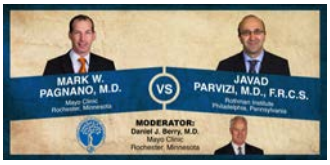
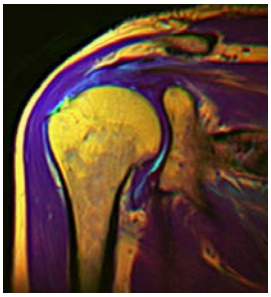
VOLUME 9, ISSUE 23 | JULY 23, 2013

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: Half the ortho stocks have reported Q2 sales results and, so far, results were slightly above expectations. But we're talking low single-digit rates of sales growth. Piper's Mike Miksic released his surgeon survey and pronounced the feedback "positive." Specifically, he said: "Our "turning the corner" hypothesis is further supported by positive feedback from our recent survey work which includes 61 completed calls with orthopaedic surgeons."

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	29.00%	11.46%	Wall Street analysts are still about a step or two off the mark with GMED. Odds of exceeding expectations are good.
2	4	Wright Medical Group	6.84	12.71	At AOFAS, Wright is highlighting its 3Di Ankle Fusion system. As far as Wall Street is concerned, WMGI can do little wrong.
3	2	NuVasive	7.53	17.16	Chances that earnings will be less than the same quarter a year ago are good. Why? Single-digit sales growth this year.
4	3	Alphatec	(4.29)	14.49	ATEC is dancing around break-even this quarter. Will they actually break through and deliver earnings? If not this quarter, then soon.
5	8	Zimmer	29.49	8.63	Most analysts are expecting a solid earnings increase this year for Q2. Yes, but.... Time to put that cash to work.
6	5	Medtronic	28.65	5.71	Non-spine business drives MDT's equity values. But spine is where market share is rising and a #1 market share has key franchise value.
7	7	Johnson & Johnson	25.58	8.68	Buyers just won't let JNJ go. Up 9% in 30 days. Highly liquid stock; 3.1% cash dividend yield. Irresistible to many investors.
8	9	Stryker	23.68	6.67	For Q2, sales growth targets were met, but margins didn't meet expectations so earnings were a bit under forecast.
9	6	Integra LifeSciences	12.44	3.36	IART also hit AOFAS with several innovative new products—led by the Next Generation total foot system.
10	10	Orthofix	19.68	(1.05)	The market right now is in a wait and see mood with OFIX. One year from now, they'll miss these valuations.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	CryoLife	CRY	$7.60	$209	24.39%
2	NuVasive	NUVA	$26.77	$1,184	17.16%
3	Alphatec Holdings	ATEC	$2.37	$229	14.49%
4	Wright Medical	WMGI	$28.12	$1,313	12.71%
5	Globus Medical	GMED	$17.41	$1,603	11.46%
6	Symmetry Medical	SMA	$8.59	$320	11.13%
7	Exactech	EXAC	$21.21	$285	10.30%
8	Johnson & Johnson	JNJ	$92.23	$259,064	8.68%
9	Zimmer Holdings	ZMH	$84.67	$14,255	8.63%
10	Stryker	SYK	$70.88	$26,731	6.67%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.38	$38	-56.92%
2	MiMedx Group	MDXG	$5.97	$573	-17.66%
3	Baxano Surgical Inc	BAXS	$2.05	$93	-10.48%
4	RTI Biologics Inc	RTIX	$4.19	$236	-1.87%
5	Orthofix	OFIX	$28.19	$548	-1.05%
6	Smith & Nephew	SNN	$60.52	$10,910	3.14%
7	Integra LifeSciences	IART	$37.87	$1,063	3.36%
8	ArthroCare	ARTC	$37.08	$1,046	4.27%
9	Bacterin Intl Holdings	BONE	$0.58	$25	4.50%
10	Conmed	CNMD	$33.16	$931	5.30%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$28.19	$548	10.97
2	Zimmer Holdings	ZMH	$84.67	$14,255	13.62
3	Medtronic	MDT	$55.02	$55,428	14.80
4	Smith & Nephew	SNN	$60.52	$10,910	14.97
5	Globus Medical	GMED	$17.41	$1,603	15.25

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$28.12	$1,313	122.26
2	NuVasive	NUVA	$26.77	$1,184	70.45
3	Symmetry Medical	SMA	$8.59	$320	29.62
4	RTI Biologics Inc	RTIX	$4.19	$236	24.65
5	ArthroCare	ARTC	$37.08	$1,046	24.08

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.41	$1,603	1.02
2	Conmed	CNMD	$33.16	$931	1.37
3	Zimmer Holdings	ZMH	$84.67	$14,255	1.47
4	Exactech	EXAC	$21.21	$285	1.52
5	Integra LifeSciences	IART	$37.87	$1,063	1.56

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$28.12	$1,313	11.46
2	NuVasive	NUVA	$26.77	$1,184	6.03
3	CryoLife	CRY	$7.60	$209	5.28
4	Johnson & Johnson	JNJ	$92.23	$259,064	2.79
5	Symmetry Medical	SMA	$8.59	$320	2.47

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.58	$25	0.73
2	Symmetry Medical	SMA	$8.59	$320	0.78
3	Alphatec Holdings	ATEC	$2.37	$229	1.17
4	Orthofix	OFIX	$28.19	$548	1.19
5	Conmed	CNMD	$33.16	$931	1.21

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$5.97	$573	21.17
2	TiGenix	TIG.BR	$0.38	$38	9.36
3	Baxano Surgical Inc	BAXS	$2.05	$93	6.36
4	MAKO Surgical	MAKO	$13.00	$610	5.94
5	Globus Medical	GMED	$17.41	$1,603	4.15

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

Would Stryker Buy NuVasive?

BY ROBIN YOUNG

Wikimedia Commons and Jonata/Logos courtesy of NuVasive, Inc. and Stryker Corporation/Photo creation by RRY Publications LLC

Slow overall procedure growth combined with an increasing concentration of vendors at the hospital level may well be laying the foundation for a consolidation of spine manufacturers. That is the opinion of senior Wells Fargo analyst Larry Biegelsen as described in his July 9 report titled "Is the Spine Market Finally Ready for Consolidation?"

The most likely candidates to be acquired, hypothesizes Biegelsen, are NuVasive, Inc. and Globus Medical, Inc. Noticeably absent from the senior analyst's list were Alphatec Spine, Inc. and Baxano, Inc.. In his view, Alphatec and Baxano were "less attractive to potential buyers due to their lack of size and scale." But, in reality, Biegelsen's exclusion of these two companies (as well as such private firms as K2M, Inc., LDR, Lanx, Inc., Paradigm Spine, LLC or SI BONE, Inc.) reflects the prevailing opinion on Wall Street of spine—that it is now a commodity industry. In commodity industries, M&A (merger and acquisition) activity is usually driven by the need to build size and scale—and only NuVasive or Globus seem capable of delivering that to Biegelsen's list of larger prospective buyers.

The Buyers

And who might be the buyers in a possible wave of consolidation?

Three companies, says Biegelsen, have the means and the motivation to step up. They are; Stryker Corporation, Biomet, Inc. and Zimmer Holdings, Inc.

DePuy, having purchased Synthes, Inc. for $20 billion last year, is still digesting that mammoth company and would not be shopping for anything large. Medtronic, Inc., with the largest market share in spine and having recently acquired the large Chinese spine and orthopedics company Kanghui, also seems to be satiated.

Survey Says

The same week as Biegelsen's report, Bob Hopkins, research analyst with Bank of America (BofA) Merrill Lynch, released a survey of leading spine surgeons that seemed to support the same view of the spine industry that led Biegelsen to make his consolidation call.

That view is that the spine industry is growing slowly—about 1% per year—and continued pricing pressures and a lack of innovation has changed the industry from an innovation driven, rapidly expanding industry to a commodity industry.

