the targeted areas by enabling and disabling the cutting burr as needed which potentially increases implant placement precision and consistency. The system does not require a CT scan and costs around $300,000 to $350,000. It's also an open platform that allows for the use of any manufacturer's implants. The RIO system, with its partial knee application, costs around $850,000 and only uses its own line of implants.

MAKO Threat?

The news caught the attention of Wall Street analysts who cover MAKO Surgical. MAKO's RIO system offers both partial knee resurfacing and hip arthroplasty.

Wells Fargo's Larry Biegelsen wrote, while he believes Blue Belt's technology is the first serious threat to MAKO in orthopedic robots, "we think it is too early to tell what impact Blue Belt will have on MAKO's business longer term. With MAKO's installed base, clinical evidence head start and hip application (and potential future applications), we believe that Blue Belt's approval will have a minimal near-term impact on MAKO's business."

Biegelsen noted the Blue Belt lacks clinical data and has been used in only 10 procedures at three sites in Europe, with a fourth site expected later this year or early 2013. Blue Belt expects the U.S. launch to be concentrated at three or four sites initially, with a full official launch at the American Academy of Orthopedic Surgeons (AAOS) in March 2013.

Blue Belt CEO: "It's Economics"

Eric Timko, president and CEO of Blue Belt said the company has remained committed to providing orthopedic surgeons and hospitals "a more precise and consistent technique to perform (unicompartmental knee replacement) procedures that takes into consideration the current economic environment in our healthcare system. We are confident that NavioPFS accomplishes these goals."

Blue Belt is developing "smart" surgical instruments with precision robotics for use initially in orthopedic procedures and then for other surgical specialties, including neurosurgery, spinal and otolaryngology.

—WE (December 16, 2012)

Sales Leadership Changes at NuVasive

NuVasive, Inc. has made "significant" leadership changes to its sales management team with a new leader for U.S. sales and a new vice president of strategic sales and operations.

These personnel changes come after the company was surprised with less than expected sales results for the third quarter. Chairman and CEO, Alex Lukianov then took over all U.S. sales responsibilities and Russell Powers was promoted to executive vice president of international sales.

Link and Durall

Lukianov is now turning over U.S. sales responsibilities to Matt Link, a new executive vice president. In addition Scott Durall assumes the position of executive vice president of strategic sales and operations.

Link joined NuVasive in 2006 after his tenure with DePuy Orthopedics and then DePuy Spine in a regional sales leadership role. The company announcement stated that Link has quickly elevated through the NuVasive sales organization as a result of his proven leadership ability and exceptional performance as sales director, area vice president and a senior vice president. "His leadership, cultural focus, dynamic energy and steadfast commitment to drive top-line growth will continue to be instrumental in expanding sales revenue."

Durall's role, according to the company, will include working with both Link and Powers with the shared objective of growing revenue through improved operational efficiencies to directly influence NuVasive sales representatives and expand the company's presence in national account networks.

Durall joined NuVasive in 2008 in a regional sales leadership role as an area sales vice president and as senior vice president of sales operations. He came to NuVasive following his time at U.S. Surgical Corp. as sales director and after 10 years with Boston Scientific Corporation.

Lukianov said the ability to promote internally for these roles is, "culturally invaluable and I have tremendous confidence in the team we have organized to help us achieve our vision to further change spine surgery now and as a $1 billion start-up."

U.S. Sales Force Rises to 329

NuVasive also announced that as of December 7, the U.S. sales force has grown rapidly from 312 at the end of the third quarter to its present size of 329.

"I am very pleased to be directly engaged with our sales executives to actively address recent competitive challenges in the field and re-build sales momentum. I believe we are making progress on multiple initiatives to ensure the sales force penetrates deeper into accounts and goes wider with new accounts that have already shown significant progress ahead of plan. Moreover, these ongoing efforts are not expected to hinder the company's outlook on profitability. We have industry leading products, outstanding support services and top executives to very effectively drive sales. Establishing the sales leadership team to execute our growth goals is mission-critical. I am very pleased with our team and our progress in this quarter has already been excellent. I look forward to working even more closely with this group of leaders to execute our market share taking strategy both domestically and internationally," added Lukianov.

—WE (December 16, 2012)

Powers, Link and Durall/NuVasive, Inc.

spine

SI-BONE Reaches 5,000 Patient Milestone

SI-BONE, Inc. has announced the publication of the first peer-reviewed journal article on the iFuse Implant System for the treatment of sacroiliac joint disruptions or degenerative sacroiliitis. The article is a retrospective study of the first 50 consecutive patients treated by a single surgeon in a single center. Patients were evaluated for pain and functional outcomes and showed early and sustained statistically significant improvement at all post-operative time points. Complication rates were low and after an average of 40 months, more than 80% of patients report that they would have the same surgery again. The company also announced it has surpassed another significant milestone with over 5,000 patients treated with the iFuse Implant System since the product became commercially available in early 2009.

