

# Orthopedics This Week

week in review

**4 Pricing Pressures Lower Spine Forecast Part 2** ♦ Pricing pressures continue to affect spinal implant supplier revenues and we are, therefore, lowering our sales forecasts for spinal implant and instrumentation companies specifically. But not all companies were affected the same way. Read on for our company specific forecasts.

**9 DePuy's State of the Union** ♦ Johnson & Johnson conducted its bi-annual device meeting with analysts on June 3. What's new for the DePuy franchise? Products, strategies and surprisingly, a self described "opportunity" for the company in a tougher regulatory environment. Read what Mike Mahoney, DePuy's Happy Warrior had to say.

**13 What Gives? Orthopedic Residency Education** ♦ The results of a residency directors peer forum are out. Some of the issues? What exactly needs to be learned in residency? How many cases of any given type a trainee should perform?

**17 Giving Amputees Their Lives Back** ♦ With each prosthetic donation, the non-profit Limbs of Love and its partner companies TMC Orthopedics and the Amputee & Prosthetic Center are transforming the lives of deserving amputees. But it's not just an artificial limb these patients are receiving; it's a new lease on life.



picture of success

**29 Dr. Claude Moorman, III** ♦ He has climbed Mount Kilimanjaro, worked with the Baltimore Ravens, and knows knees. This is Dr. Claude Moorman, III, Professor of Orthopaedics at Duke University School of Medicine.



breaking news

**21 Anulex** Raises \$18 Million  
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 Statins and **Hip Replacement**  
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 Preemption Not Applicable in **Trident Suit**  
 .....  
 1st **Nepal-America** Spine Conference  
 .....  
 High and Low Stress Tendons and **Riding Into Spinal Injuries**

**For all news that is Ortho, read on.**

# Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**This Week:** Would you want Wall Street to run your company? Didn't think so. The market's herd mentality is in full view right now as orthopedic cash flows and business fundamentals don't seem to matter to institutional investors. These equities have never been so attractive.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Johnson & Johnson	27.10%	(9.10%)	\$6 / share in annual cash flow equals a cash flow yield of 10.4% on today's stock price; 3.70% cash dividend yield.
2	5	Zimmer	27.69	(11.60)	\$5.50 / share in annual cash flow equals a cash flow yield of 10.2%, plus \$870 million cash balance.
3	7	Kensey Nash	38.72	(8.91)	\$70 million cash in the bank is almost as much as KNSY's \$80 million annual sales—16% cash flow yield!!
4	1	Medtronic	31.37	(11.94)	"Only" 9.3% cash flow yield. Still digging out from its Kyphon purchase. Down 3 spots.
5	3	Stryker	24.71	(11.59)	Cash flow yield is just 7.3% but, oh my! that cash balance is now \$3 billion. Cash dividend yield is a mere 1.2%. Hello!
6	4	Symmetry	11.48	(7.11)	14% cash flow yield but operating margins are comparatively low—which fits SMA's OEM business model.
7	8	Orthofix	13.51	(12.88)	9.5% cash flow yield, SOLID balance sheet with a resurgent profit margin. Consistently delivering upside quarterly surprises.
8	6	Exactech	12.72	(12.38)	11.5% cash flow yield but cash balances are meager. With just 12% operating margin, cash management is key.
9	9	Alphatec	(0.44)	(18.44)	Negative cash flows historically. Wall Street expects ATEC to turn the corner this year. Great top line growth should make it happen.
10	10	Integra LifeSciences	15.37	(10.48)	2.6% cash flow yield. IART has always been about a combination of the parts. Clearly the parts need to synergize some cash.

## Robin Young's Orthopedic Universe

### Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 CryoLife	CRY	\$6.19	\$177	8.8%
2 ArthroCare	ARTC	\$30.43	\$820	3.2%
3 Mako Surgical	MAKO	\$13.19	\$445	-1.2%
4 Smith & Nephew	SNN	\$46.75	\$8,310	-4.1%
5 CONMED	CNMD	\$20.46	\$597	-6.4%
6 Wright Medical	WMGI	\$17.14	\$665	-6.7%
7 Symmetry Medical	SMA	\$10.45	\$376	-7.1%
8 Synthes	SYST.VX	\$105.85	\$12,562	-7.5%
9 Kensey Nash	KNSY	\$21.48	\$209	-8.9%
10 Johnson & Johnson	JNJ	\$58.46	\$161,240	-9.1%

### Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Osteotech	OSTE	\$3.22	\$58	-25.5%
2 Orthovita	VITA	\$2.60	\$200	-24.6%
3 TiGenix	TIG.BR	\$2.28	\$70	-23.6%
4 RTI Biologics Inc	RTIX	\$3.25	\$178	-19.4%
5 Capstone Therapeutics	CAPS	\$0.70	\$29	-18.6%
6 Alphatec Holdings	ATEC	\$4.82	\$421	-18.4%
7 Orthofix	OFIX	\$29.77	\$524	-12.9%
8 Exactech	EXAC	\$17.70	\$228	-12.4%
9 NuVasive	NUVA	\$38.00	\$1,490	-12.1%
10 Medtronic	MDT	\$38.13	\$41,980	-11.9%

### Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Kensey Nash	KNSY	\$21.48	\$209	11.66
2 Medtronic	MDT	\$38.13	\$41,980	11.76
3 Johnson & Johnson	JNJ	\$58.46	\$161,240	12.53
4 <i>Average</i>			\$10,949	12.75
5 Zimmer Holdings	ZMH	\$54.01	\$10,950	13.02

### Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Smith & Nephew	SNN	\$46.75	\$8,310	66.01
2 RTI Biologics Inc	RTIX	\$3.25	\$178	54.04
3 NuVasive	NUVA	\$38.00	\$1,490	34.36
4 Symmetry Medical	SMA	\$10.45	\$376	20.85
5 CONMED	CNMD	\$20.46	\$597	18.79

### Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 CryoLife	CRY	\$6.19	\$177	0.60
2 Orthofix	OFIX	\$29.77	\$524	0.67
3 NuVasive	NUVA	\$38.00	\$1,490	0.84
4 Alphatec Holdings	ATEC	\$4.82	\$421	0.88
5 Exactech	EXAC	\$17.70	\$228	0.98

### Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 CONMED	CNMD	\$20.46	\$597	8.06
2 Symmetry Medical	SMA	\$10.45	\$376	1.98
3 Johnson & Johnson	JNJ	\$58.46	\$161,240	1.80
4 <i>Average</i>			\$10,949	1.59
5 RTI Biologics Inc	RTIX	\$3.25	\$178	1.56

### Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 Osteotech	OSTE	\$3.22	\$58	0.60
2 CONMED	CNMD	\$20.46	\$597	0.82
3 Orthofix	OFIX	\$29.77	\$524	0.93
4 Symmetry Medical	SMA	\$10.45	\$376	1.04
5 RTI Biologics Inc	RTIX	\$3.25	\$178	1.09

### Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$2.28	\$70	68.25
2 Mako Surgical	MAKO	\$13.19	\$445	11.52
3 Synthes	SYST.VX	\$105.85	\$12,562	3.70
4 NuVasive	NUVA	\$38.00	\$1,490	3.67
5 Alphatec Holdings	ATEC	\$4.82	\$421	2.92

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## Pricing Pressures Lower Spine Forecast Part 2

Matt Menze, PearlDiver Spine Analyst



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### Individual Company Commentary: Introducing Medicea

#### Medicea



We are leading off our company commentary with a new addition to our coverage list. Medicea is a pure play spine company based out of Lyon, France; specializing in scoliosis, degenerative deformity, trauma, and tumoral diseases. The company's initial public offering was in 2006, and shares now trade on the NYSE-Alternext. Medicea implants have been used in over 40,000 surgeries. Revenues rose 45% in 2009 to €13.1 million, equating to \$20 million. Medicea has been gaining market share in Europe and the U.S. According to CEO Denys

Sournac, revenues were driven by the PASS-LP fixation system, which treats deformity. Also, the company will begin marketing its Graniva cervical disc prosthesis in Europe in July. We forecast 36.6% revenue growth for 2010 which, we believe will equate to €17.9 million, or \$23.2 million.

#### NuVasive, Inc.



NuVasive delivered strong results in the first quarter. Revenues grew 36.4% to \$101.9 million (versus \$80 million in 1Q09), and the company was profitable for the quarter. Management reiterated full-year revenue guidance of \$480 million–\$500 million. NuVasive expects 25%–30% revenue growth in 2011, and stated that there is upside potential to that should

FDA approval come faster than anticipated for the PCM cervical disc. While NuVasive does see pricing pressure, management's ability to release innovative products has allowed the firm to minimize such pressures—at least as compared to other firms. We also note that NuVasive's accounts are relatively new so there remains room for both procedural growth and mix expansion. For that reason, we have not detected as much product discounting for NuVasive as we have for some of its more established competitors.

NuVasive has laid the foundation for continued strong sales growth by emphasizing a steady stream of innovative product introductions which, in turn, is facilitating deeper account penetration. Specifically:

- NuVasive is expanding indications to address thoracic spine surgery and scoliosis. The XLIF corpectomy set is also gaining traction.
- In the next few months, XLIF researchers will likely, we think, be presenting the results of their studies in three peer-review journals.
- Management announced in its most recent conference call with analysts that they have filed for a PMA (Pre Market Approval) for the PCM cervical disc replacement

device, and noted that if approval came in 2011, there was the potential for upside to revenue estimates.