Hopkins surveyed 75 U.S. spine surgeons (57% orthopedic surgeons, 43%

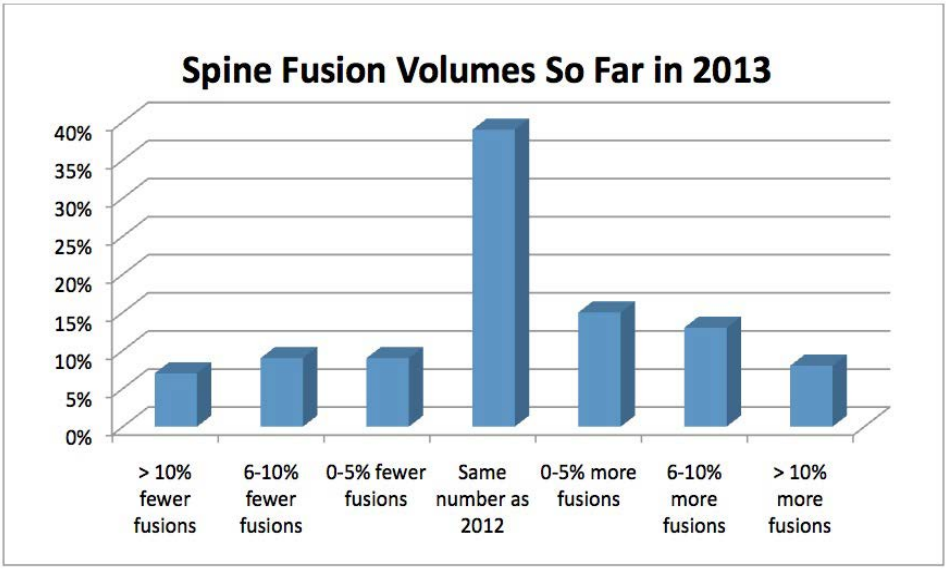
neurosurgeons) from 24 different states. Here are the main conclusions:

- **Vendor consolidation is increasing:** When Hopkins asked surgeons about vendor consolidation, 44% responded saying that their hospitals were actively reducing the number of spinal implant manufacturers supplying product. Furthermore, respondents said that, on average, their hospitals would likely reduce the number of vendors by 39% over the coming two years. Fifty-six percent of the respondents said that their hospitals would likely increase the number of vendors over the coming two years—although not by much. Overall, on a weighted average basis, the conclusion of the 75 respondents is that their hospitals would be using 19% fewer vendors over the coming two years.

- **Innovation is essentially nonexistent:** By far the most definitive result of Hopkins' survey was the nearly unanimous opinion that innovation is dead in spine. When asked this question: "Do you see any innovation coming to market in the next two years that could allow one manufacturer to take significant share of the spine fusion market?", 95% said "NO."

- **Insurance Coverage is worsening**: No matter how the question is asked, surgeons surveyed were clear in their answer—insurance companies are increasingly disinclined to pay for spine fusion surgery. Sixty percent of the survey's respondents said that willingness of payors to pay for either spine fusion or degenerative disc disease cases has worsened in the last several months.

- **Procedure volumes are flat to slightly up:** 75% of the respondents said that spine fusion volumes have been flat to slight up so far this year. Here is the chart from the BofA Merrill Lynch Survey:



Source: BofA Merrill Lynch Global Research Proprietary Survey

What Is Driving the Urge to Merge?

Like the surgeons in Hopkins' survey, Wells Fargo's Biegelsen noted in his analysis an increase in vendor consolidation and pricing pressures which are major contributing factors to prospective M&A activity. He also added three other conditions that, in his view, set the stage for purchases. Those are:

1. **Spine market stabilization.** Year-over-year growth rates have fallen significantly but recently seem to have stabilized. In Biegelsen's view, growth rates may be slow going forward, but they are stable growth rates. That de-risks purchases of the larger spine manufacturers quite a bit.

2. **DePuy/Synthes combination changed the competitive dynamic**. As much as competitors may hope for DePuy/Synthes to stumble with regards to consolidation, the reality is that this, in Biegelsen's words: "altered the competitive dynamic of the spine market" and "established DePuy Synthes Companies as a formidable competitor to the market leader, MDT [Medtronic]."

3. **Spine valuations remain reasonable.** To quote Biegelsen: "Spine companies continue to trade at a discount to the large orthopedic companies on an EV/Sales basis which suggest that the spine companies remain relatively inexpensive on this metric. …spine valuations are at a level that could be appealing to both buyers and sellers, in our view, if the buyers can generate cost synergies."

As a result, says Biegelsen, the buyers' prospective motivations are clear. By stepping up the M&A activity, compa-

nies like Stryker or Biomet or Zimmer can:

1. Acquire size and scale in spine.

2. Put their large stores of cash to strategic use. Stryker, for example, ended the first quarter with $4.5 billion of cash and equivalents. Zimmer ended this past March quarter with $1.2 billion in cash and Biomet reported $217 million for the February 2013 quarter.

3. Take advantage of the low cost debt markets. Low cost debt makes buy-outs financially attractive—particularly when the target firm has such strong cash flows (i.e., Globus Medical's 30% profit margins).

4. Boost growth rates—top and bottom line. While buying a firm certainly adds to the sales line, consolidating accounting and other administrative functions can also add to profit growth.

And, why would, for example, NuVasive entertain such a possibility? Biegelsen sees three basic motivations which could prompt a seller:

1. **Valuations are up.** Which means that the timing for a sale may well be especially good right now. Given FDA uncertainties and the ACA (Affordable Care Act) implementation, valuations may retreat in 2014 and beyond. So the time to sell is now.

2. **Exit strategy.**

3. **Various trends favor larger spine companies.** Hospitals are reducing the number of vendors. Pricing pressures across the board favor the manufacturers with the largest scale and, presumably, lowest per implant cost of manufacturing.

What If??

What if these top analysts are correct and the spine industry is entering a period of accelerated merger and acquisition activity? What might any one of these combinations look like from a purely financial point of view?

In Biegelsen's report, he analyzed the hypothetical combinations of Stryker + NuVasive, Stryker + Globus, Zimmer + NuVasive and Zimmer + Globus. Interestingly, the most favorable combination of all was the Zimmer + Globus combination.

Here are the pro-forma numbers as calculated by Biegelsen and his team at Wells Fargo. *(See Table on page 7)*

	2014	2015	2014	2015	2016	2017	2015	2016	2017
	Post-Purchase Spine Sales ($ in millions)		Hypothetical % Increase in Rate of Spine Sales Growth				Hypothetical % Increase in EPS		
Zimmer + Globus	$611	$668	(1.0%)	8.4%	8.3%	9.9%	15.3%	15.4%	16.2%
Zimmer + NuVasive	$790	$823	(5.3)%	3.1%	1.9%	3.6%	14.7%	13.5%	13.3%
Stryker + Globus	$1,116	$1,190	(4.7)%	6.6%	7.0%	7.2%	11.6%	13.3%	11.8%
Stryker + NuVasive	$1,296	$1,344	(6.9)%	3.8%	3.5%	3.6%	11.3%	12.2%	10.1%

Source: Wells Fargo analyst Larry Biegelsen: "Is the Spine Market Finally Ready for Consolidation?"

The Only Constant Is Change

It is very hard to accurately predict who could potentially buy whom. But the spinal implant business is certainly changing. DePuy's acquisition of Synthes did, indeed, change the strategic landscape. And as Hopkins' survey made clear, the nature of spinal care at the surgeon and hospital level is also shape shifting. Something may have to give. Logic would support larger companies, larger hospitals and a standardization of spinal care. But, to take the contrarian's view, how often is the conventional wisdom correct. ♦

A Bad Day in Court for Physicians and Patients

BY WALTER EISNER

Physicians can't be trusted to make decisions about medical necessity because they will abuse that power.

That's the message in a July 9, 2013 ruling by Los Angeles County Superior Court Judge John Shepard Wiley. He wrote that if physicians were to make final decisions about insurance coverage (and by extension arbiters of defining medical necessity), "inevitably a few will abuse that power by overutilization of medical procedures, imposing excessive costs on the insurer."

He made no observation about insurers abusing that power.

Judge Wiley issued a ruling in a case called Mendoza, Penner and Los Angeles County Medical Association v. Health Net of California, Inc.

Courtesy of Health Net, Inc.

Robert Mendoza and Kalana Penner, insured by Health Net, Inc., sued after Health Net denied claims for procedures recommended by their physicians. The insurer claimed the procedures were not, according to their guidelines, medically necessary. The medical association joined the lawsuit on the side of the plaintiffs, claiming it is harmed by having to fight insurers on behalf of their physician members.

They sued seeking a jury trial to determine damages. Judge Wiley denied their request for a trial and ruled in favor of Health Net. More on that later.

Source: worldpress.com/human judge

Mendoza's Medical Necessity

Mendoza, a self-employed state court interpreter, has been insured by Health Net since 1999. In February 2011, a prostate exam showed he had an elevated prostate-specific antigen (PSA) score. He was immediately referred to an oncologist for further testing.

On March 2, 2011, he was diagnosed with an extremely rare and aggressive form of prostate cancer called adenocarcinoma with signet ring cells. Less than 100 cases have been documented worldwide.

By the time he was diagnosed, his Gleason score showed the cancer was extremely aggressive and his chances of survival were low. His first doctor recommended minimally invasive robotic assisted surgery. Mendoza sought a second opinion from the head of USC's Norris Cancer Center; Gary Lieskovsky, M.D. Dr. Lieskovsky confirmed the diagnosis but recommended an open radical prostatectomy. In a nutshell,

Dr. Lieskovsky said the robotic surgery wouldn't be good enough and urged quick action.

