VOLUME 8, ISSUE 25 | AUGUST 7, 2012

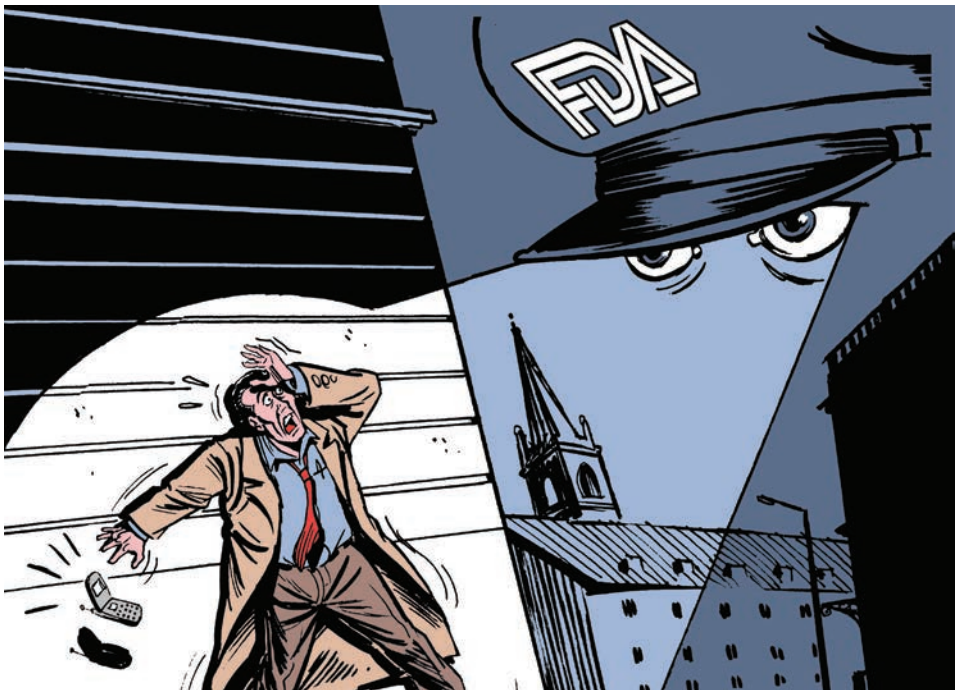
Orthopedics This Week

week in review

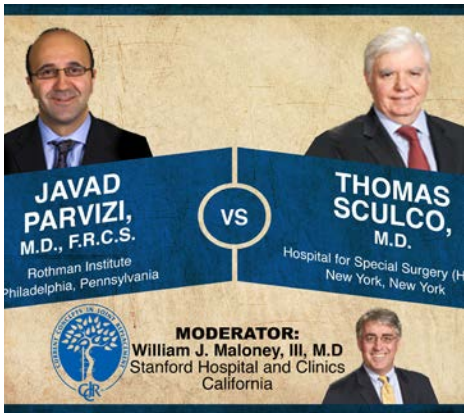
4 The FDA 9: Inside the Spy Scandal ♦ A government body charged with keeping some of the most sensitive secrets in science and medicine began to spy on its own employees to see who they were talking to and what they said. Is this East Germany in the 1960s? Nope, it's the FDA in 2009. Read the sordid details here.

8 The Top 25 U.S. Hospitals for Vertebroplasty and Kyphoplasty ♦ This month, in looking at which hospital gives the best "bang for the buck" for a given procedure, we report on the top 25 hospitals in the country for *in-patient* kyphoplasty and vertebroplasty.

11 How JNJ Bought Synthes and How it Almost Didn't Happen – Part II ♦ As they say, nothing is done until it's done. Even after its board instructed Khoury to call JNJ's Weldon back, the road to merging with DePuy would still be long, twisted and arduous. Task #1: get a higher bid. Task #2: negotiate merger payments to Synthes's senior executives. And, of course, never say never.



14 Simultaneous Bilateral TKA: Parvizi Debates Sculco ♦ "SBTKA has higher complications and mortality and should be reserved for a select group of patients," says Javad Parvizi. "But," counters Tom Sculco, "patients prefer it, there is less recovery time, only one operative procedure, symmetrical recovery, and it's less costly."



breaking news

18 Loses This Round in Stem Cell Court Battle

Biodegradable Magnesium Studied For Implants

Orthofix 2Q12: Good Quarter, Back to Business

Second Quarter **FDA Ortho Approvals**

Cataract Surgery Reduces **Hip Fractures**

Wright Medical's Slow Turnaround in 2Q12

Benvenue Medical Progresses in KAST Study

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: What happens in Wall Street's back offices really matters. Knight Trading's implosion exposed the fact that computers have taken over stock trading. A simple coding error last week almost torpedoed the market. Reliable equity trading = a healthy equity capital market for ortho. On a fundamental note, Medicare's higher-than-expected reimbursement increase last week is a major positive for SYK, ZMH, SNN and DePuy.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Johnson & Johnson	25.40%	1.59%	Last quarter's orthopedic sales growth was an amazing 59% above the growth rate in 2Q11.
2	2	Smith & Nephew	21.36	5.48	Fastest rising equity among the large diversified ortho companies. We suspect that M&A rumors are still circulating.
3	3	Integra LifeSciences	13.36	1.80	Comfortably beat Wall Street's consensus estimate for the last quarter as a result of improving sales across all segments.
4	4	ArthroCare	(0.80)	(2.58)	New product pipeline is very strong for 2013. R&D spending routinely 2x industry average.
5	5	Orthofix	16.23	(1.00)	Want to be impressed? Read OFIX's 2Q balance sheet. Cash up 58%. Total debt down 50%. Cash now exceeds total debt.
6	8	Symmetry Medical	5.63	4.56	Pow! SMA misses estimates. Profits dip. And what happens? Stock soars. Buyers clearly looking past this quarter.
7	NR	Medtronic	28.65	1.95	Back on the power rankings. Maybe Globus' successful IPO reminded folks that spine is still a strong cash flow market.
8	6	Zimmer	26.37	(8.76)	Stock beset by sellers last week. Obviously they didn't notice the BIG win over Genzyme for ZMH's single injection H/A for knees.
9	9	Stryker	23.68	(3.53)	Fifh least expensive stock in orthopedics. After 2Q's underwhelming report, very few buyers for SYK equity.
10	7	Conmed	10.09	(4.54)	Missed analysts' expectations for 2Q slightly. Arthroscopy product sales were one bright spot—up 15%.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$1.49	$63	7.97%
2	Smith & Nephew	SNN	$52.73	$9,469	5.48%
3	Symmetry Medical	SMA	$8.95	$328	4.56%
4	Medtronic	MDT	$39.81	$40,807	1.95%
5	Integra LifeSciences	IART	$37.84	$1,023	1.80%
6	Johnson & Johnson	JNJ	$69.12	$203,926	1.59%
7	TranS1	TSON	$2.65	$72	1.53%
8	RTI Biologics Inc	RTIX	$3.69	$206	-0.27%
9	Orthofix	OFIX	$41.77	$792	-1.00%
10	CryoLife	CRY	$5.21	$143	-1.14%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$12.90	$549	-50.31%
2	NuVasive	NUVA	$19.66	$855	-23.47%
3	Wright Medical	WMGI	$19.65	$772	-10.07%
4	Zimmer Holdings	ZMH	$59.02	$10,396	-8.76%
5	Alphatec Holdings	ATEC	$1.70	$152	-7.61%
6	Tornier N.V.	TRNX	$21.53	$852	-6.27%
7	TiGenix	TIG.BR	$0.58	$53	-5.40%
8	Conmed	CNMD	$26.94	$766	-4.54%
9	Exactech	EXAC	$16.26	$216	-3.79%
10	Stryker	SYK	$52.75	$20,068	-3.53%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Zimmer Holdings	ZMH	$59.02	$10,396	11.66
2	Medtronic	MDT	$39.81	$40,807	11.99
3	Stryker	SYK	$52.75	$20,068	13.56
4	Johnson & Johnson	JNJ	$69.12	$203,926	13.71
5	Orthofix	OFIX	$41.77	$792	14.26

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$19.65	$772	70.18
2	Symmetry Medical	SMA	$8.95	$328	63.93
3	NuVasive	NUVA	$19.66	$855	59.58
4	RTI Biologics Inc	RTIX	$3.69	$206	20.50
5	Exactech	EXAC	$16.26	$216	20.07

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$41.77	$792	0.93
2	Zimmer Holdings	ZMH	$59.02	$10,396	1.21
3	ArthroCare	ARTC	$29.08	$806	1.23
4	Stryker	SYK	$52.75	$20,068	1.30
5	Conmed	CNMD	$26.94	$766	1.42

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$19.65	$772	8.32
2	NuVasive	NUVA	$19.66	$855	7.50
3	Symmetry Medical	SMA	$8.95	$328	5.33
4	CryoLife	CRY	$5.21	$143	4.34
5	Smith & Nephew	SNN	$52.73	$9,469	2.20

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.70	$152	0.77
2	Symmetry Medical	SMA	$8.95	$328	0.91
3	Exactech	EXAC	$16.26	$216	1.05
4	Conmed	CNMD	$26.94	$766	1.06
5	CryoLife	CRY	$5.21	$143	1.20

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.58	$53	46.23
2	MAKO Surgical	MAKO	$12.90	$549	6.50
3	TranS1	TSON	$2.65	$72	3.77
4	Globus Medical	GMED	$13.50	$1,232	3.72
5	Tornier N.V.	TRNX	$21.53	$852	3.26

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

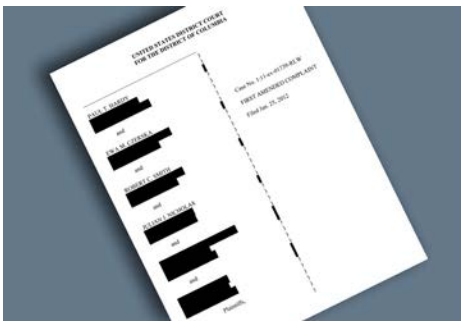
The FDA 9: Inside the Spy Scandal

By Walter Eisner

On January 25, 2012, six FDA "whistleblower" scientists filed a suit in federal court, accusing the U.S. government of illegally spying on them and using the ill-gotten evidence to retaliate against them.

The scientists say the government violated their constitutional rights and protections against reporting government corruption. And most importantly, claim the illegal spying activity will chill future federal employees from reporting official misconduct.

According the lawsuit, on January 29, 2009, the FDA "commenced a covert and secret search and seizure operation" on the "FDA 9" to intercept private communications sent by the scientists to Congressional representatives created on government issued computers, sent through government networks, or remotely connected to government networks.



FDA Complaint/RRY Publications, LLC

The electronic communications included email sent from private, third-party, non-governmental, password protected, and encrypted email accounts such as Google's email service, "Gmail," or Yahoo's email service, "Yahoo! Mail." The information was capable of capturing private and intimate communications between private citizens.

Image created by RRY Publications, LLC. Source Wikimedia Commons and Carlos Latuff

The scientists say they had a reasonable expectation of privacy. The FDA says it had every right to monitor their employees' government-issued computers. They say that employees are warned each time they log on that the information can be monitored.

Whistleblowers Arise: Corruption, Misconduct and Danger

But why did the FDA begin to spy on their scientists in the first place?

As far back as 2008, when the FDA was still being run by Commissioner Andrew von Eschenbach, scientists and reviewers began blowing the whistle on senior managers for clearing devices over their objections.

On November 17, 2008, the Chairman of the House Energy and Commerce Committee sent a letter to the Commissioner stating that FDA scientists had made well-documented allegations to the Committee that senior managers within CDRH (Center for Devices and Radiological Health) "ordered, intimidated, and coerced FDA experts to

modify their scientific reviews, conclusions and recommendations in violation of the law."

On January 7, 2009, nine FDA employees (The "FDA 9") sent a letter to John Podesta of the Obama Transition Team. The letter raised issues of "public concern, including, corruption within the FDA device review process, managerial misconduct, dangers to public health, welfare and safety, and retaliation against whistleblowers."

As an example the letter stated that in the past, computer-aided detection devices (CAD) to be used with breast mammograms were not safe or effective, but the FDA approved the devices anyway "in a flawed process that ignored the science."

