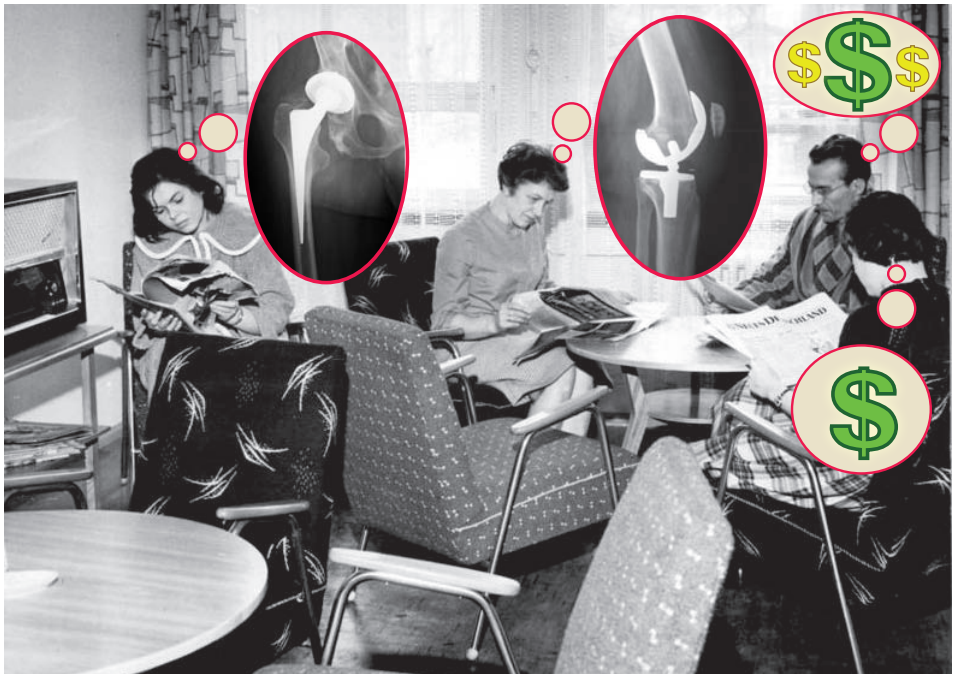
VOLUME 6, ISSUE 18 | JUNE 8, 2010

Orthopedics This Week

week in review



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Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Every orthopedic stock lost value in the last 30 days. This sure looks like a double dip. Certainly shipping, energy, FDA costs, and taxes are rising. But revenues are also increasing and cash flows are still strong compared to other sectors.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	5	Medtronic	31.37%	(11.63%)	On the basis of an astonishing 12x trailing earnings P/E, MDT rises to #1 this week.
2	1	Johnson & Johnson	27.1	(10.13)	Forward annual dividend has just reached 3.70%. The highest savings account rate in the U.S. is 2.25%
3	3	Stryker	24.71	(9.18)	Upgraded by Barclay's capital. Nearly $3 billion in cash and short-term investments on hand. Maybe they should invest in JNJ?
4	4	Symmetry	11.48	(11.25)	Attractive price-to-sales of 1.1x, but P/E of 21x earnings is higher (!) than MDT, ZMH or SYK.
5	2	Zimmer	27.69	(11.82)	And now for something different—low P/E (only 13x earnings) but a high PSR (2.69x). Reason? High profits.
6	6	Exactech	12.61	(14.48)	In terms of valuation, EXAC is 6th most attractive equity in ortho. P/E to growth rate is a solid and enticing 0.97.
7	7	Kensey Nash	38.72	(2.98)	When a company earns 39 cents on every sales dollar and has $50 million in cash, they deserve to be on the Power Rankings.
8	9	Orthofix	11	(7.92)	OFIX is another company that has earned its way onto the Power Rankings with sheer strength of cash flow.
9	10	Alphatec	-0.44	(17.94)	No other company in ortho is expected to report a stronger earnings growth in 2010 than ATEC. Period. Wall Street consensus.
10	8	Integra LifeSciences	15.37	(9.39)	P/E not so cheap, PSR 1.68 ok, not great. But IART beat the Street by 10% last quarter and has a habit of upside surprises.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	ArthroCare	ARTC	$30.62	$825	-0.4%
2	Kensey Nash	KNSY	$22.15	$216	-3.0%
3	Mako Surgical	MAKO	$12.83	$433	-6.4%
4	CryoLife	CRY	$5.01	$144	-7.4%
5	NuVasive	NUVA	$38.11	$1,490	-7.5%
6	Synthes	SYST.VX	$103.90	$12,331	-7.8%
7	Orthofix	OFIX	$30.47	$537	-7.9%
8	Stryker	SYK	$51.97	$20,620	-9.2%
9	Integra LifeSciences	IART	$38.33	$1,110	-9.4%
10	Johnson & Johnson	JNJ	$58.01	$160,000	-10.1%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$2.46	$76	-23.3%
2	Alphatec Holdings	ATEC	$5.26	$459	-17.9%
3	Osteotech	OSTE	$3.62	$66	-17.2%
4	Orthovita	VITA	$2.91	$223	-15.7%
5	Exactech	EXAC	$16.59	$214	-14.5%
6	Wright Medical	WMGI	$16.60	$644	-12.8%
7	Capstone Therapeutics	CAPS	$0.78	$32	-12.4%
8	RTI Biologics Inc	RTIX	$3.30	$181	-12.0%
9	Zimmer Holdings	ZMH	$53.18	$10,790	-11.8%
10	Medtronic	MDT	$38.00	$41,840	-11.6%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$38.00	$41,840	11.72
2	Kensey Nash	KNSY	$22.15	$216	12.03
3	Johnson & Johnson	JNJ	$58.01	$160,000	12.43
4	*Average*			*$10,888*	*12.68*
5	Zimmer Holdings	ZMH	$53.18	$10,790	12.82