In a report to the insurance company, Dr. Lieskovsky wrote that he did not believe the robotic surgery has "any significant advantages over open procedures, and I believe in fact in high-grade disease, it may clearly well be better to perform [the] open procedure."

Mendoza opted for the open procedure and worked to obtain preauthorization from Health Net.

Health Net denied the surgery saying the treatment was "not medically necessary." The insurer, according to the suit, provided no evidence demonstrating Dr. Lieskovsky's prescribed procedure was "unreasonable or contrary to community medical standards." They simply said robotic surgery was available through the first surgeon.

Mendoza asked Health Net for an explanation, but the insurer, allegedly, failed to provide one.

So Mendoza went back to his first doctor open radical prostatectomy., on April 1, 2011 to discuss the open surgery. However, according to the suit, Dr. Satterthwaite did not offer the open surgery and said he would treat Mendoza's cancer as he would any other form of cancer. He also did not believe there was a sense of urgency. The first available date for the robotic surgery was May 24, 2011.

Mendoza didn't think he could wait and went back to Dr. Lieskovsky and had the open surgery performed on April 4, 2001. He paid for the $30,000 surgery himself by cashing in his wife's life insurance policy. The insurer's formal denial letter was dated the same day.

After his successful cancer-free recovery, Mendoza went back to Health Net to appeal the denial and offered to accept any amount Health Net would have been willing to pay Dr. Satterthwaitte for the robotic procedure. Health Net denied any responsibility for the claim.

Penner's Improper Denied Coverage

Kalana Penner suffered from a medical condition known as occipital neuralgia. She had intense chronic pain in the upper neck, back of the head and behind her eyes. She exhausted all standard forms of medicine, including over 60 medications and 30 treatments, none of which provided lasting relief.

Her doctor referred her to Jamie Henderson, M.D., the director of neurosurgery at Stanford Hospital. Henderson recommended an Occipital Nerve Stimulator (ONS) trial to determine if a permanent ONS could help treat her pain.

Penner sought and received pre-authorization for the trial, which began on October 20, 2010.

The ONS trial was completely, but only temporarily successful. Pre-authorization was sought for a permanent ONS implant. Health Net denied the claim saying it was not medically necessary according to their guidelines. Penner claims Health Net was relying on ten-year-old literature. In fact the American Academy of Pain Medicine and the World Institute of Pain support the procedure that worked on Penner.

Penner claims the company made no attempt to show that the ONS procedure was plainly unreasonable or against community medical standards.

Given her extreme pain, Penner requested an expedited review, which the insurer denied. Instead Health Net hired a "peer reviewer" who determined the procedure was not medically necessary based on the insurer's own guidelines. The reviewer recommended medication which Penner had already tried and a procedure called occipital neurectomy. Penner's doctor had specifically warned that that procedure was highly invasive, destructive, commonly ineffective and carried substantial risk of returning symptoms which become untreatable.

Six months later, on April 1, 2011, the California Department of Insurance determined that Health Net had improperly denied coverage. Health Net finally approved the surgery, which was performed on April 20, 2011. The surgery was successful, but Penner says it was six months of bedridden pain too late.

So Mendoza and Penner sued, requesting an injunction against Health Net to keep it from continuing its "unlawful conduct." They also want damages to be determined by a jury.

Medical Association's Mission

The Los Angeles County Medical Association joined in saying it was harmed by being diverted from its mission of allowing doctors to spend more time "treating and healing their patients and less time haggling with insurance companies [like Health Net] who, at every opportunity, interfere with the doctor-patient relationship and second-guess the medical expertise of treating physicians."

Legal Arguments

Plaintiffs argued it in order to deny a health insurance claim on the basis that a treatment or hospitalization was not medically necessary, the legal standard is that the treating physician's judgment must be shown to be ***plainly unreasonable or contrary to community medical standards***. (Sarchett v. Blue Shield of California (1987)).

Instead, argue the plaintiffs, Health Net set up its own criteria, which is at variance with California law.

Judge Wiley noted that plaintiff's claims rested on two precedents involving Blue Shield of California and Blue Cross of Northern California. He quickly ruled neither case applied here and ruled against allowing a jury trial.

Medical Judgment v Risk Management

Instead Wiley wrote that the plaintiffs' appeal would be more appropriately directed to a policymaking body, not a court. He continued that suggesting that insurers cannot consider treatment costs when making coverage decision would "narrow the range of choices available to prospective subscribers." He continued with his coup d'etat, writing, "…it is unlikely that any insurer could permit the subscriber free selection of a physician if it were required to accept without question the physician's view of reasonable treatment and good medical practice. If the treating physician makes the final decision whether the treatment he prescribes is covered by the policy, inevitably a few will abuse that power by overutilization of medical procedures, imposing excessive costs on the insurer." (Emphasis added.)

He continued that "subscribers would pay the price in reduced insurance alternatives and increased premiums." (Emphasis added.)

Wiley went further and said that he could find no support for the plaintiff's assertion that under case law, the insurer must justify a denial of coverage by establishing the physician's judgment is unreasonable or contrary to good medical practice. He said the court already rejected the argument that an insurance policy should be "construed in light of the reasonable expectations of the insured so as to cover any treatment the treating physician recommends, simply because the physician has recommended it."

Contract Language Rules

He concluded that the subscriber's expectations can be "best fulfilled not by giving his physician an unreviewable power to determine coverage, but by construing the policy language liberally, so that uncertainties about the reasonableness of treatment will be resolved in favor of coverage."

In other [our own] words, the language of contracts and lawyers trumps the medical judgment of physicians in determining medical necessity.

The courts have not been consistent in interpreting medical necessity wrote Morris Landau, J.D., M.H.A, for the University of Houston Law Center in 2000. "Although some courts have held that the sole responsibility for determining medical necessity should be placed in the patient's physician's hands, other courts have held that medical necessity is strictly a contractual term in which a patient's physician must prove that a procedure is medically appropriate and efficacious. One U.S. District Court defined 'medically necessary' as a treatment that is commonly recommended, or not outside the mainstream of the usual customary practice of medicine, or meets the common standard of care. Whitehead v. Federal Express Corp., 878 F. Supp. 1066 (W.D. Tenn. 1994)."

A spokesperson for the plaintiffs told us that the parties plan to appeal Judge Wiley's decision not to give them a trial.

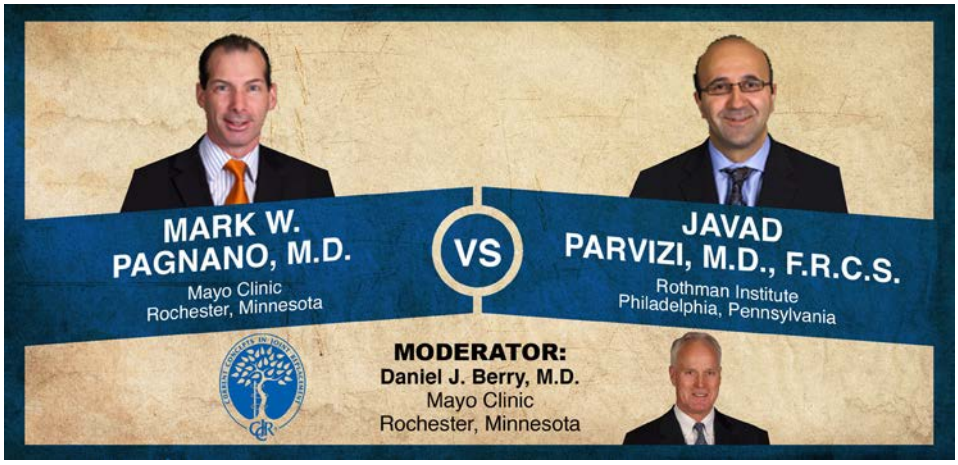
In the end, we're left with the question every patient asks: "Who do I trust to do what's best for me?" When it comes to insurers and physicians, only one took an oath to do what's in the best interest of the patient. Maybe a jury will get to decide. ♦

Pagnano, Parvizi Debate the Direct Anterior Approach

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Mark Pagnano says, "Anterior THA [total hip arthroplasty] results in no difference at two hours, two days, two weeks, two months, or two years… compared to other ways of doing THA." Jay Parvizi counters, "Future data will show that direct anterior leads to a lower bleeding rate, less postop pain, etc. Direct anterior is here to stay."

