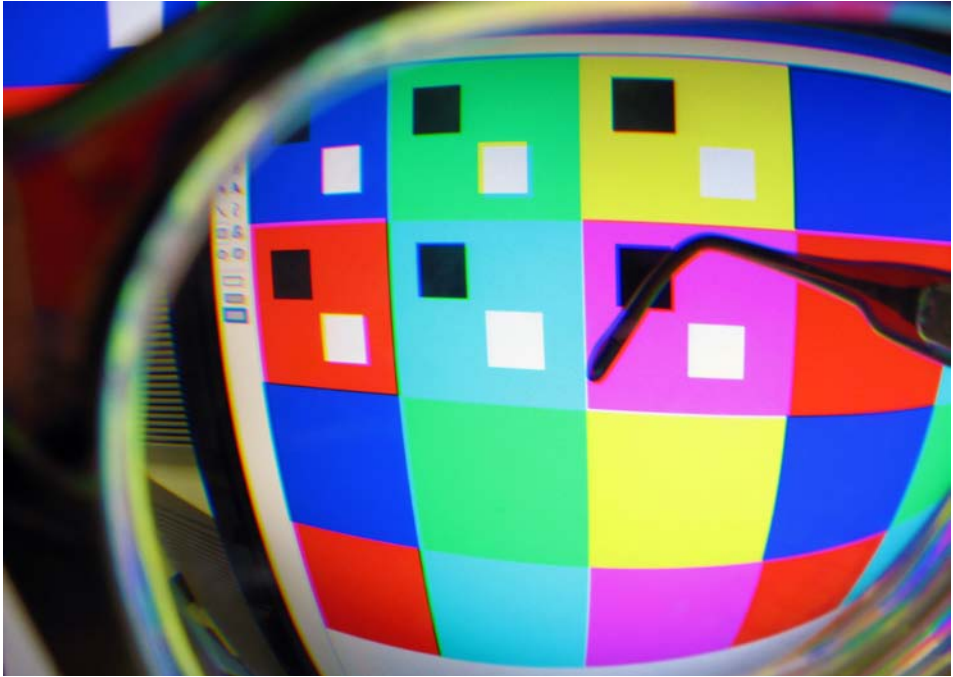


Orthopedics This Week

week in review

4 Got Vision? ♦ Could orthopedic company values be poised to rise during the coming election year? There is strong evidence from several quarters that indicate that, yes, orthopedic values will be higher a year from now. Here is a uniquely positive vision for orthopedic companies.

8 Is Wright Medical Back on Track? ♦ After a tumultuous spring and summer, Wright Medical enters the fall with a plan to restructure, settle their fight with the feds, hire a new leader, and get back to business. It's been a heck of a ride. So where does Wright stand now?



13 Reporter's Notebook ♦ Concerns over mega companies, spine surgeons who can't make a living, a magic cost containment wand, and, on one of several positive notes, famed Dr. Izzy Liberman's jungle trek to deliver a Torah.

picture of success

26 Dr. Clarence Shields ♦ Dr. Clarence Shields, also known as "Mr. Sports Medicine," was once President of the AOSSM. He has treated the famous and the indigent...and he has treated them just alike. His pride and joy? TEAM Heal...his foundation that helps impoverished young athletes.



breaking news

- 16 Biologics Growth Faster Than Implants**
- Historic Patent Reform Bill Signed Into Law**
- PODs, Senators and the OIG**
- Medtronic Wins Phase One, NuVasive Vows Appeals**
- TranS1 to Raise \$20.1 Million**
- Plastic Outwears Metal in Joints**
- Athletes Opt for Stem Cells**
- DePuy Touts UK Registry Hip and Knee Data**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: As we write in this week's OTW (see *Got Vision?*), signs are pointing to an orthopedic equity value bounce sometime around December, early January. In the meantime rumors of purchases are keeping prospective buyers interested. The latest to be subject to such a happy (?) rumor is Wright Medical.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Zimmer	27.75%	0.07%	Didn't decline in value—1 of only 5 orthopedic stocks that gained ground last month.
2	2	Medtronic	28.63	(3.36)	That was a short honeymoon! Now it's about business. One piece of good news for MDT—solid and rare win in court last week.
3	3	Stryker	25.23	(1.83)	Valuation starting to slip a bit, but most analysts think SYK can beat other major ortho by posting a solid 15% Q3 sales growth.
4	8	Orthofix	14.72	(0.45)	Quietly buyers are picking up some cheap OFIX shares. Stock actually was one of the better performers in past 30 days.
5	7	Smith & Nephew	22.8	(5.27)	Most analysts expect SNN to crack the psychologically important billion dollar/quarter sales level this quarter.
6	4	Wright Medical	8.76	20.15	New CEO will burnish WMGI. Will big ortho be attracted to shiny new Wright? 20% jump means WMGI got a little expensive.
7	5	Johnson & Johnson	26.33	(5.18)	JNJ is now officially the most expensive orthopedic stock on the Power Rankings.
8	6	Kensey Nash	34.24	(13.62)	Down earnings expected this quarter then BIG jump next quarter. Wall Street seems confused, sells off.
9	9	Conmed	9.65	(6.99)	CNMD is certainly cheap, but it's trading as if no growth left. Indeed, Wall Street's analysts are forecasting flat, flat, flat sales.
10	10	Integra	15.38	(6.89)	We do like the purchase of Ascension. Pyrolytic carbon is one cool, though difficult to work with, material.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Wright Medical	WMGI	\$17.71	\$698	20.15%
2 Alphatec Holdings	ATEC	\$2.58	\$230	12.17%
3 MAKO Surgical	MAKO	\$35.25	\$1,461	12.08%
4 RTI Biologics Inc	RTIX	\$3.64	\$201	7.37%
5 Zimmer Holdings	ZMH	\$53.52	\$10,194	0.07%
6 Orthofix	OFIX	\$35.32	\$650	-0.45%
7 Stryker	SYK	\$46.16	\$17,925	-1.83%
8 Medtronic	MDT	\$33.06	\$34,911	-3.36%
9 Johnson & Johnson	JNJ	\$61.59	168,778	-5.18%
10 Smith & Nephew	SNN	\$44.57	\$7,958	-5.27%

Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 TranS1	TSON	\$3.05	\$86	-25.25%
2 Kensey Nash	KNSY	\$24.42	\$211	-13.62%
3 TiGenix	TIG.BR	\$0.89	\$81	-11.88%
4 CryoLife	CRY	\$4.53	\$127	-11.87%
5 NuVasive	NUVA	\$19.04	\$760	-11.81%
6 Tornier N.V.	TRNX	\$20.32	\$796	-8.47%
7 Bacterin Intl Holdings	BONE	\$1.89	\$75	-8.25%
8 Synthes	SYSTVX	\$159.38	\$18,931	-7.64%
9 Conmed	CNMD	\$21.57	\$616	-6.99%
10 Symmetry Medical	SMA	\$7.49	\$272	-6.96%

Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Medtronic	MDT	\$33.06	\$34,911	10.05
2 Zimmer Holdings	ZMH	\$53.52	\$10,194	11.53
3 Johnson & Johnson	JNJ	\$61.59	\$168,778	12.60
4 Smith & Nephew	SNN	\$44.57	\$7,958	12.94
5 Stryker	SYK	\$46.16	\$17,925	13.11

Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Wright Medical	WMGI	\$17.71	\$698	25.30
2 NuVasive	NUVA	\$19.04	\$760	23.80
3 Synthes	SYSTVX	\$159.38	\$18,931	20.17
4 ArthroCare	ARTC	\$28.46	\$781	19.90
5 Exactech	EXAC	\$13.75	\$180	18.09

Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 Integra LifeSciences	IART	\$36.50	\$1,004	0.82
2 Orthofix	OFIX	\$35.32	\$650	0.85
3 Kensey Nash	KNSY	\$24.42	\$211	1.04
4 Medtronic	MDT	\$33.06	\$34,911	1.11
5 Zimmer Holdings	ZMH	\$53.52	\$10,194	1.20

Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 ArthroCare	ARTC	\$28.46	\$781	3.32
2 Johnson & Johnson	JNJ	\$61.59	168,778	2.26
3 Wright Medical	WMGI	\$17.71	\$698	2.07
4 CryoLife	CRY	\$4.53	\$127	1.90
5 Symmetry Medical	SMA	\$7.49	\$272	1.70

Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 Symmetry Medical	SMA	\$7.49	\$272	0.75
2 Conmed	CNMD	\$21.57	\$616	0.86
3 Exactech	EXAC	\$13.75	\$180	0.95
4 CryoLife	CRY	\$4.53	\$127	1.09
5 Orthofix	OFIX	\$35.32	\$650	1.15

Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$0.89	\$81	130.45
2 MAKO Surgical	MAKO	\$35.25	\$1,461	32.98
3 Synthes	SYSTVX	\$159.38	\$18,931	5.13
4 Tornier N.V.	TRNX	\$20.32	\$796	3.50
5 TranS1	TSON	\$3.05	\$86	3.28