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$45.42	$8,070	64.14
2	RTI Biologics Inc	RTIX	$3.30	$181	54.87
3	NuVasive	NUVA	$38.11	$1,490	34.46
4	Symmetry Medical	SMA	$10.49	$377	20.93
5	ArthroCare	ARTC	$30.62	$825	18.38

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.01	$144	0.60
2	NuVasive	NUVA	$38.11	$1,490	0.90
3	Exactech	EXAC	$16.59	$214	0.97
4	Alphatec Holdings	ATEC	$5.26	$459	1.08
5	Smith & Nephew	SNN	$45.42	$8,070	1.09

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$19.82	$578	8.31
2	Symmetry Medical	SMA	$10.49	$377	2.13
3	Johnson & Johnson	JNJ	$58.01	$160,000	1.72
4	RTI Biologics Inc	RTIX	$3.30	$181	1.72
5	*Average*			*$10,888*	*1.54*

Lowest Price to Sales Ratio (TTM)

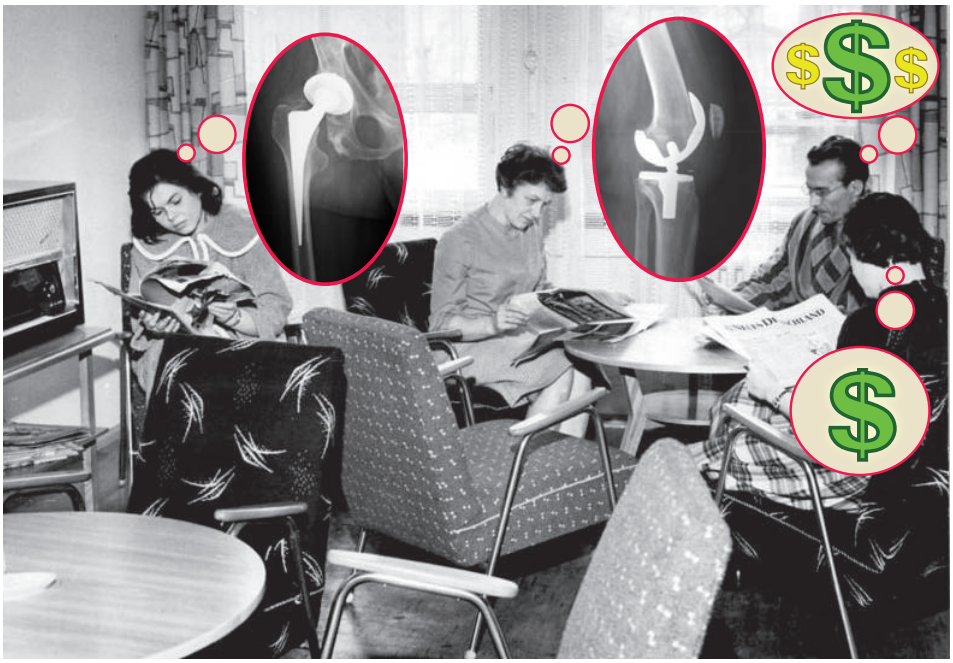
	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.97	$72	0.73
2	CONMED	CNMD	$19.44	$567	0.81
3	Orthofix	OFIX	$30.61	$539	0.99
4	RTI Biologics Inc	RTIX	$3.22	$176	1.09
5	Symmetry Medical	SMA	$10.82	$389	1.16

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.46	$76	73.57
2	Mako Surgical	MAKO	$12.83	$433	12.05
3	NuVasive	NUVA	$38.11	$1,490	3.93
4	Synthes	SYST.VX	$103.90	$12,331	3.63
5	Alphatec Holdings	ATEC	$5.26	$459	3.62

Do Patients Trust Surgeons?

By Walter Eisner



RRY Publications

What do patients undergoing hip, knee or spine surgery think about the relationship between their surgeon and medical device companies? Do they believe their physician will choose an implant based on the patient's best interest or to the best interest of the physician's pocketbook?

A survey of 1,000 patients from the Mayo Clinic conducted by Scott McGovern, M.D., between 2003 and 2007, found that the vast majority of patients believe that surgeon/industry relations are beneficial for their care. Nearly all patients believe their surgeon will choose the implant that is best for them.

However, there was one noteworthy statistic.