This week's Orthopaedic Crossfire® debate is "The Direct Anterior Approach: Here Today, Gone Tomorrow." For the proposition is Mark W. Pagnano, M.D. from Mayo Clinic in Rochester, Minnesota; against the proposition is Javad Parvizi, M.D., F.R.C.S. from the Rothman Institute in Philadelphia, Pennsylvania. Moderating is Daniel J. Berry, M.D. from Mayo Clinic in Minnesota.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Pagnano: "It's my contention that the direct anterior total hip replacement (THA) results in no difference at two hours, two days, two weeks, two months, or two years…compared to other ways of doing THA. Recall the introduction of the two incision hip, and the accompanying mainstream media coverage. This generated substantial interest from patients and surgeons, but is noted for a complete lack of scientific, peer-reviewed data during the introductory phase."

"There were claims that it was a fundamentally different operation, and that no muscle or tendon was damaged. It was accompanied by zealous promotion and a lack of data."

"What we have subsequently seen is that many of the early claims of minimally invasive hip arthroplasty have been disproved or are still not tested. The most dramatic example is the two incision hip. There are now multiple randomized controlled trials that show no difference in function compared to a contemporary mini posterior approach."

"It's certainly possible to do a direct anterior hip in a variety of patients. That's been demonstrated by multiple orthopedic centers. We must weigh any purported benefits against the price with regard to operative time, equipment and personnel, and complications."

"Let's first look at the claim of rapid recovery. For today's hip replacement there's no difference based on surgical technique, at two hours, two days, or two weeks…or at two years. There's likely none at two months."

"At two hours and two days all patients have excellent pain relief because they've gone through a comprehensive protocol. They are all started on a rapid rehabilitation protocol, and can all ambulate with an assistive device. That's been proven in Jay Parvizi's study…a randomized trial that showed no difference in analgesic requirements, blood transfusions, length of stay, or discharge to home or rehab. All of our patients get those benefits from the advanced pain management, the rapid rehab protocols, and the patient education initiatives."

"There's no difference at two weeks. Contemporary hip replacement patients are all ambulating well with assistive devices; some have gotten rid of those devices. They can climb stairs and do daily activities. That's true whether it's a direct anterior, an anterolateral, or a mini posterior."

"There's no difference at one or two years. We all assumed that long term differences would be unlikely given the excellent function attained by today's contemporary THA patients. It's been demonstrated in Jay Parvizi's study, a study from Munziger in Zurich, and Nakata from Japan. There was no difference between a mini posterior and a direct anterior at one year in the latter two studies; there was no difference a two years in Jay's study."

"And the two-six week interval? Gait analysis from Klausmeir shows us that neither approach—direct anterior nor

anterolateral—resulted in faster recovery. Larry Dorr looked at the difference at six weeks and could find no difference. Paul Beaule's gait analysis found that stair climbing was not better with the direct anterior approach. Is there one study that shows a difference in the two-six week range? Yes. The one from Rothman showed slightly better SF-36 and WOMAC scores with direct anterior at six weeks…and a tiny difference in the time to get rid of a cane (2.4 weeks versus 3.4 weeks)."

"But if you compare that to other contemporary studies the difference is one, two, or three days. Is that clinically important and reproducible? That remains to be determined. Finally, people like to consider direct anterior for better stability. If we combine the data from multiple studies, however, the mean dislocation rate for a direct anterior approach is just under 1%. If we look at contemporary posterior approaches with a capsular repair, again, a mean dislocation rate that's under 1%."

"It's cumbersome, time consuming, expensive, and many times awkward. There are unique complications that can be attributed to this technique, including lateral femoral cutaneous and peroneal nerve injuries. So in conclusion, a direct anterior approach is a success in 2012 for the majority of patients. But the biggest advocates were people who were previously doing direct lateral approaches. It's relatively uncommon to find a high volume posterior surgeon who is switching."

Dr. Parvizi: "In life and in medicine you can belong to one of two camps. The status quo camp where you think there is no need for innovation; or the futuristic camp where you strive for a better outcome for patients…and you are an innovator."

"There is room for innovation in THA in many areas, including surgical approach. We *have* innovated in surgical approach; remember that total hip replacement used to be done through the greater trochanter osteotomy. A level one study from my institution showed that you could perform the surgery through a direct lateral approach without having to do a trochanteric osteotomy—and these patients did fine."

"Recently we've fallen victim to many innovations that have not advanced our field. There is a learning curve with any of these innovations. But imagine what would have happened if endoscopic vascular surgeons gave up after the first aorta burst when they were trying to do the endovascularized triple A treatment. We would still be flaying open the abdomen in an effort to repair the triple A."

"I disagree with Dr. Pagnano that you need a fluoroscopy and a special table. At my institution over the past five years we've never used a Hana table for any of these direct anterior approaches."

"I'd also argue that direct anterior is not the two incision technique that Dr. Pagnano articulated…that was overzealously introduced by some surgeons without proper evaluation. Any of the literature he's just discussed with the two incision THA does not apply to direct anterior. There's plenty of evidence—all level one—that shows direct anterior is better than direct lateral."

"Based on evaluation of every available study direct anterior is as good as direct lateral; in many cases the former is better than the latter. This is particularly true regarding functional results; less postoperative pain, less blood loss. There are many studies showing that direct anterior versus other approaches

may have promise. There are two articles in press comparing direct anterior versus posterolateral and found that they both have better outcome with the direct anterior even versus posterolateral."

"In the future I'm sure the data will show that direct anterior leads to a lower bleeding rate, less post-op pain, shorter length of stay, better functional recovery…and in our hands, a shorter operation time than direct lateral. I think direct anterior is here to stay, and I predict that it will be one of the most popular approaches to THA in the future."

Moderator Berry: "Mark, a 30-second rebuttal to Jay's comments?"

Dr. Pagnano: "With the direct anterior we're no longer in an innovative phase. It's been around now for at least a half a decade so we no longer have to accept learning curve issues and the like. We can now look at what is the marginal benefit or the marginal cost of that technique versus another. So I'll give you that perhaps there are some marginal differences at two to six weeks compared to a direct lateral approach; I'm not prepared to give up any differences compared to a contemporary mini posterior approach."

Dr. Parvizi: "I don't care about the two months/two years. I think it matters what patients do within the first day, first week, and the first two weeks. So if you were to have a hip replacement the first questions you'd ask would be, 'When can I get in the car? When am I off narcotics?' Based on the literature and my experience, there is a much better early functional outcome with direct anterior compared to direct lateral."

Moderator Berry: "Jay, who is a poor candidate for a direct anterior approach?"

Dr. Parvizi: "Patients with massive abdomens where, for example, the pannus hangs over the wound during the healing process. Another group would be patients with proximal femoral deformities with hardware in place. That is usually placed through a lateral approach so you might as well make a lateral incision in that patient group. Then there are patients with an extremely tough and stiff hip that makes the exposure of the femur difficult."

Moderator Berry: "Mark, let's say the functional results are pretty close to the same. Are there some patients in whom you're so worried about dislocation that it would be nice to preserve the whole posterior capsule?"

Dr. Pagnano: "That's one of the areas people are focusing on—the dislocation rate. Yet if you go back to the big series that have been published, the dislocation rate is not different. People have been comparing historical posterior approaches where there was a big capsulectomy and no repair of the posterior structures…no one does that today. Everyone does a posterior approach where they repair the posterior capsule."

Moderator Berry: "Jay, what are the unique complications that can occur with a direct anterior approach?"

Dr. Parvizi: "First is this numbness across the lateral thigh. There have been some strategies to try and minimize it, but it still happens to about 10-15% of patients. It can be a nuisance, but it's not a major problem. Also, with use of these tables if you're overzealous with the hook…you put it around the greater trochanter without doing release of the saddle area, you're likely to fracture the greater trochanter. And if you don't get a good exposure of the femur you're likely to get an intraoperative fracture. What I meant by learning curve is if you've never done an anterior approach you should be going to cadaver labs and watching surgeons do it, and then implement it in your practice."

Moderator Berry: "Jay, the direct anterior is probably an approach that requires the surgeon to sneak around the muscles more, so many people will say that it constrains their use of the type of femoral component that they need to use."

Dr. Parvizi: "Most people say that shorter stems are easier to put through the anterior approach. We've never done shorter stems. I don't think you need to change too many things when you're bringing the approach in; should be using the stem that you are familiar with."

Moderator Berry: "Mark, do you agree?"

Dr. Pagnano: "I think it's fair to say that a straight, double tapered stem is tougher to put in with this type of approach. It's hard enough to get far enough out into the greater trochanter to get it perfectly down the middle than it would be with some other designs."