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

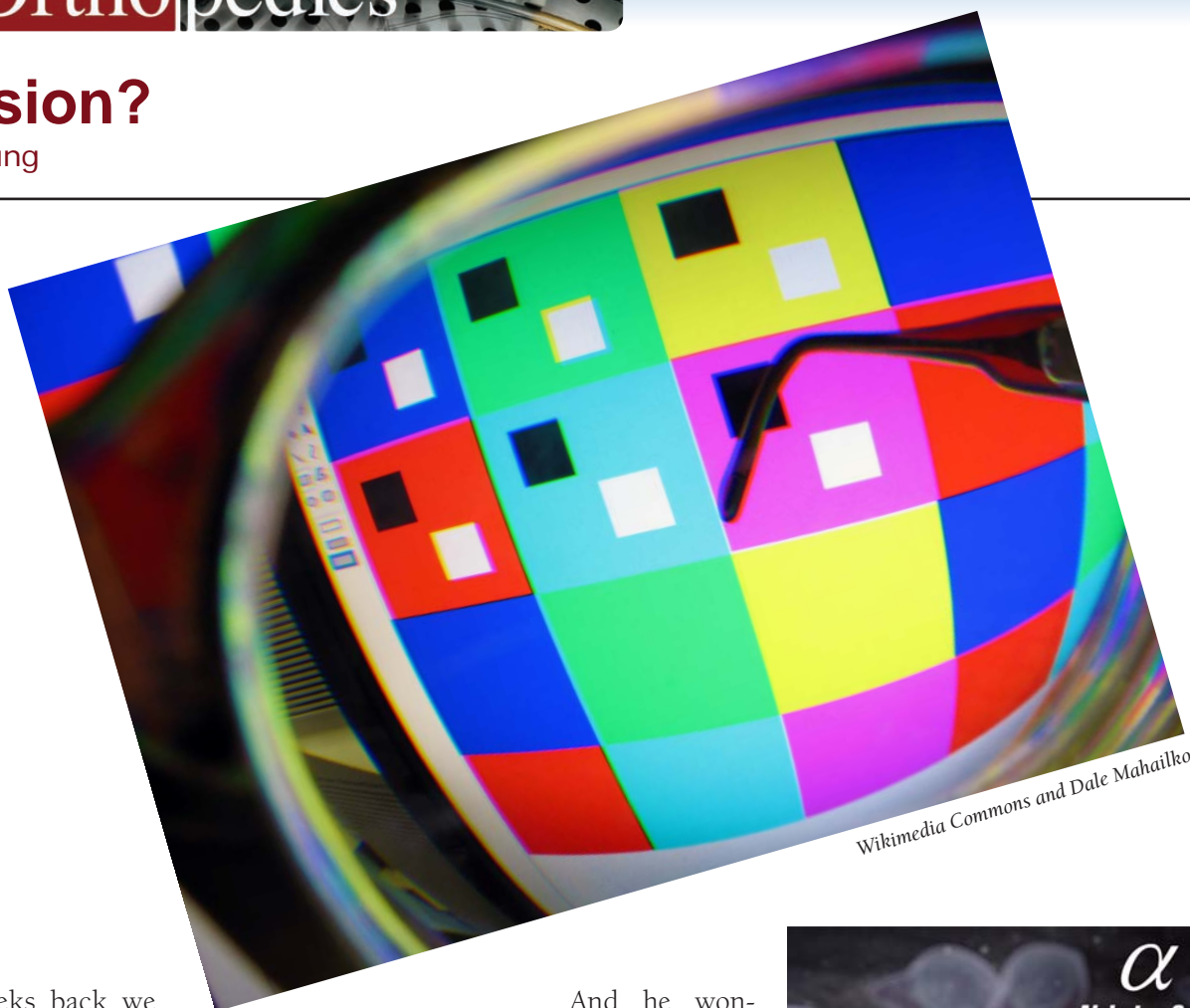
Advertise with Orthopedics This Week




Click Here for more details
or email tom@ryortho.com
Tom Bishow: 410.356.2455 (office)
or 410.608.1697 (cell)

Got Vision?

By Robin Young



Wikimedia Commons and Dale Mahailko

A couple weeks back we named the top ten trends that will likely affect orthopedic surgeons, hospitals, suppliers, and implant sales people over the remainder of this current decade. This week we narrow our focus to the next 12 months and orthopedic company values.

And we have found some unexpectedly reassuring patterns.

Wells Fargo Security's senior analyst, Larry Biegelsen, looked back at the 2008-2009 financial crisis (admittedly uncomfortably similar to today's credit downgrade and EU economic turmoil), the recovery that followed (2009-2010), the 2010 correction, the 2010-2011 recovery and then today's downturn.

And he wondered if there was any particular pattern for how medical stocks in general and orthopedic stocks in particular performed. As it happens, there was a clear pattern. If that pattern holds true, the next 12 months will likely be better for orthopedic company values than the last 12 months.

Between 2008 and 2009, when the global economy was free falling through the worst financial crisis since the Great Depression, all investors wanted to do was find a bottom. A floor to stand on. And all orthopedic executives wanted was a source of working capital and a healthy bank to lean on.

The one searing lesson we remember from those days is that public company

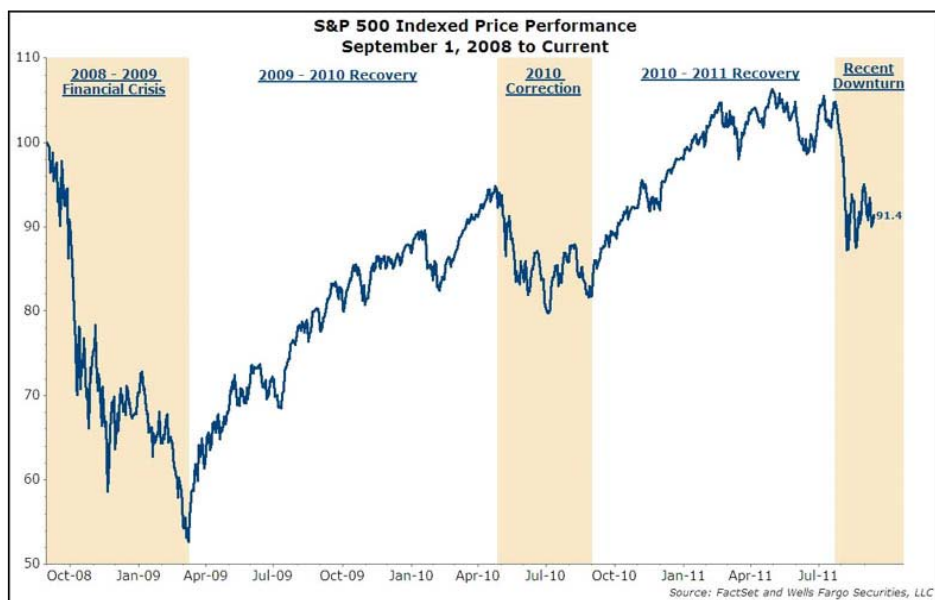
UPGRADE YOUR CELL PLAN

PUREGEN™
Osteoprogenitor Cell Allograft

Processed for safety and functionality
Up to 2x osteogenic potential of BMA or MSCs!
Collected from live healthy donors

For more information visit www.alphatecspine.com
or contact Customer Service at 800-922-1356

Advertisement



Source: FactSet and Wells Fargo Securities, LLC

execs worried more about their bank lines than they did about their stock prices. Stock prices could swing all over the place, but with no bank lines, there was no business.

Here's how everyone did in those chaotic days of 2008-2009.

Table 1

'08 - '09 FINANCIAL CRISIS		
Group	Absolute Return	Relative to S&P
Diversified	(28.5%)	18.7%
Supplies	(38.7%)	8.5%
S&P 500	(47.3%)	0.0%
Cardiology	(48.4%)	(1.1%)
Orthopedics	(53.2%)	(5.9%)

Source: Wells Fargo Securities

During the financial meltdown of 2008-2009, the S&P lost about 47% of its value (Table 1). Orthopedic companies **underperformed** the overall market by losing 53% of their values which was 5.9% worse than the overall market. Given the chaos of the time, most orthopedic company execs probably didn't notice.

But executives certainly did notice what happened next.

On March 9, 2009 the S&P 500 hit a 12-year low. Then it bounced for the next 13 months. From March 10, 2009 to May 26, 2010, the value of the S&P rose 68%. Orthopedic stocks **soared 79%**.

So where orthopedic stocks underperformed the overall market indices by 5.9% in the financial crises of '08-'09, they **outperformed** the same market indices by nearly double that or 10.8% in '09-'10.

Table 2

'09 - '10 RECOVERY		
Group	Absolute Return	Relative to S&P
Orthopedics	79.2%	10.8%
S&P 500	68.4%	0.0%
Supplies	53.3%	(15.1%)
Cardiology	49.2%	(19.2%)
Diversified	21.3%	(47.1%)

Source: Wells Fargo Securities

This pattern of worst to first continues for each of the next set of market swings.

The recovery ended in time for summer in 2010 and for the next four months what started out as profit taking grew to become a full blown correction. With the economic recovery sputtering and the political leadership in Washington and Europe proving to be equally ineffective, investors started to look for safe capital havens again. Again orthopedic companies took the brunt of the selling.

Table 3

2010 CORRECTION		
Group	Absolute Return	Relative to S&P
Diversified	(8.3%)	3.0%
S&P 500	(11.4%)	0.0%
Supplies	(15.8%)	(4.4%)
Cardiology	(22.1%)	(10.8%)
Orthopedics	(23.1%)	(11.7%)

Source: Wells Fargo Securities

From first to worst. After being whipsawed so thoroughly it may be hard to remember where the orthopedic values started and where they were at the end of the correction (August 31, 2010).

Down 53% during the financial crisis, up 79% then down 23%—leaving the aggregate values of orthopedic stocks at 65% of their values before the financial crisis hit. To simply return to, in effect, par as of 2008, orthopedic company values would need to rise by 54%.

For the next 11 months, orthopedic stocks tried to do exactly that. Several orthopedic companies dusted off their shelf registrations and tried to enter the market. Tornier succeeded with a \$166 million stock float on February 2, 2011.

And, yet again, orthopedic stocks traveled the long road from worst to first.

Table 4

'10 - '11 RECOVERY		
Group	Absolute Return	Relative to S&P
Orthopedics	29.1%	4.6%
Supplies	27.6%	3.1%
Cardiology	25.0%	0.5%
S&P 500	24.5%	0.0%
Diversified	14.3%	(10.2%)

Source: Wells Fargo Securities

By July 22, 2011 the value of orthopedic companies was roughly 84% of their values from before the 2008 debacle.

And now we come to today's eerily familiar financial crises. There is anxiousness, a fear and a feeling that it's 2008 all over again. Where that crisis was effectively an unraveling of the banking system, this time it is the economic dis-

solution of countries. Is Greece too big to fail? If not, then who saves it?

Sure enough, there go the orthopedic stocks. Down.

Table 5

RECENT DOWNTURN		
Group	Absolute Return	Relative to S&P
Diversified	(5.5%)	7.3%
Cardio	(9.8%)	3.0%
Supplies	(12.3%)	0.5%
S&P 500	(12.8%)	0.0%
Orthopedics	(14.6%)	(1.8%)

Source: Wells Fargo Securities

The Trend is Your Friend

It may strain credibility to say that this pattern of first to worst and back again is positive. But for the next 12 months this may in fact be pointing to an unusually rewarding capital market for orthopedic company equities.

If, as most economists assume, the global community starts to pull itself out of this economic maelstrom by, say, December or January, orthopedic equities will almost certainly lead the market out. How high could orthopedic stocks go? If the past patterns repeat, orthopedic equities should outperform the overall market by between 500 and 1,000 basis points.

Should capital flows move back in the direction of orthopedic companies, a new question emerges—what will they be able to buy?

The orthopedic industry appears to be in the middle of a consolidation phase. Synthes is being purchased by JNJ. Rumors have Smith & Nephew and Wright Medical disappearing as public

companies into the folds of larger, more diversified firms.