Approximately one quarter of patients tended to agree with the statement that physician's choice of implant was based upon the potential for personal financial gain of the physician.

Commenting on the percentage, McGovern told us,"We surveyed patients and asked difficult questions to determine their perception of our decision process in choosing implants for surgery. Ninety-five (95%) [percent] of patients believe that their doctor will choose the best implant for them.

"Mayo Clinic instituted a written disclosure statement shortly after the time of the surveyed population in 2008 to disclose that doctors do not receive any additional reimbursement or royalties for implants for surgery performed at our institution. We believe this disclosure helps to alleviate patient anxiety about financial decisions for implant choice."

McGovern said that the clinic's written disclosure guidelines and other practices are designed to demonstrate to patients that their particular surgical needs are not only superior to the physician's financial situation but are the only needs being considered.

The Social Contract

The physician/patient relationship rests upon one of society's oldest social contracts first articulated by Hippocrates.

The patient's perception and expectation is that the physician will act in the patient's best interest. That perception is the foundation that gives each patient the confidence to literally put their life into the hands of the physician. It also conveys upon the physician enormous power in determining the course of care for that patient.

Now, shifting gears slightly but still keeping the patient in mind, physicians and industry engineers must collaborate in order to develop and produce improved instruments and devices—again, for the benefit of the patient. This activity also carries with it a financial benefit—for the inventor/physician, consulting physician and manufacturer. It is, as is well known, the financial component of this collaboration that has generated concerns regarding surgeon conflicts of interests and their role in patient care. Finally, those concerns are finding expression in the form of legislation generally and more specifically, the recently enacted Patient Sunshine Act.

First Data

Until now, there has been little, if any, data which purports to measure patient attitudes and opinions regarding surgeon relationships with industry. What, for example, is the patient's perception of surgeon/industry relationships and have they changed patient's attitudes and is the trust basis of the physician/patient relationship changing?

McGovern and his colleagues, Robert Trousdale, M.D. and Bradford Currier, M.D., surveyed 1,000 patients who were at the Mayo Clinic to undergo hip, knee or spine surgery.

Two groups of patients representing primary total joint arthroplasty and instrumented spinal surgery were randomly selected from the overall population of patients undergoing primary total hip, total knee or instrumented spinal fusions. The two groups of patients were then matched with cohorts of non-surgical patients during the same time period with correlating diagnoses.

Four equal groups of 996 patients were then mailed the surveys. Survey responders had an average age of 66 years. Fifty-one percent (51%) of the responders were male. Forty-two (42%) percent were spine patients while the remaining were hip and knee patients. Two-thirds of responders had prior surgery with implants, and of these 80% characterized their outcomes as either very good or excellent.

McGovern told us that he decided to perform the survey because recent concern generated in the media, legal and scientific communities have been "alarming to physicians." He said the authors recognized that the patients perceptions on the surgery performed

Approximately one quarter of patients tended to agree with the statement that physician's choice of implant was based upon the potential for personal financial gain of the physician.

was not defined and they sought to inquire about this as well as comparing responses from surgical and non-surgical patients.

Legitimate Collaboration, Trust and Choice

The vast majority (93%) of patients believe that it is beneficial for doctors to advise manufacturers of surgical implants. However, only one-third believe that surgeon-owned device companies are appropriate and beneficial to their care.

While 82% of patients said the physicians should be compensated for helping to design new implants, less than half that number (41%) of patients believed that physicians should receive compensation for only offering advice to the companies. That number dropped to 33% when the patients identified themselves as someone who works in the healthcare field. Ten percent (10%) of patients believed physicians should receive additional payment for each implant used.

Over 90% of patients tended to agree that the choice of implant affects the outcome of the surgery. Moreover, the overwhelming majority of surgical patients (96%) and non-surgical patients (94%) trust their doctor to choose the best implant.

Scott McGovern, M.D.

McGovern told us that he decided to perform the survey because recent concern generated in the media, legal and scientific communities have been "alarming to physicians." He said the authors recognized that the patients perceptions on the surgery performed was not defined and they sought to inquire about this as well as comparing responses from surgical and non-surgical patients.

Eighty-five (85%) percent of patients believe their doctor chooses implants based upon either familiarity/personal preference, or medical research.

Seven (7%) percent tended to agree that hospital or insurers should have the sole choice of implant. Fifty-six (56%) percent believe doctors should have the sole choice of implant, and 26% tended to agree that patients should have sole choice of implant.

Patients who had undergone previous surgery were more trusting of physicians.

Twenty-six (26%) percent of patients who had undergone prior surgery

tended to disagree that physicians should receive financial reimbursement for an advisory role alone, while slightly fewer than half of patients (44%) without prior surgery tended to disagree.

While the large majority of patients without prior surgical implants (80%) tended to agree that doctors should disclose this relationship, only 68% of surgical patients with prior surgical implants tended to agree that doctors should tell patients of this relationship.