Moderator Berry: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

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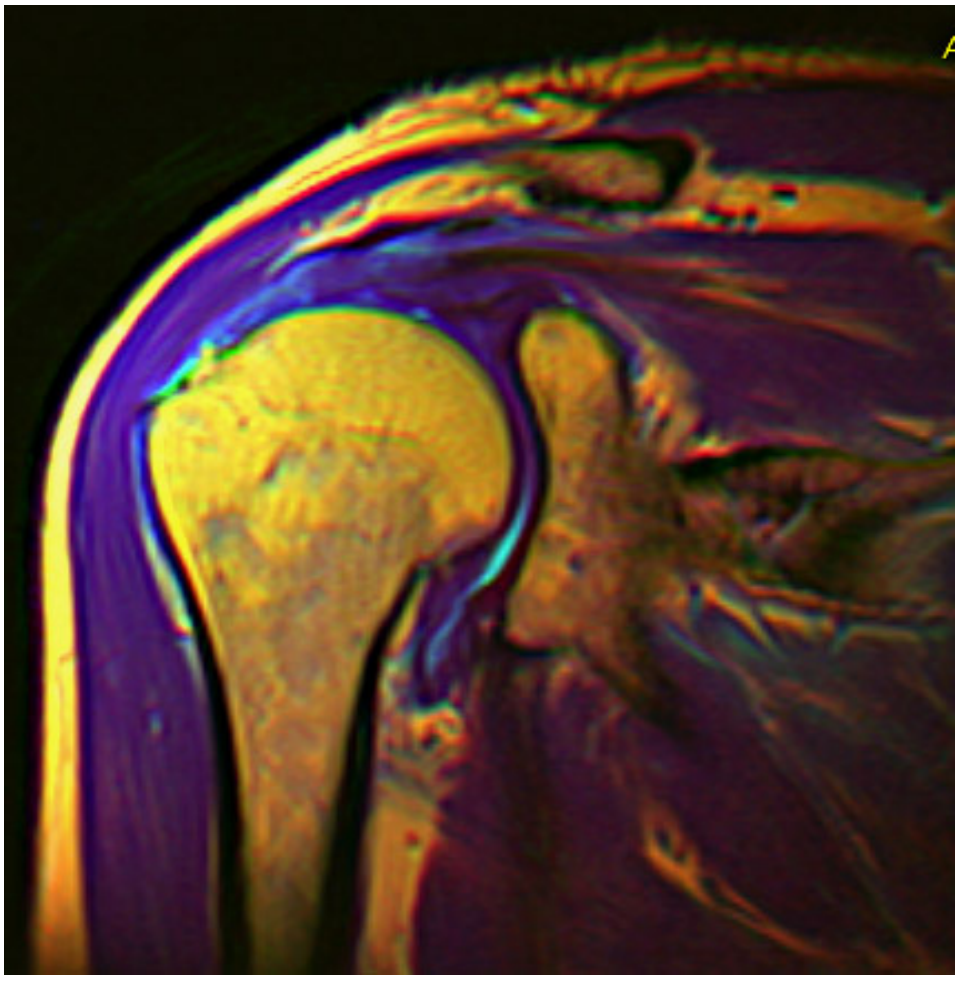
Guarantee a Surgical Outcome? Really? Harvard Takes a Stab…New Shoulder Study Tackles Instability…Massive Study Spots Stress Fracture Solution and more

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

New Shoulder Study Tackles Instability Shoulder instability doesn't just get operated out of existence, unfortunately. Indeed, there remains a gray area surrounding this condition. Matthew T. Provencher, M.D., M.C., U.S.N.R. is the chief of Sports Surgery at Massachusetts General Hospital and associate professor of Surgery at Harvard University. He tells *OTW*, "Orthopedic surgeons continue to be cautious of patients with bone loss and who present with risk factors for recurrence. We are still defining what those variables mean and how much each contributes to the overall picture when evaluating a patient with shoulder instability. To this end, we are conducting long term prospective studies on the outcomes of several different types of treatment. At present, in addition to focusing on characterizing glenoid and humeral head bone loss in recurrent anterior shoulder instability, we are also examining patient demographics, risk factors for developing recurrent instability, as well as variables associated with successful treatment outcomes."



Wikimedia Commons and © Nevit Dilmen

"Variables taken into account include history and examination findings of the instability condition, high fidelity radiographic imaging and risk assessment based on activity. We want to know what makes it likely that the shoulder will have recurrent injury and how can we best determine treatment based upon desired activity. Rugby, for example, has a higher reinjury rate than most other sports. Currently, we are in the data analysis phase, and are fortunate to be able to use our large database of shoulder instability information from the Naval Medical Center in San Diego. Our preliminary findings are that if you are young, recurrence is not necessarily related to your sport or your being a contact athlete…this is very different than what we previously thought. And we can have reasonable confidence in these findings; we have a high number of enrolled patients—approximately 350 participants—and because of that we can ask more directed questions."

"Ideally, we would be like to be able to say to someone, 'Here are the major risk factors for your likelihood of recurrence after an instability event. If someone has these factors—patient factors,

radiographic findings, or the type of surgery proposed—then we will better predict how patients will do the first time. One thing is for sure…revisions after an initial stabilization procedure are a huge challenge, so we should really be looking at how to optimally treat this condition and be able to get it right the first time."

Guaranteeing the Outcome? Really? Harvard Takes a Stab. "Prove your worth" is the increasingly louder refrain from the government and insurers. It gets down to value, says Jon J.P. Warner, M.D., chief of the Massachusetts General Shoulder Service and director of the Boston Shoulder Institute Fellowship. He tells *OTW*, "'Value' means many different things to different parties. With the advent of healthcare reform and social transformations which is occurring in care delivery, it's becoming ever more important to consider value. To try and get further clarification on value, and how to measure and implement it, I am fortunate to be working with a group from Harvard Business School. Leading things on the Harvard side is Professor Michael Porter, known for his work on 'Value Based Healthcare.'"

"Value, which is outcome divided by cost, is really interpreted differently by many parties. The patient receives value if they get a solution to their problem (i.e., the pain is gone, etc.). To the surgeon, value has a more economic meaning…the more volume of surgery they do the more value they get. This is because the government and insurers have reduced payments to such an extent that doctors may be naturally inclined to increase their volume to offset lower payments. This is paradoxical, of course, because then the value for the patient is negatively affected (less time spent with the doctor)."

"In my practice I do many revision reconstructions of failed surgeries; we see numerous failures and try to understand the reasons for this. Unfortunately, it's often the volume problem, i.e., volume is rewarded, not outcome. Looking specifically at a hospital episode for rotator cuff repair, there is a cost attributed to the hospital for the anesthesia, labs, etc. This is the majority of the cost of care. Then you have the surgeon's fee, which accounts for 5-10% of care. The growth of costs for hospitals is greater than that for doctors. The hospital basically allocates costs, which may result in higher charges for some things to make up for other cost areas. This therefore reduces value overall. Insurance companies want to limit their payments in order to stay solvent; this can lead to increased demand to offset lower payments (increasing volume and resulting in less value for patients)."

"We are working on creating a single bundled payment for rotator cuff surgery. Our model is such that the payor gives one dollar amount over the entire episode of care, say one year which includes the surgical procedure. It is critical that the costs for such an episode are calculated accurately and we are using a sophisticated accounting method which allows us to calculate the actual costs according to time and activity spent on patient care. Moreover, as we have data on the success of such surgery we are able to then offer a guarantee on the outcome for one year. In the case of a failure then the cost of additional care would be covered."

"It is important, we believe, that the physician experts drive this process in collaboration with the hospital, as physicians are the only ones who clearly know the necessary care steps and can thus avoid unnecessary treatments and diagnostic studies."

"This is, fundamentally, an effort to align incentives. Hospitals may be resistant because they can't allocate costs and make large profits on some surgical cases in order to cross subsidize other care which loses money; surgeons may or may not like this approach because it incentivizes outcomes but imposes risk."

"Healthcare reform has always been predicated on the management of cost, not value. This has not seemed to change with Obamacare. This means that if one surgeon delivers a service and has a bad outcome and another delivers a service and has a good outcome, then the insurance company or the government (in the case of Medicare) pays the same for both. This system incentivizes process without connecting it to outcome to value; we need to incentivize outcome."

"Our goal for 2014 is to provide an example of value-based shoulder care in order to incentivize others to follow this approach. We are completing the first half of the accounting study at Brigham and Women's Hospital, and the second half at Massachusetts General. Upon completion, we will propose a single bundled payment for rotator cuff repair with a one year guarantee on results, which will be less expensive than the way we do it now. It will provide a margin to both the hospital and physician and will incentivize outcome. Patients will derive value as they will have a guarantee on their outcome with the assurance that the physician and the hospital share some risk with the patient. This approach will allow for better value as outcome will go up and cost will go down."