We estimate 2Q10 revenues will be \$116 million (31.1% YOY growth). We estimate full-year revenue 2010 to be \$497.4 million, which is a 34.2% YOY growth.


#### TranSI, Inc.



First quarter 2010 revenues declined 22.8% to \$6.7 million (down from \$8.7 million in 1Q09). The company reported that surgeons performed 692 Axial Lumbar Interbody Fusion (AxiaLIF) procedures worldwide (537 domestic) in the quarter (down from 751 in 1Q09). Worldwide AxiaLIF procedure growth, a key driver of revenues, decreased 22.2% YOY in the fourth quarter.

Physicians are encountering problems being reimbursed by payors due to the category III CPT (Current Procedural Terminology) code under which AxiaLIF is being reimbursed. However, TranSI procedures treating the complex spine, such as scoliosis or deformity cases, are not being as severely affected because the access code in question is not as critical for reimbursement. The company believes there is opportunity in the complex spine for the TranSI approach and will present this to surgeons at the APSS (Association of Pre-sacral Spine Surgeons) meeting. The company's direct sales force stood at 49 reps. The average selling price (ASP) of AxiaLIF was \$11,000 up \$400 from 1Q09. We

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estimate 2Q10 revenues to be \$6.3 million (-20.3% YOY growth)

#### Zimmer Inc.



Zimmer Spine struggled during the quarter and the business has not yet stabilized. Reimbursement pressures regarding the Dynesys Dynamic Stabilization system (which is a significant contributor to U.S. spine revenues) and weak sales force execution continue to hurt revenue growth. Zimmer reported that spinal implant and biologic sales in 1Q10 were \$60.0 million (down from \$64.6 million in 1Q09 or 7.1%, 9% constant currency YOY). We estimate that the spinal implant products acquired

from Abbott in 2008 contributed \$19.5 million to revenues which is essentially flat with the immediately preceding quarter. The components of Zimmer's spinal implant sales decline are as follows: a negative 9% based on procedure volume/mix, no impact from pricing, and a positive 2% based on foreign exchange for an overall 7% rate of sales decline.

Management noted that the domestic spine business struggled, but they see opportunities for growth in international markets. Spine revenues grew 15% in Europe and 18% in Asia Pacific. Management noted that both the Pathfinder MIS platform and the Ardis Interbody System sold better year-over-year. Zimmer's spine division is hoping to return to spinal implant market sales growth rates by the end of this year through increased

penetration in domestic markets and new MIS (minimally invasive surgery). Indeed, if management achieves these goals, it would mark a significant turnaround from the immediate past. We are forecasting that full-year 2010 revenues will rise 1.3% to \$256.8 million. We estimate that Zimmer's 2Q10 spine revenues will be \$64.8 million (1% YOY growth).

#### Biomet, Inc.



Biomet's first quarter spinal repair and implant revenues (fiscal 3Q10) increased 4.3% YOY to \$56.1 million, falling short of PearlDiver estimates of \$58.5 million. U.S. sales rose 3%. This marks the sixth consecutive quarter of single-digit U.S. spine hardware growth. During the April 14 conference call, management stated that strong growth in spine hardware sales was offset by a slight decline in the spinal stimulation business. Management also noted that they were also experiencing spinal implant pricing pressures. The ESL PEEK-OPTIMA 4 Posterior Spacer was Biomet Spine's top performer and helped to increase the overall sales growth rates for Biomet's interbody products. Biomet's Polaris Deformity System helped drive sales growth for the company's thoracolumbar product line. The MaxAn Anterior Cervical Plate System, which was launched nationally during the first quarter, contributed to Biomet's overall cervical hardware sales growth in the quarter.

We estimate that 2Q10 (Biomet's 4Q10) revenues will be \$65 million (5.7% YOY revenue growth) and for calendar year 2010 revenues will be \$250.6 million (7.3% YOY revenue growth).

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#### Stryker Corporation



Stryker Spine delivered strong revenue growth both on an absolute level and as compared to such rivals as DePuy and Biomet. In 1Q10, Stryker's spinal repair and implant revenues rose 10% to \$141.5 million (up from \$128.6 million in 1Q09). Stryker's domestic spine product business grew just 5% YOY (vs. 4% in 4Q09). The company reported that overall international spine product revenues increased 25% during the quarter (+16% constant currency). As we heard from virtually every other spinal implant company, Stryker management also said that pricing pressures were affecting sales growth rates. In addition, management

mentioned that there were gaps in their spine portfolio that was keeping sales growth rates down. Stryker launched two cervical plating systems in order to fill this gap and to help bring unit volume growth rates closer to the company's historic growth rates. Management is guiding analysts to expect better top-line spinal implant growth rates in the second half of the year—which is when new products will be available. Stryker expects pricing pressure to continue throughout the year, but procedure volumes to remain strong, growing in the high single digits.

We estimate that 2Q10 revenues will grow 10.6% YOY reaching \$155 million. We estimate that full-year 2010 revenue will be \$624.5 million (11.8% YOY growth).

**Orthofix International**

Orthofix Spine began 2010 with solid spinal implant sales growth rates. First quarter spinal repair and implant sales rose 8% to \$71.7 million (up from \$66 million in 1Q09), falling short our estimates of \$73.65 million. Spine revenues now represent 52% of the company's total revenues. Spine stimulation revenue increased 12% to \$41.9 million while implant and biologic revenues increased 3% to \$29.8 million. International revenues were strong as well. While overall spinal implant and biologic revenue increased 3%, it should be noted that revenues from metal implants grew 10%. This was driven by the Firebird pedicle screw system and the PILLAR interbody device. Orthofix continues to gain share in the spine stimulation market. The just completed quarter is the tenth consecutive quarter of double-digit revenue growth. Indeed, Biomet noted a slight decline in spine stimulation sales during their call. Biomet's loss may have been Orthofix's gain.



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Trinity Evolution continued to gain market momentum as supply issues are solved and additional surgeons have access to the product. While little has been released publicly regarding the patent infringement lawsuit that NuVasive announced at its second quarter conference call, Orthofix CEO

Alan Milinazzo stated that the company “absolutely did not infringe” on the patent.

Management anticipates revenue growth to increase throughout 2010 and believes that Orthofix can grow above

spine market growth rates in the long term. We estimate that 1Q10 spine revenue will rise 8.2% to \$76.5 million and full-year 2010 spine revenues will grow 9.4% to \$305.48 million.

**Alphatec Spine, Inc.**

Alphatec began 2010 on a strong note and once again posted revenue growth well above market rates. On May 10, Alphatec reported record first quarter revenues and reiterated full-year 2010 revenue guidance of \$220 million to \$225 million. Alphatec's fourth quarter revenues grew 25.6% to \$38.4 million (up from \$30.6 million in 1Q09). U.S. revenues grew 19.4% in 1Q10, exceeding overall spinal repair and implant market growth rates—which are 6.4% overall. U.S. revenues were driven by the ILLICO minimally invasive retractor system. This marked the eleventh consecutive quarter of record revenues and the ninth straight quarter in which YOY revenue growth has exceeded 25%. In 1Q10, international sales, (Europe and Asia) comprised 26% of revenues, or \$10 million, up from \$6.8 million in 1Q09.

During the quarter, Alphatec entered the stem cell space by entering into an exclusive distribution agreement with Parcell Spine, LLC. Alphatec will be distributing Parcell's proprietary osteoprogenitor adult stem cell product. The company also continues to execute its strategy to become the leader in the aging spine. Over 900 patients have been treated with the Osseofix Spinal Fracture Reduction System in Europe. OsseoScrew,

which is an expandable pedicle screw designed to be used in osteoporotic patients was launched in Europe in 4Q09 and this will continue throughout 2010 along with the launch of HeliFix.

Alphatec continues to execute well by broadening its core product portfolio,

entering high growth markets such as minimally invasive surgery, and innovating products for the aging spine patient. Uptake also seems to be positive in Europe and Asia for Alphatec products. For 2Q10, we estimate that sales for the combined entity (Alphatec and Scient'x) will reach \$60.7 million.

### Looking Forward

While growth in the spine market has declined over the past few quarters, and pricing pressure has become more apparent, we believe that strong fundamentals will continue to drive revenue growth in the future, albeit at a slower pace. ♦

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## DePuy's State of the Union

By Walter Eisner

If there is a happy warrior in Orthopedics, Mike Mahoney, head of Johnson & Johnson's DePuy franchise certainly qualifies for the title of happiest of the happy.



Mike Mahoney

And why shouldn't he be elated? His DePuy franchise has been pulling J&J's wagon for the last few years as the medical giant's pharmaceutical sales have slowed while sales of medical and diagnostic devices have grown faster than the market.

That means Mahoney is taking market share from his competitors as devices have become J&J's largest business. Total sales of \$23.6 billion last year from devices alone now account for about 38% of total J&J sales and 43% of total operating income.

DePuy sales for orthopedics were \$5.4 billion in 2009 with 40% of sales coming from outside the U.S.

### Bi-Annual Device Report

J&J does not break out specific product areas during their quarterly earnings conference calls with analysts, so the company conducts a bi-annual Medical Device and Diagnostics (MD&D) analyst meeting. At its most recent of these meetings, held on June 3, management provided an overview of the various business segments, expectations for market growth, upcoming product launches, and challenges and opportunities facing the business over the next four years.