Whenever institutional stock buyers return, they will surely find fewer shares to buy. That, in turn, would probably drive equity prices higher still.

2012 Is an Election Year

Of the last 20 election years, there have been only three years where the S&P 500 index had a negative return during an election year. The last time was 2008—which, given the axiom of regression to the mean, sets 2012 up as a positive year.

Marshall D. Nickles, Ed.D., wrote about the correlation of positive stock market returns and presidential elections in his paper called "Presidential Elections and Stock Market Cycles." He writes that a profitable investment strategy would be to purchase equities on October 1st of the second year of a presidential term and then sell on December 31st of year four.

Dean A. Junkans, CFA, Wells Fargo's Chief Investment Officer and James P. Estes, Ph.D., CFP, Wells Fargo's Senior Investment Manager conducted their own study and concluded that the average market return in the fourth year of a presidential term (that would be 2012 in Obama's term) is twice that of the return in the first year of a president's term (that would be 2009 in Obama's term—when the recovery was underway).

Got Vision?

The period from 2008 to 2009 was, in retrospect, the perfect storm for orthopedic companies. Both the capital markets and the banking system were unraveling. The U.S. Government,

Advertisement

which through CMS (Centers for Medicare and Medicaid Services), its military and VA systems, and Medicaid account for a majority of reimbursement for orthopedic surgeries in the U.S., was dealing with the orthopedic industry from a position of mistrust if not outright antagonism.

Could it get worse?

Sure, there could be a big fight over healthcare reform and a medical device products tax. Which, of course, happened. In 2009.

But really, that probably was the worst period for orthopedic companies.

Wall Street, as an industry, is roughly two and a half times older than the modern orthopedics industry of Zimmer, DePuy, Stryker, Biomet or Smith & Nephew. The first trading desk was a table under a button wood tree beside the wall that formed the lower boundary of Manhattan in 1792. Through booms and bust, Wall Street has tracked every single known industry. There are charts of equity prices, interest rates and economic activity that go back two hundred years.

Ortho in 2012

We've seen this movie before.

Using past patterns as a guide, here's how, we think, this orthopedic industry drama likely plays out over the next 12 months:

- Orthopedic company values will likely be higher than they are today
- There will be fewer independent orthopedic implant suppliers
- Both CMS and the FDA will endure budget constraints
- Strategic investors (large private equity companies and pharma

companies) will be eyeing the comparatively strong operating profit margins for orthopedic companies and be looking for ways to add hips, knees, spine and extremity care to their portfolios

In short, the next 12 months may well be a more positive, supportive time for orthopedic suppliers which is certainly the most optimistic vision we've had in about four years. ♦

**Customer FOCUSED. Patient DRIVEN.
Always RESPONSIVE.**

FIREBIRD™
DEFORMITY CORRECTION SYSTEM

PHOENIX™
Minimally Invasive Spinal Fixation System

Spinal Implants | Biologics | Spine Fusion Stimulation | MIS | Bracing

orthofix.com

ORTHOFIX®
Spine

Advertisement

Is Wright Medical Back on Track?

By Walter Eisner

At one point in its long history Wright Medical Group, Inc. was in the breast implant business and its CEO flew around in a gold-plated private jet. Ah the good old days.

Over five days this September, the company announced layoffs, a cost reduction plan, a settlement with the federal government to extend their Deferred Prosecution Agreement (DPA) for a year, and a new CEO.

After this year's series of very public blow ups, could Wright be getting back on track? After asking various insiders and outsiders this question the consensus is: probably.

Restructuring

On September 15, four days before naming a new CEO, the company announced a restructuring plan that's designed to reduce costs and, hopefully, increase earnings. The plan eliminates 80 positions and will entail a layoff of about 6% of the company's workforce. With margins and economies of scale well below those of the larger orthopedic implant manufacturers, some analysts viewed this as a step toward bringing the company's cost structure more in line with the current orthopedic market fundamentals, and perhaps become a more attractive acquisition target.

Lance Berry, the company's chief financial officer, agreed with that assessment in an interview with *OTW* on September 22, although he didn't acknowledge the acquisition part.



Wikimedia Commons/Wright Logo

The initial phase of the restructuring will likely be completed by mid-2012 and the remainder of initiatives will be implemented over the balance of 2012 and beyond.

Wright's management also expects to streamline its international selling and distribution operations, reduce the number of international products, adjust plant operations, and rational-

ize R&D projects over the next nine months.



morgueFile.com and cohdra

We asked Berry about specifics of the reduction of international products. Said Berry, “At this point we’re staying away from details. I will tell you we have a very large number of products that we sell in the international markets in particular. Some of them are legacy products we’ve sold for a very long time and are very low volume and we’re just taking a hard look at them.”

Enhanced Prospects for Growth and Value Creation

David Stevens, Wright’s board chair who stepped into the interim CEO role when the tide rose last spring, said the industry continues to face a challenging economic environment and, after exten-



Wright Medical Group, Inc. building

sive analysis and consideration, “We believe this plan will enhance the company’s prospects for growth and value creation. We are taking these actions now to better position the company to grow its earnings in 2012 and we are confident that this plan will result in a leaner, more cost efficient operation, which is in the best interest of our busi-

ness and all of our stakeholders. Additionally, the company continues to have a strong balance sheet and is positioned well for investments in acquisitions to drive future growth.”

Wall Street’s analysts are forecasting that Wright will likely earn \$0.76 per share this year up from \$0.68 last year, which is an 11% rate of earnings growth. For 2012, analysts are forecasting that Wright will earn \$0.87 per share which is a 14% rate of earnings growth.

Deferred Prosecution Agreement Extension

On the same day that Wright announced its plan to reduce its employee count, management also disclosed a resolution to the government investigation of a willful breach of their Deferred Prosecution Agreement signed in 2010.

PIONEER SURGICAL MOTION | FUSION | BIOLOGICS INFINITE POSSIBILITIES

WE’RE BREAKING BARRIERS, EXPLORING NEW IDEAS
AND PRODUCING SOLUTIONS FOR YOU.

VISIT US IN MILAN, ITALY
AT EUROSPINE, BOOTH NO. 55
OCTOBER 19-21, 2011



Advertisement



Wikimeida Commons

The company announced the agreement with the U.S. Attorney's Office for the District of New Jersey and the Office of the Inspector General (OIG), U.S. Department of Health and Human Services to voluntarily agree to extend the term of the DPA for 12 months. The DPA will now expire on September 29, 2012 and calls for no penalties or further actions.

Disruption

Perhaps no company in orthopedics had as much disruption as Wright Medical from the federal investigations into industry surgeon relationships.

Wright entered into a DPA with the U.S. Attorney last year and paid a \$7.9 million penalty to resolve allegations of improper relationships with surgeons. The agreement seemed to follow along the same path as previous agreements between the government and Wright's larger competitors (Zimmer Holdings

Inc., Biomet, Inc., DePuy Orthopaedics, Inc. and Smith & Nephew).

The government agreed to defer prosecution of those companies if they paid more than \$310 million in fines, hired federal monitors and made reforms. The cases ended in 2009.

The Blow Up

But shortly before a Wright board meeting on May 4, 2011 to talk about compliance issues, the wheels came off. There was an unexpected and shocking announcement that Gary Henley, the CEO since 2006, resigned "without good reason."

In addition, the board fired Frank S. Bono, the company's chief technology officer. Bono was fired for "failing to exhibit appropriate regard for the company's ongoing compliance program." The company also eventually accepted the resignations of Senior Vice Presi-

dent, General Counsel and Secretary Raymond Kolls; Vice President of Clinical & Regulatory Affairs Alicia Napoli; and Senior Vice President for EMEA Commercial Operations Cary Hagan. All three executives resigned without "good reason," according to a company statement.

The company said it had found "credible evidence of serious wrongdoing" regarding its compliance with the DPA. On May 5, prosecutors said Wright had "knowingly and willfully breached" the DPA.

Then came another surprise as Lisa Michels, resigned as vice president and chief compliance officer on August 16. The resignation was effective immediately and the company stated that Ms. Michels is eligible for severance benefits.



Advertisement

None of the former employees have responded to OTW's requests for interviews.

“Extensive Cooperation” and Settlement

“Wright Medical and our Board of Directors have taken significant steps to enhance the company's compliance,” said interim CEO Stevens. “We believe that voluntarily extending the term of the DPA will provide the company with an opportunity to further demonstrate its commitment to the highest standards of ethical conduct. We will continue to work closely with the Monitor, the USAO, the OIG and other regulators to ensure that the company complies with all laws and regulations that govern our business practices.”

“As a direct result of the federal monitorship, Wright has made significant and wide-ranging changes in corporate culture and tone at the top,” First Assistant U.S. Attorney J. Gilmore Childers said in a press release. “Our Office is pleased with the extensive cooperation from the newly appointed interim senior management team. Today's extension will allow Wright to make the transition from interim to permanent senior management while still under the terms of the DPA and the surveillance of the federal monitor.”

Sales Grow

In spite of all the disruptions the company reported a pretty good second quarter. Reported sales rose 4% to \$132.5 million during the quarter and net income rose from \$4.8 million to \$6.1 million. The income number included \$2.4 million associated with the DPA situation. Wright continued to launch new products for the foot and

ankle market including the Fusionflex Demineralized Moldable Scaffold and the Inbone II Total Ankle Replacement System.

To date, the only negative impact to business the company has attributed to the federal monitoring activities was a decline in sales due to disruption of surgeon training programs.

We asked CFO Berry about those programs and how they will be resumed.

Berry said the company has made a number of changes to their training processes. “We definitely saw a slow down in the amount of medical educa-

tion that we were able to move through those processes and execute. We do have approval for medical education events in the fourth quarter and hopefully we will be able to get those ramped back up to a more normalized level as we move into 2012.”

Wright's larger competitors also experienced disruptions to training programs and we asked Berry if Wright's experience was similar to those companies. Berry said, “Our situation is just more about the time it takes to implement and changes to processes to get things processed through. It was not a situation where our monitors were telling us, you can't do these things per se.”

Discover Our Full Range of Osteobiologics

New Regenerative Products



SKYE
ORTHOBIOLOGICS

310.944.5402
skyeorthobiologics.com

Distributors Please Apply

Advertisement

Palmisano Hired

With the decks of the government investigation and monitoring cleared and a cost reduction and corporate reorganization program in place, Stevens and the board executed their next strategic move by naming Robert Palmisano to become Wright Medical's new president and CEO on September 19. Palmisano's hiring was effective September 17. Stevens will go back to just being chairman.