The vast majority of surgical patients (91%) tended to trust their doctor to put the patient's medical needs above all other considerations compared to 83% of nonsurgical patients. While slightly more than half of non-surgical patients (52%) believe that what their doctor tells them must be true, two-thirds of patients with prior surgery tended to agree that what their doctor tells them must be true. A large majority of patients with prior surgery (88%) believe their physician is an expert in musculoskeletal care, while slightly more than half of patients without prior surgery (52%) tended to agree.

Marketing and Promotion

With respect to marketing of surgical implants, only one-third of patients believe that doctors should help promote the implants they helped design. Seventy-seven (77%) percent were aware that private companies manufacture implants for surgery and over half of patients have seen advertisements for surgical implants. Slightly less than one quarter (24%) of patients tended to agree that private companies should advertise directly to consumers. Most patients (65%) believe private companies should advertise directly to physicians.

Gender and Educational Level

Males prefer more disclosure. More than three-quarters of male patients tended to agree that doctors should tell patients about a financial relationship versus only two-thirds of female patients. The vast majority of male patients (92%) believe their doctor is considerate of their needs versus 82% of female patients.

Ninety-five (95%) percent of patients with higher education (college or more) tended to agree more strongly than less educated patients (89%) that it is beneficial for doctors to advise manufacturers.

Less than one-third of patients with higher education level (31%) believe surgeon-owned medical device companies are appropriate and beneficial to their care while greater than one-third (38%) of less educated patients.

Strengthening the Social Contract

The authors of the study noted that there is a clear concern among patients for physician-owned device manufacturers as well as surgeons promoting the devices he or she has helped design. "These types of perceptions should be explored further and either potential conflict of interest managed differently or greater transparency and education for our patients may be needed," concluded the study.

McGovern told us that he hopes this study was successful in revealing patients' perceptions of the surgeon/industry relations.

"With this information, physicians may alter disclosure practices to better inform patients of their role in design of implants. Surgeons and patients should recognize that potential conflict of interest occurs with surgeon involvement in the design and implantation of devices from private industry.

"Patients demonstrate a strong trust in physicians, whether or not they have had prior surgery. Surgeons must ensure that potential conflict of interest is managed in a transparent and ethical manner to preserve this trust."

If Dr. McGovern is right, his work may well help strengthen that fraying social contract between patients and physician.

To read the entire results of the survey, please click here: http://ryortho.com/McGovernPatientPercepDocsInd.pdf ◆

Orthopedics This Week

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To Seth, With Love

By Robin Young

American educator A. Seth Greenwald lives and works in Cleveland, Ohio, in an educational hive of activity known as the Current Concepts Institute that he has spent a lifetime designing. Dr. Greenwald (D. Phil., Oxon), and a staff of seven run the largest independent education enterprise dedicated solely joint arthroplasty in the world.

During the last week of May in Las Vegas, *OTW* spent quite a bit of time backstage with Dr. Greenwald as he presented his 11th annual Current Concepts in Joint Replacement (CCJR) meeting—sponsored jointly by Case Western Reserve School of Medicine. Dr. Greenwald's CCJR meeting in Orlando passed the quarter century mark in 2008. Neither his Orlando meeting nor his Vegas meeting show any sign of, shall we say, middle age. CCJR-Vegas attendance topped 900 surgeons and like his Orlando meeting, it was standing room only during several of the presentations. Both meetings train about 2,000 surgeons from 45 countries every year.

Seth Greenwald is without doubt one of the most influential educators in orthopedics. We estimate that between 10,000 and 15,000 orthopedic surgeons, nurses, techs, company executives, engineers, and, yes, sales people from all over the world have been taught by Dr. Greenwald's panoply of educational experiences, presentations and multi-media materials.

Dr. Greenwald's "School Room"

Welcome to Dr. Greenwald's "school room." But Dr. Greenwald's influence on surgical technique and product development goes well beyond the numbers.

At breakfast on the first day of this year's meeting, we looked around our table and the surgeon to the right was from Tokyo, the surgeon next to him was from Chile, the next two surgeons were from the U.S. and the surgeon on our left was from India. Each person paid $850, round trip airfare, hotel and other expenses to attend. Both surgeons from Tokyo and Chile were attending their fifth CCJR. Why?

Free of Commercial Bias

"This is the most up-to-date meeting in the world for surgeons. Everyone on the podium is an expert. This is different from AAOS where the speaker's level of expertise is more uneven. Seth's meeting is free of commercial bias. At other meetings, market forces cause devices to be introduced to surgeons without critical judgment. At this meeting, experts' debate and we can make up our minds."

That comment came from the surgeon from Chile who'd spoken with us as we were walking into the meeting. He wanted to be sure we understood how unique and valuable this meeting was for him.

Prince Charles visited the Cleveland Clinic's Biomechanics Laboratory. After seeing the wrist replacement implant demonstrated by A. Seth Greenwald, DPhil (Oxon). The Prince wondered aloud if one of the devices could be saved for him for when his many years of handshaking were over, 1976/Photo courtesy of Dr. Greenwald

He continued. "There is a momentum, a rhythm and pace to this meeting. It's quick, organized and lean but you still learn."

By 7:25am we are settled into our seats in a large auditorium in the new and frankly awe-inspiring Aria hotel and, standing rock still at the podium, is otherwise congenial Seth Greenwald waiting for his floor director to cue the 7:30am sharp start.