Mahoney's boss, Alex Gorsky, worldwide chairman of Johnson & Johnson's Medical Devices &

Diagnostics business, said the company plans to launch 80 new products from its devices unit through 2012 expanding into new markets including biosurgicals and electrophysiology.

The devices unit includes Cordis (which focuses on heart conditions), the spinal and orthopedics care franchise DePuy, Ethicon surgical products, contact lenses and other franchises.

Overall, according to the company's website, J&J dominates, cornering about 62% of the \$350 billion worldwide medical device and diagnostics market and expecting medical device sales to grow an average of 6% each year through 2014.



Albert Bierstadt, 1863/ Oregon Trail (Campfire)/Wikimedia Commons/Photo manipulation by RRY Publications

During the first quarter, J&J's revenue rose 4% to \$15.63 billion, spurred on by a 4% boost from mostly favorable currency exchange rates. However, medical devices outperformed other units, with sales up 8% excluding rates.

### DePuy Franchise

Mahoney bounded to the podium with expressions of "neat," "excited" and "fantastic" when describing how the DePuy franchise performed over the past year, predicting that the franchise will continue to benefit from the tailwinds of demographics and emerging markets. Happy, but sober, Mahoney also noted headwinds of increasing pricing pressures, stronger government regulation and the FDA.

### Regulations: "A Unique Opportunity"

But none of the J&J leaders were complaining. In fact, during a question and answer session with analysts, company leaders acknowledged that regulatory requirements will get more "demanding, especially as [innovation] moves up the technology ladder." They noted they anticipated greater demand for data and see the challenging regulatory environment as a "unique opportunity" for the company.

**"The system of a surgeon inventor and engineer coming up with a 'cool' idea is something that probably isn't going to work anymore," said Mahoney. More on that later.**

### Large Joints and Spine

First we'll take a look at Mahoney's outlook for hips, knees and spine as the company positions itself to seize additional market share.

Mahoney said the company expects to see mid- to high- single-digit growth rates over the next year. He's observed an uptick in procedures from 2009, a low point in the market, but the recovery is not at the same levels the company has seen historically.

"What's neat," said Mahoney, "is that DePuy is typically number one, two or three in their markets."

Sure enough, he noted the company's 7.9% growth in hips last year was,

while paying special attention to the elimination and reduction of infections in the area of hips.

Overall, Mahoney is determined to continue growth rates by investing in portfolio expansions and improving efficiencies for their customers. To achieve that goal, it means developing procedures and devices that reduce operating times, which in turn will allow surgeons and hospitals to increase the number of procedures without increasing infrastructure capacity.

## 2009 DePuy Growth Exceeds Market Growth Faster Than Market in Most Segments

	OPERATIONAL DEPUY GROWTH	OPERATIONAL MARKET GROWTH (INTERNAL ESTIMATE)
Hips	7.9%	3.5%
Knees	4.9%	4.3%
Trauma & Extremities	10.1%	7.9%
Spine	10.9%	8.8%
Sports	12.0%	8.5%
Neuro	4.2%	6.6%*
Total	7.5%	6.4%

\* Includes neuromodulation  
Source: Internal Estimates  
Note: All figures operational

*Johns & Johnsons*

DePuy company reports

"almost twice the market rate of growth," while knees were up 4.9%, also above the market. And spine? DePuy Spine has a "lock" on the number two position behind Medtronic.

Mahoney was particularly excited about DePuy's plans to launch 15 new products in 2010 and noted a specific strategy in spine and biologics to go after back pain, which he called a "terrific unmet need." In addition, DePuy will focus on cartilage regeneration and customized implants for growth in the knee category,

### Hips

Mahoney says the company expects to see a 5% compounded annual growth rate (CAGR) between now and 2014, with the total hip market reaching \$8.1 billion by 2014.

DePuy is awaiting FDA approval for the Pinnacle Complete Acetabular Hip System. This is the first ceramic-on-metal hip bearing to be considered for approval by the FDA. Mahoney said the Pinnacle combines the durability and stability of metal with the enhanced wear characteristics of ceramic.

Mahoney was particularly ramped up about the Finsbury Orthopedics acquisition of the past year, which gives DePuy an entree into hip resurfacing, metal-on-metal and ceramic-on-ceramic hips. He noted Finsbury's large diameter DeltaMotion hip, which is currently only sold only in Europe, will have special indications for female patients.

Another acquisition, Gloster Europe, gives DePuy a presence in the area of decontamination technologies that help prevent hospital acquired infections. Also noted were the Corail and ReClaim hip revision systems.

### Knees

Mahoney expects the knee market to grow by a 6% CAGR through 2014 reaching \$9.6 billion.

New key knee products for DePuy include the Sigma high performance partial knee system (used in various combinations of medial, lateral, and patellofemoral), AOX poly inserts (an anti-oxidant infused highly crosslinked poly), and TruMatch patient specific instruments.

Sigma has more than one million units installed and over 20 years experience.

### Spine

J&J expects the spine market to grow by a 7% CAGR through 2014 reaching \$12.2 billion.

Mahoney outlined three strategies for the spine division. First, the company will focus on degenerative spinal care (one- and two-level fusions). Second, the company will concentrate on developing new products for complex

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spine surgeries such as scoliosis, and finally, offer new products for vertebral body augmentation for compression fractures in older patients.

In degenerative spinal care, novel products include: the Viper, a minimally invasive device for thoracic to lumbar spine surgery applicable in both simple and complex cases; the Cougar LS, J&J's lateral approach—uses standard hospital neuro monitoring equipment, which management estimates will allow up to a 50% savings versus other lateral approaches; full launch is expected in the third quarter of 2010 in the U.S., and, the Expedium Spine System, a sophisticated deformity system boasts new favored angle screw facilities and a universal connector set (which enables seamless revision constructs).

DePuy spine sales were up 10.9% in 2009, although in 2010 Mahoney said the spine market stalled with more price pressure due to vertebroplasty and kyphoplasty procedures evolving to outpatient processes that demand lower prices.

### Regulatory Strategy: "Design to Value"

As earlier mentioned, perhaps the most notable take away from the call with analysts was a singular comment about the good old days of the surgeon/engineer collaboration probably becoming an archaic model.

Gorsky and his device chiefs acknowledged that clinical trials will become more rigorous as the number of patients and duration of trials, as well as the construction of trials, change.

“We’re seeing that in dialogue with the agency,” said Gorsky, as the company has been deeply engaged with the FDA in preparing for approval requests.

J&J’s “unique opportunity” rests on the company’s “Design to Value” strategy.

Gorsky said manufacturers will now have to look at all stakeholders. Companies will have to ask up front: Does the innovation bring value to the marketplace and manufacturing methods? What are the regulatory, clinical and commercial strategies?

“The FDA is really working with us,” added Gorsky.

By engaging the agency early and in greater detail than before, Gorsky believes the company enhances its chances of getting innovation through the regulatory process.

As the largest health care company in the world, J&J has more at stake than anyone else in seeing a smooth and predictable regulatory process. Will J&J be the canary in the coal mine in this new strategy with the FDA?



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We'll know the answer to this question when the company submits its 80 new submissions over the next couple years to the FDA. Everyone should be watching.

In an upcoming issue of *OTW*, we'll take a closer look at J&J's "Design to Value" strategy. ♦

## What Gives? Orthopedic Residency Education

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

More to learn, less time to learn it, and a field that is not always exactly in agreement about what should be learned...these are some of the issues facing hospital administrators, educators and others standing on the shifting sands of U.S. residency education. Now, thanks to a few visionaries in New York, they have found firmer footing.

Laura Robbins, DSW, a researcher at Hospital for Special Surgery (HSS), is lead author on an article recently published in the *Journal of Bone and Joint Surgery* that outlines the results of an orthopedic residency directors peer forum. She says, "In 2006-2007 we at HSS began to seriously look at the issue of how to maintain our world class orthopedic residency training program and still meet the stringent external requirements such as the work hour restriction mandated by the Accreditation Council for Graduate Medical Education (ACGME). The issue arose in a number of meetings and we all came away feeling like we were the only program experiencing these difficulties. A 'eureka' moment struck, and we decided to convene a meeting of program directors from several other top level training programs in order to determine what issues our colleagues were facing. I think everyone was a bit relieved to learn that we are all dealing with the same challenges."

When the 12 program directors came together for two days in May 2008, they had already done some pre-

meeting homework. Dr. Robbins: "Prior to the event the program directors were asked to evaluate whether the traditional residency model is appropriate for the training of future surgeons, and to note approaches that have been successfully implemented in residency programs. Our hope was that by outlining areas of need, those who provide oversight regarding residency requirements will move forward with us to find solutions."

As the two-day meeting progressed, certain themes took shape. "Nearly everyone has felt the crunch of the 80-hour work hour restrictions mandated in 2002," says Dr. Robbins. "You will find much in the literature about how learning basic orthopedic surgery skills may be compromised because of things such as less time in the OR, reduced continuity of care, and less experience with disease process evolution. In our discussions we reviewed the possibility that these issues may also be affected by other ACGME restrictions, such as the eight-hour break between shifts



U.S. Navy photo by Photographer's Mate 2nd Class Johansen Laurel/Wikimedia Commons

and mandated 'one day off in seven' days. To meet these challenges, most if not all programs have made changes to their call systems, hired more Physician Assistants and Nurse Practitioners, and restructured the scheduling of night floats."