An analyst from Robert W. Baird & Co., said the naming of Palmisano increases the likelihood that the company eventually will get sold.

Analyst: "Clear Signal for Sale"

Another analyst reportedly said Palmisano is well known as a turnaround specialist and for having successfully sold a number of medtech companies

in recent years, including ev3, IntraLase and Summit Technology.

"Palmisano is a serial fixer-upper and seller of medical technology assets," said BMO Capital Markets analyst Joanne Wuensch. "There is a lot of work that can be done at Wright Medical."

We asked CFO Berry about that. He told us that Palmisano has a great track record of managing and executing efficiency programs at companies and if his efforts are successful at Wright, shareholders will benefit. He did not comment on any potential merger and acquisition possibilities.

Back on Track

The river of disruption seems to have settled back into its banks at Wright. Now what does the company need to do to make investors happy?

BMO Capital Market's Wuensch, who knows Palmisano well and thought it was a great hire for the board, said the company needs to address the increasing scale at the competitor level, (noting the DePuy/Synthes merger) by managing expenses in a bloated cost structure.

Mike Matson at Mizuho Securities said the company needs to expand its upper extremities offerings, such as shoulder replacements, reduce costs and increase their scale through a merger and acquisition, either as a seller (preferred) or buyer.

Many challenges remain for Wright Medical in a tough market. But with a new leader and a new plan, the company can focus on business. ♦



WHAT'S YOUR ANGLE?

primaLOK™ polyaxial technology can handle it.

next generation
posterior fixation & fusion solutions

Visit us at CNS booth 1644
October 3rd - 5th

colson A COLSON ASSOCIATE



OSTEOMED | SPINE
800.456.7779
www.osteomed-spine.com
info@osteomed-spine.com

Advertisement

Reporter's Notebook

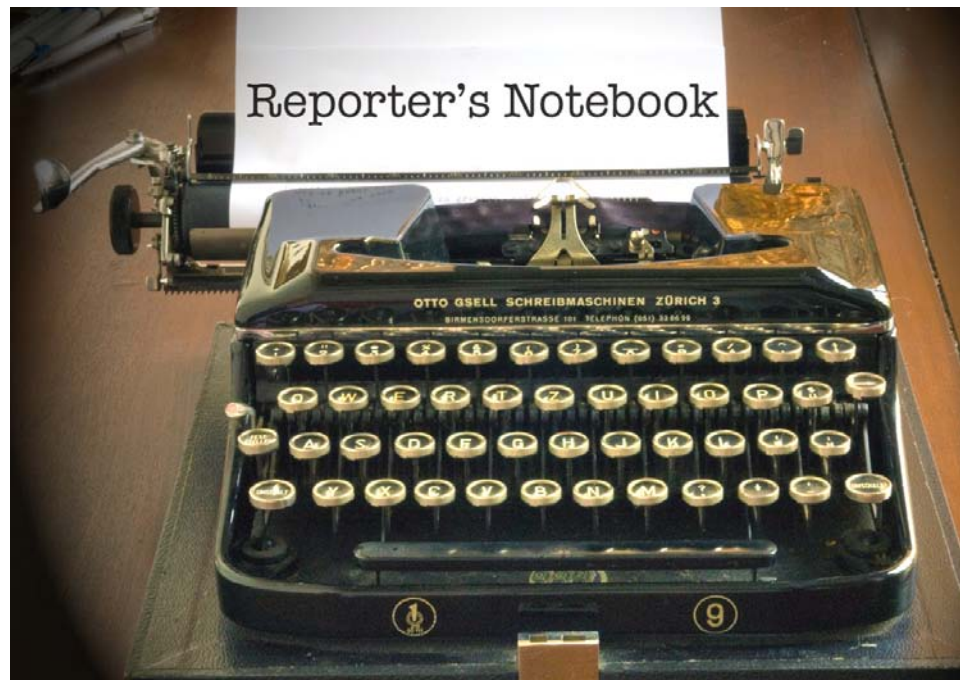
By Elizabeth Hofheinz, M.P.H., M.Ed.

Dear OTW Reader:

Spine surgeons fleeing to the cities, worrisome retrievals, suffering patients who can't get care, and, on one of several positive notes, the famed Dr. Izzy Lieberman's jungle trek to deliver a Torah.

Spine Party Over? A concerned spine surgeon tells OTW, "The bubble has burst in spine. I'm hearing a lot of concern about where we are going with innovation. Between FDA bottlenecks, product development relationships, royalty agreements, etc. innovation is in 'stall' mode. Take MIS, for example. We've done a lot, but to get it to the next level we have to build on the existing foundations—good luck in this environment. *No one wants to shell out the enormous funds needed for an IDE [investigational device exemption]; and companies don't want to work with doctors whose names are going to end up in the New York Times!* I've recently met with industry leaders who are concerned about the increasing merger trend that could create mega companies that control 80-90% of the market. On the physician side, we are seeing a trend in small towns where spine surgeons are fleeing to big metropolises because they can't make a living. We need to turn this around."

Top Flight Care for Military Athletes Brett Aldridge, director of the Andrews Institute Foundation, told OTW, "Recently, we had more than 120 people join in our golf fundraiser to support the Eagle Fund. Because of this fund, created by the Andrews Institute and Athletes Performance, military athletes now have



Wikimedia Commons

access to a level of care that they wouldn't otherwise have. *Lots of programs get athletes back to the 80-90% performance threshold, but 10% is a big difference if you are on the battlefield.* This all began when a soldier approached us and said, 'I need help.' We treated him pro bono and then he later made a donation and said, 'Let this be the start of a fund that will allow others to get the kind of treatment I have received.'"

Robert J. Palmisano Now Heading Wright Medical The Board of Directors at Wright has appointed Robert J. Palmisano as president and chief executive officer. Palmisano, who holds a B.A. degree in Political Science from Providence College, was most recently president and CEO of ev3, Inc, an endovascular device company. During his tenure, that company's market

capitalization more than tripled, from approximately \$800 million in April 2008 to \$2.6 billion in July 2010. Palmisano has also served as president and CEO of IntraLase Corp. and previously he was president and CEO of MacroChem Corporation. Earlier in his career, he served as president and CEO of Summit Technology Inc. until it was acquired by Alcon Inc. OTW wishes Palmisano all the best

Magic Cost Containment Wand? A spine surgeon tells OTW, "In my state—North Carolina—we are concerned about the bar being raised even higher in order to get approval for fusions. Medicaid is figuring out that they can use the same cost containment strategies as everyone else, namely, precertification. A year from now I think more people will be showing up underinsured

or uninsured, and will be straining the system. And people who really could benefit from novel spine technologies are going to have a tough time getting those. *There are people who are almost bone on bone...they don't have gross spinal stenosis, but they are miserable and by all criteria need a stabilizing procedure. But the insurance precertification system doesn't acknowledge that group of people.* The challenge is for us to provide evidence so that we can say, 'XYZ is the best treatment for this condition.'"

Spreading Wound Coverage Techniques Worldwide

The Institute for Global Orthopaedics and Traumatology (IGOT)—an entity started by the UCSF Department of Orthopaedic Surgery—recently held its Second Annual IGOT International Flap Course and first Clinical Research Training Seminar in partnership with and preceding the SIGN Conference in Washington. Richard Coughlin, M.D., director of IGOT, told *OTW*, "Fifty-five orthopedic surgeons from resource-constrained countries such as Ethiopia, the Philippines, and Haiti, came to learn simple flap techniques. *Orthopedists in most developing countries don't have the luxury of a plastic surgeon so these patients go untreated—and sit in a hospital bed for months. Each participant was given a flash drive and they are already showing these procedures to their colleagues at home... instant multiplier effect.*" Also involved with the course is Ted Miclau, M.D., who told *OTW*, "Our ultimate goal is to help build infrastructure in these countries. We also took advantage of everyone being in the same place to work on developing a global research consortium that would, in part, give doctors abroad access to 'developed world' research infrastructure and techniques."

Worrisome Retrievals *OTW* hears: "I am concerned about corrosion of

modular prosthetic devices on or at the base of the neck (not prosthetics used for revisions but those used in primary surgeries). Most manufacturers are introducing modular necks and they could end up being a major problem. It is very desirable for orthopedic surgeons to have the ability to use a modular neck, but given the possibility of failure, I feel we should use modularity when we really need it. *There have been a number of failures and worrisome retrievals reported.*"

Getting Professional About Professionalism

Ken Egol, M.D., is vice chair for education in orthopaedic surgery at the NYU Langone Medical Center. He tells *OTW* about their interesting new program: "We are using the Objective Structured Clinical Exam to assess and improve the professionalism and communication skills of our residents. *Actors pretend to have clinical issues, and also present various ethical/professional situations. It may be dealing with an impaired colleague, a hostile staff*



Advertisement

member, disclosing medical errors to families, etc. We videotape each situation and review the tapes with the residents. Each actor has a checklist and evaluates whether the trainee explained things well, was respectful, etc. It's a great learning tool, and I think we are pioneering it in orthopedic surgery."

Preliminary Bone Graft Device Brett Crist, M.D., co-chief of Orthopaedic Trauma at the University of Missouri, is making strides in fracture care. "Many people are trying to maximize fracture healing rates and minimize fracture healing time through biological adjuncts. Part of the problem is that our bodies do it with a vast number of chemical pathways and investigators are trying to identify single compounds to augment or block. Unfortunately clinical trials are currently lacking that convincingly shows a magic bullet to address all of the bone healing problems. Due to the potential risks of bone graft harvesting, including pain, people are looking for alternatives that are commercially available on the shelf. However, the gold standard for treating fractures that don't heal, is still autograft bone. A newer technique for harvesting large amounts of bone graft from primarily the intramedullary canal of the femur is commercially available that may or may have fewer complications than taking bone graft from the patient's iliac crest. Clinical studies are ongoing that are comparing the clinical effectiveness of this device and several basic science studies show that active bone healing compounds are present in the graft as would be expected. We have compared the viability of cells harvested using this technique versus standard iliac crest harvesting and the data shows that the graft is equally viable and able to produce bone."