Jeffrey Dunn, President and CEO of SI-BONE stated in the December 11, 2012 news release: "We are delighted to have this first peer-reviewed publication available showing additional evidence of the safety and effectiveness of the iFuse Implant System for treating patients with degenerative sacroiliitis or sacroiliac joint disruption. It also is our understanding that a number of surgeons have submitted, or are in the process of submitting, manuscripts to peer reviewed journals describing their experience with the iFuse in SI joint fusion. We continue to believe that sacroiliac disease has been underdiagnosed and under-treated for many years, and that these results validate the effectiveness of iFuse in this patient population."

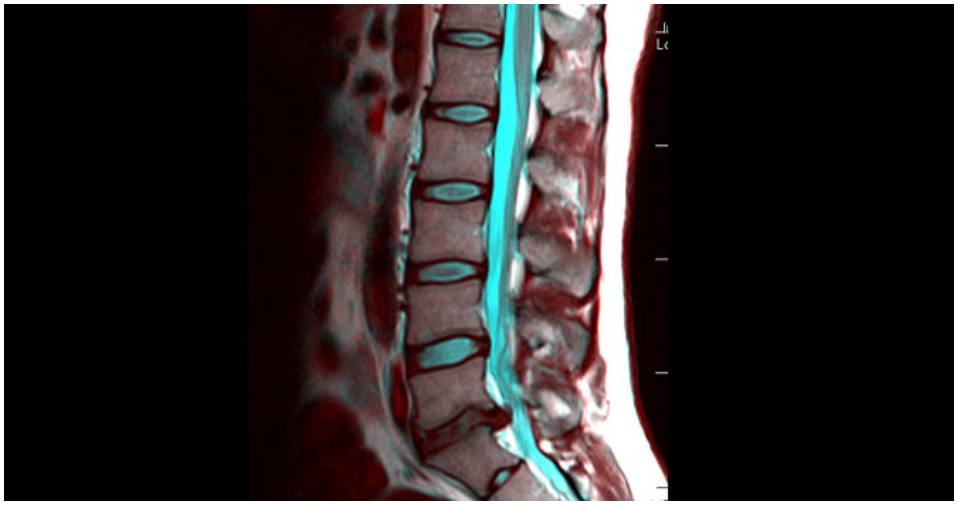
SI-BONE, Inc.

Dunn told *OTW*, "Many of these patients are two years out from surgery and some are out three years and the satisfaction level from patients is self evident. As a company we receive many emails about patient experience and it's exciting to see how they are doing. An oil worker who fell down oil rig stairs told us, 'Anyway, I just wanted to touch base with you and say THANK YOU for the amazing product as it saved my life.' From a Washington State resident: 'All I can say is WOW! After a two night hospital stay I returned to Washington State with a new lease on life. My horrible vaginal pain (due to constant irritation of the sacral nerves) was eliminated, leg pain gone, SI pain gone. All I can say is thank you. This new procedure gave me my life back.'"

Asked where he hopes the company to be in a year, Dunn told *OTW*, "We are now doing about 400 cases per month and we would expect that a dozen peer reviewed PubMed searchable journal papers will be published in the next 6-9 months. As well, surgeons are more experienced now than three years ago when we pioneered minimally invasive sacroiliac surgery so we also believe that efficacy and safety scores will continue to get even better. Finally, our mission of helping improve diagnostic examination expertise as it relates to the lower back is undoubtedly happening as doctors across the country include the sacroiliac joint in their differential diagnosis efforts."

—EH (December 12, 2012)

Breakthrough in Arthritis Research



Wikimedia Commons and Nevit Dilmen

Researchers at Western University in Canada have made a discovery that could lead to a better understanding of what the Arthritis Society indicates is the second most common form of arthritis—"diffuse idiopathic skeletal hyperostosis" or DISH.

DISH is a form of degenerative arthritis and is characterized by the formation of excessive mineral deposits along the sides of the vertebrae in the neck and back. Those suffering with this malady usually experience spine pain and stiffness and in advanced cases, difficulty swallowing and damage to spinal nerves. The cause of DISH is unknown and there are no specific treatments… but there is progress.