As for HSS, they are glad to see their 70 physician assistants walk in the door each morning. "Most programs have hired physician assistants and nurse practitioners to handle some of the pre and post surgical care. The major issue everyone in a hospital faces is the challenge of delivering appropriate continuity of care to each patient. To do that, program administrators must clearly delineate roles, understand each person's responsibilities and ensure effective team communication so that nothing gets 'dropped.' Some programs have had success with

electronic communication, but I think for everyone to be on the same page, face-to-face communication between team members, for instance with team rounding, is essential to good patient care.”

Is it possible that orthopedists might need to know less about lupus and more about reading an MRI? “The group examined each training year and developed four recommendations regarding the first year of residency. We thought it best to assess the impact of the work hour restriction as early as possible in training.

The group’s first proposal was that training programs should reclaim three months of general surgery, meaning that PGY1 would expand to include six months of orthopedics. The second proposal was that programs should



U.S. Navy photo by Photographer's Mate 2nd Class Johansen Laurel/Wikimedia Commons

determine whether residents are spending time in rotations that maximize their knowledge acquisition. This may mean, for example, less rheumatology and more imaging. Third, the group advised that night rotations should only be utilized when there is a clear educational value and that there is good communication and handoff of the patient at the start of the morning shift.”

Then the group turned its attention to an area prone to turf battles...what exactly is the most important knowledge that orthopedic residents need to learn? Dr. Robbins says, “Program administrators must look at what it means for residents to be competent in the exam room and in the OR.

While this is a broad topic, the group did identify the first step, which is to define what core orthopedic knowledge should be imparted to residents during their training. To do that, the group suggested that administrators examine such issues as how many cases of any given type a trainee should perform, how much exposure to X,Y and Z a resident should have outside of the OR, etc. The ACGME does not prescribe how much residents need to know for any given surgery, and while required to ensure prep or postop time engaged in these activities, it is left to the individual program to figure out the right formula for effective resident learning.”

**New forms, new labs, new focus...these are some of the core knowledge recommendations flowing from the HSS meeting.**

**“The group developed 10 recommendations, some of which include: have a reading list that captures core knowledge,**



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define and require a minimum of cases by anatomic area and difficulty, and require a number of cases where the resident has a specific operative role. With the growing knowledge in the field of orthopedics coupled with specialized operative techniques, program directors are beginning to identify those procedures and skills which are essential to educate a competent orthopedic resident. ACGME also requires that residents engage in research, so the group recommended that each resident be required to have institutional review board training and certification in order to ensure that they are prepared for research training. By making this a requirement, the group hoped to foster a cadre of researchers who would be able to add to new orthopedic knowledge and surgical advances. Also, the program directors suggested that educators develop a standard comprehensive preoperative planning form.”

One of the core knowledge recommendations dovetails nicely with the fact that orthopedists love nothing more than being in the OR. And with the decreased time on the job due to work hour restrictions, they need as much hands on experience as possible. Dr. Robbins explains, “Because cadaver labs have been found to be effective in developing and refining coordination and psychomotor skills, the group felt that a psychomotor lab skills course should be required in the second year of training. The thinking was that due to the expense of such an effort, a consortium of programs

could join forces to create one or more national laboratories that would be open to all.”

The third theme emerging from the meeting of orthopedic minds captured a trend in the field... measuring. “Outcomes research is the current trend, and for good reason. The group recommended that program directors and administrative oversight groups should define and require standard formats for measuring residents’ performance (such as resident portfolios). Tools such as the portfolio would allow useful performance outcomes such as resident self learning case vignettes that can then be used with more objective performance data such as OITE [Orthopaedics In-Training Examination] scores by teaching faculty and program directors to improve the overall resident curriculum. Among the other proposals was that there should be a standard format for the biannual evaluation process. The program directors selected the Duke University School of Medicine’s format as a model. That format employs a resident-completed pre-evaluation form and an evaluation that includes input from mentor physicians, attending physicians, nurses, patients, other residents, and medical students. Lastly, it involves a face-to-face debriefing session between the resident and the faculty mentor to provide useful feedback and areas of mutual agreement for further training and development.”

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Also included in the benchmarking proposals was a recommendation that residents be provided with more meaningful feedback about their performance. Dr. Robbins notes, “Letters of commendation could be shared with faculty and other residents; also, administrators should explore ways of codifying the behaviors that led to the commendation. Another suggestion was that programs debrief residents who scored in the top 10% of the Orthopaedics In-Training Examination, with an eye toward understanding their study strategies, documenting them, and then disseminating them to other residents.”

The final theme addressed by the group members brought into focus a very real shift in wider society that has, quite naturally, made its way into residency training...how people of varying ages acquire information. “It is a different world today, and there

is a general consensus that real generational differences exist between faculty and residents. The program directors cited a number of examples in which residents displayed a distinct preference for digital and experiential learning as well as interactivity and immediacy. Thus the group recommended that programs put as much educational material as possible into an electronic format and place it on the Internet. They also suggested that administrators delineate clear and explicit roles, goals, and expectations for both faculty and residents for each rotation, program component, and even each case.”

Saving perhaps the hottest potato for dessert, the group convened by HSS did exchange a few words about the length of orthopedic residency training. “There is always the question percolating in the background, namely, ‘Should orthopedic residencies be extended to six years?’ This idea has gained ground because of the explosion of knowledge and the other issues mentioned here. The group that we convened made no hard recommendation on this topic, but there was extensive discussion. Many people say that if we extend programs that will give us more time on the front end to focus on core surgical expertise and the latter years to focus on specialization.”

On all of these issue, time—and a lot of work—will tell. ♦

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## Giving Amputees Their Lives Back

By Jacqueline Rupp

The loss of a limb can be a traumatic and certainly life-altering experience. The effects can explode through a patient's life like a sledgehammer through glass. Thankfully, advancements in prosthetic limbs have made amputations more tolerable and given amputees a mobility, freedom and independence—in other words, a new lease on life.

But not all amputees can take advantage of the latest prosthetic technologies. Many remain confined to a wheelchair or are relegated to the sidelines of life. New technologies are expensive and many patients can't afford the most advanced prosthesis. This is where Limbs of Love comes to the rescue!

### An Obvious Need

Limbs of Love was founded in 2007 by Texas entrepreneur Joe Sansone, CEO of TMC Orthopedics and The Amputee and Prosthetic Center (which boasts 12 amputee employees itself). His employees encountered stories of needy amputees on a regular basis. Joe and his employees wanted to do something so they created Limbs of Love ([www.limbsoflove.com](http://www.limbsoflove.com)), a non-profit organization which provides advanced technological prosthetic limbs to deserving individuals.

"I own several medical companies that offer braces and prosthetic limbs and as a provider of limbs we ran into so many patients who did not have the money for the proper prosthetic and it was

just heartbreaking to see," said Joe Sansone. Advanced technology prosthetic limbs are one of the most expensive orthopedic devices because they employ electronics, server motors and other cutting-edge inventions in small, life-like shapes and spaces. The least expensive below-the-knee limb may run about \$10,000. An average high-tech limb can cost around \$20,000. The cost of the most advanced prostheses can skyrocket to \$80,000 or more. These are truly modern engineering marvels with built-in hand manipulation or computer-guided knees with microprocessors.

Said Joe: "So we ran into these patients that didn't have the funds and were faced



Paul Lingois rock climbing at the 2010 Amputee Muscles and Metal Expo/Limbs of Love

with the dilemma: give it to them for free or let them go without.” Of course giving away limbs for free wasn’t a viable business option, but for Sansone, allowing patients to leave knowing there was a prosthesis that could change their life was also unacceptable. “When someone has an amputation, they are no longer a productive member of society, they no longer can work or take care of their family, and they become dependent upon other people for care and are isolated. It is a horrible spiraling nightmare.”

### Insurance Issues

Many times people don’t realize that insurance won’t cover a prosthetic until they are faced with an amputation. It’s not a high-profile coverage point and many insurance companies deliberately cut out coverage in order to lower premiums and remain competitive. Sansone says the trickle down result to employees is surprisingly insignificant with a savings of around 25 cents a year per employee. “But if you’re an insurance company,

not covering an \$80,000 limb is a fairly significant savings.” Sansone says many businesses probably don’t even realize that this gap exists. Ironically it was one of Joe Sansone’s own employees who was a victim of such an insurance exclusion. When Sansone realized that his insurance wouldn’t cover his employee he decided to jump into the political battle to bring insurance coverage for prosthetics up to a basic level.

“Seventeen states have already passed Prosthetic Parity regulation which requires that private insurance covers prosthetics on par with Medicare.” Sansone adds that this is just the most basic of coverage. Medicare isn’t a generous payor for prosthetics. It’s not easy to get limbs approved through Medicare. “So this is really just on par with the most basic coverage.”

Sansone, a self-described “staunch Republican,” says he’s finding common ground with Democrats on this issue and adds that this isn’t about across-the-board prosthetics, but about

people paying insurance premiums and not being insured for an artificial limb. “No one will abuse this requirement,” adds Sansone. Senate hearings on the issue continue and you can be sure Sansone will be one of the advocates there lobbying for change.