Congress Warns FDA

The next day, The *Wall Street Journal* published an article about the letter and the FDA 9. That same day, according to the lawsuit, Senator Charles Grassley warned the FDA Commissioner in a letter that senior officials should assure their employees that it is both acceptable and within their rights to speak to Congress, should they feel compelled to do so.

Senator Grassley reminded the Commissioner that "FDA employees have a right to talk to Congress without interference and/or threats from the Agency [and] they have a right to talk to Congress confidentially."

By January 23, 2009, the scientists say the FDA learned the identities of the persons who signed the Obama Transition Team letter.

Disclosure of Proprietary Information

According to the scientists, the FDA began the spying program six days later after complaints from companies that the whistleblowers were revealing confidential information to Congress and the media from their FDA submission documents.

Industry has to submit proprietary scientific, medical and technical information to FDA reviewers in order for the applications to be processed. The FDA assures people who submit applications to the FDA that those documents are safe and private.

The FDA acknowledges that it began the surveillance program to make sure no proprietary information was being leaked to anyone outside the agency. The spying program allowed agency managers to capture every key stroke on the scientists' computers as well as save screen images on the monitors.

The scientists claim the agency then used information gathered during the surveillance program to retaliate against them.

MorgueFile and wax115

The "FDA 9" and a "Short-Pant Communist"

Who are the FDA 9? What's their beef and what Iron Curtain country did FDA leaders think they were emulating by spying on their employees, journalists, private citizens and members of Congress.

The FDA 9 include: Paul T. Hardy, Ewa M. Czerska, Robert C. Smith, Julian J. Nicholas and two others with names redacted from the Complaint. Their suit is against 12 individuals, the FDA, the U.S. Public Health Service, HHS (Department of Health and Human Services) and the U.S. of A. Some of the named individuals include Jeff Shuren, head of the FDA's Center for Devices and Radiological Health; William Maisel, the FDA's top scientist; Regina Benjamin, the U.S. Surgeon General; and FDA Commissioner Margaret Hamburg and HHS Secretary Kathleen Sebelius.

Paul T. Hardy is a former officer of the U.S. Public Health Service Commissioned Corps, with a B.S. degree in biomedical engineering from Marquette University.

Ewa M. Czerska, M.D., Ph.D. is a former FDA employee. She received an M.D. following completion of medical studies in Poland in 1971, and a Ph.D. in genetics in 1978. She performed extensive research in nonionizing radiation, resulting in several publications and presentations in local and international meetings. From 2007-2009, she was president of the Bioelectromagnetics Society.

Robert C. Smith, M.D., J.D., is a former FDA employee. He received his M.D. from Yale University.

Julian J. Nicholas, M.D., Ph.D. is a former FDA employee and former federal contractor who worked for the FDA under the Oak Ridge Institute for Science and Education program. Nicholas holds an M.D. from the University College of London and a Ph.D. from Oxford University in Neurosciences.

Their lawyer is a whistleblower rock star named Stephen Kohn, chairman of the National Whistleblower Center.

While at Boston University (BU) in the '70s, Kohn was one of the founders of the *B.U. Exposure*, a student-run independent newspaper dedicated to exposing the ethical irregularities of the administration of BU President John Silber. In an interview with Mike Wallace on *60 Minutes*, Silber denounced the *B.U. Exposure* staff as "short-pants communists."

Accusations

The FDA 9 is accusing the FDA of:

- Taking and converting private emails without due process or just compensation in violation of the Fifth Amendment of the Constitution
- Initiating searches and seizures in violation of the First and Fourth Amendments
- Violating the First Amendment by chilling free speech with searches and seizures
- Violating the First Amendment by chilling Plaintiffs' and the public's right to associate with whistleblowers
- Violating Plaintiffs' right to representation
- Chilling Plaintiffs' protected First Amendment right to free speech

Whistleblowing Round 2

The scientists weren't done blowing their whistles in 2008.

Another round began in March 2009 when Nicholas began reviewing a CT colonography device for FDA clearance. General Electric, the device manufacturer, wanted to use the device for population screening. Nicholas concluded that the device was neither safe nor effective for that purpose.

In spite of his objection, the FDA indicated on April 13, 2009, that they would clear the device anyway.

According the FDA 9 lawsuit, "Within the FDA, a Branch Chief, two Deputy Division Directors, a Division Director, and four to five scientists in the Office of Science and Engineering Laboratories all opposed the approval in writing, emails, or at internal meetings."

They also claim that two to three staff members had complained in emails about Dr. Tillman's [Donna-Bea Tillman, the FDA's top device reviewer at the time] mismanagement.

Nicholas asked Smith to independently review the submission the following month. Smith concluded on May 29 that the device posed a serious public health risk. He also sent an email to Dr. Joshua Sharfstein, then Principal Deputy Commissioner at FDA, blowing the whistle on FDA managers regarding the review of the GE device.

Off to Congress, Confronting Shuren

Smith then sent an email on June 11, 2009 to the House Energy and Commerce Committee regarding his and Nicholas' concerns surrounding the device. By September the whistleblowers, including Nicholas and Smith, met with members of the House Committee.

On September 28, 2009, Nicholas participated in a joint email to Jeff Shuren with the subject line "Accountability, Transparency, and Enforcement at CDRH." The email outlined the group's concerns about dangers to the public health, safety and welfare. Specifically, Nicholas and Smith explained to Shuren how they tried to prevent the approval of the CT colonography devices.

Three days later, Nicholas sent Shuren another email describing his concerns over his management's misconduct and fears that he may be retaliated against. On October 6, Congressman Chris Van Hollen informed Commissioner Hamburg that he was "deeply concerned" that Nicholas faced termination as a consequence of bringing forward major concerns.

Terminations

On October 31, 2009, the FDA let Dr. Nicholas' employment contract expire. On July 31, 2010, the FDA did not renew Smith's employment contract. Almost two years later, Hardy was informed by the Public Health Service on September 9, 2011 that his commission would be terminated on October 9, 2011.

Various federal agencies considered requests from the FDA and the FDA 9 to charge the other with crimes or misdeeds. Nothing was settled. So now we go to federal court.

Device companies should be paying close attention to how their proprietary information is handled. You don't want to find out that your scientific data was found in Maxwell Smart's shoe. ♦

The Top 25 U.S. Hospitals for Vertebroplasty and Kyphoplasty

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

If you are saddled with a painful vertebral compression fracture and you live in North Carolina, North Dakota, or Indiana, then you're in luck…that is where the top three hospitals for *in-patient* kyphoplasty and vertebroplasty are located. This month, in looking at which hospital gives the best "bang for the buck" for a given procedure, we report on the top 25 hospitals in the country for *in-patient* kyphoplasty and vertebroplasty.

What does it take to be the best in this realm? Comfortable catheterization? Pretty balloons? Success lies more along the lines of a full consult, detailed imaging studies, minute attention to sterilization, and more. Behold the top 25 hospitals in the country for kyphoplasty and vertebroplasty.

This ranking takes into consideration: How many procedures, how many problems, and how much, namely, procedure volume, complication rates, and charge for the procedure. Since the procedures measured are in-patient, by definition these tend to be older patients with more co-morbidities and are, therefore, more complex cases.

(See the table on the following page)

Number One

Mission Hospital, Inc. in Asheville, North Carolina, aced the number one spot, but alas, chose not to respond to our questions.

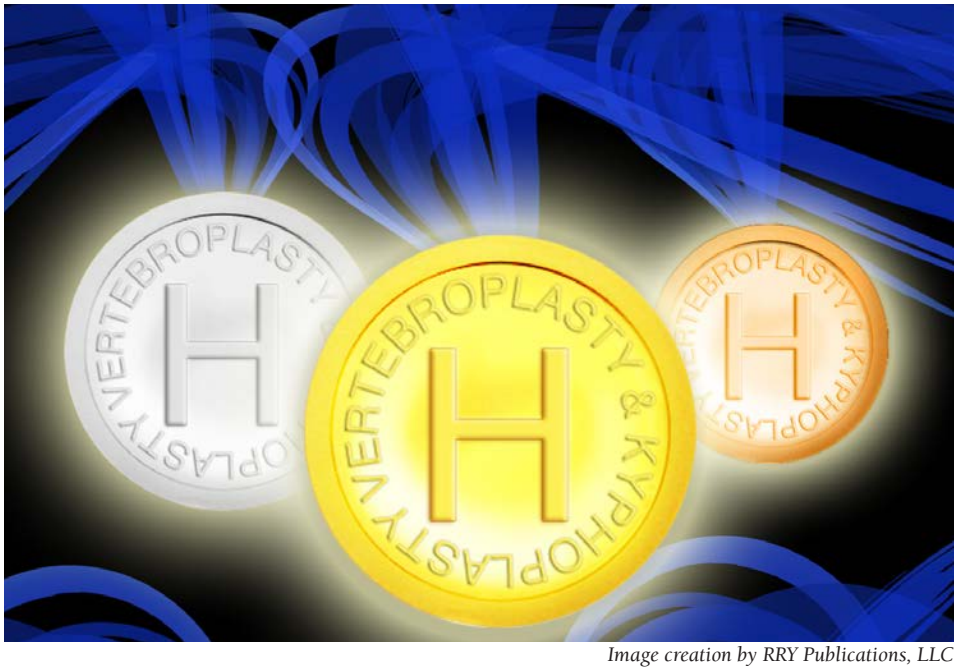


Image creation by RRY Publications, LLC

Number Two

Sanford Health (formerly Meritcare Hospital) in Fargo, North Dakota, took the number two spot for kyphoplasty and vertebroplasty. Asked why their facility has been ranked number two for these procedures, Corey Teigen, M.D., Sanford Health Chairman of Interventional Radiology, told *OTW*, "A lot of it is the way we treat the patients. All patients referred for these procedures are given a full history and physical examination by the performing physician. They are also given a full consult and have detailed imaging studies that allow us to select those patients that would be best served by vertebroplasty and kyphoplasty. We also follow our patients closely post procedure and initiate treatment of their osteoporosis if that's the cause of their fracture."

Regarding their complication rate for this surgery—6.7%—Dr. Teigen told *OTW*, "We are a high volume site, which gives us a lot of experience in many different fractures and patients. It's because of those high volumes that we do a lot of complex patients and gain experience from those procedures. Given our process of getting a detailed history, physical examination and imaging studies, it allows accurate planning prior to the procedure."

The average charge for a kyphoplasty or verbroplasty at Sanford Health is $13,947. Commenting on this figure, Dr. Teigen said, "The vast majority are

National Ranking	Provider Name	State	Average Charge	Average LOS	Complication Rate
1	Mission Hospital, Inc.	NC	$22,076	4	5.4%
2	Sanford Health	ND	$13,947	3	6.7%
3	Deaconess Hospital, Inc.	IN	$35,802	3	2.3%
4	Spectrum Health Hospitals	MI	$22,795	4	7.0%
5	North Florida Regional Medical Center, Inc.-North Florida Regional Medical Center	FL	$64,052	4	3.6%
6	Naples Community Hospital Inc.-NCH Healthcare System Inc.	FL	$44,753	4	7.2%
7	Oklahoma Surgical Hospital, LLC	OK	$14,966	2	9.1%
7	The Williamsport Hospital-The Williamsport Hospital & Medical Center	PA	$23,724	5	3.2%
9	Christiana Care Health Services, Inc.	DE	$35,792	4	2.5%
9	St Elizabeth Medical Center Inc.	KY	$32,835	1	5.1%
11	Munson Medical Center	MI	$27,630	4	6.9%
12	Ohio Health Corporation-Grant/Riverside Labs	OH	$32,407	4	9.5%
13	Memorial Health Care System Inc.-Memorial Hospital	TN	$41,802	3	4.5%
14	St Dominic-Jackson Memorial Hospital	MS	$34,542	5	16.3%
15	Adventist Health System-Sunbelt Inc.-Florida Hospital	FL	$65,466	4	10.4%
16	Fawcett Memorial Hospital, Inc.-Fawcett Memorial Hospital	FL	$80,747	3	3.6%
17	Sanford Medical Center-Sanford USD Medical Center	SD	$39,155	3	7.4%
17	Seton Healthcare-Seton Medical Center Austin	TX	$51,597	4	7.4%
17	Methodist Healthcare System Of San Antonio, Ltd., L.L.P.-Metropolitan Methodist Hospital	TX	$65,699	4	12.3%
20	NSHS @ Plainview	NY	$52,870	4	13.1%
21	Baptist Health/Medflight	AR	$38,492	3	7.8%
22	Covenant Health System-Covenant Medical Center	TX	$54,451	4	5.7%
23	Sun Health Corporation-Sun Health Boswell Hospital	AZ	$43,158	4	9.7%
23	Humility Of Mary Health Partners-St. Elizabeth Health Center	OH	$39,614	3	10.6%
25	Cedars-Sinai Medical Center	CA	$115,370	5	10.1%

Source: PearlDiver Data Technologies
Note: the duplicates in ranking are due to the total of complication rates, procedure volume and charges being the same.

outpatient procedures, where patients are discharged the same day, which reduces costs. Given our high volume, our efficiency with the use of personnel and facilities also helps to reduce costs. Additionally, inpatients experience early performance of the procedure. The hospitalists that see patients with back pain refer their patients right away to myself and colleagues, therefore patients get their procedure earlier in their hospital stay, allowing them to be discharged earlier." (The average length of stay for these procedures at Sanford is three days.)