Now researchers at Western University's Bone and Joint Initiative, with collaborator Doo-Sup Choi at the Mayo Clinic in Rochester, Minnesota have discovered the first-ever mouse model of this disease. The research is published online in the *Journal of Bone and Mineral Research*.

"This model will allow us for the first time to uncover the mechanisms underlying DISH and related disorders. Knowledge of these mechanisms will ultimately allow us to test novel pharmacological treatments to reverse or slow the development of DISH in humans," says corresponding author Cheryle Séguin in the December 3, 2012 news release. Séguin is with the Skeletal Biology Laboratories and the Department of Physiology and Pharmacology at Western's Schulich School of Medicine & Dentistry.

Graduate student Derek Bone, working under the supervision of pharmacologist James Hammond, was studying mice that had been genetically modified to lack a specific membrane protein that transports adenosine when he noticed that these mice developed abnormal calcification (mineralization) of spinal structures.

Changes in the backbone of these mice were characterized by an interdisciplinary team which included: Sumeeta Warraich, Diana Quinonez, Hisataka Ii, Maria Drangova, David Holdsworth and Jeff Dixon. Their findings established that spinal mineralization in these mice resembles DISH in humans and point to a role for adenosine in causing abnormal mineralization in DISH.

—EH (December 10, 2012)

people

Nawana Lands COO Role at Alere, Inc.

Namal Nawana, the recently departed head of DePuySynthes Spine, has a new job as COO of Alere, Inc.

The Waltham, Massachusetts-based company founded in 2001, has about 11,000 employees worldwide. The health management company's products and services breadth ranges from lab-based diagnostics to in-home monitoring with a focus in the areas of cardiology, infectious disease, toxicology, diabetes, oncology and women's health.

NamalNawana

Nawana was replaced by Max Reinhard after being on the job since 2011 and going through the DePuy/Synthes merger. He was with Johnson & Johnson for 15 years.

He begins his new duties on December 30, 2012, and will assume responsibility for all commercial, R&D and operational functions, globally.

According to a company SEC filing, Nawana's compensation will consist of an annualized salary of $800,000, and he will be eligible for a salary review in April 2014. He will also be paid a $275,000 sign-on bonus in February, 2013.

In the same week the announcement of Nawana's hiring was made, the company also completed its offering of $450 million aggregate principal amount of senior notes.

The company will use the net proceeds finance a cash tender offer to repurchase senior notes due 2016, to repay all outstanding revolving borrowings under its credit agreement and for working capital and other general corporate purposes, including the financing of potential acquisitions or investments, stock repurchases and capital expenditures.

—WE (December 16, 2012)

UnitedHealthcare Executive Bolsters Zimmer's Board

Changes in board membership at the large orthopedic companies are usually not big news.

But Zimmer Holdings, Inc.'s recent appointment of Gail Boudreaux to the board caught our attention.

Boudreaux is the executive vice president of UnitedHealth Group and CEO of UnitedHealthcare. UnitedHealth Group covers more than 75 million people worldwide, large chunks that presumably are covered for orthopedic services.

She's also one of America's most influential business executives, being named the 54th most powerful woman in 2009 by Forbes.

Boudreaux is powerful in more ways than one. She was a standout 6'2" center for Dartmouth Big Green Women's basketball team from 1978 through 1982. She also set the Massachusetts girls' state shot-put record with a throw of 44 feet, six inches.

Gail Boudreaux/Dartmouth.edu

Landing such a big fish from the health insurance industry to their board, assures that the Zimmer board is fully informed and aware of the increasing role payers will play under the nation's new health care system.

Boudreaux assumed overall responsibility for all UnitedHealthcare health benefits businesses in 2011. She joined UnitedHealth Group in May 2008 as executive vice president and as president of UnitedHealthcare. Before joining UnitedHealthcare, she was executive vice president of Health Care Services Corporation (HCSC) and prior to that served as president of Blue Cross and Blue Shield of Illinois, a division of HCSC. Before joining HCSC she held senior management positions at Aetna, Inc.

Boudreaux earned a master's degree in business administration at Columbia Business School and a bachelor's degree in psychology at Dartmouth College. Active Dartmouth college alum, she currently serves on the college's Board of Trustees.

"For the past 30 years, Gail Boudreaux has pursued an extraordinary career leading the design and delivery of health benefit programs at the regional and national level. Her unique perspective leading one of the world's largest health benefits providers will prove invaluable to Zimmer," said John McGoldrick, chairman of Zimmer's board of directors. "We are extremely pleased that Gail has agreed to join the board and we look forward greatly to her participation in shaping the company's long-term strategic vision."

—WE (December 16, 2012)

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