### The Start of Something Good

Limbs of Love has grown consistently since its founding. Prosthetic donations have increased from just

4 per year to about 36 per year now. Still, demand is higher than supply and the organization has to turn down at least 15 patients a month. At the current rate, Limbs of Love receives approximately \$1.3 million in prosthetic donations annually. Much of that cost is contributed by the associated business partners of the organization like the Prosthetic and Amputee Center. Sansone’s employees play a critical role by organizing fundraising events each year. Not only do these events, like the Annual Airborne Amputee Skydive ([http://ryortho.com/extremities.php?news=501\\_Amputees-to-Skydive-Over-Houston](http://ryortho.com/extremities.php?news=501_Amputees-to-Skydive-Over-Houston)) raise funds, they also help spotlight the achievements of those with artificial limbs.

One amputee, Sansone recalls, was initially declined by insurance for a prosthesis but was so determined to obtain one that she actually bought one for \$20 on EBay. Of course there was no way this limb would work for her since prosthetics are customized for a patient. She came to the organization to ask for it to be fitted and had to hear the news that it wouldn’t work for her.

Instead of feeling dejected, the patient chose to donate the limb to the organization so that another patient could use it. Because of this action, Limbs of Love decided to work with her and secured a prosthesis that has since transformed her life.

“She landed a job and has since donated money back to us, which makes us feel great because she is now a productive member of society, supporting her family and that’s why I feel so strongly about this charity,” explains Sansone.

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Joe Sansone accepting the 2010 Healthcare Hero Award/Limbs of Love

For his efforts, Sansone was recently named the 2010 Health Care Hero of the Year by the *Houston Business Journal*.

### Amanda's Story

Like many teens girls in high school, Amanda McDaniel loved to play soccer, get good grades and practice her cheerleading routines. Her normal young life came to a traumatic crossroads when she was diagnosed with osteogenic sarcoma of the left pelvic region, encompassing her ileum to the base of her spine. To save her life, Amanda made the decision to have her left leg, hip and part of her pelvic region removed.

"When she lost her leg," explains Sansone, "we verified her benefits, she had health care coverage and so our company crafted a prosthesis which as you can imagine would be a challenge to create because of how much bone was taken from the pelvic region. We

actually designed it so it would affix to the hip socket." In reality, Amanda's insurance only covered \$2,500 of the \$80,000 price tag. "We had promised this limb to her so to say you are going to fall \$75,000 short was just unthinkable," says Sansone. "I can't promise this to a 17-year-old girl who just lost her leg and not deliver."

Amazingly upon receipt of the limb, Amanda was back in a matter of months doing all the things she loved doing before her life was put on hold. Rock climbing, snow skiing and of course, cheerleading were all back on Amanda's schedule.

Sadly, Amanda died on May 15, 2010.

Her cancer had returned. Amanda, however, left a remarkable footnote to her own Limbs of Love story. As she was dying and realizing she no longer had a use for the prosthesis, she took two weeks to compose a letter to the organization, donating the limb she had named Lucille (in honor of Lucille Ball) back to the charity so someone else would have the same opportunities that she had all but briefly enjoyed.

Orthopedic oncologist, Dr. Valerae Lewis of The University of Texas' M.D. Anderson Cancer Center has nothing but good things to say about her patient's experience with Limbs of Love. "Amanda was my patient and she was amazing. Limbs of Love did such a wonderful job getting her the best limb, and I think it was an incredibly special thing that she was able to walk through her battle with osteosarcoma. She was up and walking in her sister's wedding, which meant so much to her. That would not have been possible had Limbs of Love not stepped in to help."

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### Offering New Hope

Limbs of Love has touched so many lives. We close our story with the words of patient Glenda Miller who spoke to *OTW* as she was waiting for her new prosthetic limb. “Limbs of Love has been so great every step of the way! Thank God for them! I am just plain giddy, I feel like a kid on Christmas morning!”

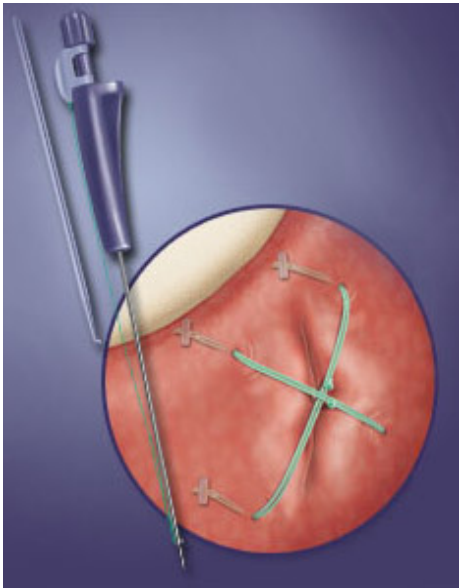
“I’d suggest that everyone consider supporting Limbs of Love because these people have changed my life.”

For more information about Limbs of Love contact PR Director, Leslie O’Donnell: [lodonnell@tmcortho.com](mailto:lodonnell@tmcortho.com)



Glenda Miller with a Limbs of Love staffer/Limbs of Love

## company

**Anulex Raises \$18 Million***Anulex Xclose Repair System/Anulex*

Minnesota-based Anulex Technologies, Inc. has raised another \$18 million to finish the post-market study of its Xclose Tissue Repair System.

Company President and CEO Rich Lunsford announced on June 3, the first closing of its fifth round of private equity financing which will total a minimum of \$20 million. Lunsford noted the company was able to raise these funds during a very challenging funding environment.

“This financing will give us the ability to expand our commercialization efforts and complete the follow-up phases of our ground-breaking Xclose Tissue Repair System post market clinical study. The study represents one of the largest prospective random-

ized clinical studies in spine with the goal of providing further evidence to support the benefits of preservation and repair of the annulus. This funding will also provide additional investment for a feasibility study for our Rimclose product and further support the company’s innovative research and development strategy.”

Once the Series E financing is completed, Anulex will have raised approximately \$68.6 million through five rounds of equity financing.

The Xclose Tissue Repair System uses small braided polyester bands to make an X-shaped stitch over openings in the soft tissue around the spine. The device is designed to prevent discs from re-herniating after surgery and to speed healing. Some patients need additional surgery when the opening in the outer layer of the disc (annulus) remains after the surgery, leading to pain and discomfort.

The company’s investors include Affinity Capital, Delphi Ventures, MB Venture Partners, New Enterprise Associates, SightLine Partners, Split Rock Partners and newcomers Hatteras Late Stage VC Fund 1, L.P and an unnamed strategic investor.

—*WE (June 10, 2010)* ♦

**Lanx Snags Michael DeMane**

The man once thought to be in line for the top job at Medtronic, is now the Chairman and Chief Executive Officer of Lanx, Inc.

Michael DeMane was named to the position on June 7 and is a big-time catch for the small privately held spine device company.

**Former Medtronic Spine Chief**

DeMane has established and grown implantable medical device businesses, ranging in size from \$30 million to \$13 billion, in highly competitive global markets. DeMane was formerly Chief Operating Officer of Medtronic, the world’s largest medical technology company. He joined Medtronic in 1999 with Medtronic’s acquisition of Sofamor Danek Group, Inc. As President of Medtronic’s Spinal Systems business, DeMane was instrumental in building one of the largest global spine franchises and his tenure was marked by a period of substantial new product flow and rapid revenue growth.

In 2005, DeMane assumed responsibility for leading Medtronic’s businesses in Europe, Canada, Latin America and Emerging Markets, before being named COO in 2007. Prior to his roles at Sofamor Danek and Medtronic, DeMane led Smith & Nephew’s Orthopedic Implant division and subsequently its commercial operations in Australia and New Zealand.

**Fulton to CTO**

The announcement from the company stated that Co-Founder and former CEO Michael Fulton will assume the role of Chief Technology Officer, and will continue to guide the company’s innovation and new technology initiatives.

Fulton said, “The Board and I are extremely excited to have an executive of Michael’s industry stature accept this leadership role at Lanx. His decision to join our company is a testament to the innovation and dedication to technology that has driven our growth to date.”

Jeffery Thramann, Co-Founder and former Chairman, said, “Michael Fulton and I are extremely proud to have grown Lanx into a leading spine company underpinned by a team of dedicated professionals. Michael DeMane unquestionably has the ability to lead the organization and will be a catalyst for taking Lanx to the next level of growth and expansion.”

#### Be Like Alex?

We couldn’t help but ask the company if DeMane was looking to replicate the success of challenging Medtronic by another former head of Medtronic’s spinal business, Alex Lukianov at NuVasive.

“Lanx does not intend to target any company. Lanx aspires to continue leveraging its culture of innovation and focus on technology to bring solutions to surgeons that ultimately improve patient care,” replied a company spokesperson.

Lanx develops and markets a full line of fusion technologies with a focus on minimally invasive and biologics products. The company was founded in 2003 and is headquartered in Broomfield, Colorado. Its flagship product is the Aspen Spinous Fixation System, which is used as an adjunct to interbody fusion and/or posterior fusion with decompression treatment from T1-S1.

—WE (June 9, 2010) ♦

## legal & regulatory

### Preemption Not Applicable in Trident Suit

A federal judge in Tennessee has ruled that a patient is not “preempted” by Riegel from suing Stryker in a product liability lawsuit because the patient alleges that Stryker did not meet FDA standards.