Calling Talented Adventurers Peter Trafton, M.D., professor of orthopaedics

at the Alpert Medical School of Brown University, is the director of the Ghana site for Orthopaedics Overseas—and they are recruiting volunteer orthopedic surgeons—especially those strong in trauma. Dr. Trafton tells OTW, "Orthopedics Overseas is seeking orthopedists to go to Ghana for at least two weeks. We are looking for people who are strong on trauma care, those who have some interest in pediatric orthopedics, those interested in general orthopedics, and people with a minimum of the basics of fracture care. There are good things happening in Ghana...including a new residency program that has the full support of the hospital. *Come help your orthopedic colleagues in Ghana develop their skills...you will change a country for generations.*" Please visit www.hvousa.org, or contact Andrea Moody for more information: a.moody@hvousa.org.

The 80-Hour "Card": A Resident Speaks A resident taking the pulse of his peers tells OTW, "There is no scientific basis for the 80 hour work week... and there are lots of studies showing the negative effect of this edict. Example: A junior resident was on duty one night when a patient with a certain type of fracture came in. He worked it up, read up on it, but then had to go on to another rotation...so he wasn't around when the attendings taught about the case. *None of the residents present knew the patient and none could speak in an informed, educated manner about it. The people coming in on the day shift come in and they are the ones operating on the patient—and they don't know how to manage the disease.* It's really aggravating the attendings because more and more the burden of taking care of things is falling to

them. They are also not thrilled about this: **there are times when residents leave in the middle of a case because they have reached their limit...they are pulling the 80-hour card.**"

Izzy Lieberman, M.D. Delivers Torah to Uganda As part of a recent medical mission to Uganda, Dr. Isador Lieberman of the Texas Back Institute braved the mud roads to deliver a Sefer Torah to an excited, small village in remote Uganda. Dr. Lieberman tells OTW: "I learned of an orthodox Jewish village with about 300 people...I met their leader, Rabbi Enosh, last year. He showed me their small Sefer Torah, which was made of paper and is essentially what you give as a souvenir at a bar mitzvah. In a lapse of reasoned thinking I promised him a real Sefer Torah. *When I—along with a team of volunteers including my mother—delivered it a couple of weeks ago there was a procession where the rabbi and others carried, paraded and danced the Torah into the synagogue.* I have run marathons, but their enthusiasm which lasted well over two hours, completely exhausted me...there was a real excitement in the air while they welcomed the new Sefer Torah into their village." ♦

VB

VISCOGLIOSI BROS., LLC

OUR MISSION IS
TO CREATE, BUILD AND
FINANCE COMPANIES
FOUNDED ON INNOVATIONS
DEVELOPED BY SURGEONS.

CONTACT: MARC VISCOGLIOSI
MVISCOGLIOSI@VBLLC.COM

Advertisement

company

TranS1 to Raise \$20.1 Million

On September 20, TranS1 Inc. announced that the company intended to offer shares of its common stock in a public offering. The next day, the company announced a price of \$3.25 per share for the offering of 6.2 million shares.

The company expects to raise \$20,150,000 in the offering.

Piper Jaffray & Co. is acting as the sole book-running manager for the offering and Canaccord Genuity is acting as co-manager.

TranS1 has granted the underwriters a 30-day option to purchase up to 930,000 additional shares of common stock to cover over-allotments, if any. The gross proceeds to TranS1 from the sale of shares, before expenses and any

over-allotment exercise, are expected to be \$20,150,000. The closing of the offering is expected to take place on September 26, 2011.

TranS1 currently markets the AxiaLIF family of products for single and two level lumbar fusion and the Vectre and Avatar posterior fixation systems for lumbar fixation supplemental to AxiaLIF fusion. AxiaLIF received 510(k) clearance from FDA in the fourth quarter 2004. The company says over 10,000 AxiaLIF procedures have been performed to date.

The company was founded in May 2000 and is headquartered in Wilmington, North Carolina, and in October 2007 completed an initial public offering (IPO) on the NASDAQ stock exchange.

The company's common stock was trading around \$3 per share on September 21.

—WE (September 21, 2011)



Wikimedia Commons and Luis Villa del Campo/OTW

legal

Medtronic Wins Phase One, NuVasive Vows Appeals

A federal jury in San Diego, California, found on September 20 that NuVasive, Inc. infringed on three Medtronic, Inc. Gary Michelson-based patents and awarded Medtronic \$101.2 million in damages for lost profits and back royalties. The jury also concluded that Medtronic infringed on a NuVasive's neuromonitoring patent (patent 7,470,236) and awarded NuVasive \$660,000 in damages.

Gary Michelson, M.D., who testified at the trial, told OTW on September 20 that this trial was not about science and technology, but a morality play: "People have to be respectful of intellectual property."



Image creation by RRY Publications, LLC. Source: morgueFile

The NuVasive products that the jury found infringed on the Medtronic patents were the Coroent XL implants (patent 5,860,973), Maxcess II and III retractors (patent 6,945,933), and Helix and Helix mini anterior cervical plates (patent 6,592,586). Those patents are related to implants for the

InQu BONE GRAFT
EXTENDER & SUBSTITUTE

**DISCOVER THE
BIOSYNTHETIC**

**A more natural approach.
A more natural response.**

- Biomechanically and radiographically equivalent to autograft*
- Compressive resistant
- Available in 3 configurations
Matrix | Paste Mix | Granules

**Bio meets synthetic.
That's the power of InQu.**

1-888-705-ISTO (4786)
www.istotech.com

InQu is a registered trademark of ISTO Technologies, Inc.
Patents pending.

ISTO
Technologies, Inc.

* Walsh WR, Oliver SA, Gage G, et al. Application of resorbable poly (lactide-co-glycolide) with entangled hyaluronic acid as an autograft extender for posterolateral intertransverse lumbar fusion in rabbits. *Tissue Eng Part A*. 2011;17:213-220.

Advertisement

thoracic and lumbar spine, a plate and screw system for the cervical spine and a tissue retractor.

The eight-member jury wasn't asked to decide whether to impose injunctions. In computing damages, jurors decided upon patent royalty rates of 3%, 6% and 10% in awarding "lost profits damages (with royalty remainder)" for the three Medtronic patents, and a 5.5% "patent royalty rate" for the NuVasive patent, according to the verdict form.

Lukianov: "Will Fight Vigorously"

In a conference call with analysts on September 21, NuVasive Chairman and CEO Alex Lukianov said he did not believe the judge would issue an injunction, but assess ongoing royalties. He estimated such royalties would cost NuVasive \$5 million for the remainder of 2011 and approximately \$11 million in 2012. Any future royalty amounts will not be determined until a final judgment is issued, which is expected in the coming months.

"Let me be clear," said Lukianov, "this verdict is in no way impacting the daily operations of our business." Added Lukianov, "This is only phase one of a multi-phase, multi-year process."

He said NuVasive will "vigorously" fight this case. He noted that there were still a lot of post-trial details to be finalized which will likely last into next year. The company will appeal the verdict and any post-trial rulings which will likely last another year after that.

Phase Two to Come

The lawsuit was initially filed in 2008 and Medtronic asserted a total of nine

patent claims against NuVasive. NuVasive countersued and asserted three patents against Medtronic. The court broke the trial into phases, and the first phase included three Medtronic patents and one NuVasive patent. The court has not set a time for the future phases.

According to data compiled by Bloomberg, the verdict is the 14th-largest jury award in the U.S. so far in 2011 and the 4th-largest in a patent infringement claim. The largest patent jury verdict in 2011 was for \$482 million in a lawsuit against a Johnson & Johnson unit over stents.

Wall Street Responds

Wall Street analysts weighed in immediately. BMO Capital Markets' Joanne Wuensch wrote that it could have been a lot worse for NuVasive, given that Medtronic had asked for \$380 million and a 23% royalty payment. "Bloodied but still standing," wrote Mike Matson of Mizuho Securities. He estimates that NuVasive faces paying royalties on 35% of its overall sales and would therefore reduce the company's operating margin by 2.1%. "Painful but manageable," said Jefferies' Raj Denhoy.

NuVasive's stock dropped by around 6% after the news, before recovering slightly by mid morning on September 21.

Medtronic wins this phase. Six patents are still to be litigated and numerous post-trial rulings and the jury's verdict are promised to be appealed.

Send in more lawyers.

—WE (September 21, 2011)

PODs, Senators and the OIG

On June 9, 2011 a group of U.S. senators asked the Department of Health and Human Services' Office of Inspector General (OIG) to conduct an inquiry into physician-owned distributorships (PODs).

The senators wanted the OIG to assess the adequacy of the guidance that had been issued addressing the legality of PODs and other physician-owned entities under the Federal Anti-Kickback Statute and to indicate whether the OIG believes further guidance, legislation, or enforcement actions were required to address PODs.

The senators asked that the OIG provide an initial finding by August 12.

On September 13, Daniel R. Levinson, the Inspector General, provided an interim response which, according to Senate staff, does not commit to anything specific regarding additional guidance, but does commit the OIG to continuing a study on the POD issue.

OIG: Initiating Review

In the letter to the senators, Levinson said the OIG is, "Initiating a review of PODs that will seek to determine the extent to which PODs provide spinal implants purchased by hospitals." The study will be nationally representative of hospitals that bill Medicare for spinal surgery. The OIG will:

- Review information from hospitals and other sources to establish how widespread PODs are,
- What services PODs offer to hospitals, and
- Whether PODs save hospitals money in the acquisition of implants



Image creation by RRY Publications, LLC. Source: Wikimedia Commons

The OIG will also analyze Medicare claims data to determine whether the PODs they identify in their review are associated with high use of spinal implants.

Anti-Kickback Statute and PODs

The Federal Anti-Kickback Statute, according to Levinson, is a criminal, intent-based statute that plays a central role in addressing improprieties in PODs.

"The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations."

For these reasons, Levinson says the OIG's ability to issue guidance about the application of the statute to these business structures is limited.

Levinson went on to say that when evaluating the legality of a physician's investment in a POD, the OIG would, "consider, among other factors, the terms under which a physician may invest in the entity and, conversely, the terms under which a physician-owner may be required to divest his or her ownership interest; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician-investors."

The OIG says it has repeatedly expressed this view, and listed these factors, in various guidance documents, including Special Fraud Alerts, advisory opinions, and published letters to the industry.

Levinson concluded by telling the senators that the OIG is committed to the ongoing monitoring of physician-owned entities and to taking enforcement actions when appropriate. He gave no date on when the review will be completed.

—WE (September 20, 2011)

Historic Patent Reform Bill Signed Into Law

While Washington seems gridlocked on every major public policy item under the dome, the signing by President Obama of the “America Invents Act” was a remarkable bipartisan achievement.