Darla Dobberstein, RN, executive vice president for Orthopedics and Neurology, told *OTW*, "These procedures are done by both neurosurgeons and interventional radiology physicians at Sanford Health. The physicians review each case individually prior to performing a procedure. The departments have focused on standardizing their workflow and treatment protocols to provide the best outcomes to patients."

Number Three

In third place for vertebroplasty and kyphoplasty is Deaconess Hospital, Inc. in Evansville, Indiana. Susan Brumley, Radiology Manager for Deaconess told *OTW*, "We have a highly skilled and respected interventional radiolo-

gist that is responsible for leading our effort. The procedure offers excellent results to our patients in terms of pain control and function. Referring physicians schedule directly with a trained interventional radiology technologist. We coordinate physician to physician consults when needed to insure the patients' circumstances are taken into account so that we may provide the utmost in safe patient care."

Informed that their complication rate for this surgery is 2.3%, Brumley commented to *OTW*, "All of our interventional cases take place in a procedural suite set up to mirror a surgical suite. We operate under strict sterile technique and follow the same stringent hospital standards as the operating room. Our staff and physicians take sterile technique very seriously for our patients' safety."

Regarding their average charge for this surgery—$35,802—Brumley stated, "We work very diligently with our supply representatives from various vendors to obtain the most competitive pricing. We participate in bulk buys as we can and also try very hard to utilize the same products house-wide. Our physicians and staff are very conscious of expenses and standardize when possible."

This research was performed by PearlDiver Data Technologies, an Orthopedics This Week-affiliated company with a proprietary database that includes more than one billion patient records and includes de-identified Medicare and private payer data as well as specific industry data as compiled by PearlDiver analysts.

The overall ranking is determined by the facility's ranking in each of three categories: Procedure Volume, Complication Rate, and Pricing. The ranking only includes facilities with 100 or more estimated procedures. Estimated procedure volume is determined by the total volume of procedures reported to Medicare extrapolated to include all age groups/payer types. Average charges are determined based upon the actual charges billed to Medicare divided by the total number of procedures reported to Medicare. Finally, complication rate is the rate at which complications were reported within Medicare following the primary procedure. The Overall Best Hospital is arrived at by the sum of the three rankings, which is treated as a total score. This score is then ranked to determine the Overall Best Hospitals.

NOTE: Estimated volumes account for all payer types and all age groups based upon data from the National Inpatient Sample release by AHRQ. It is assumed that each facility follows the same age and payer type trend. ♦

How JNJ Bought Synthes and How it Almost Didn't Happen – Part II

By Robin Young

Last week in Part I: With U.S. healthcare reform in the offing and troubles with the Office of Inspector General as well as scandals among some of its former executives, Synthes and its CEO, Hans Wyss decided to explore the sale of their company. Despite strong bids from three private equity firms and a low ball bid from Bill Weldon at JNJ, the Synthes's board decided that JNJ was their best alternative.

As they say, nothing is done until it's done.

Image created by RRY Publications. Sources: Corporate logos

We Need a Higher Price

On February 10, 2010, Synthes' board asked 13-year board veteran Amin Khoury to call JNJ's Chairman and CEO Bill Weldon.

When he reached him, Khoury told Weldon that Synthes had received an all-cash offer (non-binding) from another party and that was higher than JNJ's bid. If JNJ wanted Synthes, the price would have to move up—to CHF 160 per share. But, also important, said Khoury, was that any purchase by JNJ would have to be structured in way that there would be no price or closing risk. Market conditions, in other words, could not be a factor.

A few days later, February 16, Bill Weldon called Khoury and raised JNJ's offer to CHF 155 per share ($18.5 billion). The offer, Weldon told Khoury, was subject to complete due diligence and was a final bid. He had no authority to go higher. (The final price would eventually rise to $21.3 billion).

But, Wait, There's Still More

Apparently CHF 155 was good enough to let the word sink deeper into both companies that the largest, most far reaching merger in the history of orthopedics was in the works.

All through March teams from both organizations plowed through truckloads of product, market, organizational, financial, contractual, sales, distribution and intellectual property materials.

On March 28, Synthes' legal counsel, Shearman and Sterling, gave to JNJ the draft merger agreement.

One more issue popped up. And it was the toughest one of all—management compensation as a condition of closing.

Literally on April Fools' Day, Synthes' compensation committee met to look at a plan to incentivize the very executives that would be essential to transfer the Synthes operations to JNJ. These were extraordinarily tricky and potentially explosive discussions. At the end, the committee recommended lucrative severance payments to 16 executives plus two other senior executives, as well as retention bonuses and a reward bonus pool for other groups of key employees.

By now, seven months after that fall, Synthes board meeting where Khoury was authorized to being exploring the sale of Synthes, rumors began circulating on Wall Street about a merger. On April 18 Synthes issued a public statement disclosing that, yes, it was in merger talks with JNJ.

That same day Mike Mahoney, JNJ's Worldwide Chairman of Medical Device and Diagnostics, called Synthes to say that they ***could not go along*** with the severance compensation packages the board had approved for senior management. JNJ wanted to change the agreement—before merging. No changes in the compensation plan, no merger.

Synthes came back to Mahoney saying, in effect, we won't discuss anything related to executive compensation until you complete negotiating the terms of the merger agreement and that the shareholder voting agreement is basically done.

Oh, and JNJ raised the price to CHF 159.00 per share on April 25, with 65% of the consideration being in the form of Johnson & Johnson stock (subject to a 7% "collar") and 35% of the aggregate consideration being in the form of cash. If the deal didn't happen, JNJ agreed to pay Synthes a "reverse termination fee" of $650 million.

With a new, higher price on the table, Mahoney came back to the issue of executive compensation and even offered to talk to the affected senior executives himself. All day and all night on April 25, Gorsky for JNJ and Khoury for Synthes worked over the transaction terms. The key sticking item: the damn Synthes retention and severance arrangements.

That same day, both boards of directors unanimously approved the merger terms.

The next day Mahoney had a conference call with the 15 Synthes executives whose deal compensation JNJ and Mahoney specifically wanted to change. Making it even more difficult, the deal had already been approved by Synthes board. No one has disclosed how long the call lasted or what was said. All that is known is that at the end of that call, by some miracle, the Synthes execs agreed to change their compensation in order to get the merge done.

That same night, April 26, the merger agreement and voting agreement were signed.

The press release hit the wires on April 27, 2011.

Synthes' Management Compensation

See table below

On June 12, 2012, Johnson & Johnson announced that it has received all regulatory approvals for the $21.3 billion deal.

Hans Wyss, with 45.8 million shares and 38.6% of Synthes received an aggregate value of more than $8 billion.

Financial Impact

By paying for the Synthes purchase through its off-shore pharmaceutical company, JNJ was able to book an increase per share of $0.03 - $0.05—a sharp reversal from its earlier guidance to Wall Street analysts that the purchase would dilute earnings by $0.22 per share. Next year, 2013, Johnson & Johnson has told its investors that for the first full year of the combined businesses, Synthes will add about $0.10 – $0.15 per share to earnings.

Name	Title	Payment at Closing	Retention Payments	Single Trigger Payment	Double Trigger Payment
Michael Orsinger	President and CEO	$7,959,501	$3,979,757	$30,967,287	$53,256,693
Robert Donohue	Chief Financial Officer	3,076,896	1,538,448	11,003,985	19,959,383
Ciro Roemer	President, European Operations	-0-	5,285,028	7,337,893	11,311,145
Steven Murray	President, Spine	-0-	2,475,030	3,323,148	7,049,145
Harry Hall IV	President, Trauma	-0-	2,169,570	2,966,741	6,332,015
Michael Mazzio	President, CMF	-0-	1,654,110	-0-	-0-
William Wachter	President, Power Tools	-0-	615,460	-0-	-0-
All Other Execs as a Group	-0-	13,311,972	-0-	-0-	6.9%

Source: Johnson & Johnson

What Now?

JNJ's new CEO, Adam Gorsky, had his debut call with Wall Street's analysts a couple of weeks ago. One of his more memorable comments was: "We are the largest, most innovative and comprehensive orthopedic and neurological business in the world. Our integration work is well underway our regional and functional leaders represent a combination of talent from both DePuy and Synthes. We have already organized a combined sales force of in-house and contract resources. Meanwhile, our manufacturing, marketing and other functional teams are actively at work on implementation of their integration plans."

DePuy's sales for the June quarter included a couple weeks of Synthes results so, instead of $1.5 billion in quarterly sales, DePuy reported $1.6 billion. In this coming third quarter, DePuy's reported sales are expected to rise to $2.3 billion, 66% higher than last year.

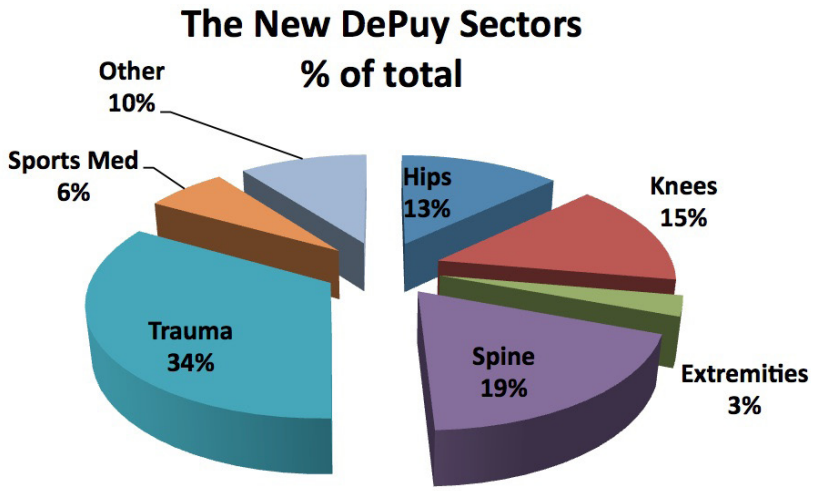
In the galaxy of billion dollar operating units that is JNJ, DePuy Synthes Companies now ranks #1 in terms of annual sales—more than $9.8 billion in 2013, over $10 billion in 2014. DePuy Synthes is now more than four times larger than Cardiovascular Care (formerly Cordis), 40% larger than General Surgery, 2.3 times larger than McNeil and twice as large as Remicade.

All told, DePuy Synthes will now contribute close to 14% of mother JNJ's total sales and those sales, most analysts are forecasting, will deliver 30% operating profit margins, rivaling the profitability of JNJ's Pharmaceutical unit.

For 2013, most forecasters are saying that DePuy Synthes will ship in excess of $3 billion of hip, knee and extremity implants and instruments making it the #1 supplier in those sectors.

DePuy				
$ in millions	Before Synthes - 2011		After Synthes – 2013est	
Hip Recon	$1,244	21%	$1,275	13%
Knee Recon	1,407	24%	1,445	15%
Extremities	281	5%	297	3%
Spinal Implants	1,033	18%	1,841	19%
Trauma	282	5%	3,304	34%
Sports Med / Mitek	600	10%	641	7%
Other	963	17%	1,012	9%
Total Revenues	$5,809	100%	$9,815	100%

Source: RRY Publications LLC



Source: RRY Publications LLC and Wells Fargo Estimates

Already, by way of clever financial engineering, the transaction has made money for JNJ.