#### Riegel

The Supreme Court ruled in *Riegel v Medtronic* in 2008 that if the FDA has approved a product, manufacturers are protected from being sued under state product liability laws. This legal theory is called “preemption”. Since that ruling various federal district courts have thrown out lawsuits against medical device manufacturers by citing *Riegel*. Just this past May a federal judge in Texas threw out another claim citing the decision.

#### Surviving Preemption

According to a June 8 report on [MassDevice.com](http://www.massdevice.com), Judge Thomas Varlan of the U.S. District Court for Eastern Tennessee ruled on June 3 that preemption does not apply in a case before him because Stryker, allegedly, failed to comply with federal regulations in manufacturing the implant. The

company issued a recall of the device in 2008, following an FDA Warning Letter relating to the manufacturing procedures at the Cork, Ireland, plant where the implants were made.

“Plaintiff advances several theories of state common law liability to link those compliance failures to the ultimate failure of the device implanted in [the patients’] hip. These state law claims, which “parallel” federal requirements, thus survive preemption,” Varlan wrote. “They also contain sufficient factual matter, accepted as true, to state a plausible claim for relief.”

The patient, Marty Phillips, had a Trident hip implanted in 2006. By July 2008, according to the story, Phillips began experiencing increasing pain in the hip, including “popping sensations.” In September 2009, X-rays showed that the device failed due to the loosening of the implant’s acetabular shell. Phillips’ doctor then recommended that he undergo revision surgery. He sued Stryker in November 2009.

There was no word on if, and when, the lawsuit would proceed to trial.



<http://cltlblog.files.wordpress.com/2009/01/courtroom.jpg>

What will be of interest now is to see how an FDA Warning Letter is used to demonstrate failure to comply with federal regulations.

—WE (June 10, 2010)◆

## large joint

### Too Much Calcium?

Too much of a good thing indeed... researchers from the University of Pennsylvania are shedding light on the negative health effects related to taking an excess of supplemental calcium. These effects are on the rise, according to a commentary appearing in an upcoming issue of the *Journal of the American Society Nephrology*. The incidence of the so-called milk-alkali or calcium-alkali syndrome is growing in large part because of widespread

use of over-the-counter calcium and vitamin D supplements. As indicated in the news release, the milk-alkali syndrome goes back to the early 1900s when patients ingested abundant amounts of milk and antacids to control ulcers, something that increased the risk of dangerously high levels of calcium in the blood. Such elevated calcium levels could cause high blood pressure and even kidney failure. With the advent of new ulcer medications, the incidence of the milk-alkali syndrome declined. It is making a “comeback,” however, due to an increased use of over-the-counter calcium and vitamin D supplements. In many cases, patients with the syndrome require hospitalization.

Stanley Goldfarb, M.D. and Ami Patel, M.D., both of the University of Pennsylvania School of Medicine, recommend changing the name of the milk-alkali syndrome to the

calcium-alkali syndrome because the condition is now associated with a large intake of calcium, not milk. Postmenopausal women, pregnant women, transplant recipients, patients with bulimia, and individuals who are on dialysis have the highest risks of developing the calcium-alkali syndrome due to various physiological reasons.

Regarding the impetus for this research, Dr. Goldfarb told *OTW*, “We encountered a patient with this condition and decided to review the clinical experience in the modern era.”

According to the authors, the obvious preventive strategy against the calcium-alkali syndrome is to limit the intake of calcium to no more than 1.2 to 1.5 grams per day. “Calcium supplements taken in the recommended amounts are not only safe but are quite beneficial. Taken to excess is the problem,” said Dr. Goldfarb in the news release. “Even at the recommended dose, careful monitoring of any medication is wise and yearly determinations of blood calcium levels for those patients taking calcium supplements or vitamin D is a wise approach.”

As for what he would like orthopedists to know about this work, Dr. Goldfarb told *OTW*, “They should encourage their patients to follow guidelines regarding dosage of vitamin D and calcium and to emphasize the risk of excessive intake.”

—EH (June 9, 2010)◆



Calcium supplements / Wikimedia Commons

## Statins and Hip Replacement

Lower cholesterol, lower chance of hip revision... Researchers from Denmark have found that drugs commonly prescribed to help lower cholesterol levels—statins—may help to decrease complications among patients undergoing total hip replacement (THR).



X-ray of a pelvis showing a total hip joint replacement Wikimedia Commons

“We found that use of statins substantially reduced the risk of revision after hip replacement surgery, indicating that the biological effects of statins may play a role in the sustainability of hip implants,” said Theis Thillemann, M.D., in the news release. Dr. Thillemann is a fellow in the department of orthopaedic surgery, Aarhus University Hospital, Denmark.

Using a national database of hip replacement patients, Dr. Thillemann and his colleagues evaluated the effect of statin use on the need for revision surgery and found that patients who were taking statins for cholesterol control postoperatively had a significantly lower risk of revision during the 10-year period following THR. In addition, the researchers found that the risk of revision decreased with longer use of the statins.

Dr. Thillemann indicated that these drugs may improve THR outcomes by encouraging bone formation, which may improve the fixation of the implant to the bone; it may also help reduce inflammation. He said that

future research will help determine whether statins should be prescribed prior to THR in otherwise healthy patients, as well as to determine optimum dosing regimens.

“For the clinician, it is important to know that statins may improve longevity of hip replacements,” Dr. Thillemann noted in the news release. “In our research group, we continue to our look into the role of statins in the prognosis of hip implants, both in clinical and experimental study designs. Ideally, further studies will confirm our results and make it possible to recommend statin therapy to all patients undergoing hip replacement surgery.”

Dr. Thillemann told *OTW*, “We have examined the association between hip replacement survival and other medications including bisphosphonates, which have also revealed very interesting results. We are continuing our examination of other patient-related prognostic factors in hip prosthesis surgery based on Danish databases. We are also investigating statins’ effects

on bone ingrowth to the implants, the fixation and mechanical properties of orthopedic implant in dogs. Further, we are investigating different dosages both in topical and systemic administration of statins in experimental studies. Finally, we are hoping to be able to conduct a radiostereometric analysis (RSA) study evaluating the effects of statins in otherwise healthy patients undergoing hip replacement surgery.”

The study was published in the May 2010 issue of the *Journal of Bone and Joint Surgery (JBJS)*.

—EH (June 8, 2010) ♦

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## extremities

**High and Low Stress Tendons**

Yearlings, fillies, and stallions... We should thank them all for helping out the humans. Researchers from University College London have discovered that tendons in high-stress and strain areas, like the Achilles tendon, repair themselves less frequently than low-stress tendons. Tendons such as the Achilles tendon in humans and the superficial digital flexor tendon (SDFT) in horses, have to bear a lot of weight and strain. The team indicates that their work could provide new information on the increased vulnerability of certain tendons to injury during aging.

Dr. Helen Birch and her colleagues examined protein turnover in the tendons of horses of various ages and found that the high-strain superficial digital flexor tendon—at the rear of the limb—repairs much less frequently than the low-strain common digital extensor tendon (CDET)—at the front of the limb.

The team measured protein age in the horse tendons, and found that non-collagen proteins in tendon have an average half life of 2.2 years in SDFT and 3.5 years in CDET, which would be expected. However, SDFT collagen had a half-life of 198 years, compared to 34 years for CDET collagen. That means that every year, only 0.25% of the injury-prone collagen gets replaced in SDFT tissue. Over time, degraded protein and other mechanically-induced micro-damage



U.S. Air Force surgeons Dr. Patrick Miller (left), Dr. Michael Hughes (right), and surgical technician SrA Ray Wilson from the 379th Expeditionary Medical Squadron, repair the ruptured Achilles tendon/Wikimedia Commons

could reduce the overall integrity of the tendon, which, say the researchers, may result in large-scale injuries. As to why the body would seemingly put its more important tendons at greater risk, the researchers say that too much repair may compromise the strength and stiffness of these tendons which are used heavily, so the body tries to preserve their structural integrity at the expense of increased injury risk later in life.

Dr. Birch told OTW, “The legend of Achilles in Greek mythology is well known. As athletes build up to the London 2012 Olympics they would do well to remember that their Achilles tendons and others if not properly cared for can easily end their Olympic dream. Yet even today with the advancement of sports science, little is known about tendon health management. Our research has shown that paradoxically to sustain maxi-

mum strength may increase vulnerability of the Achilles tendon.”

Dr. Birch also commented to OTW, “I would like orthopedists to have an awareness of the reason why Achilles tendon problems are so common. As for our next step, it is to determine whether reduced turnover rate is due to decreased cell activity or differences in the matrix itself which make it more resistant to turnover. What stimulates the tendon cells? Can we increase cell activity and rate of turnover by giving specific exercises?”

—EH (June 7, 2010) ♦

## spine

**1st Nepal-America Spine Conference**

In 2009 there were a mere 27 children's spine surgeries in Nepal, a country with 27 million people. This is the challenge faced by those who are concerned about those in need in this South Asian country, and who are dedicated to augmenting the capabilities of the Nepalese orthopedic community. Progress is being made, however... from March 21-22, 2010, in the Kathmandu Valley, a group of specialists came together for the first ever Nepal-America Spine Conference.