Laminectomy Out, Decompression In? Spine surgeons in Florida are shaking up the conventional thinking when it comes to treating spinal stenosis in adults. Antonio Castellvi, M.D. is a spine surgeon with the Florida Orthopaedic Institute. He tells *OTW*, "Using cadavers we looked at data on the volume of the neural canal and the neural foramina pre and post op. Then we performed surgery on 50 patients and found that we were able to resolve symptoms of claudication with improvement in canal volumes. We followed these patients out two years and saw no significant degradation of those improvements. This was surprising, of course, because the gold standard is laminectomy… and yet I was enlarging the canal by 20-30% and still getting good clinical outcomes. We have followed some patients up to four years and no one

had to go back to the OR for a laminectomy."

"Using indirect decompression on the neural structures can be effective, although I suspect it will take a while to gain popularity. The procedure is done with an anterior cage that distracts the disc space; it can be done laterally or with a straight ALIF."

2,000 Patient Study Spots Solution to Female Stress Fractures Women have three times the risk for stress fractures than men. And when it comes to lower extremity stress fracture risk, how you move may be an important risk factor according to some researchers. Kenneth L. Cameron, Ph.D., M.P.H., ATC, is Director of Orthopaedic Research at Keller Army Hospital in West Point, New York. He told *OTW*, "We studied nearly 2,000 military cadets and found that injury prevention programs may indeed help prevent stress fractures in athletes and military personnel. While other studies have indicated that lower extremity movement patterns and strength are associated with stress fractures and overuse injuries, our study is one of the first to identify dynamic knee rotation and frontal plane angles as important prospective risk factors for lower extremity stress fractures."

"In this study, which we recently presented at the American Orthopaedic Society for Sports Medicine, we found that the incidence rate for stress fracture injuries among females was nearly three times greater than among males. Specific lower extremity movement patterns appear to be predictive of subsequent lower extremity stress fracture injury and athletes with more internal knee rotation and knee valgus, and limited hip and knee flexion, are at greatest risk."

"Going forward it will be important to see if movement retraining interventions to increase knee flexion and extension strength, increase knee and hip flexion motion, and limit knee abduction (valgus) and internal rotation can reduce the risk of lower extremity stress fracture in athletic and military training populations. It will also be important to refine field assessments for high risk movement patterns that can be used to screen and identify those at greatest risk to lower extremity stress fracture." ♦

COMPANY

2Q DePuy Synthes Report Card

Orthopedic sales of $2.39 billion at Johnson & Johnson's (J&J) DePuy Synthes unit were up 48.9% for the second quarter. Excluding the impact of last year's Synthes, Inc. acquisition, operational sales were up approximately 3%.

Operationally, hip sales were up 4%, knees were up 2%, spine was down 2% and trauma was up 4%.

According to company officials, strong hip sales were driven by primary stent platform sales. Knee sales were driven by the Attune fixed bearing knee as well as revision platforms. Declining spine sales were attributed to softness in the market, as well as "attrition of the commercial sales organization" as the Synthes business is integrated.

Synthes Integration

Alex Gorsky, the J&J's chairman and CEO told analysts on July 16 that he and his colleagues are really pleased with the way the integration is going. "Taking on a company the size of Synthes with a reputation that scale [and] its capabilities is no small undertaking. Bringing those together the way that our teams have, I think, they are really to be commended for it. We have got a multi-phased program in place to bring it together commercially, the entire research and development organization as well as all the supporting functional areas...While we still have work to do in certain areas of the integration, we are making good progress."

Gorsky said he was encouraged by what the company is seeing in orthopedics, particularly in hips and knees and trauma over the past quarter.

DePuy/Synthes Corp. Logo / stateimpact.npr.org

DePuy Synthes 2Q2013	Sales ($ in millions)	% Change*
Total Reported Sales	**2,396**	**46.5%**
Knees		2.0%
Hips		4%
Spine		down 2%
Trauma		4%

Source: Johnson & Johnson
** Constant Currency and includes Synthes, Inc.*

Spine Transitional Issues

Addressing the decline in spine sales, Gorsky said he thinks the company is commensurate with the spine market being down 2%. "In the U.S., we have seen the performance when we were down about 7% versus the market that was down about 3%. We were clearly impacted by some transitional issues with our sales force during that period. We've put a comprehensive plan in place, where we think that we project that will do much better going forward."

He added that more important when looking at the offerings the company's representatives have across the minimally invasive segment, degenerative, spine, a number of other areas combined with the rest of the portfolio, they are going to be in a very good position in that marketplace. "So, we remain very optimistic, pleased with the performance around the integration."

Lawsuit Against Former Reps

On that same day as the conference call with analysts, the company filed a $3 million lawsuit against two former sales reps and their new employer in a Virginia federal court. The company claims the two former reps have shared trade secrets and undermined the company's ability to compete in eastern Virginia's spinal device market after they resigned their DePuy positions and joined Sky Surgical Inc.

Utilization Rates Remain Flat

J&J CFO Dominic Caruso told analysts that while there were some indicators of general economic improvement during the quarter, the healthcare market data in terms of utilization is still relatively flat over the prior year, with just a modest sequential improvement over the first quarter utilization data.

He also noted $560 million in special costs during the quarter for litigation expenses related to the DePuy ASR hip program cost. And, as expected, continued costs associated with the global integration of Synthes.

Piper Jaffray analyst Matt Miksic said the results and commentary thus far from Biomet, Inc., J&J and Stryker Corporation indicate that second quarter orthopedic growth is tracking to either be in-line or slightly better than his previous estimates.

—WE (July 19, 2013)

Bacterin's DBM Putty Cleared for Spinal Fusion

Bacterin International Holdings, Inc. has received FDA 510(k) clearance to market its OsteoSelect DBM Putty for use in spinal fusion.

The putty, comprised of demineralized bone matrix (DBM) allograft is a moldable bone graft substitute designed to withstand irrigation while exhibiting osteoinductive properties for improved bone regeneration. In a July 16, 2013 press release, the company states the cohesive nature of the product provides an advantage over other commercially available DBM putties which can readily wash away after placement in wet, surgical environments.

The osteoinductive potential of every lot of the putty is confirmed after sterilization in an animal model, according to the company, thus providing surgeons with a bone grafting solution that is both safe and biologically active.

As part of the regulatory approval process, Bacterin provided funding to Hospital for Special Surgery in New York to perform a study evaluating the efficacy of OsteoSelect in a rabbit posterolateral lumbar spine fusion model. Biomechanical, radiographic, and histological analysis indicated that OsteoSelect showed equivalence to a control of autologous iliac crest bone graft.

Obtaining another indication for the use of the product will provide Bacterin with additional marketing opportunities, commented Gregory Juda, Ph.D., Bacterin's chief scientific officer. "In the three-plus years of OsteoSelect being on the market, we have seen considerable adoption by the orthopedic community across a variety of surgical specialties. Our post market surveillance supports the efficacy of OsteoSelect and the results of the preclinical work validate the clinical findings."

Mechanical and biological characteristics of the product include:

- Osteoinductive
- Device-level sterility (SAL 10-6)
- Exceptional handling characteristics
- Sterile, room-temperature storage
- Will not dissipate upon direct irrigation
- Contains 74% DBM by dry weight

The company develops, manufactures and markets biologics products to domestic and international markets. According to the company, its proprietary methods optimize the growth factors in human allografts to create the ideal stem cell scaffold to promote bone, subchondral repair and dermal growth. These products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain, promotion of bone growth in foot and ankle surgery, promotion of cranial healing following neurosurgery and subchondral repair in knee and other joint surgeries.

—WE (July 17, 2013)

Bacterin International Holdings, Inc./OsteoSelect DBM Putty

Kineflex FDA Panel Meeting Cancelled

SpinalMotion, Inc.'s two-day FDA orthopedic panel meeting scheduled July 24 and 25, 2013 has been cancelled.

Image created by RRY Publications, LLC / Source: FDA Orthopedic Panel

The FDA announced the cancellation on July 11 without comment. The company told us they have no comment on the cancellation.

The company was to present evidence of the safety and effectiveness of the Kineflex/C Cervical and the Kineflex Lumbar Artificial Discs.

The Kineflex/C is a metal-on-metal (cobalt chrome molybdenum alloy) cervical total disc replacement device. The device is indicated for reconstruction of the intervertebral disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy or myelopathy due to a single-level abnormality localized to the disc space.

The Kineflex Lumbar disc is a metal-on-metal (cobalt chrome molybdenum alloy) lumbar total disc replacement device. The device is indicated for reconstruction of the intervertebral disc at one level (L4-L5 or L5-S1) following single-level discectomy for lumbar degenerative disc disease (DDD) where DDD is defined as discogenic back pain with degeneration of the disc as confirmed by patient history, physical examination, and radiographic studies.