Culturally, the effect of the JNJ corporate culture on Synthes should be, we think, an overall positive. JNJ pays its employees well, allows them quite a bit of work flexibility with many senior executives working from home or remote locations. The pace of work at JNJ is notoriously heavy with senior executives routinely working 12-14 hour days. Politics, of course, is also a key fact of the JNJ life and turning the mother ship is not easy nor fast.

Synthes' culture had been buffeted lately with the Office of Inspector General investigations, the defections of senior people—some of whom went into active competition with Synthes—and began to feel sclerotic, reactive but with a European patina.

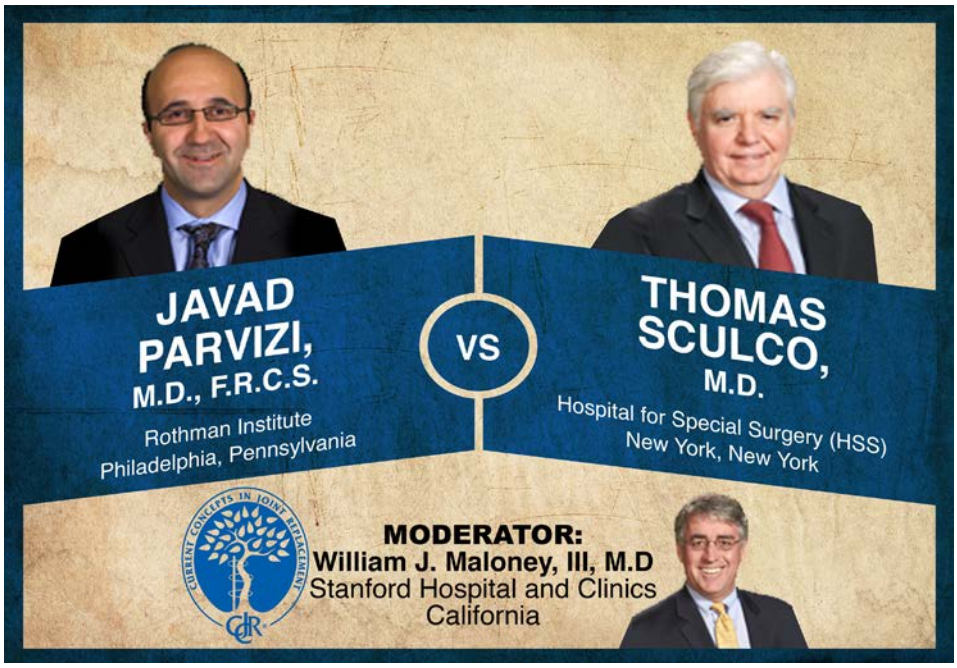
How will JNJ's brand focus, credo values style align with the former Synthes folks? We think it will play well. Well enough, we think, to actually deliver something that may look like, sound like and walk like—synergy. ♦

Simultaneous Bilateral TKA: Parvizi Debates Sculco

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

"SBTKA has higher complications and mortality and should be reserved for a select group of patients," says Javad Parvizi. "But," counters Tom Sculco, "patients prefer it, there is less recovery time, only one operative procedure, symmetrical recovery, and it's less costly."

This week's Orthopaedic Crossfire® debate is "Simultaneous Bilateral TKA: Double Trouble." For the proposition was Javad Parvizi, M.D., F.R.C.S. from the Rothman Institute in Philadelphia. Against the proposition was Thomas Sculco, M.D. from Hospital for Special Surgery (HSS) in New York; moderating was William J. Maloney, III, M.D. from Stanford Hospital and Clinics in California.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Parvizi: "If having white hair and looking semi-attractive and coming from the East Coast is a sign of intellect, then our next speaker will qualify. He will say that simultaneous bilateral total knee arthroplasty (SBTKA) is best because you can do it under single anesthesia, have one preoperative workup, one hospital admission, one rehab, it's less costly and more convenient for the patient."

"Not so fast! Let's first define SBTKA: both knees under the same anesthesia at the same hospital admission. There isn't much data in terms of Level 1 studies; there is a lower level of evidence based on meta-analyses. We performed a meta-analysis on nearly 28,000 patients undergoing TKA from 1966-2005. Number one finding: cardiac complications are significantly higher in SBTKA."

"Although the DVT risks were lower, pulmonary embolism (PE) was much higher; urinary and gastrointestinal complications were also higher. Most significantly, mortality was much higher in patients undergoing SBTKA. The neurologic complications were also higher in this patient group. And if you're doing both knees under the same anesthesia within a short period of time this patient will have to deal with the physiological adverse effects of marrow and embolic load in the right side of the heart."

"And if patients have patent foramen ovale then some of that embolic load can transmit to the brain. Data from Dr. Sculco's institution, performed by one of the anesthesiologists…incredible work based on the Nationwide Inpatient Survey of over 206,000 patients undergoing bilateral total knee replacement. Just about every single complication is higher in patients who undergo SBTKA—approximately eight fold higher compared to single."

"He will try to convince you that the cost is lower in these patients, and that's probably true if you're looking at hospital charges. But some of this cost saving will be offset by the higher cost of dealing with the complications."

"SBTKA takes longer, so you must modify your anesthesia technique; patients

must lie awake under regional anesthesia for several hours, which pushes some of these institutions to administer general anesthesia…which has a higher risk for complications. These patients have a higher incidence of blood transfusion."

"Infection is very difficult to manage in these patients. So should it be done? Sure…in select patients, by select surgeons, in select institutions."

"Based on Dr. Sculco's study, the groups at high risk are those over 65, male gender, patients with comorbidities. The recommendation of that paper was that these patients should be admitted to at least a Level 2 care unit with detailed observations rather than routine general orthopedic wards. So if you don't have a full ICU then perhaps you shouldn't do this operation."

"In conclusion, SBTKA has higher complications and mortality and should be reserved for a select group of patients. If you listen to Dr. Sculco, he's probably going to lead you into a ditch."

Dr. Sculco: "I am speaking in favor of bilateral one stage TKR. I do these procedures because overwhelmingly patients prefer it, there is less recovery time, one operative procedure, symmetrical recovery, and it's less costly. It's particularly useful in patients with severe flexion contraction. If you fix one knee the other knee will accommodate the side with the flexion contraction, and you will not achieve full extension in both knees."

"In a study we published in 2004 there were 500 patients with no deaths, strokes or myocardial infarctions. We found increased morbidity in the over 75 age group (that comes to patient selection), and in those that had increased preoperative comorbidities."

"A recent study from Korea found that perioperative mortality was greater in the unilateral population, and with no significant difference in major or minor complications in either group. In our own series of over 21,000 knee replacement patients there are 3,000 patients who had one stage bilateral procedures (about 15% of patients at our institution have one stage bilaterals). Mortality is less in the bilateral versus the unilateral population. That's probably because of patient selection. Interestingly, our infection rates were lower in the bilateral one stage versus the unilateral population."

"Savings? In that same study, Dr. Parvizi is correct…there is more rehab in these patients and maybe that does end up costing more, but certainly in the perioperative management the reduction in that series was about $25,000 per patient."

"Patient selection is key…this is what reduces complications…better anesthetic techniques, improved perioperative monitoring, and expeditious surgery. A lot of what Dr. Parvizi cited in his paper is from 2004 and previously…it's a whole different world taking care of these patients today."

"Here is a randomized series of patients looking at the use of hydrocortisone to reduce fat embolism and lung injury. This involved use of hydrocortisone preoperatively at two aliquots eight hours apart postoperatively; the IL 6 levels indicate a hit to the lung and also active inflammation. There was signifi-

cant reduction when compared to the control population in this double blind study."

"Additionally, we looked at Desmosine. We found a reduction noted in those patients who had perioperative cortisone in terms of reduction in lung injury if you use this hydrocortisone preoperatively and immediately postoperatively to reduce lung injury and increases in IL 6. The hydrocortisone patients also had greater knee range of motion and a reduced need for pain medication; no infections in this series."

"So I think this may be something for the future. The use of perioperative hydrocortisone appears to be protective of fat embolism syndrome in bilateral TKA patients and facilitates recovery."

Dr. Parvizi: "The data speaks for itself. I can't see that Dr. Sculco presented anything that convinces me otherwise."

Dr. Sculco: "Javad, you don't do bilateral one stage knee replacements?"

Dr. Parvizi: "I do what Seth has told me, so I came up here to argue against bilateral total knee replacement."

Moderator Maloney: "Do you do bilateral total knee replacement?"

Dr. Parvizi: "Yes."

Moderator Maloney: "What's your selection process?"

Dr. Parvizi: "Very healthy patients… ASA 1 [American Society of Anesthesiologists]."

Moderator Maloney: "No ASA 2?"

Dr. Parvizi: "No. I wouldn't do it in diabetics, nor in anybody over the age of 70 or in patients who have underlying conditions like hypertension."

Moderator Maloney: "You just eliminated my entire practice."

Dr. Parvizi: "Mine too. Honestly, I don't know how many bilateral total knees I would do."

Moderator Maloney: "At Jefferson what percent of the knees are bilaterals?"

Dr. Parvizi: "5-6%."

Moderator Maloney: "Tom, tell us about your criteria."

Dr. Sculco: "Patients see an internist, an anesthesiologist…and they must be cleared by both to go through the funnel to be selected for bilaterals. There are patients who are 70 who are fitter than my patients who are 60, so I use physiologic age."

Moderator Maloney: "So what are the contraindications in your mind?"

Dr. Sculco: "Morbid obesity, significant cardiovascular disease."

Moderator Maloney: "Congestive heart failure has been documented in many studies to have a higher morbidity…COPD [chronic obstructive pulmonary disease]?"

Dr. Sculco: "COPD, severe lung disease. In my practice about 15-17% I do are one stage bilaterals."

Moderator Maloney: "Jay, what about deformity? Tom showed a case that's got bilateral 20 degree fixed flexion contractures in varus deformities…you do one knee and three months later they come back for the other knee and the patient's got a 20 degree flexion contracture when they come in for their six week. Are you going to push it to an ASA 2?"

Dr. Parvizi: "No, the selection criteria is clear. You don't have to wait three moths. You can bring these patients back and based on studies that I've evaluated the major…"

Moderator Maloney: "What's the safe time period?"

Dr. Parvizi: "The data doesn't quite clarify it and hopefully that threshold will be determined soon. I think two weeks is fine. By then the heart and lungs would have cleared the embolic load and you can bring the patients back…their preoperative clearance is still valid during those two weeks. They've lived with a flexion contracture all their lives—they can live another two weeks."

Moderator Maloney: "Tom, two weeks worries me a little."

Dr. Sculco: "I think it's the worst time to do it. Patients are hypercoagulable for four to six weeks, so I'd wait a minimum of six weeks out to three months to do the second surgery."

Moderator Maloney: "I've been leaning toward six weeks too…that hypercoagulable state does worry me. What about pain, Tom? A patient comes in with routine osteoarthritis, mild varus deformity, range of motion is 5-105 degrees; one knee hurts a lot (8 out of 10 on the pain scale) and the other hurts maybe a 3 out of 10. Do you say, 'We'll do the bad knee and we'll wait and see how the other one does.'"

Dr. Sculco: "That's exactly what I would do. Just because they have involvement of the other knee is not a reason to do both knees. They have to be symptomatic on both sides."

Moderator Maloney: "Jay?"

Dr. Parvizi: "I agree. It's the only thing I agree with."

Moderator Maloney: "Jay, when you guys do bilaterals do they get a medical workup ahead of time or are you making that call yourself?"

Dr. Parvizi: "Everything is done by a multidisciplinary team so I don't see the patient and say, 'Your radiograph shows arthritis…I'll see you in six weeks in the OR.' We're involved with every process; we check their labs, look at their hemoglobin, etc. I think it's critical and that's probably the reason for the huge success at HSS because they really have that incredible involvement in every step."

Moderator Maloney: "Tom, comment on that because we don't want to give the audience the impression that if you're at a community hospital you don't have great medical backup."