According to Mindy Gregory, a member of the Spinal Health International (SHI) Board of Directors, "The most challenging thing with regard to bringing appropriate spine care to Nepal is funding. Spinal implants are expensive, and spinal surgery is the most significant part of the Hospital and Rehabilitation Centre for Disabled Children (HRDC) budget. We were fortunate that monetary support was provided by K2M, Inc., Globus Medical and DePuy, and that Globus Medical sent implants to Nepal in support of the 2010 mission. Going forward we hope to find more practical alternatives to expensive spinal implants. We also received a generous offer from Medtronic to send implants to Nepal."

Dr. Sutterlin, Director of SHI and Klimb 4 Kidz, told *OTW*, "The first Nepal-America spine conference was a great success with 85 Nepalese attendees in attendance. Guest faculty from the U.S. included Dr. Ray Woo, a pediatric orthopedist, and Dr. Dave Pincus, a pediatric neurosurgeon, both from the University of Florida."



*Spinal Health International*

Gregory also commented to *OTW*, "Early recognition and prompt appropriate care remains a great challenge, especially because there is no deformity screening program. We hope to establish annual week-long camps in each Nepal district to perform follow up visits and conduct screening. Ideally, we will have sufficient volunteer staff and funding to duplicate this effort every six months instead of every 12 months. With regard to sustainability, it is critical that there be a dedicated team effort; at present, however, there is no ICU and only one qualified recovery room nurse. To remedy this, we hope to help locate funding

for additional staff and advance skill enhancement opportunities for staff including nurses and residents."

As for the future of the conference, Gregory told *OTW*, "Spinal Health International will work with Nepal surgeons to organize (and fund in part) the 2nd Annual Nepal American Spine Conference in Spring of 2011 to provide skill enhancement opportunities to Nepalese orthopedic residents, practicing surgeons and support staff. Our long-term goals include the expansion and improvement of hospital-based capabilities,

the development and improvement of rural outreach programs, as well as the promotion of independent, self-sustaining, cost-effective systems of care."

*The event was organized by the HRDC and B and B Hospital Pvt. Ltd., both in Nepal, as well as Spinal Health International (SHI) and the Nepal Orthopedic Association.*

*For more information, please visit [www.spinalhealthinternational.org](http://www.spinalhealthinternational.org)*

*—EH (June 9, 2010) ♦*

## Riding Into Spinal Injuries

For the first time doctors have published statistical evidence that shows the true dangers associated with mountain biking. The findings show that serious spinal injuries are often sustained in an accident.

Flying down trails, careening over hills and swerving to avoid multiple obstacles at any given moment...such is a typical day out for a mountain bike enthusiast. But many riders are getting much more than a temporary adrenaline rush. Serious spinal cord injuries can also result from a day riding of extreme outdoor biking.

In the review published in the May issue of *The American Journal of Sports Medicine*, doctors from the University of British Columbia looked at patients from the province between 1995 and 2007. It marks the first time that mountain bike-related spinal injuries have been studied and assessed at any length. While analyzing the injury cases, the doctors attempted to organize the data to get a read on averages for things like demographics, severity of injuries, treatments and outcomes.

The numbers show interesting statistics and significant injuries. With 102 men and only 5 women included in the injury stats, it's obvious that men make up the majority of riders who sustained spine injuries. The mean age was approximately 33 years old. As far as the actual injuries go, nearly 80% were cervical, while the minority of cases involved thoracic or lumbar injuries.

Specifically, 40% of the patients suffered from a spinal cord injury of varying degrees. For instance, 42%

of those with a spinal cord injury were classified along the American Spinal Injury Association (ASIA) impairment scale in Class A, meaning there was no motor or sensory function preserved in the sacral segments. In 11% of the spine injury cases sensory, but no motor function was preserved below the neurological level (Class B) and 23% of the injuries were listed as ASIA class C and D, respectively. The majority (62%) required surgery with hospital stays averaging nearly 17 days. About a third of these patients needed intensive care treatment. On the healing side of things, around 30% received inpatient rehab, with 32% of those injured improving by one ASIA level, one patient even improved by two levels. But two patients did remain ventilator-dependent.

Because mountain biking involves significant speed paired with drops over steep terrain, head injuries that result in spinal injuries are common when there is a fall. And because of the high velocity of such crashes, helmets and body armor don't seem to offer an adequate defense against these high-impact falls.

—JR (June 8, 2010) ♦



Cross country mountain biking/Wikimedia Commons

## people

**Bishop Named  
OrthoWorx ED**

Brad Bishop,  
OrthoWorx Executive Director

**B**rad Bishop was named the first Executive Director of Warsaw, Indiana-based OrthoWorx on June 3. He will take his post on June 23.

Bishop, who helped form

the industry/community group in 2009, will lead efforts to promote the area's orthopedic capabilities and try to lure some new businesses into the community.

Warsaw has been at the center of the orthopedics world ever since Revra DePuy figured out that the trees in Kosciusko County had the perfect qualities to make splints for wounded soldiers. Founded in 1895, DePuy begat Zimmer in 1926, followed by the engineer Miller who spawned Biomet in 1977. Eventually Danek, now Medtronic, joined them. Today, the area is home to one of the most concentrated clusters of manufacturing anywhere in America.

A 2009 BioCrossroads report stated, "These enterprises earn more than \$11 billion in annual revenues, representing better than a 50% market share in the United States, and more than a 33% market share in the world." Since 2001 the orthope-

dic industry employment base has grown by 39%, adding 2,800 jobs to reach nearly 6,000 jobs today.

**Memphis Competition**

In recent years, Memphis has made a run at Warsaw to compete for orthopedic device company expansions and start-up. Partly to ward off that competition and to get into the business development competition, leaders of the orthopedic community formed OrthoWorx in 2009.

Bishop is currently Zimmer's Director of Public Affair.

His colleague at Zimmer, Senior Vice President and Chief Science Officer, Cheryl Blanchard, Ph.D., is the Chairperson of the OrthoWorx Board of Directors.

Blanchard said, "Having Brad as a full-time employee of OrthoWorx will help drive all of our initiatives forward." Those initiatives include efforts to promote talent and workforce Development, community development, transportation and logistics, education, and innovation.

**Hometown Hero**

Bishop brings over 20 years of orthopedic industry experience to his new job as Warsaw's chief orthopedic promoter. At Zimmer he was responsible for internal and external communications, corporate philanthropy, community affairs and state and local government relations, and served as treasurer of the Zimmer Political Action Committee.

He joined Zimmer in 1988 and has served in a variety of public

affairs and communications roles for Zimmer and for its former parent company, Bristol-Myers Squibb.

"Brad has been an integral part of the Warsaw community for more than 20 years. His background in the orthopedics industry and his leadership roles on community initiatives provide a solid foundation for his new position with OrthoWorx," said David Floyd, OrthoWorx board member and President of DePuy Orthopaedics.

Bishop has served on a number of association and civic boards, including the Indiana Health Industry Forum, Kosciusko Development, Inc., the YMCA of Kosciusko County, the Kosciusko County Convention and Visitors Bureau, the Orthopedic Capital Foundation and the Kosciusko County Community Foundation, where he is the current board president. He is a past president of the board of directors of the United Way of Kosciusko County and graduated from Ball State University with a BS in Journalism and Public Relations.

—WE (June 9, 2010) ♦



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## THE PICTURE OF SUCCESS

### Dr. Claude Moorman, III

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

Once a team doctor for the Baltimore Ravens, Dr. Claude Moorman, Professor of Orthopaedics at Duke University School of Medicine, turned 40 during the team's post Superbowl celebration in 2001. Born at Duke University Hospital and married in the school's chapel, Dr. Moorman's Duke roots run deep.

"My father was briefly a resident in orthopedics at Duke and my mom was an OB/GYN nurse at Duke. My parents divorced and my mom remarried Dr. Sid Fortney, who was the greatest man I ever met. He was devoted to our family, and taught me the value of hard work and perseverance. My biological dad was diligent about attending our many life events, but because he went to fight in Vietnam, he could not be present on a daily basis."

**As a young man, Claude Moorman caught 'athletic fever' and found a tie in with medicine. "The truth is that sports drove me into medicine. I attended Duke as an undergrad and was blessed to encounter Dr. Frank Bassett, a team doctor and the most charismatic man I have ever met. He loved the athletes and lived and died by Duke sports; I**

**found myself striving to be like Dr. Bassett, namely, respected by one's colleagues and patients."**

Aware that he wasn't setting the academic world on fire, Claude Moorman said a few prayers. "My goal was the University of Cincinnati College of Medicine, in part because my grandfather was encouraging me to come to the area. In addition, my godfather was an All-American football player who had had been athletic director at Cincinnati, and he insisted that I apply. I was not admitted to Duke, something that bothered me initially because my dad and stepdad had gone there. As for Cincinnati, I was not a great candidate there either (my average was barely a 3.0). But by the grace of God, I was admitted."

Over time, Dr. Moorman's perspective regarding his Duke rejection letter has evolved. "I soon realized that not being admitted to Duke was a blessing. Why? Because I had two years of basic science research at Cincinnati with the famed sports medicine specialist, Dr. Frank Noyes. The time in his lab gave me the opportunity to co-author two publications with him



Dr. Claude Moorman, III

that were very helpful to my career. The irony of these years? I now sit on the admissions committee of Duke University School of Medicine."