That’s the opinion of famed inventor Gary Michelson, M.D., who attended the signing at a science and technology high school in Virginia on Friday, September 16. The legislation was sponsored by the respective Chairs of the U.S. Senate and House Judiciary Committees, Senator Patrick Leahy, a Vermont Democrat and Representative Lamar Smith, a Texas Republican. The Senate passed the bill on an 89-9 vote.

The Act is the first major patent law change in the U.S. since 1952. Supporters of the bill say the reform is meant

to ensure that the patent office, now facing a backlog of 1.2 million pending patents, has the money to expedite the application process. It now takes an average of three years to get a patent approved. In 2009, the patent office received some 483,000 patent applications and granted 192,000 patents. According to the patent office, there are approximately 1.2 million applications currently under review or waiting for a review, including 700,000 applications waiting to be acted on and 500,000 in process.

Michelson told *OTW* that America’s intellectual property system was constipated, killing jobs and keeping investors from putting their money into new ideas. “When Edison was inventing, it took seven weeks to get a patent approved. Seven years ago it took two years and today it’s taking three years,” added Michelson.

“Somewhere in that stack of applications could be the next technological

breakthrough, the next miracle drug,” President Obama said at the signing. “We should be making it easier and faster to turn new ideas into jobs.”

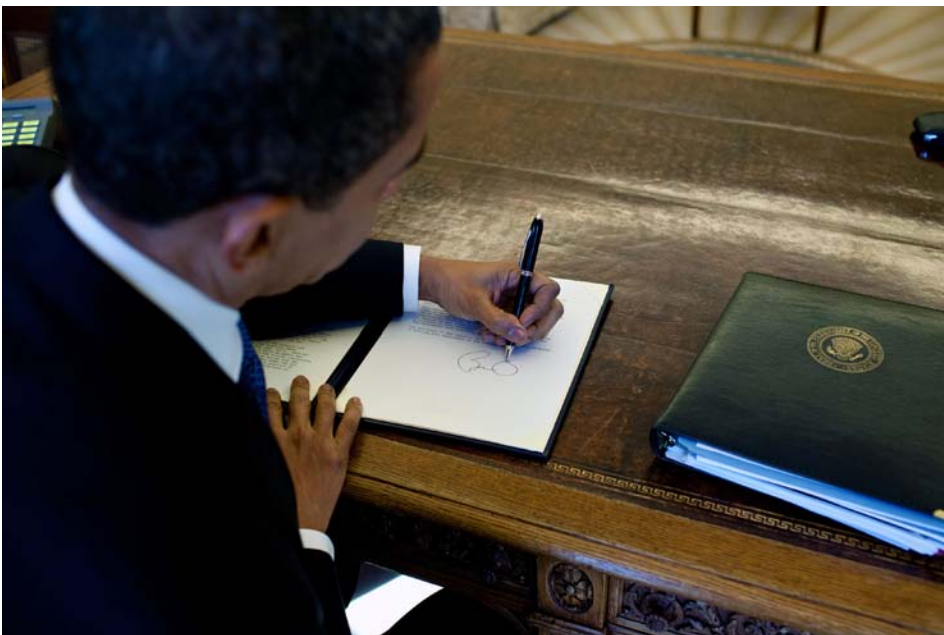
In addition to streamlining the patent process to bring it into harmony with other patent systems around the world, the reform also seeks to reduce legal battles. It was backed by companies including Google and Apple as well as the U.S. Chamber of Commerce. Small-scale inventors were divided on the legislation, with some arguing that it gives an advantage to big corporations who would have an advantage in moving to a “first-to-file” system.

“It’s a big lie that it would hurt the little inventor,” said Michelson. “You still have to be the true inventor first-to-file.” The law includes a post-grant review process where inventors can challenge someone else’s filing. According to proponents of the bill, this would also keep more disputes out of court.

Under the new law, the patent office will be able to set its own fees, with any money in excess of the budgeted amount going to a fund that can only be used by the agency. The office plans to hire as many as 2,000 more examiners in the coming fiscal year, revamp an outdated information technology system that it has described as “beyond horrific,” and open satellite offices across the country to tap into local workforces.

OTW published an extensive review of the legislation in a March 22, 2011 feature. [Click here to read that story.](#)

—*WE* (September 20, 2011)



Barack Obama/Wikimedia Commons

biologics

Athletes Opt for Stem Cells

The news that Peyton Manning went to Europe to receive stem cell therapy on his neck has thrust that treatment—still unapproved by the FDA—back into the medical spotlight. A report by Fox Sports relates that the Colts quarterback and four-time MVP asked for the stem cell therapy after two surgeries did not relieve the pain in his neck from a bulging disc.

The National Football League does not prohibit stem cell treatment “unless a banned substance is used as part of the procedure,” an NFL spokesperson said.

Dr. Barth Green, founder of the *Miami Project to Cure Paralysis*, says his center is in the final stages of getting FDA approval to treat spinal cord injuries with Schwann cells—which are adult, peripheral nerve cells that are believed to help with regeneration. However athletes such as Manning and Yankee pitcher Bartolo Colon are not waiting for approvals. Because more and more

athletes are requesting unproven sports medicine procedures that may allow them to return to competition more quickly, such as stem cell and platelet-rich plasma (PRP) treatments, some doctors are providing them.

Other doctors remain uneasy and unconvinced about the efficacy of stem cell and PRP therapies. Of particular concern is whether introducing substances such as human growth hormone into either procedure will improve the results. Even more daunting for those involved in the war on doping in sports is whether the treatments cross the line between healing injuries and enhancing performance.

“It’s a dicey issue,” says Dr. Ken Mautner, a sports medicine physician at Emory University. Mautner has been using PRP therapy for three years, but says he has never used HGH on his patients. “When you’re dealing with pro athletes, you can’t use HGH in any capacity. But with the regenerative type of medicine, I think that’s where the whole sports field may be going.”

—BY (September 22, 2011)

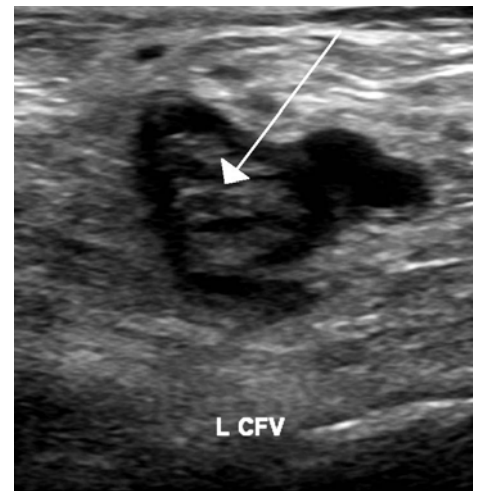


Peyton Manning/Wikimedia Commons and Ytoyoda

New Blood-Thinner Reduces DVT Risk

A new blood-thinning drug, called Apixaban, has been found in clinical trials conducted in Great Britain to prevent clotting—a major threat to patients who undergo joint replacement surgery. “Blood clots are responsible for around 25,000 preventable deaths in the UK annually and preventing them following, for example, major joint surgery, is a priority for the National Health Service. Apixaban represents a new option in clot prevention for UK surgeons,” said Dr. Ander Cohen Honorary Consultant Vascular Physician at King’s College Hospital, London.

“Apixaban is an oral option for patients once they return home after surgery—the time when they are most at risk of clotting complications. As it is taken by mouth, it offers patients an alternative to an injected anticoagulant.”



Wikimedia Commons and James Heilman, M.D. / DVT in Left Femoral Artery Captured by Ultrasound Imaging

The medication is now available in Britain for the thousands of patients, often elderly, who undergo joint replacement surgery that leaves them at higher risk of developing deep vein thrombosis (DVT) while immobile or recovering.

Clinical trials involving more than 8,000 patients, all of whom had undergone planned hip or knee replacement surgery, found that apixaban reduced the risk of blood clots while not putting them at greater risk of bleeding. Clinical data from the trials showed that apixaban was more effective than the anticoagulant enoxaparin and there was no increase in bleeding rates compared to enoxaparin.

Two pharmaceutical giants, Bristol-Myers Squibb and Pfizer, have been working since 2007 to develop the new blood-thinning pill. Dr. Rick Lones, UK Executive Medical Director, Bristol-Myers Squibb, said: "By making apixaban available to doctors and their patients in the UK—an important milestone—we hope to help reduce the burden of blood clots in patients undergoing elective hip and knee replacement."

—BY (September 22, 2011)

Satisfy your need for speed.

Introducing **tercet**™
TRIPLE-LEAD THREAD PEDICLE SCREW

Unique triple-lead thread design accelerates insertion and reduces user fatigue.

AMEDICA®
US SPINE®

www.amediacorp.com

Advertisement

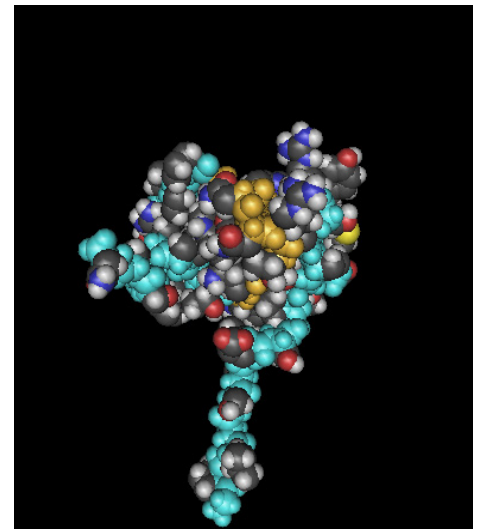
Biologics Growth Faster Than Implants

The rush to engage in stem cell research is leading to double-digit annual sales growth in the orthopedic biomaterials market, according to the health care market research firm Kalorama Information. A factor driving revenue growth for biomaterials is that insurance companies are more likely to approve reimbursement for biomaterials than for standard materials, indicated Bruce Carlson, publisher of Kalorama Information. "Their efficacy in reducing healing time and increasing the chance that an implant surgery will be successful has led to acceptance among physicians and insurance bodies," he said.

In its recently published report, "Orthopedic Biomaterials, the World Market," Kalorama said biomaterials represented 14% of the global orthopedics market, or about \$5.8 billion in 2010. "While the conventional market may only see growth rates of 2% to 4% due to the recession, insurance procedure denials and delays and competitive effects on pricing growth rates for the biomaterials market are almost triple that at 8% to 11%," said Carlson.