Dr. Sculco: "I think it's key; it's patient selection, perioperative management and anesthetic management. All these people were done under regional anesthesia; all patients spend a night in a recovery room which is an ICU setting. Things do happen and I think you must be prepared for it in the immediate postoperative period. But most of these people do extremely well."

Dr. Parvizi: "The anesthesia team at HSS is one of the best in the world. That is critical. Tom talks about these Desmosine inhibitors…they were the one part of these lipoprotein inhibitions, the intraoperative administration of Heparin IV. Most of these things have emerged from HSS thanks to their fantastic anesthesia team. So of course they will do better at HSS."

Moderator Maloney: "The hospital makes more, and it may save the system a little money, but the surgeon makes less if he does them both at once."

Dr. Sculco: "That's a deterrent to doing it because if you do bilateral one setting you get half the reimbursement for the second side."

Moderator Maloney: "Jay, can't you change the system and…"

Dr. Parvizi: "I don't get paid for these cases anyway…$200 for a primary knee in Philadelphia. But it does make a difference in the long run if you are a high volume surgeon you should have the profit sharing with the hospital."

Moderator Maloney: "Thank you gentlemen." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."

company

Wright Medical's Slow Turnaround in 2Q12

Image created by RRY Publications. Source: Corporate logo

On August 1Wright Medical Group, Inc. reported $123.3 million in revenue for the second quarter.. While that number was down 5% on a constant currency basis over the previous year's quarter, the underlying story is all about the company's plan to turn around a business that has been beset with regulatory and sales problems.

BMO Capital Market analyst Joanne Wuensch wrote that with two quarters into a massive turnaround, "We are beginning to see signs that the plan is in place with increased confidence in management's ability to execute on the restructuring, focus the company on extremities, and increase cash flow."

Robert Palmisano, president and CEO, said the company made significant progress during the quarter on implementing changes to transform Wright's business and deliver significant shareholder return. "Although we are early in the execution phase of our plan, we are very encouraged by the initial results on our key measures with global foot and ankle constant currency growth of 13% and outstanding free cash flow generation for the first half of the year."

"In addition to significant foot and ankle sales growth, the conversion of a major portion of our foot and ankle distributor territories to direct sales representation is ahead of schedule, and we are pleased with our execution to date. We believe this increase in U.S. direct foot and ankle sales representation, coupled with our large and growing product portfolio and our increased investment in medical education, will enable us to continue improving our foot and ankle growth rate throughout 2012 and to exit the year at well above market growth rates."

Wright Medical Group, Inc. 2Q12	Sales ($ in millions)	% Change*
Total Reported Sales	**$123.3**	**down 5%**
Ortho Recon	$71.3	down 9%
Hips	$40.1	down 10%
Knees	$30.2	down 8%
Other	$1.0	down 18%
Extremities	$51.9	1.0%
Foot & Ankle	$28.8	13.0%
Upper	$6.3	down 8%
Biologics	$15.4	down 13%
Other	$1.3	down 14%

Source: Wright Medical Group, Inc.
** Constant currency*

Palmisano said U.S. sales were negatively affected by previously announced distributor transitions that occurred in the third quarter of 2011, challenges associated with implementing enhancements to the Company's compliance processes, and the impact of the previously announced agreement with Kinetic Concepts Inc. (KCI).

Sales Rep Conversions

Also commenting on Wright's turnabout, Mizuho Securities analyst Mike Matson said the company has converted around 85 foot and ankle sales reps to direct reps and now has 150 direct reps and 50 indirect reps. He expects the newly direct reps to focus more on the company's products pushing productivity (revenue per rep) much higher than before.

Surgeon Training Expansion

With previously reported problems of the company's deferred prosecution agreement with the Department of Justice now seemingly under control, the

company is now also resuming relationships with surgeons and increasing training programs. Wright increased spending on medical education during the quarter and trained 470 physicians during the second quarter and 770 in the first half of the year. The company expects to exceed its goal to train 1,200 surgeons for the year.

While the company beat consensus by over $1.5 million for the quarter, they lowered anticipated full year 2012 net sales by $4 million to be in the range of $476 million to $485 million. Wright also beat consensus earnings by a nickel for the quarter and raised the low end of year-end earnings-per-share by $0.04.

Hips, Reconstructive Sales and Free Cash

Wuensch noted other items of interest from Palmisano's call with analysts on August 1.

Regarding modular hip stems the company said it had no indication that there is an increased risk of adverse events due to taper junction fretting and corrosion, or fractures of the Profemur cobalt chrome modular necks based on product complaint data to date. In addition, the company said it was important to note that Stryker's recalled products use a different material and a different design than Wright's products. Therefore, it would be inappropriate to assume the reasons for Stryker's recall would be [applicable] to Wright's products.

Reconstruction product sales will likely still take a hit from revenue dissynergies associated with some distributor terminations, although management reiterated that the amount remains within its $10 million initial estimate.

Importantly, said Wuensch, management increased 2012 guidance for free cash flow (a key metric in the company's turnaround) to a range of $40 million-$45 million from $25 million-$30 million.

So the turnaround at Wright continues. With much larger competitors bulging with cash and consolidation all around in orthopedics, the company's thriving foot and ankle business may be a tempting target.

—WE (August 3, 2012)

DePuy Synthes Spine Gets First FDA Nod

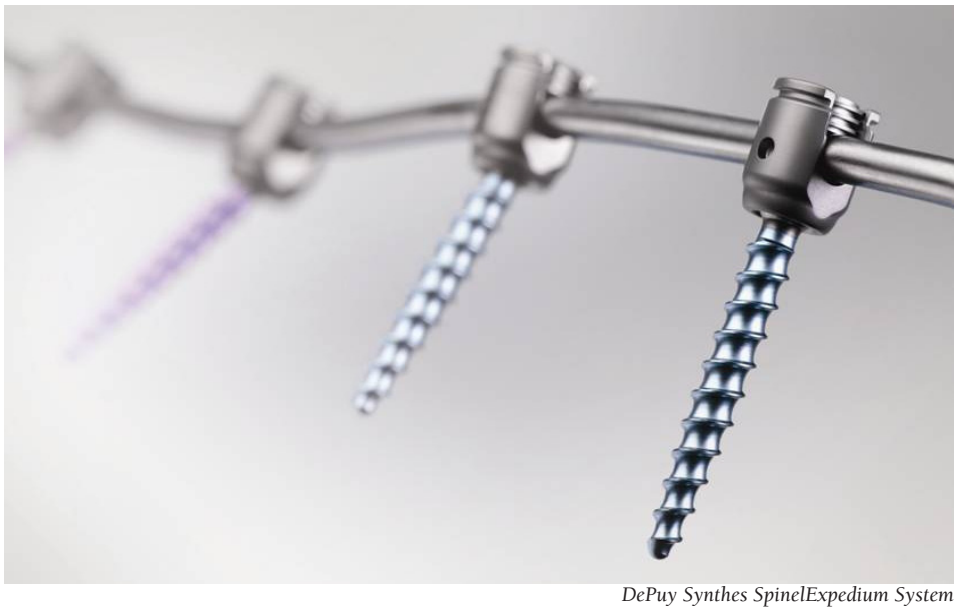
We have our first official DePuy Synthes Spine FDA 510(k) clearance announcement.

The new company announced on August 2, 2012 that the FDA has given clearance for use of its Expedium, Viper, and Viper2 Spine Systems on patients with adolescent idiopathic scoliosis (AIS), an abnormal curvature of the spine that typically affects children between the ages of 10 and 18. The clearance expands the scoliosis indication for the pedicle screw systems, which now are indicated for both adolescents and adults.

According to the company, the Expedium technology was first introduced in 2004. The Viper and Viper 2 Spine Systems have been used in minimally invasive spine surgery for a wide range of pathologies since 2005 and 2008, respectively.

The new indication clearance, which was received in July, clears the way for the devices to be used in posterior non-cervical pedicle screw fixation in adolescent patients and for the company to provide training and education about its appropriate use.

"AIS is a serious challenge to surgeons, patients, and their families. New treatment options based on proven technologies provide surgeons with more choices to help more patients," said Suken Shah, M.D., sSpine Ssurgeon at



DePuy Synthes SpinelExpedium System

the Alfred I. duPont Hospital for Children in Wilmington, Delaware. The company noted that Dr. Shah is a paid consultant to DePuy Synthes Spine.

Scoliosis

Scoliosis, according to the company announcement, can lead to chronic back pain and reduced respiratory function and impact quality of life by limiting activity and affecting self-esteem. If the curvature of the spine is between 25 to 45 degrees, back bracing is generally recommended in an attempt to stop curve progression. If the curve progresses beyond 45 degrees, spinal fusion surgery is considered to strengthen and straighten the spine. Most patients do not progress to a degree needing surgical intervention.

According to the National Scoliosis Foundation, scoliosis patients make more than 600,000 visits to private physician offices, 38,000 children undergo spinal fusion surgeries and about 30,000 children are braced each year in the United States.

DePuy Synthes Spine

Perhaps as interesting as the 501(k) clearance announcement, is how the merged DePuy Synthes Spine company describes itself.

The press release said, "DePuy Synthes Spine is one of the largest spine companies in the world dedicated to developing treatments and solutions for the full spectrum of spinal disorders including adult and adolescent deformity, spinal stenosis, trauma and degenerative disc disease. The company provides total solutions that range from devices for minimally invasive and complex spine surgery to procedural solutions that advance patient care. DePuy Synthes Spine is part of DePuy Synthes Companies of Johnson & Johnson which builds upon a legacy of innovation by filling unmet clinical needs and improving patient and economic outcomes across joint reconstruction, trauma, spine, sports medicine, neurological, craniomaxillofacial, power tools and biomaterials."

The new orthopedic superpower has fired its first spine shot.

—WE (August 3, 2012)

Orthofix 2Q12: Good Quarter, Back to Business

The news from Orthofix International NV over the last month has been mostly about legal settlements as the company cleans up problems related to marketing activities under previous leadership.

But the company got back to business with a second quarter sales report on July 26 that showed a 5% rise in revenue to $119.5 million. The sales number was slightly below consensus due to currency headwinds, but profits beat expectations.

Spine Continues Growth

Overall on a constant currency basis, biologics and implant sales rose 4%. Spine stimulation sales posted their best growth in seven quarters at 9%, which is significant as this is the company's largest product line. Orthopedic sales only rose 2% as the company saw increased competition in Brazil and slower growth in Southern Europe.

Spine growth improved for the third consecutive quarter and company margins have moved significantly higher following the sale of Breg.

Orthofix International NV 2Q12	Sales ($ in millions)	% Change*
Total Sales	**$119.5**	**5.0%**
Spine Stim	$43.3	9.0%
Implants/Biologics	$38.5	4.0%
Total Spine	$81.8	7.0%
Orthopedic	$37.7	2.0%

Source: Orthofix International NV
** Constant currency*

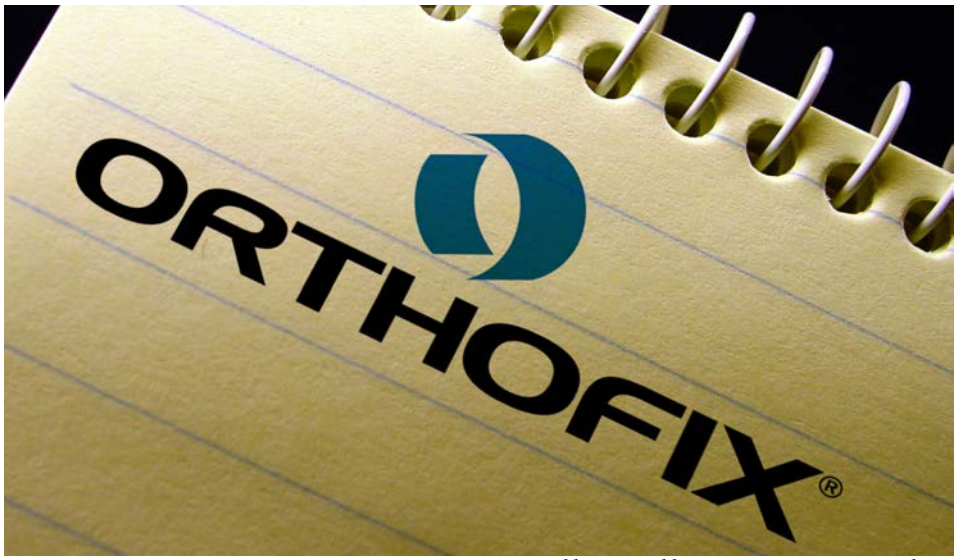


Image created by RRY Publications. Source: Corporate logos

Upcoming new product launches such as foot and ankle implants should benefit orthopedic growth in coming quarters and are a notable move for the company as it moves into extremities.