Kineflex Roadmap

The company received IDE (Investigation Device Exemption) approvals from the FDA in 2005 to commence studies. The cervical trial involved over 20 U.S. sites. The lumbar trial also involved over 20 U.S. sites, and was a randomized study comparing the disc to another FDA approved lumbar artificial disc. Both trials required a two-year follow-up period.

In June 2007 the company completed enrollment of its cervical clinical trial. Enrollment in the company's first IDE clinical trial, evaluating the lumbar disc was completed in 2006.

On March 20, 2012 the company announced that it received CE Mark for two sub-5mm Kineflex/C cervical total disc replacements.

The company conducted the IDE clinical study of the cervical disc compared to anterior cervical discectomy and fusion in the U.S., and submitted its premarket approval (PMA) application in 2010. A cervical disc paper was selected for the Best Papers section at the 2010 North American Spine Society's Annual Meeting.

In October 2010 the company announced it completed enrollment in an international clinical study evaluating the lumbar disc inserted via a minimally invasive lateral approach.

—WE (July 15, 2013)

LEGAL

Former ArthroCare CEO Indicted

The ongoing saga of DiscoCare has now landed its biggest fishes. Michael Baker and Michael Gluk, the former CEO and former CFO, respectively, of ArthroCare Corporation have been charged with defrauding the company's shareholders in a $400 million scheme by falsely inflating company earnings by tens of millions of dollars.

Bonesupport.com/Michael Baker

Indictment

On July 17, 2013, the Department of Justice (DOJ) unsealed a 17-count indictment which was returned the previous day. Baker and Gluk are charged with securities and wire fraud. Both defendants surrendered to authorities on the 17th.

According to the indictment, between 2005 and 2008, Baker, Gluk and other senior executives and employees of ArthroCare allegedly falsely inflated company sales and revenue through

a series of end-of-quarter transactions involving several of ArthroCare's distributors. According to court documents, Baker, Gluk and others determined the type and amount of product to be shipped to distributors based on ArthroCare's need to meet Wall Street analyst forecasts, rather than distributors' actual orders. The defendants then allegedly caused ArthroCare to "park" millions of dollars worth of the company's devices at its distributors at the end of each relevant quarter. The company would then report these shipments as sales in its quarterly and annual filings at the time of the shipment, enabling the company to meet or exceed internal and external earnings forecasts.

Inflating Revenue

The indictment alleges that the distributors agreed to accept shipment of millions of dollars of product in exchange for substantial, upfront cash commissions, extended payment terms and the ability to return product, as well as other special conditions, allowing ArthroCare to falsely inflate its revenue by tens of millions of dollars.

Baker, Gluk and others allegedly used DiscoCare as one of the distributors to cover shortfalls in ArthroCare's revenue. According to the indictment, at Baker and Gluk's direction, ArthroCare shipped product to DiscoCare that far exceeded DiscoCare's needs.

$400 Million Investor Hit

In addition, Baker, Gluk and others allegedly lied to investors and analysts about ArthroCare's relationships with its distributors, including its largest distributor, DiscoCare. According to the indictment, Baker and Gluk caused ArthroCare to acquire DiscoCare specifically to conceal from the investing public the nature and financial significance of ArthroCare's relationship with DiscoCare.

According to court documents, between December 2005 and December 2008, ArthroCare's shareholders held more than 25 million shares of ArthroCare stock. On July 21, 2008, after ArthroCare announced publicly that it would be restating its previously reported financial results from the third quarter 2006 through the first quarter 2008 to reflect the results of an internal investigation, the price of ArthroCare shares dropped from $40.03 to $23.21 per share. The drop in ArthroCare's share price caused an immediate loss in shareholder value of more than $400 million.

ArthroCare's former senior vice president of strategic business units, John Raffle, recently pleaded not guilty to misleading investors to artificially inflating the company's stock price.

On May 9, 2013, the DOJ announced that David Applegate, the company's former senior vice president in charge of the company's spine division pleaded guilty to two charges of conspiracy to commit securities, mail and wire fraud, and with a false statements violation.

According to his LinkedIn page, Baker was at ArthroCare for 12 years. Prior to that, he was a vice president and general manager at Medtronic, Inc. He is currently the president and CEO of a San Francisco Bay area company named Pulmonx.

—WE (July 18, 2013)

LARGE JOINTS

ACL, Total Knees and Muscle Atrophy: Progress!

DJO Global, Inc. has announced the launch of the Empi Phoenix, an electrical stimulator designed to help simplify treatment of muscle atrophy before and after surgery for total knee replacement or ACL (anterior cruciate ligment) repair. The product, which has FDA 510(k) clearance, combats disuse atrophy, increases range of motion, and helps manage pain and reduce swelling. The device can even help prepare patients prior to surgery by helping to treat muscle atrophy in the muscles supporting the joint.

DJO Global, Inc.

"This new method of delivering neuromuscular electrical stimulation (NMES) to my patients is comparable to standard physical therapy in helping them recover from knee replacement surgery," noted Dr. Michael Levine in the July 11, 2013 news release. Dr. Levine is an orthopedic surgeon and lead researcher of a recent clinical trial on the effectiveness of electrical muscle stimulation post-operatively. He added, "When combined with traditional physical therapy, the Empi Phoenix creates an excellent scenario for recovering patients."

Anthony Strike, Market Manager of Electrotherapy, told *OTW*:

> "DJO Global's Empi Phoenix is a multi-functional electrotherapy device that utilizes neuromuscular electrical stimulation (NMES) to treat muscle disuse atrophy, transcutaneous electrical nerve stimulation (TENS) for pain management, and a pulsed net direct current for edema treatment. Addressing atrophy, pain and swelling is key to rehab from major knee surgeries, and the Empi Phoenix is designed to offer treatment across the recovery cycle."
>
> "The Empi Phoenix has four preprogrammed therapy options built into the easy-to-use device, simplifying electrotherapy for clinicians and patients and eliminating the need to cycle through countless steps to adjust the device. The therapy is delivered through electrodes on the skin. The comfortable Empi Phoenix conductive garment makes application of NMES easy by simplifying electrode placement."
>
> "Despite the benefits electrotherapy offers patients rehabilitating from a major orthopedic surgery like a total knee replacement or ACL repair, many surgeons have typically shied away from prescribing this therapy as a standard part of rehab because of the complexity of previous devices. Others are just not as familiar with the studies and potential benefits to their patients' rehabilitation."

Mike Mogul, president and CEO, told *OTW*, "Phoenix was designed to offer a simple therapy option that would be convenient enough for orthopedic surgeons to start feeling comfortable prescribing it directly to their patients for home use. The device is essentially 'turn on, turn up.' The garment further simplifies the process with its pre-set electrode placements. Even the paperwork has been simplified, and Empi can deliver the product to the patient directly and take care of all customer support. This simplicity, combined with the positive clinical support for electrotherapy and lack of negative side effects makes the Empi Phoenix well-suited to break through as an excellent new tool for healthcare professionals to prescribe as part of their patients' rehab."

—EH (July 17, 2013)

Found! Molecule to Help With OA

Scientists in the UK have found a naturally occurring molecule in the body which may have important consequences for treating osteoarthritis (OA). Researchers from The University of Manchester and the University of Westminster have found that a molecule known as Urocortin protects cells in the joints from being destroyed. The study has been published in the journal *Cell Death and Disease*.

In the July 11, 2013 news release, Professor Paul Townsend, joint lead researcher along with Dr. Ian Locke of the University of Westminster, said, "In osteoarthritis many different programmed cell-death chemicals are produced which cause chondrocytes to die. Our research shows that the naturally occurring molecule, Urocortin, produced by the body is essential for these chondrocyte cells to survive."

Dr. Locke, director of Postgraduate Studies at the School of Life Sciences at the University of Westminster, said, "We now need to look in more detail at how Urocortin helps cells to survive in order to develop new medicines to prevent joint degradation. Discovering a role for this naturally occurring molecule in joint physiology opens up exciting new avenues of research towards the cause, prevention and, eventually, treatment of OA."

The researchers found that removing Urocortin caused large numbers of the chondrocyte cells to die. However adding it protected chondrocyte cells from programmed cell-death induced by chemicals present in osteoarthritic cartilage.

Professor Townsend told *OTW*, "We were most surprised to learn that a naturally occurring molecule from the body has the ability to both protect

Prof. Paul Townsend, The University of Manchester

and treat signs of osteoarthritis. This is akin to the interesting recent observations concerning tamoxifen being able to treat and protect from many women with breast cancer."