Musculoskeletal conditions are the most common cause of chronic disability as they comprise over 150 diseases and syndromes, which are usually progressive and associated with pain. Those conditions with the greatest impact include rheumatoid arthritis, osteoarthritis, osteoporosis, lower back pain and limb trauma.

"Advances in gene therapy and stem cell research may offer new solutions for state-of-the-art treatments for musculoskeletal conditions," said Carlson. "Many researchers believe that geneti-



Wikimedia Commons and National Library of Medicine

cally engineered stem cells will have a significant impact on the fields of regenerative medicine and tissue engineering as a powerful cell source that will work, in conjunction with biomaterials, to treat tissue and bone loss."

"Many of the companies that are getting into the biomaterials market are the same companies that sell traditional products commonly used in knee, hip and spine replacement surgeries," said Carlson. "This is a way for them to diversify."

Among these companies are Zimmer Holdings, Inc., Johnson & Johnson (through its DePuy Division), Medtronic, Inc. and Stryker Corp. All are aggressively competing in the hip, knee and spine implant markets, as well as other areas, said Carlson.

According to Carlson, Garry Clark, Zimmer's director of public relations, confirmed that the company is developing "orthobiologic products due to a desire to expand across all areas of care," as is Stryker which recently acquired the orthobiologics company Orthovita.

—BY (September 20, 2011)

large joints

DePuy Touts UK Registry Hip and Knee Data

DePuy Orthopaedics, Inc. says findings in the 2011 Annual Report of the National Joint Registry of England and Wales, “confirm the continued clinical success” of current DePuy hip and knee joint replacement products.

Andrew Ekdahl, DePuy’s new president, said in a September 19 statement: “In each case, the report confirms that those products continue to perform well. We’re proud of our 40-year heritage of developing leading joint replacement products and technologies that have helped so many patients around the world.”

Hips

According to DePuy, the registry data shows that more than 97% of Pinnacle Acetabular Cup System and Corail Total Hip System combinations were still in place five years after they were implanted, exceeding the five-year cementless total hip replacement survivorship rate

of 96% across all hip replacement products and manufacturers.

Together, according to the company, the systems continue to be the most commonly implanted construct in England and Wales, with the Corail the most implanted cementless stem with 15,239 implantations and the Pinnacle the most implanted cementless cup with 14,246 implantations last year.

Knees

The company also noted registry data showing that the PFC Sigma Knee System was the most implanted knee in England and Wales in 2010 with 24,215 implantations. More than 98% of the systems were still in place five years after they were implanted. In addition, the LCS Mobile Bearing Knee System was implanted 2,772 times in 2010, with a five-year survivorship rate of 97%. Both are in line with the industry-wide knee replacement survivorship rate of 97%.

Metal-on-Metal

This was some welcomed news for the company from the registry that reported a high failure rate of DePuy’s metal-on-metal ASR hip implant resulting in a product recall and countless lawsuits.

Since the recall, use of all-metal hip replacements has fallen, according to the registry. In 2006, metal hip replacements were used in about 15% of procedures; that’s now dropped to about 5%.

The UK registry includes records from about 1 million people who had hip, knee, and ankle replacements and is the world’s largest joint database. There is no such registry yet in the U.S. The American Academy of Orthopaedic Surgeons is working on establishing a comparable registry.

—WE (September 23, 2011)

Plastic Outwears Metal in Joints

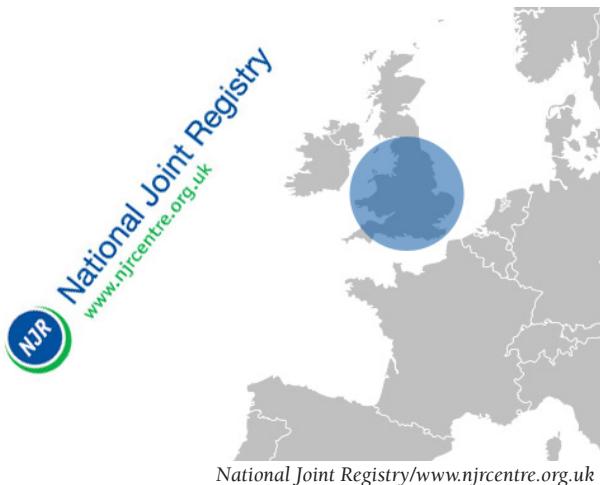
An analysis of the rate of hip joint replacements by the National Joint Registry of England and Wales found that metal hip replacements are more likely to be replaced than are plastic ones. According to an Associated Press account of the report, almost 14% of patients who got an all-metal hip replacement had to have the prosthesis removed or replaced after seven years.

Just 3% of the patients who had a plastic joint needed a replacement within the same period of time. The average age of patients who received the hip replacements was 67.



Wikimedia Commons

The National Joint Registry contains records from about one million people who had hip, knee, and ankle replacements and is the world’s largest joint



National Joint Registry/www.njrcentre.org.uk

database. There is no similar registry in the U.S. The report noted that the use of all-metal hip replacements has fallen. In 2006, metal hip replacements were used in about 15% of procedures. That has now dropped to about 5%.

According to the report traditional hip replacements usually last more than ten years but the obesity epidemic appeared to be having an impact. An increasing number of patients needing hip and knee replacements were overweight or obese.

—BY (September 22, 2011)

Juvenile Arthritis Patients: Good News

Novartis announced today positive results of the first pivotal Phase III trial of ACZ885 in patients with systemic juvenile idiopathic arthritis (SJIA). The results of this four week, randomized study, presented at the 2011 Euro-

pean Pediatric Rheumatology Congress in Bruges, Belgium, showed all primary and secondary endpoints of the study were met.

According to the company, most patients receiving ACZ885 (83.7%) experienced at least a 30% improvement in symptoms vs. 9.8% for placebo; a third of ACZ885 patients (32.6%) achieved a 100% improvement vs. 0% for placebo. ACZ885 is an investigational, fully human monoclonal antibody that neutralizes interleukin-1 beta (IL-1 beta), which is a key driver of inflammation in SJIA.

“These results are a positive development for patients suffering from this very severe auto-inflammatory condition,” said David Epstein, head of the Pharmaceuticals Division of Novartis, in the September 16, 2011 news release. “We are committed to investigate ACZ885 in a range of inflammatory diseases where interleukin-1 beta plays a key role and high unmet medical needs exist.”

The results of a second pivotal Phase III trial, aimed at determining whether ACZ885 can extend the time to next flare and reduce or eliminate corticosteroid use, will be presented later this year. Worldwide regulatory submissions for ACZ885 in SJIA are planned for 2012.

The study was a Phase III, randomized, double-blind, placebo-controlled study involving 84 patients between the ages of 2 and 19 years, with active SJIA. Patients were treated with either a single subcutaneous dose of ACZ885 (4 mg/kg, up to 300 mg) or placebo.

Daniel Lovell, M.D., one of the study investigators and Professor of Pediatrics at the Cincinnati Children's Hospital Medical Center, told OTW, “SJIA is the most severe form of juvenile arthritis and there is a critical need for new treatment options. This study showed ACZ885 effectively treated both the systemic manifestations and the arthritis

seen in SJIA and evaluated in the trial, demonstrating a much-needed benefit for this patient population. It is important to note that ACZ885 is not currently approved for SJIA.”

As for where they go from here, Dr. Lovell told OTW, “The results of a second pivotal Phase III trial, aimed at determining whether ACZ885 can extend the time to next flare and reduce or eliminate corticosteroid use, will be presented later this year.”

—EH (September 21, 2011)



Wikimedia Commons and EJ Fox

extremities

Long-Term Study Supports Wrist Surgery

A really long-term study has demonstrated the durability of distal scaphoid resection arthroplasty. Study author Michael C. Vance, M.D. reported on up to 23 years follow-up in a paper presented to the 2011 Annual Meeting of the American Society for Surgery of the Hand.

“Distal scaphoid resection is a simple and safe procedure,” he said during his presentation. “It provides rapid recovery, a high level of patient satisfaction [and] predictable results, and excellent treatment options remain available if the procedure should fail.”

For their retrospective study, Vance and colleagues Louis W. Catalano III, M.D., and Matthew M. Malerich, M.D., performed a longer follow-up of 18 patients who underwent distal scaphoid resection for arthritis secondary to scaphoid nonunion. They had published their original results, from a follow-up of 49

Why use a polymer barrier when natural covering is available?

We got you covered!



Advertisement

months, in 1999. For this latest study, the patients had an average follow-up of 14 years.

The investigators found that patients had maintained their range of motion at levels found in the 1999 study.

“Grip strength decreased 17%, but did so symmetrically,” Vance said. “There was no significant progression of deformity or carpal collapse. No cases regularly required narcotic pain medications, and patient satisfaction was 96% since the original publication and 89% overall.”

Five patients developed asymptomatic capitulate arthritis. The investigators found no developments of radiolunate arthritis or progression of radial scaphoid arthritis. Overall, two patients required revision procedures. The study authors believe that distal scaphoid resection is a great option because it burns no bridges, and the usual salvage procedures can still be done later.

—BY (September 20, 2011)



Wikimedia Commons and Janothird

people

**Mahmoud Hafez, Ph.D.
Joins ConforMIS**

Getting assistance from an expert in computer-assisted surgery... ConforMIS has announced that Professor Mahmoud Hafez, Ph.D., a professor of orthopaedics and the head of the Orthopaedic Department at October 6 University in Cairo, Egypt, has joined the ConforMIS Scientific Advisory Board. He received his training in hip and knee arthroplasty via centers in the U.S., UK, Egypt, and Canada and was an early pioneer in patient-specific surgical instruments.

“It is exciting to see patient-specific orthopaedics gaining increased acceptance in the field,” said Professor Hafez in the September 15, 2011 news release. “ConforMIS is the leader in patient-specific approaches to orthopaedics, not just in instruments but in the actual implant design. I am excited by the opportunity to work on new enhancements to their image-to-implant technology.”

Professor Hafez has been widely recognized for his expertise in the design and application of individual templates for orthopedics and in computer assisted orthopedic surgery. He has served as faculty at international orthopedic conferences including SICOT, ISTA, AAOS, and CAOS International. He is also the author of numerous articles and book chapters on computer-assisted surgery and patient-specific cutting guides for use in knee arthroplasty. In 2010, Professor Hafez won the HAP Paul Award from ISTA for his work on the laboratory validation and clinical application of patient specific instruments for total knee replacement.

EXPERIENCE
XIAFLEX[®]
collagenase clostridium histolyticum

Offer your patients a choice they may appreciate.

Go to XIAFLEX.com or call **1-877-XIAFLEX**
(1-877-942-3539) for more information.