Bob Vaters, company president and CEO, told analysts on July 26 that, "The second quarter results demonstrate the strength of our Regenerative Solutions and highlights our strategy to leverage our differentiated product offerings across both our Spine and Orthopedic business units. In addition, the close of the Sports Medicine divestiture provides us with the financial capacity and flexibility to make the necessary investments to drive long-term growth."

Trinity Trumping Infuse

Vaters cited the increasing adoption of the company's Trinity Evolution in spine applications, leading to 48% increase in sales of the biologics business. Jefferies analyst Raj Denhoy noted that Trinity Evolution sales continue to benefit from safety concerns surrounding Medtronic, Inc.'s, Infuse. He also said the company remains very positive regarding a new biologic product it is working on with partner MTF (private not-for-profit Musculoskeletal Transplant Foundation) that is slated for 2013 and which should provide another tailwind to the biologics business.

Going Shopping

Mike Matson, senior analyst with Mizuho Securities, said the company's intention to use its new balance sheet to go shopping for an acquisition may be coming at a good time. Matson said he believes that private company valuations have declined and the medical device excise tax starting in 2013 only adds to the pressure on smaller med tech companies.

The company lowered its revenue guidance to $481 million – $491 million from $487 million –$497 million due to the increased currency headwind.

Vaters came in to the company as the chief financial officer in 2008, not chief legal officer. He must be relieved to get back to business.

—WE (July 31, 2012)

Zimmer 2Q12: Slowing Sales, Growing Market

Weaker than anticipated reconstructive sales brought Zimmer Holdings Inc.'s reported sales down by 1.1% during the second quarter of 2012. Sales increased 1.8% on a constant currency (cc) basis.

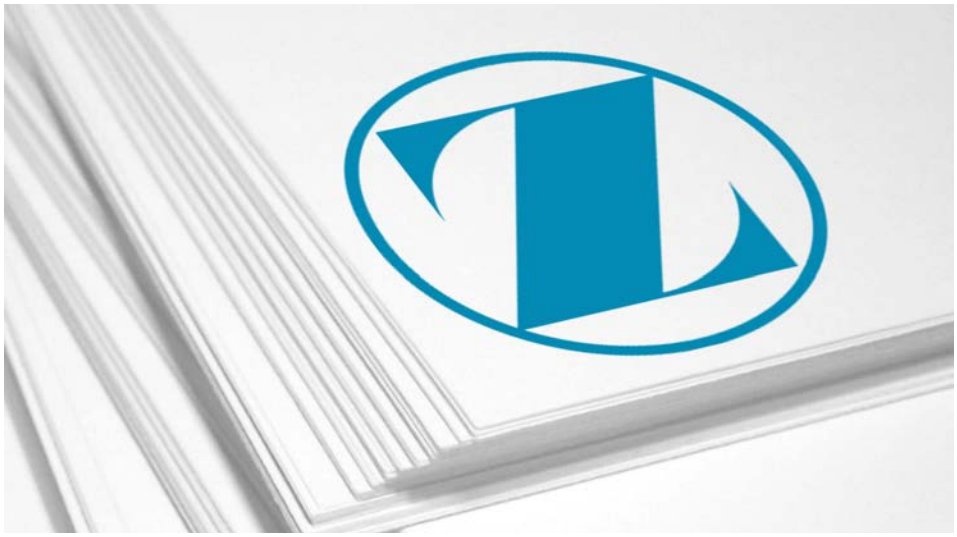
Excluding the impact of currency, knees were up 1%, slightly below consensus and decelerated compared to the 2.4% growth in the first quarter. Hips were up 2%, also slightly lower than consensus, but in line with the first quarter. Extremities missed consensus, rising 6%, but accelerated over a first quarter growth rate of 4.8%. Trauma climbed 9% while spine dropped 4%, but both improved over first quarter growth rates.

New Knee to Drive Growth

David Dvorak, Zimmer president and CEO, told analysts on July 26: "Moving through 2012, we expect to accelerate revenue growth through ongoing new product introductions and to continue to drive improved leverage in operating margins."

Zimmer 2Q12	Sales ($ in millions)	% Change*
Total Reported Sales	**$1,125**	**1.8%**
Reconstructive	$843	2.0%
Knees	$461	1.0%
Hips	$349	2.0%
Trauma	$74	9.0%
Spine	$52	down 4%
Extremities	$42	6.0%

Source: Zimmer Holdings, Inc.
** In constant currency*



Courtesy: Zimmer Holdings Inc.

The new product launches include a new knee system expected to be fully launched in the fourth quarter and released on a limited basis during the second quarter. The company has not provided many details about the knee system, but the company has said that it is the largest development project it has ever undertaken and that the full launch will be the company's largest ever.

Full 2012 Guidance

The company said full-year revenues are expected to increase between 2.5% and 3.5% on a constant currency basis from 2011. The company now estimates that foreign currency translation will decrease revenues between 2.0% and 2.5% for the full year 2012, resulting in reported revenue growth between 0% and 1.5%. Previously, the company had estimated foreign currency translation would decrease revenues by approximately 1.5% to 2.0%.

Losing Market Share

Larry Biegelsen, Wells Fargo's analyst, said after Zimmer's report that the orthopedic market was improving, but that Zimmer likely lost market share in hips and knees during the quarter. With Zimmer's report, roughly 80% of the orthopedic market has reported for the quarter.

U.S. Ortho Market Strengthening

Biegelsen estimates that the global recon market grew approximately 2.5% on a constant currency basis in the second quarter, a slight improvement over the first quarter as strength in the U.S. recon market (around 3% cc growth) was somewhat offset by softer OUS (outside U.S.) markets. Globally, Biegelsen says hips and knees were both up around 2.5% cc during the quarter, but growth in hips improved approximately 70bps (basis points) sequentially while knee growth was unchanged. In the U.S., hips grew 4.5% while knees were up 2.8%.

"Recent commentary on the hip and knee markets has been relatively consistent, suggesting that the U.S. market is strengthening as procedure volume moves toward historic levels (+3-5%), while most international markets continue to be challenged," concluded Biegelsen.

—WE (July 27, 2012)

NuVasive Gaining in a Stable Market

NuVasive, Inc.'s 2012 second quarter revenue of $154.4 million was up 16.1% on a reported basis from the previous year. The company also reported a profit of $2.9 million on a GAAP (generally accepted accounting principles) basis.

NuVasive, Inc. 2Q12	Sales ($ in millions)	% Change*
Total Reported Sales	**$154.40**	**16.1%**
U.S. Lumbar	$89.90	4.7%
U.S. Cervical	$14.80	17.0%
U.S. Biologics	$25.40	5.0%
U.S. Monitoring	$10.20	-1.9%
International	$14.10	41.0%

Source: Wells Fargo Securities

The company raised its revenue guidance for the full year by $10 million to approximately $625 million.

Aiming for #3

Company Chairman and CEO Alex Lukianov told analysts on July 25 that the company made strong improvements in profitability and expects to improve top line growth to become the #3 spine company in the world. Goldman Sachs gave NuVasive its #1 ranking for M&A (merger and acquisition) at the beginning of the month.

Growth Drivers

Growth was driven by a reported 17% rise in U.S. cervical sales as well as a 40% increase in international sales.

Image created by RRY Publications, LLC. Corporate logo courtesy NuVasive

Lumbar and biologics increases of 5% fell from the first quarter. Overall sales also slowed from 22% in the first quarter. Management noted that it believes that the spine market was stable but did not explain the slowdown.

Monitoring sales for the quarter were approximately $10 million resulting in lowered 2012 monitoring sales guidance by $3 million to $42 million due to lower reimbursement.

Spine Market Update

BMO Capital Market analyst Joanne Wuensch reported that it was a solid quarter, but wondered if it was enough.

"We believe expectations were running hot and heavy that the company would beat (consensus), and in-line revenue may not be enough. The good news is that the spine market appears stable, and NuVasive continues to take share," wrote Wuensch in an investor note on July 26.

Wuensch continued that management believes the U.S. market is declining about 2%, and that OUS (outside the U.S.) markets are "showing modest growth rates." "The good news is that there are continued signs of stability and that we are likely bumping along the bottom, and price declines have also stabilized and remain in the low-single digits. Unfortunately there are no immediate signs of relief, with payer pushback still an obstacle, and few catalysts likely to lead to accelerating volumes. That said, NuVasive continues to take share as the minimally invasive segment of the market grows."

2012 Uncertainties

The company is still awaiting a final determination of the royalty rates that it must pay to Medtronic, Inc. Management now thinks this could take until the fourth quarter or later. Guidance is based on the rates suggested by the jury. The company is also still awaiting FDA approval of its PCM cervical disc and AttraX biologic. Neither of these products is factored into 2012 guidance.

—WE (July 27, 2012)

legal

Second Quarter FDA Ortho Approvals

Now that second quarter orthopedic sales results are in, we thought we'd bring you the second quarter Premarket Approvals (PMA) Original and Supplemental Approvals from the FDA.

The FDA approved 6 Original PMAs during the quarter while granting 315 positive Supplemental Approvals during the quarter. None of the Original PMAs were related to orthopedic devices.

Original PMA decision times (receipt to decision) increased from 113.2 days in in April to 221.8 days in June. The FDA portion of that decision time went from 92.7 days in April to 188.6 days in June.

April 2012

Four Non-Orthopedic Related Original (PMA) Approvals:

- Bond Oracle Her2 IHC System for Leica Biosystems Newcastle Upon Tyne, United Kingdom
- Presillion plus CoCr Coronary Stent on RX System for Medinol Ltd. Tel-Aviv, Israel
- Architect HBsAg Qualitative Calibrators and Controls for Abbott Laboratories Abbott Park, Illinois
- Epic Vascular Self-Expanding Stent System for Boston Scientific Corporation Maple Grove, Minnesota

Orthopedic-Related Supplemental Approvals:

Exactech, Inc., Gainesville, Florida

- Novation Ceramic Articulation Hip System (AHS)
  Approval for use of an additional package sealer for the acetabular liner and femoral head sterile barrier packaging processes

Wikimedia Commons and FitzColinGerald

- Novation Ceramic AHS Articulation Hip System
  Approval for changes to the Novation AHS Instructions for Use to reorganize information for clarity, remove information that is redundant, and ensure consistency

DePuy Orthopaedics, Inc., Warsaw, Indiana

- DePuy Pinnacle CoMplete Acetabular Hip System
  Approval for the addition of the Trilock BPS (Bone Preserving Hip Stem) to the list of compatible femoral stem components. The device, as modified, will be marketed under the trade name DePuy Pinnacle CoMplete Acetabular Hip System and is indicated as a single use device intended for uncemented fixation. The device is intended as a primary joint replacement prosthesis in total hip arthroplasty for skeletally mature patients suffering at least moderate pain in the hip joint from non-inflammatory degenerative joint disease (NIDJD) and its composite diagnoses of osteoarthritis (OA) or post-traumatic arthritis. The device's inserts (Pinnacle Ultamet) are only intended for use with DePuy's femoral and acetabular components having matching outer and inner diameters.
- Duraloc Option Ceramic Hip System
  Changes to the sterile barrier package sealing process used for the ceramic femoral heads and acetabular liners
- Ceramax Total Hip System
  Changes to the sterile barrier package sealing process used for the ceramic femoral heads and acetabular liners
- CoMplete Acetabular Hip System
  Changes to the sterile barrier package sealing process used for the ceramic femoral heads and acetabular liners

May 2012

No PMA Approvals

Orthopedic-Related Supplemental Approvals

Integra LifeSciences Corporation, Plainsboro Township, New Jersey

- Integra Artificial Skin, Dermal Regeneration Template, Integra Dermal Regeneration Template – Terminally Sterilized (IDRT-ts)
  Approval for a manufacturing site located at Integra Neurosciences in Anasco, Puerto Rico
- Integra Dermal Regeneration Template – Terminally Sterilized (IDRT-ts)
  Approval for a manufacturing site located at Synergy Health AST, LLC in Denver, Colorado