According to Dorothy Granchi, M.B., CCJR Course Coordinator, Dr. Greenwald was never been late in 26 years of opening a CCJR meeting.

Seth's Tips and Tricks

Sitting in a CCJR meeting is like attending an expert fellowship and learning from a curriculum designed by an *educator*. Not a surgeon. Not a committee. Not a manufacturer. Truly, CCJR is the singular vision from this Oxford University and M.I.T educated, bushy-haired, crinkly-eyed Dean. He is about to call his 900-member class to order.

A pint of English ale

After a very brief introduction, Dr. Greenwald sets in motion the opening session—a five-hour shoulder arthroplasty session. Because of overlapping surgeon interests and potential conflicts, he opened the morning with three debates. Point. Counterpoint. Affirming the use of arthroscopic rotator cuff repair was Reuben Gobezie, M.D. "This is going to be like taking candy from a baby." Opposing the use of arthroscopic rotator cuff repair was John J. Brems, M.D. "Are you kidding me? Get real!" These are full contact debates.

Debating Society

Dr. Greenwald's D.Phil. is from Oxford University, the home of the original debating society. CCJR is home to the only orthopedic debating society and it is clearly one of the highlights of his meetings. Each surgeon forcefully presents his arguments and attacks the other side. Nine hundred attending surgeons are invited to send up questions and at one point in the first debate of the day, Dr. Brems actually called for an audience vote. It wasn't even close. Arthroscopic rotator cuff repair went down to a crushing defeat at the impromptu poll.

Two more debates followed.

What Do the Outcomes Tell Us?

Debates are step one in Dr. Greenwald's master plan. Step two is the review of the literature or as Seth puts it, "What do the outcomes tell us?" A panel comprised of the expert shoulder surgeons (we're talking Drs. Crosby, Gobezie, Galatz, Brems and Bigliani) review current literature and critique it. "This data is at odds with my clinical experience." "Solid study design, sample size is bit small." "While the numbers may not be on target, the conclusion mirrors my own outcomes."

No one leaves this meeting. An hour and half has passed. Step three is the live surgery. Not just any live surgery. Russell Warren, M.D., from the Hospital for Special Surgery performed a reverse shoulder reconstruction live, in full color with Evan Flatow, M.D., providing color commentary and channeling questions from the audience for Dr. Warren while he was operating. It was not surgery. It was true performance art.

After the debates, after the review of the literature, it was amazing to see a master put many of the debated and discussed concepts into action.

Stump the Experts

Step Four is teaching what to do when the best laid plans go awry. Dr. Warren's surgery magically wrapped up by 10:30am when the morning shifted to the session led by Dr. Leesa Galatz dedicated to dealing with difficulties. Step five is a version of stump the experts. Led by Dr. Louis Bigliani, this session threw difficult problems at the experts to see how they'd tackle them. "What would YOU do?"

The capstone of the morning was the closing Tips, Tidbits and Surgical Pearls: How I Do It!. Tricks of the trade.

That was the morning of the first day. Over the next two and half days, Dr. Greenwald's schoolroom would cover knees and hips employing not only all the steps we just experienced with shoulders but the entire meeting is recorded and memorialized in print, electronics and over the net so it becomes the gift of learning that keeps on giving.

Affecting the Trajectory of Orthopedics

Not surprisingly, Dr. Greenwald's meetings have shaped the trajectory of orthopedic technology and practice. It was at CCJR that the flaws and challenges of the 2-incision hip approach were first discussed and debated. Five years ago, the squeaking ceramic-on-ceramic hip video was first shown, discussed, debated and dissected. Gender knees sparked one of the most memorable debates at CCJR.

Also not surprising is the fact that top executives from Zimmer, DePuy, Wright, Stryker and Biomet are as rapt students as any surgeon.

Dr. A. Seth Greenwald

A. Seth Greenwald prefers not to talk about himself. To hear him tell it, his educational contributions of meetings, publishing and bio-mechanical research were the result of a number of happy accidents. Here is Dr. Greenwald's story, as he tells it, of how he made the career shift to orthopedics.

Turn the clock back to the 1967 and a young M.I.T-educated aeronautical engineer from New York and his young wife (expecting their first child) have just arrived in the United Kingdom. Seth Greenwald had been accepted at Oxford University to study the effects of vibration on nuclear power plant cooling towers and, in the process, read for a Doctorate from one of the most prestigious educational institutions in the history of man.

But, waiting for engineer Greenwald was a note from his would be mentor saying, in effect, "sorry old chum, but I'm off on my sabbatical and you'll have to fend for yourself." Stranded and abandoned Seth walked into a pub to mull his future with the assistance of a pint of good English ale. This is Oxford, England, of course, and the denizens of pubs are not exactly like those in, say, Oxford, Mississippi.

Joining Seth that very day, at the specific hour and at that exact pub were two other gentlemen with their own set of problems. Mr. John Goodfellow (orthopedic surgeon) and Dr. Peter Bullough (pathologist) were wallowing

in the deep end of a conceptual question: "How does weight bearing across articulating human hip joint surfaces contribute to cartilage degeneration resulting in arthritis?"