Then in 1987 it was back to Duke for residency, where Dr. Moorman would encounter a bit of (white) cloak and dagger intrigue. "The towering figure during this time was Dr. David Sabiston, the greatest educator in history of American surgery. His commitment and discipline were unparalleled, and he forced us to follow the decorum of the Duke tradition—no scrubs outside the OR, no seeing patients without a pressed white coat, etc. He had spies monitoring our every move, and out of that doggedness created some of the finest physicians around."

**Dr. Moorman's confidence in himself and his profession grew significantly under the tutelage of another high level surgeon. "Dr. Jim Urbaniak, a consummate physician/scholar, was**

**the head of orthopedics. We residents were fearless in the OR when he was there because we knew that he could fix anything we messed up. His mantra: you can succeed if you have a thorough knowledge of anatomy and excellent common sense. Too often now surgeons put technology ahead of common sense. In the end, however, we must know who we can't fix."**

Technically, there is no Disney World in New York. Dr. Moorman found one, though. "In 1993 I headed to Hospital for Special Surgery (HSS) to do a sports medicine and shoulder fellowship. Forget the candy store...HSS was like Disney World for someone with strong academic interests. Dr. Russ Warren, the developer of the second generation total shoulder, was my mentor. He was completely devoted to furthering research and poured all of his royalties into the lab."

"I also learned much from Ronnie Barnes, the head trainer for the New York Giants. Ronnie had grown up under segregation, but had reached a pinnacle in his career and was incredibly knowledgeable. He really spurred my interest in working with high level athletes."

Returning home to Durham, North Carolina, Dr. Moorman joined a private practice. "I worked with Dr. Bill Mallon, an authority on Olympic athletes; we agreed that when either of us encountered a complex shoulder case, we would get the other involved. Those two years were particularly challenging because I had to get comfortable with the business side of medicine."

**And not only did he get that special ring, Dr. Moorman acquired some behind the scenes expertise with that American phenomenon, the Superbowl. "A colleague of mine had been approached by an orthopedic group in Maryland that was under consideration to work with the Baltimore Ravens. Via this connection, I was selected to be the Director of a new sports medicine group at the University of Maryland—one that would work with the Ravens. The only problem was that we had not yet been selected to be the team doctors. Despite heavy competition from Johns Hopkins and other local entities, we were chosen to treat the team. I worked with the Ravens for six years, with the highlight being the Superbowl championship."**

Dr. Moorman was also busy creating an outstanding sports medicine program at the University of Maryland. Then in 2001 the telephone rang. "Dr. Urbaniak called and said, 'We have problem at Duke and we need you to come home.' There was a 'For sale' sign on our lawn the next day. I quietly met with the Ravens owner, Art Modell and told him about the situation. He told me, 'I support you but let's not make it public until after the playoffs.' Little did we know, the Ravens would beat the Broncos in the first round, and go on to the Superbowl."

On the field or in the lab, Dr. Moorman is open to surprises. "My early research at HSS was honored with the Neer Award by the American Shoulder and Elbow Surgeons. It involved the role of the coracoacromial ligament, which up until our work was

considered to be the appendix of the shoulder. The issue typically affects two patient groups, the first being people with massive rotator cuff tears where the ligament is the last stop on the supra subluxation of the shoulder. And, as Dr. Frank Jobe showed in his research, it also affects throwing athletes. He found that only 30% of throwers returned to their prior activity level after coracoacromial release. Our finding, obtained through dissection, revealed a connection between the coracoacromial ligament in the underlying shoulder capsule that is very important in stabilizing the shoulder for throwers. Unfortunately, this connection is inadvertently released in many of the most commonly performed operative procedures. This is an explanation for why many previous surgeries have failed in this particular group."

"Now I am working with Louis Defrate, Ph.D., on developing an in vivo model to undertake the dynamic evaluation of ACL reconstructions. This is the second of several studies, which thus far have shown that anatomic placement of the ACL on the femoral side appears to be the key to success with long term ACL reconstruction. Until we did this work I tended to do one of the less anatomic types of ACL reconstructions because patients seemed to do well in the short term. We are now finding that with graft elongation the kinematics are much more normal after anatomic reconstructions."

**Dr. Moorman's other work has extended what is possible for his colleagues...and made things safer for patients. "In 2002 my colleagues and I were honored with the Aircast basic science award from the American Orthopaedic Society for Sports**

Medicine for our work on the posterolateral corner of the knee. We found a less complicated way of fixing this corner based on previous work showing that the simple re-creation of the popliteo fibular ligament would be successful in stabilizing the knee. It became clear that the fibular approach was as effective in restoring functioning to the knee. The most significant outcome was that surgeons who do not do many of these operations can perform them easily...meaning increased safety for patients."

Dr. Moorman doesn't need Nike to motivate him (à la "Just do it."). But he does want them as supporters. "Nike has graciously funded our exceptional sports performance lab, where we focus on movement science. We use force plates to measure shear and loading, and study ways to improve orthotics, such as measuring angular velocities, etc. Most recently we have studied long snappers in football to determine how to optimize their biomechanics. We are inviting top level long snappers from professional teams to come here so that we can analyze their movements. Additionally, we assist Nike with shoe design, at one point helping them develop the



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best cleat for the new field turf surface when it was introduced."

And just maybe, Dr. Moorman and his family will be wearing Nikes when they climb Mount Olympus. "I want my tombstone to read, 'Life was an adventure.' I climbed Mount Kilimanjaro with my son, and have asked both of my daughters to formulate potential

adventures that we can share together. My daughter Virginia has indicated an interest in climbing Mt. Olympus, so that is on 'the bucket list.' My extraordinary wife Lynne is our family's glue and keeps me accountable as a man and a Christian."

Dr. Claude Moorman...bringing out the best in patients and colleagues. ♦

# Can't remember the last time you "tuned up" your procedure and reimbursement reports?

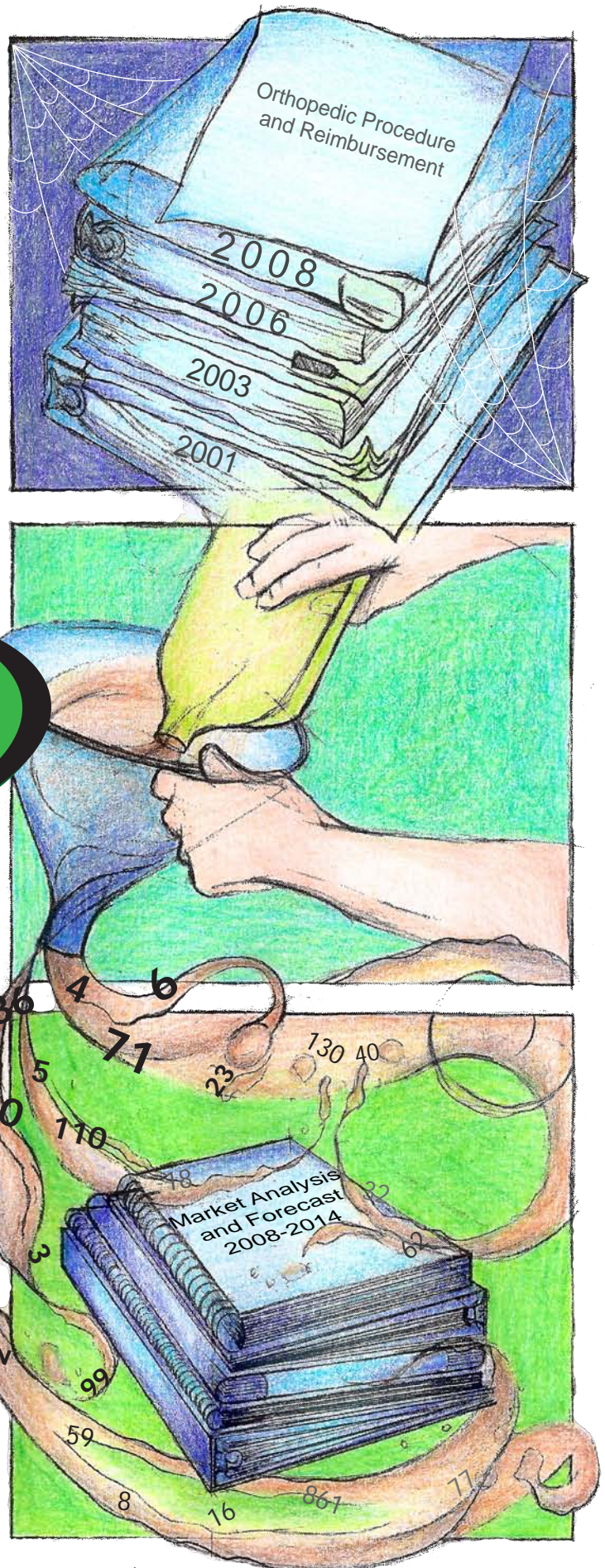
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## Orthopedics This Week | RRY Publications LLC

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

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

**Walter Eisner**  
Senior Writer  
walter@ryortho.com

**Tom Bishow**  
Vice President of Sales  
tom@ryortho.com

**Jacqueline Rupp**  
Writer  
jackie@ryortho.com

**Suzanne Kirchner**  
Print Production  
suzanne@ryortho.com

**Jayne Johnson**  
Production Coordinator  
jayme@ryortho.com

**Dana Bader**  
Graphic Designer  
dana@ryortho.com

### Main Contact Information:

**RRY Publications LLC**  
116 Ivywood Lane • Wayne, PA 19087  
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