"We need to investigate further how the details of Urocortin work in a number of experimental models, especially in humans. We've started this work and are incredibly encouraged by the results so far."

—EH (July 16, 2013)

Hip Replacement for 8'4" Chinese Actor

Eight-foot four-inch, Wang Fengjun, Asia's tallest man, has been hospitalized for a hip replacement in Zhengzhau, China.

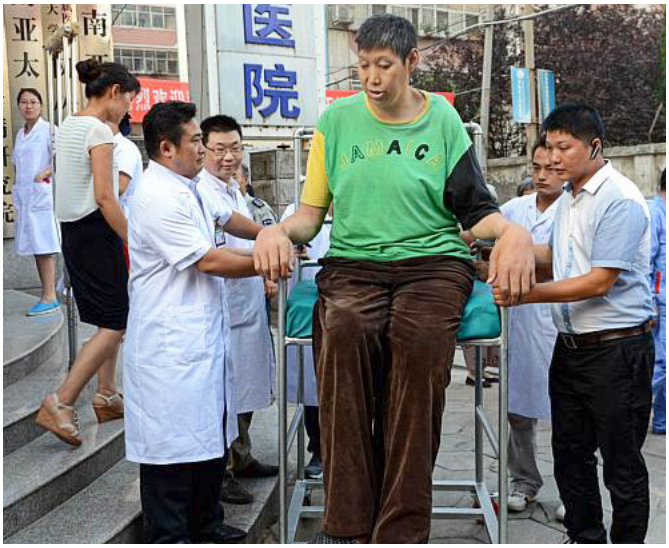
Various media outlets, including the *Zhengzhau Evening News*, reported on July 8, that 37-year-old Fengjun was diagnosed with osteonecrosis of the femoral head four years ago, which results from an interruption of blood supply. Repeated and prolonged pressure on his legs has been linked to his disease.

Fengjun was born to a rural family in Sanmenxia in Henan providence. He has five brothers and sisters, who are normal size. At 2.55 meters, he is 29 centimeters (11 inches) taller than China's most famous former basketball player, Yao Ming. His agent reportedly claimed Fengjun is even taller than Bao Xinshun, the tallest man in the world listed in the *Guinness Book of World Records*.

According to published reports, Fengjun began growing 10 centimeters a year starting at age 13. He ceased growing in 2005 at age 29.

Fengjun will receive free treatment in a hospital in Zhengzhou, which will cover the total treatment expense of 500,000 yuan ($81,550). It is expected to take two years for him to recover.

He is well known in the country, having played numerous roles on Chinese TV. According to his agent, many companies invite him to participate in their promotion activities. Meanwhile, he still practices flute and saxophone regularly, and he is very good at magic.



Agence France-Presse/Wang Fengjun arrives at hospital

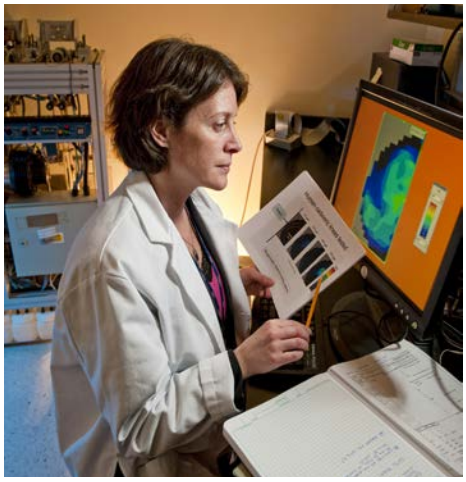
To see a video (and a quirky Chinese ad) of Fengjun, click here: http://www.56.com/u95/v_NDc5NDA2MzY.html#st=76&fromoutpvid=NDc5NDA2MzY&

—WE (July 15, 2013)

Knee Shape as Determinant of ACL Reconstruction

Researchers at Hospital for Special Surgery (HSS) have provided the first evidence that the shape of a person's knee could be a factor in the decision of whether a patient should undergo anterior cruciate ligament (ACL) reconstruction after an ACL tear.

"This is the first study to show that after your ACL is ruptured, the changes in the mechanics of the knee can really


Suzanne Maher, Ph.D.
Image Credit: Hospital for Special Surgery

be affected by the shape of the knee," said Suzanne Maher, Ph.D., associate director of the Department of Biomechanics at HSS, New York City, in the July 2, 2013 news release. "Previously, researchers had only conducted studies looking at whether a particular knee shape makes a person more likely to have an ACL injury, specifically in the athletic population."

The investigators used nine cadaveric knees to examine how knee shape impacts knee mechanics during walking, after a person has torn their ACL. The researchers used a sensor that measured the contact stresses of a critical

weight-bearing area (the tibial plateau). They then mounted the knees on a machine that flexed and extended the specimens while applying forces in many directions (mimicking walking).

Asked about the most surprising thing to come to light, Dr. Maher told *OTW,* "The most surprising finding was the variability in contact mechanics after ACL rupture; with some knees showing significant increases in contact stresses and others showing minimal or no changes."

"The knees that showed changes in the front of the knee had specific shape features. For example, they had a less concave tibial plateau," said Dr. Maher in the news release. "If the tibial plateau has a very deep valley and then you have a femur (thigh bone) sitting in a deep well, that is going to give you a very stable knee. So, when you tear your anterior cruciate ligament, it is not going to have a huge effect." Increased tibial slope was another predictor of increased stress.

Regarding future research, Dr. Maher told *OTW*, "We measured changes in contact stresses in cadaveric knees after ACL rupture, but it is unclear how changes in contact stress relate to tissue damage in patients knees. We are about to embark on an innovative study, funded through the AOSSM [American Orthopaedic Society for Sports Medicine], where we will measure contact stresses in patients' knees and then follow them with MRI scans—in a goal to connect contact stress with likelihood of tissue damage. Ultimately, we will use this information, together we with what we have learned from our cadaveric study, to design a clinical study to more comprehensively define if specific osseous anatomic features can predict increased likelihood of joint degeneration after ACL injury."

"The complexity of the response of the human knee to ACL injury is in part driven by variability in osseous geometry. Future clinical-based studies that can explore this issue in greater detail will conceivably add yet another dimension to the decision of choosing ACL reconstruction after injury."

—EH (July 15, 2013)

TRAUMA

High Bone Marrow Fat a Risk Factor for Osteoporosis

A group of Boston researchers have found that obese people with higher levels of fat in their liver, muscle tissue and blood also have higher amounts of fat in their bone marrow, putting them at risk for osteoporosis and possibly, a fracture.

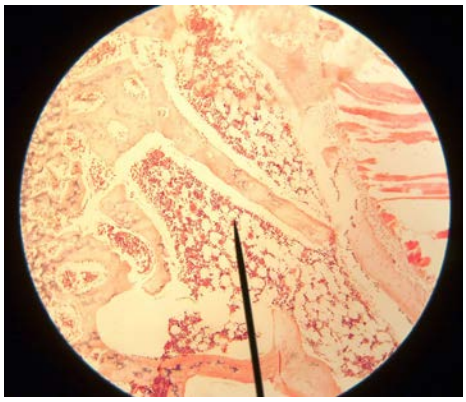
"Obesity was once thought to be protective against bone loss," said study lead author Miriam A. Bredella, M.D., a radiologist at Massachusetts General Hospital and associate professor of radiology at Harvard Medical School in Boston, in the July 16, 2013 news release. "We have found that this is not true."

While other studies have examined the relationship between visceral fat and bone mineral density, this study looked at fat inside bone marrow, the spongy tissue inside the bones of the body that produces stem cells.

"In our study, we focused on bone marrow fat because that is where our stem cells can develop into osteoblasts—the cells responsible for bone formation—or fat cells," Dr. Bredella said. "We also wanted to look at the relationship between bone marrow fat and other fat components, such as those in the liver and muscle."

Dr. Bredella and colleagues used proton magnetic resonance spectroscopy (MRS), a technique that allows for precise measurement of fat, to examine 106 men and women, ages 19 to 45 years, who were obese based on body mass index measurements, but otherwise healthy.

The MRS results showed that people with more liver and muscle fat had higher levels of fat in their bone marrow, independent of body mass index, age and exercise status. HDL cholesterol, the "good" type of cholesterol that is associated with a lower risk of heart disease, was inversely associated with bone marrow fat content.



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The team also found that triglycerides also had a positive correlation with bone marrow fat, possibly because they stimulate osteoclasts, a type of cell that breaks up bone tissue. Dr. Bredella also noted that cell-signaling molecules called cytokines are known to promote the conversion of stem cells into fat. "Obesity can shift stem cell lineage, resulting in more bone marrow fat," she said.

—EH (July 18, 2013)

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