A pint of fine ale later and young Mr. Greenwald found himself signing up to work on a doctoral thesis in orthopedic and engineering sciences—the first received at Oxford University in this newly emerging cross discipline.

Consider, however, if Dr. Greenwald had tried a different pub or picked a different hour, he might be the world's leading educator of nuclear or environmental scientists.

But, and here is Dr. Greenwald's 'thing', he is a passionate, creative and effective educator. He may not have thought of himself in precisely those terms in those Oxford days. But looking back, the common denominator in all of his "happy accidents" is the urge, the imperative to educate.

Dr. Louis Bigliani: "Seth's course provides its delegate surgeons with the best forum for education. He blends accepted concepts with cutting edge techniques and technologies. He has a novel way of presenting material which makes it interesting. Seth also keeps a lot of the politics out of the meeting. He makes sure we leave our egos at the door."

This year's meeting was no exception and in future editions, *OTW* will review the key aspects of this year's CCJR meeting in Vegas. ◆

Pricing Pressures Lower Spine Forecast Part I

Matt Menze, PearlDiver Spine Analyst

Pricing pressures continue to affect spinal implant supplier revenues and we are, therefore, lowering our sales forecasts for spinal implant and instrumentation suppliers.

For the first quarter of 2010, spinal implant suppliers reported product sales of $2.283 billion, which fell just short of our 1Q10 forecast of $2.366 billion. We have therefore decreased our industry 2010 sales estimate from $9.768 billion to $9.490 billion. Revenue growth slowed sequentially for each of the last three quarters. Overall, sales of spinal implants and instruments grew 11.1%, 9.9%, and 8.6%, respectively, for 2Q09, 3Q09 and 4Q09. The trend continued in the first quarter of 2010 as growth rates declined to a 6.4% rate of year-over-year increase.

- **Pricing Pressures and Product Mix:** The theme is not new, but the impact continues. Competitive pricing pressure was noted by DePuy's management in their quarterly conference call as being one of the primary reasons behind their reported lower revenue growth rate in spine. DePuy and Integra both noted mid-single-digit price declines. Stryker, Biomet, and even NuVasive acknowledged that pricing pressures are now part of the spinal implant market landscape. Synthes discussed pricing concerns rather candidly in its first quarter conference call, noting that hospitals are reducing the number of spine vendors in order to demand price discounts. Now for the "Catch 22." Despite the comments of competitors, Medtronic claimed that construct pricing was flat to down 1%. The question moving forward will be whether or not mix can mitigate potential price decreases, as most companies indicated that procedure volumes were stable.

- **CMS Payment Changes**: On April 19 CMS (Centers for Medicare and Medicaid Services) issued the proposed rule for the IPPS (Inpatient Prospective Payment System) for 2011. Spine procedures fared well with lumbar fusion and vertebral augmentation procedure reimbursement increasing 4.4% and 5.6%, respectively.

- **Consolidations:** The urge to merge is still coursing through larger company board rooms, although at, we suspect, a diminished rate. On March 1, Baxter announced that it would acquire ApaTech for total consideration of $330 million. ApaTech had $60 million in sales in 2009 and markets Actifuse, a synthetic bone graft. On March 16, Alphatec Spine shareholders voted overwhelmingly to issue new shares of common stock to help pay for the acquisition of Scient'x.

Wikimedia Commons

Revenue Growth Rate Declines

Revenue growth rates at larger companies slowed which pulled overall industry growth rates down. Medtronic, Synthes, and DePuy reported that revenue growth rates were 0%, 5%, and 3%, respectively, during the quarter.

In Table 1 we list and rank the quarterly sales for each major spinal implant company with our estimates for 2011 and 2012. As the table illustrates, sales of spinal implants and their related biologic products rose 6.4% in 1Q10, down from 8% growth in 1Q09. For all of 2010, we estimate that spine revenues will rise 8.0% to $9.49 billion.

Table 1: Quarterly and Annual Sales Revenue for Spine Product Companies

Revenue ($ millions)	1Q10	2Q10E	3Q10E	4Q10E	2010E	2011E	2012E
Medtronic	880	914	876	858	3,528	3,722	4,038
DePuy	258	280	253	255	1,046	1,121	1,210
Synthes	245	253	254	268	1,020	1,119	1,231
Stryker	141	155	152	168	616	687	759
Zimmer	60	65	64	69	257	281	311
Orthofix / Blackstone	74	78	77	82	311	348	388
Biomet	56	65	64	66	251	272	294
NuVasive	109	116	130	142	497	626	790
Globus	76	85	85	102	348	460	598
Alphatec	38	61	57	66	222	259	298
Pioneer Surgical	32	34	33	35	134	158	179
K2M	27	28	28	29	112	129	157
Osteotech	11	12	12	13	48	51	54
Orthovita	24	27	26	28	104	122	144
ArthroCare	4	4	4	6	19	28	35
Scient'X	15	-	-	-	-	-	-
SeaSpine	18	19	18	20	75	89	105
RTI Biologics	7	7	11	12	37	42	43
U.S. Spine	12	12	12	13	50	58	65
Integra Spine	11	12	12	12	46	52	59
Trans1	7	6	7	7	27	29	31
LDR	13	13	13	14	53	73	93
Spinal Elements	8	8	8	9	33	41	49
MEDICREA	5	6	6	7	23	30	40
Exactech (Altiva)	2	2	1	2	7	8	8
Other	**150**	**157**	**155**	**166**	**629**	**714**	**809**
Total Revenues	**$2,283**	**$2,418**	**$2,357**	**$2,448**	**$9,490**	**$10,519**	**$11,789**
Total Growth	**6.4%**	**6.9%**	**8.6%**	**10.5%**	**8.0%**	**10.8%**	**12.1%**