Genzyme Corporation, Cambridge, Massachusetts

- Synvisc and Synvisc-One
  Approval for the addition of a new product data and laboratory information management system

June 2012

Two Non-Orthopedic Related Original (PMA) Approvals:

- Glaukos iStent Trabecular Micro-Bypass Stent (Models: GTS-100R, GTS-100L) and inserter (GTS-l00i). Glaukos Corporation, Laguna Hills, California
- Access Hybritech p2PSA on the Access Immunoassay Systems. Beckman Coulter, Inc., Chaska, Minnesota

Orthopedic-Related Supplemental Approvals

Smith & Nephew, Inc., Memphis and Cordova, Tennessee

- Reflection Ceramic Hip System
  Approval for addition of an alternate site for the machining processes for R3 Acetabular Shells
- Exogen 4000+ Ultrasound Bone Healing System
  Change in supplier

DePuy Orthopaedics, Inc., Warsaw, Indiana

- Duraloc Ceramic Hip
  Approval of the post-approval study protocol
- Duraloc Option Ceramic Hip System
  Changes to the device sterile packaging
- Ceramax Ceramic Total Hip System
  Changes to the device sterile packaging
- Pinnacle CoMplete Ceramic-on-Metal Acetabular Hip System
  Changes to the device sterile packaging

Medtronic Sofamor Danek, Memphis, Tennessee

- Infuse Bone Graft
  Approval for the proposed labeling revisions related to the appearance of the reconstituted product and warning statement about use in patients suspected of having cancer at the product application site

—WE (August 2, 2012)

biologics

Loses This Round in Stem Cell Court Battle

Courtesy of Regenexx Corporation

Federal judge Rosemary Collyer has ruled that stem cell therapy for orthopedic patients constitutes a drug—a ruling that exposes manufacturers to liability for adulteration and misbranding. According to Ryan Abbott, writing July 16 for *Courthouse News Service*, the Food and Drug Administration has, since 2008, argued its position that the stem cell procedure should be classified as a drug, making it subject to Federal Food, Drug and Cosmetic Act regulations.

This case is the latest round in Regenexx's battle to be able to provide autologous stem cell therapies to their clients. In January 2011, the U.S. government filed a motion for summary judgment and made the claim that there was no issue of material fact in the case since, in their view, Regenexx was manufacturing a "drug" (the cultured stem cells) and selling it "after one or more of its components have been shipped in interstate commerce." The government also argued that Regenexx did not comply with current Good Manufacturing Practices.

The government also argued that the autologous stem cells were misbranded since they did not bear the symbol "Rx only" and do not have adequate directions for use.

Regenexx countered by saying that the practice of medicine is outside of the FDA's jurisdiction and that the FDA may not "interfere with a physician prescribing lawfully marketed products for uses other than those for which they are approved, licensed, or cleared by FDA, the agency's role in determining the availability of therapeutic products inevitably affects the options available to practitioners seeking to use or prescribe those products."

The Government's lawyers then answered by saying that while it is true that the FDA may not directly interfere with a physician's prescribing habits, it CAN limit what drugs are available to physicians to prescribe in the U.S. market. Therefore the Government argued, the FDA was not impinging on the clinic's ability to practice medicine as it is only requiring a drug product to be approved for sale in the U.S.

In deciding the case, Judge Collyer wrote, "It is a close question but ultimately the court concludes that the Regenexx Procedure is subject to FDA enforcement because it constitutes a 'drug' and because a drug that has been shipped in interstate commerce is used in the solution through which the cultured stem cells are administered to patients." Collyer permanently enjoined Regenexx from using the procedure, which she described as "a non-surgical procedure for patients suffering from moderate to severe joint, muscle, tendon or bone pain due to injury or other conditions."

In August 2010, Regenexx accounted for about one-third of the procedures performed by a Colorado-based clinic. The practice argued that Regenexx "constitutes the practice of medicine as defined by Colorado law," and that the FDA lacked jurisdiction to regulate it. However Judge Collyer disagreed.

Regenexx and the U.S. Government have now been arguing this case for more than ten years. Parsing out where the government can enter the practice of medicine and where it can't is still an extremely close call when it comes to the patient's own cells and tissues. We expect that this fight is still in its middle rounds.

—BY (July 30, 2012)

Quest for Cartilage Growth Continues

The search for a method to grow cartilage—the shock-absorbing lining of hip and knee joints—goes on. Tissue engineers at Johns Hopkins University School of Medicine, in Baltimore, Maryland, have used tiny artificial fiber scaffolds thousands of times smaller than a human hair to coax stem cells into developing into cartilage. Has it worked? To a degree, yes.

Jennifer Elisseeff, Ph.D., Jules Stein Professor of Ophthalmology and director of the Translational Tissue Engineering Center, said, "Joint pain affects the quality of life of millions of people. Rather than just patching the problem with short-term fixes, like surgical procedures such as microfracture, we're building a temporary template that mimics the cartilage cell's natural environment, and taking advantage of nature's signals to biologically repair cartilage damage."

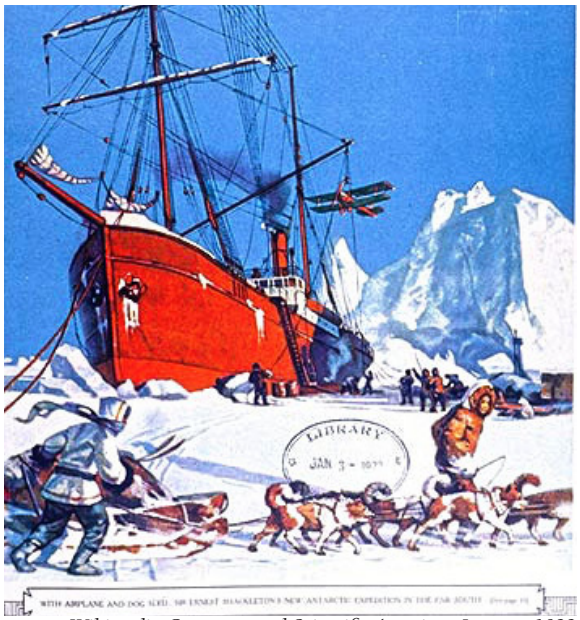
According to the June 17 press release, Elisseeff's team is trying to build scaffolding that mimics the cartilage cell environment and generates new cartilage tissue. This environment is a 3-dimensional mix of protein fibers and gel that provide support to connective tissue throughout the body, as well as physical and biological cues for cells to grow and differentiate.

In the laboratory, the researchers created a nanofiber-based network using a process called electrospinning, which entails shooting a polymer stream onto a charged platform, and added chondroitin sulfate to serve as a growth trigger. They then seeded goat bone marrow-derived stem cells in various scaffolds to see how the stem cells responded to the material.

The cells developed into voluminous, cartilage-like tissue. "The nanofibers provided a platform where a larger volume of tissue could be produced," Elisseeff said. They implanted the nanofiber scaffolds into damaged cartilage in the knees of rats, and compared the results to damaged cartilage in knees left alone.

They found that the limbs with damaged cartilage treated with nanofiber scaffolds generated a higher percentage of the more durable collagen (type 2) than those damaged areas that were left untreated. "Whereas scaffolds are generally pretty good at regenerating cartilage protein components in cartilage repair, there is often a lot of scar tissue-related type 1 collagen produced, which isn't as strong," says Elisseeff. "We found that our system generated more type 2 collagen, which ensures that cartilage lasts longer."

—BY (July 30, 2012)

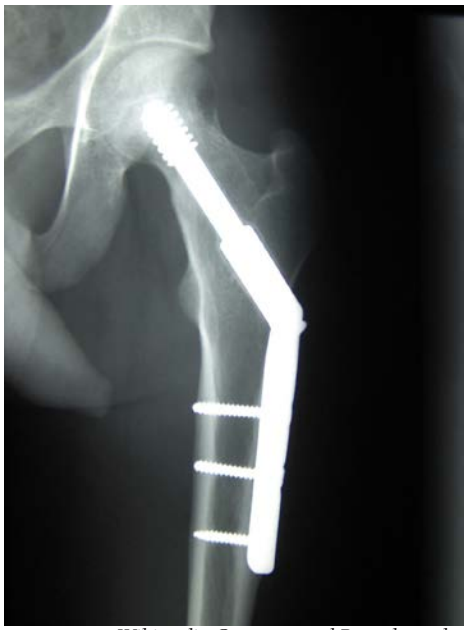


Wikimedia Commons and Scientific American January 1922

large joints

Cataract Surgery Reduces Hip Fractures

It only makes sense…if you can see better, then you see that thing you're about trip over. Researchers from the University of California, Los Angeles (UCLA) and Brown University have found that Medicare patients 65 years and older who underwent cataract surgery had a lower odds of hip fracture one year after the procedure when compared with patients with cataract who did not have cataract surgery. Their study appears in the August 1 issue of the *Journal of the American Medical Association.*



Wikimedia Commons and Booyabazooka

Victoria L. Tseng, M.D., of the Warren Alpert Medical School of Brown University, Providence, Rhode Island, and colleagues examined the association between cataract surgery and fracture incidence at one year. The study included a 5% random sample of Medicare

Part B beneficiaries with cataract who received and did not receive cataract surgery from 2002 through 2009.

There were 1,113,640 Medicare beneficiaries 65 years and older with a diagnosis of cataract between 2002 and 2009 in the 5% random sample. Of patients with cataract, 36.9% underwent cataract surgery during the study period. During this period, the overall one-year fracture incidence was 1.3% for hip fractures. Analysis of the data indicated that cataract surgery was associated with a 16% decrease in the adjusted odds of hip fracture one year after the procedure. "In patients with severe cataract, the association between cataract surgery and lower odds of hip fracture was even stronger, with a 23% reduction in the adjusted odds of hip fracture in the cataract surgery group compared with the cataract diagnosis group," the authors wrote in the July 31, 2012 news release.

Osteoporosis was the most common fracture-related comorbidity (co-existing illness) (12.1%). The most common ocular comorbidity was glaucoma (19.1%).

The study's principal investigator was Anne Coleman, M.D., Ph.D., an ophthalmologist with the University of California, Los Angeles. When asked what stands in the way of more patients this age getting the surgery, she told *OTW,* "Many patients do not realize how much their poor vision is affecting them because their vision has slowly gotten worse over the years, and they have made lifestyle adjustments such as not driving at night. They think that poor vision is a normal part of the aging process so they do not desire to have surgery. Another possible reason is that providers might be uncertain about recommending a surgical procedure for patients over 80."

Asked what else she would like orthopedists to know about this issue, Dr. Coleman commented to *OTW*, "When a patient with a fracture presents to their office or emergency room, it would be very helpful to make sure that the patient has been evaluated by an ophthalmologist for vision loss secondary to cataracts or other treatable conditions. If they haven't, please refer them."

—EH (August 2, 2012)

Biodegradable Magnesium Studied For Implants

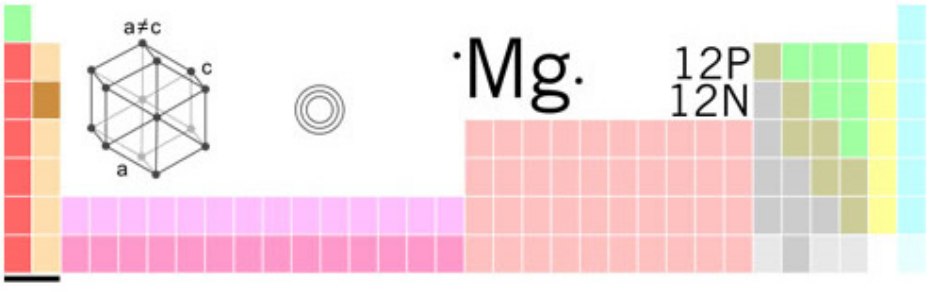
Scientists with a cluster of German hospitals have organized a "virtual institute" to fabricate implants made of degradable magnesium and examine how they work in animal studies. Aluminum free, load bearing, biodegradable, magnesium alloys can be used for orthopedic implants for children. The advantage is that magnesium implants dissolve in the body and therefore a second operation in order to remove the implant is not necessary.