AUXILIUM
Innovations for Life[®]

© 2011 Auxilium Pharmaceuticals, Inc. 0611-048.a

Advertisement



Mahmoud Hafez, Ph.D./ConforMIS

“I am extremely pleased that Professor Hafez has joined our Scientific Advisory Board,” added Philipp Lang, CEO of ConforMIS. “Professor Hafez has a rich base of knowledge and historical expertise in patient-specific systems and we are thrilled that he will be working with us on future applications for our patient-specific implant and instrument technology as well as clinical and scientific studies.”

Philipp Lang told *OTW*, “Professor Hafez will be reviewing our technology in detail and we will be engaging him in the design of iTotal clinical and scientific studies to help validate the technology.”

—EH (September 22, 2011)

THE PICTURE OF SUCCESS

Dr. Clarence Shields

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

As a young Clarence Shields handed out soup at a homeless shelter, he was setting the stage for a lifetime of giving. Unbeknownst to Shields, later named president of the American Orthopaedic Society for Sports Medicine (AOSSM), he would at one point be in a position to do significant good for those around him—especially for children with no resources, but big dreams.

Once named “Mr. Sports Medicine” by the AOSSM, Dr. Clarence Shields gives substantial credit to his Jesuit education for putting and keeping him on the right path. “The Jesuits taught me that giving back is a vital part of a full life... and that when you do this good things happen.”

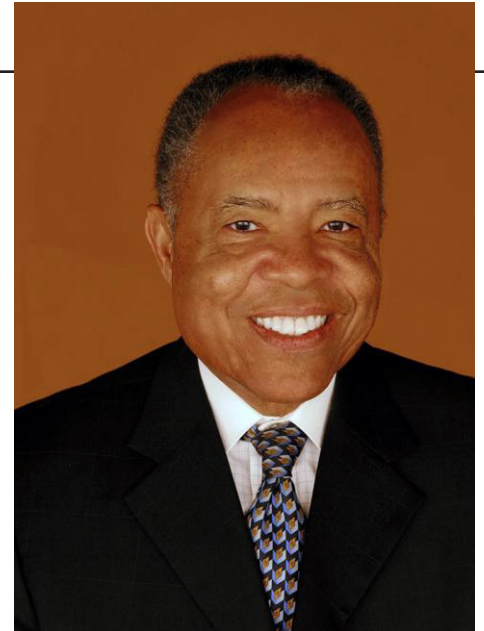
An orthopedic surgeon at the famed Kerlan-Jobe Orthopaedic Clinic in Los Angeles, Dr. Shields spent the first two years of his life in Arkansas, and then moved to Los Angeles with his carpenter father and restaurateur mother. “I

did remodeling jobs with my dad and learned to use tools early on. Afterwards, there was always a hot meal waiting for us at my mom’s restaurant. This early exposure to drills, saws, etc. made a big difference in my career... I was even repairing tools and taking things apart by the age of ten. My father finally said, ‘Stop taking things apart, Clarence. They are not broken.’”

Perhaps frustrated then, the elder Shields would have been proud this summer when his manually gifted son was inducted into the Sports Medicine Hall of Fame. “This was an honor that was only enhanced by the fact that I had been the one to induct Drs. Kerlan and Jobe into the Hall of Fame.”

On his road to fame, Dr. Shields has met the mighty and the needy...and gave them all his pinpoint attention and compassion.

A former orthopedic consultant to the Los Angeles Rams, Dr. Shields says,



Dr. Clarence Shields

“It’s very exciting to be a young doctor going to games and being exposed to these superbly talented athletes. It gets difficult when you have to leave your regular practice at 5pm, go to the training room for a while, and attend all of the practices and games. The upside is that is it really stimulating. You become closely aligned with the athletic trainers because they are with the athletes on a daily basis. They usually diagnose the problem and you close the loop with an MRI or an operation, etc. Then you ‘return them’ to the trainer. It was pretty different years ago when athletes were not paid very much and they did sports solely for the love of the game. Today, big money is involved, so it is easy to

“ Drs. Robert Kerlan and Frank Jobe opened their doors to me—something they had never done for a resident—and then two years later they asked me to join their practice. Their ‘experiment’ with me had gone so well that we put our heads together and started bringing other residents in to spend time with us. ”

“ I was doing clinic with the team and there was a young boy who waited until I was done and then approached me. I had treated him just prior to forming Team HEAL, and I knew that his family was having a tough time. He handed me a card that said, ‘One day I will make you proud.’ ”

get the impression that some are in it just for that benefit.”

As a neutral physician for the National Football League, Dr. Shields was essentially judge and jury when a player was injured. “There are times when the team doctor and manager decide that they don’t want a player to continue on their team. They would file a grievance saying that this person is not ready to play football, and as a neutral physician I would have to evaluate the situation and decide if the person had or had not recovered. As you can imagine, it’s not easy to tell a player that his time is up with a team.”

Years earlier, Dr. Shields’ talent was obvious to two doyens of the field—Drs. Kerlan and Jobe. “I was in my orthopedic residency at Los Angeles County/University of Southern California Medical Center, and in my third year I received the opportunity to do an elective that meant spending time in a physician’s office. Drs. Robert Kerlan and Frank Jobe opened their doors to me—something they had never done for a resident—and then two years later they asked me to join their practice. Their ‘experiment’ with me had gone so well that we put our heads together and started bringing other residents in to spend time with us.”

“It was 1973, the time when there was some inkling that sports medicine might become an official specialty. We were attempting to develop a training

program, but there were no guidelines. The biggest challenge was to create a program with a balance of research and clinical experience; this was made more difficult by the fact that there wasn’t the official body of knowledge that we have now for sports medicine. We proceeded by jotting down what we thought made sports medicine different from general orthopedics. Our primary focus was protecting the athletes’ future.”

One of his most famous patients? Jack Youngblood of the Los Angeles Rams. “He broke his ankle during the play-offs, but was determined to play in the Superbowl. He and I sat down and came

to the decision that he could play if he could function (he had to be able to push off and run). He played the entire game with a brace on...I was holding my breath!”

Opening a window into his daily practice, Dr. Shields says, “Aside from the many professional athletes I have treated, there are also people involved in some unusual sports...like motorcross. It’s a fast sport and the riders wear little protection. It’s amazing how much they can bounce back from some pretty serious injuries. What most people don’t take into consideration when thinking about professional athletes who get



Dr. Shields and Crenshaw High School Football Team/Courtesy of Dr. Shields

injured is that their bodies are at maximum performance level when they get hurt...that is why they recover so fast.”

Dr. Shields also treats another kind of patient...injured children with a potential for an athletic career. “If I am able to change their future by repairing an injury and keeping them on track for a college scholarship, then that is what it’s all about.”

Such wisdom and talent are what propelled Dr. Shields to the pulpit as head of the AOSSM in 2001. “I was elected to be president...then came 9-11. I did my best to make sure that our society could help in any way possible. I reached out to cities to see what they needed in the way of disaster preparedness; I also created a disaster preparedness taskforce. Many of our members helped out in the wake of 9-11, a role that was perfect for sports medicine specialists because we are accustomed to dealing with trauma in multiple systems.”

Other than his own children, perhaps nothing else makes Dr. Shields beam with pride more than the other “baby” he created...Team HEAL. “Because I grew up in L.A., I know many of the local high school coaches. Several coaches started bringing injured young athletes to see me—kids with no financial resources. I did that sporadically until the Rams left town—then I knew I would have the time to help on a broader scale.”

Dr. Shields used his good standing, and secured space at Rams Park to treat young athletes—along with a full time athletic trainer. “Several patients of mine in the entertainment industry

stepped up and held a benefit concert, and we raised enough to develop a training room with rehab equipment at one high school. The next year we held a masquerade ball and as a result we added a second school. After being featured in the *Los Angeles Times*, a generous group called the Wasserman Foundation phoned and said, “Find a school and we’ll pay for it.”

Dr. Shield’s friends from other fields have gotten on board, and are helping to ensure that the kids have access to internal medicine care, cardiac care, as well as dental and eye care. “One of my most powerful memories is when a coach friend of mine brought a child to me and said, ‘Please fix him. He is in a foster home and has nothing...except a pretty good chance at a college scholarship.’ Years later I got a picture of this young man in his cap and gown.”

And then there is that long ago encounter at the Rams training facility. This, says Dr. Shields, left an indelible mark on his life. “I was doing clinic with the team and there was a young boy who waited until I was done and then approached me. I had treated him just prior to forming Team HEAL, and I knew that his family was having a tough time. He handed me a card that said, ‘One day I will make you proud.’ That is when it struck me that I absolutely had to move forward with creating Team HEAL. The young man did graduate... and made me proud.”

Dr. Shields knows he makes a difference, but he doesn’t let it go to his head. If there is ever any danger of that, he says, all he needs to do is go to the Grand Canyon. “There is no way that

someone can sit and see that expansive beauty and think that they themselves are grand...we’re really pretty small.”

Dr. Shields doesn’t stare into the wilderness alone. “We are a camping family. While all of our kids are grown, my wife Barbara and I still get our three children and seven grandkids together at least once a year. As for other hobbies, I just may go to cooking school when I retire. Right now I am experimenting with key lime pie; so far, my dessert reviews are going very well.”

Dr. Clarence Shields...a surgeon for all.

◆
For more information on Dr. Shields’ foundation, please visit TeamHEAL.org

7th Annual Stem Cell Summit
**NEW YORK
STEM CELL
SUMMIT '12**
Register Early and Save

If you haven't already saved the date of February 21, 2012, mark your calendar now. And if you want to ensure your spot at 2012's Stem Cell Summit AND save more than \$500, take advantage of our low early bird registration rate today. Preregistration is now open!

www.stemcellsummit.com

Advertisements



data guys

How can we help?

Move Beyond
simple REAR-VIEW
mirror forecasts.


PearlDiver
unfathomably deep data retrieval

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

Orthopedics This Week | RRY Publications LLC

Main Contact Information:

RRY Publications LLC

116 Ivywood Lane • Wayne, PA 19087

TOLL FREE: 1-888-749-2153

Fax: 610-260-6451

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

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

Walter Eisner
Senior Writer
walter@ryortho.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Biloine W. Young
Writer
bgwy@msn.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayne Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com



Don't miss your chance!
Advertise with Orthopedics This Week

Orthopedics This Week

Click Here for more details or email tom@ryortho.com
Tom Bishow | 410.356.2455 (office) or 410.608.1697 (cell)