Source: PearlDiver estimates, Wall Street reports, SEC filings; Synthes, Globus, and DePuy are estimated revenues; Osteotech spine-related revenue assumes 70% DBM revenue is spine related

We believe that 2010 will be the trough in spinal implant and instrumentation sales growth rates. Despite the current pricing pressures, procedural volumes will, we believe, continue to grow steadily due to a number of powerful factors including obesity, diabetes, aging and the increasingly sedentary lifestyle in the U.S., Europe, Japan and the rest of the world. By 2012 a combination of new, more effective technologies combined with higher procedure counts throughout the world will drive sales growth rates up significantly to 12% year-over-year.

In Table 2 we display specific company market share gains or losses for the first quarter of the year. NuVasive and Globus gained, we estimate, the most market share points rising 1.1% and 0.8%, respectively in the quarter. Of the 11 major spinal implant companies we follow, five reported market share gains and six reported sales that indicate market share declines. The greatest market share decline, we believe, was reported by, Medtronic. We are currently forecasting that Medtronic will return to market rates of sales growth in 2012.

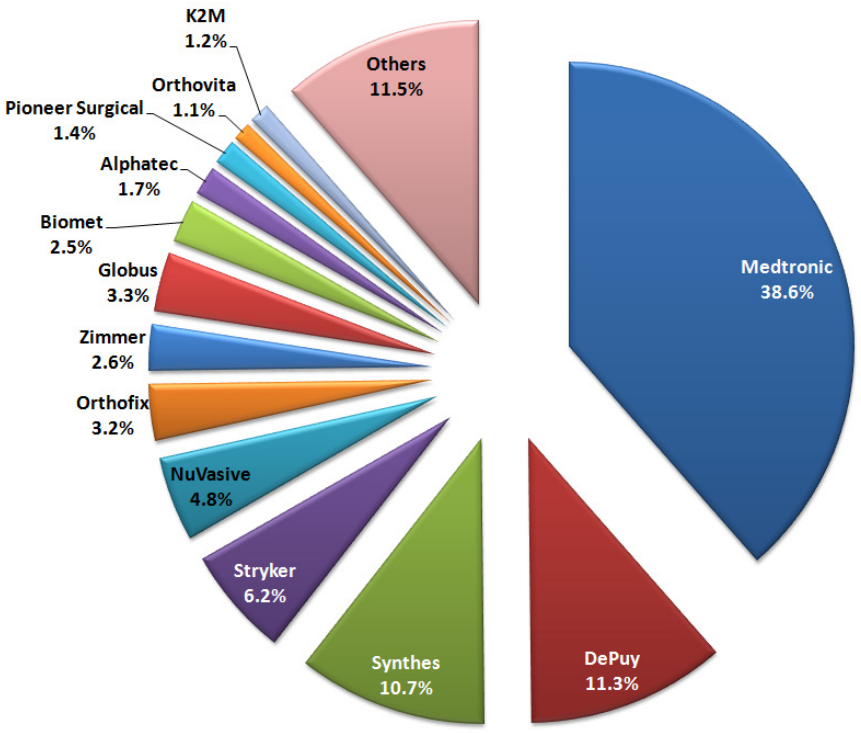
Table 2: Market Share Changes

Company	1Q09	1Q10	Est. Market Share Δ
NuVasive	**3.7%**	**4.8%**	1.1%
Globus	2.5%	3.3%	0.8%
Alphatec	**1.4%**	**1.7%**	0.2%
Stryker	6.0%	6.2%	0.2%
Orthofix	**3.1%**	**3.2%**	0.2%
Biomet	2.5%	2.5%	0.0%
Trans1	**0.4%**	**0.3%**	-0.1%
Synthes	10.9%	10.7%	-0.2%
DePuy	11.7%	11.3%	-0.4%
Zimmer	3.0%	2.6%	-0.4%
Medtronic	41.1%	38.6%	-2.5%

Source: PearlDiver Technologies estimates, Wall Street reports, SEC filings

Chart 1: Spine Market Shares (1Q10)