The research will be under the direction of Professor Regine Willumeit, head of the department at the Institute of Materials Research at the Helmholtz-Zentrum Geesthacht, and will be conducted by the partner clinics in Hamburg, Hannover and Graz. "Our centre is the worldwide leader in the development of magnesium based implant materials", said Willumeit in the July 18 press release. "We are now searching for factors to tailor the degradation of the material in an application specific manner."

The chemical and biological processes which occur when magnesium dissolves are partially understood by the scientists and, according to Willumeit, can be tested in the laboratory. However, he notes that magnesium behaves differently when it is installed in a body and, therefore, the materials need to be examined in animal studies—an important step towards applications in humans.

The participating institutions are the Helmholtz-Zentrum Geesthacht with the University Medical Center Hamburg-Eppendorf, the Hannover Medical School and the Laura Bassi Centre of Expertise of the University of Graz in Austria.

—BY (July 30, 2012)



Wikimedia Commons and atanamir

spine

Benvenue Medical Progresses in KAST Study

Benvenue Medical, Inc.

Benvenue Medical, Inc., a company developing minimally invasive solutions for spine repair, has met the predetermined stopping rules for enrollment completion in the KAST (Kiva System as a Vertebral Augmentation Treatment – A Safety and Effectiveness Trial) clinical trial. The KAST study is a randomized controlled trial comparing Kiva to balloon kyphoplasty; the trial enrolled 300 patients at 21 centers in the U.S., Canada, Belgium, France and Germany. The study is being conducted to support a subsequent 510(k) filing for market clearance from the FDA.

"The KAST study enrolled ahead of schedule, and we believe the positive response we received is due to our investigators' enthusiasm for a new treatment option for painful and debilitating osteoporotic vertebral fractures moving away from traditional vertebroplasty or balloon-based vertebral augmentation," said Sean M. Tutton, M.D., FSIR, Co-Principal Investigator in the KAST Study and Professor of Radiology and Surgery at the Medical College of Wisconsin in Milwaukee, in the July 31, 2012 news release.

"We appreciate the efforts of the investigators and research coordinators, as well as the spine community's enthusiasm to evaluate the potential benefits of the Kiva System. The results will be important to guiding treatment recommendations for VCFs [vertebral compression fractures]," said Steven R. Garfin, M.D., Co-Principal Investigator of the KAST Study and Professor and Chairman of the Department of Orthopaedic Surgery at the University of California, San Diego Medical Center.

Success will require non-inferiority on the primary endpoint, which is a composite of pain, function, and safety at one year of follow-up on patients treated on study. The study is designed to evaluate superiority on key secondary endpoints including PMMA (polymethyl-methacrylate) cement volume, extravasation rate, and height restoration as well as other endpoints. The Kiva VCF Treatment System features a proprietary flexible implant made from PEEK-OPTIMA, and is designed to function as a mechanical support structure and a reservoir to contain and direct the flow of bone cement.

The implant is delivered percutaneously in a continuous loop fashion into the vertebral body with an all-in-one disposable device through a small diameter, single incision. The amount of the Kiva Implant can be determined by the surgeon in the OR; the implant is delivered over a removable guidewire, and is designed to provide structural support to the vertebral body and to directionally control and contain bone cement.

—EH (August 3, 2012)

Stem Cells Injected Into Spinal Cord

As reported in the August 2012 issue of *Neurosurgery*, some breathtaking human clinical trials have been reported injecting stem cells into the spinal cord. Until now, no United States-based clinical trials have attempted delivery of biological therapies directly to the spinal cord for treatment of amyotrophic lateral sclerosis (ALS). The reason? There has been no meaningful U.S. Food and Drug Administration-authorized cell candidate nor a validated delivery approach.

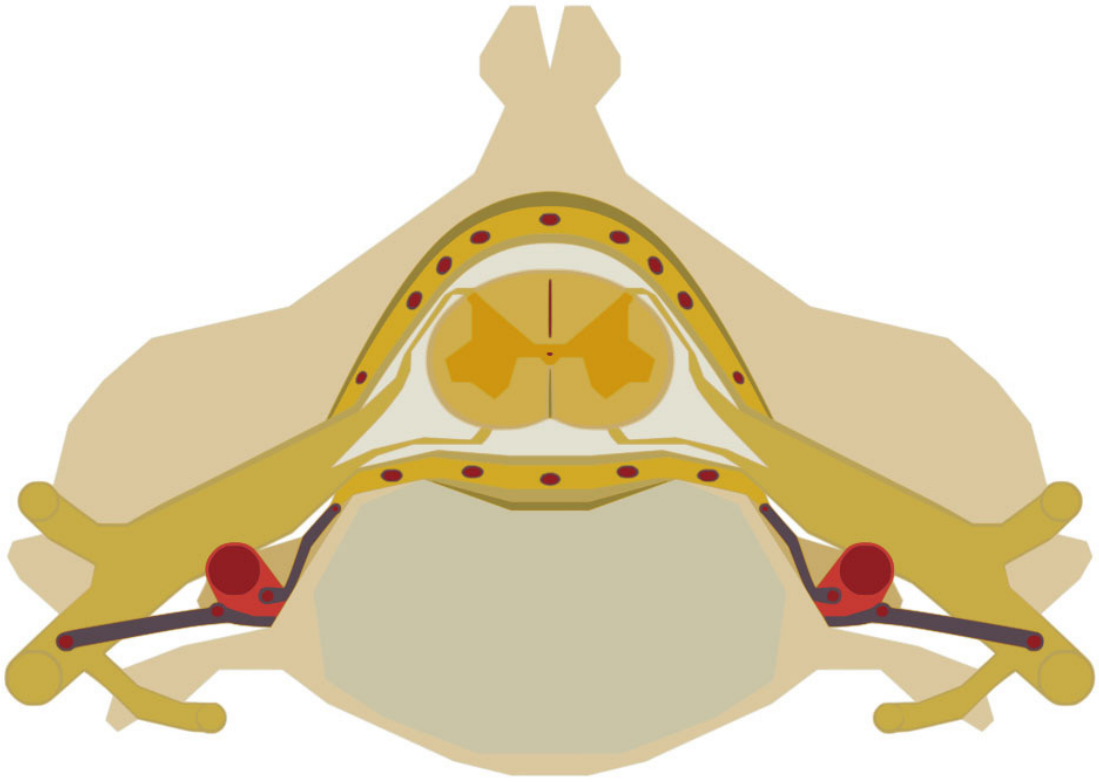
The Departments of Neurosurgery and Neurology of Emory University, Atlanta, took on the problem of the delivery approach. Researchers wanted to assess the safety of delivery of a neural stem cell-based treatment into the upper lumbar segments of the amyotrophic lateral sclerosis (ALS) spinal cord. It was the first U.S. Food and Drug Administration-authorized phase I trial of this procedure.

Researchers treated 12 patients with either unilateral or bilateral injections. Each injection deposited 100 000 neural stem cells derived from a fetal spinal cord and each microinjection series was comprised of five injections (10 µL/injection) separated by 4 mm. Group A, which consisted of non-ambulatory patients, underwent unilateral (n = 3) or bilateral (n = 3) lumbar microinjections. Groups B and C were ambulatory (n = 3 each) and received unilateral or bilateral injections. Researchers followed patients clinically and radiologically to assess the potential toxicity of the procedure.

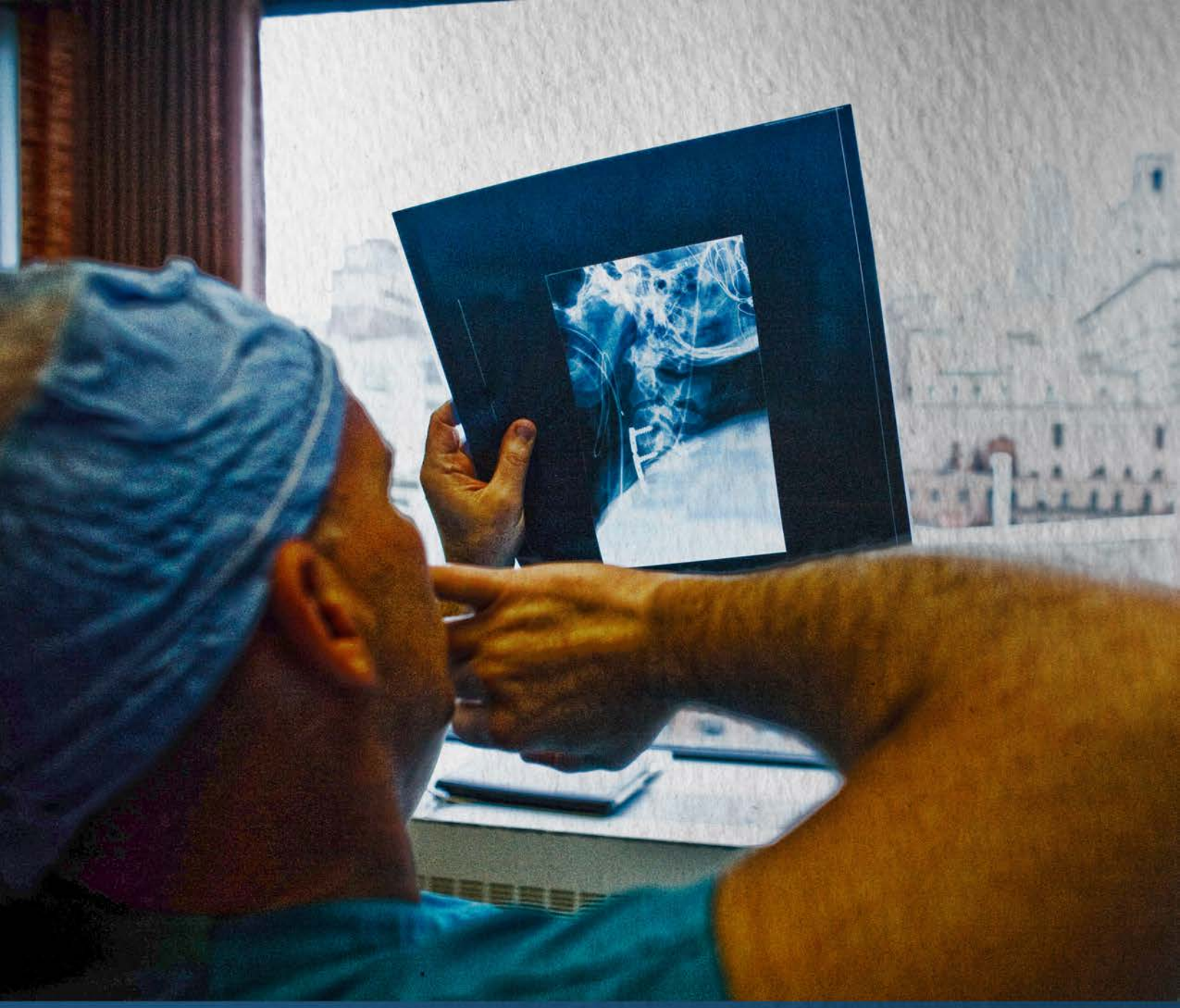
Of the 12 patients who received a transplant there was one instance of transient intraoperative somatosensory-evoked potentials depression and one episode of urinary retention requiring Foley catheter reinsertion. By discharge, none had a documented motor function decrement. Two patients required readmission and reoperation for cerebrospinal fluid leak or suprafascial wound dehiscence (n = 1 each). Two deaths occurred at 8 and 13 months post surgery but neither was related to the surgical transplant.

The researchers' experience with their 12 patients supports the procedural safety of unilateral and bilateral intraspinal lumbar microinjection. Investigators now plan to perform cervical and combined cervical and lumbar microinjections in ALS patients.

—BY (July 31, 2012)



Wikimedia Commons and Time3000



And he reads Orthopedics This Week.

THE ORTHOPEDICS THIS WEEK PHYSICIAN
HONEST. EXCELLENT. IRREPLACEABLE.

ADVERTISE. HERE.

ryortho.com

To advertise contact Tom Bishow at Tom@ryortho.com and to subscribe contact Jayme@ryortho.com. I Follow us on Twitter: @ryortho1

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

Biloine W. Young
Writer
bgwy@msn.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com