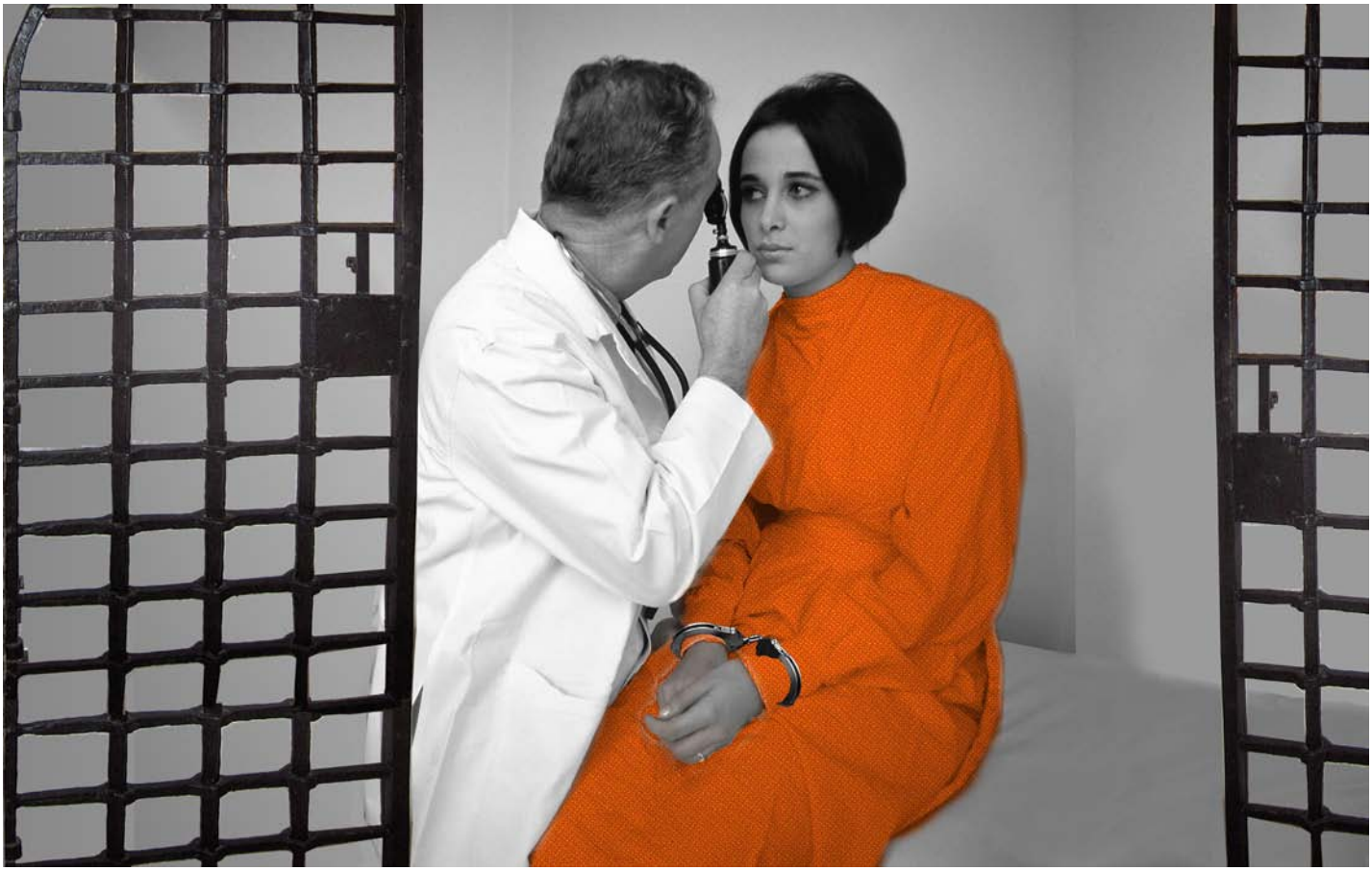
Next week, we review the first quarter sales performance for major suppliers of spinal implants and instruments and then also provide a brief company specific outlook for the remainder of 2010. ◆



Source: PearlDiver Technologies estimates, Wall Street reports, SEC filings

White Coats, Orange Jumpsuits: Treating Prisoners

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



RRY Publications LLC

Under the Eighth Amendment to the U.S. Constitution, which prohibits cruel and unusual punishment, U.S. prisons are required to provide healthcare to their inmates; the fastest growing prison population in the United States is the elderly (defined as being over 55 years of age). Between 1999 and 2007, the number of elderly prisoners in U.S. prisons leaped 82% to approximately 90,000 inmates.

The statistics are sobering. In federal, state and local jails, 38% of inmates, 43% of inmates and 39% of inmates, respectively, have a chronic medical condition and most of those are such problems as diabetes, HIV or heart disease. (data from the U.S. Bureau of Justice Statistics). But, mirroring the society at large, orthopedic conditions are becoming an increasingly prevalent public healthcare problem because inmate populations are aging.

Dan Thompson, the President of Beaumont Bone and Joint Institute, is a traumatologist who has treated approximately 1,000 inmates. How is treating an inmate population different from treating a non-inmate population? Dr. Thompson notes, "While many people would have sort of a gut level fear about working with this population, I can honestly say that I have never had a prisoner be overtly aggressive with me. In fact, most prison patients are *more* cooperative than the general public because a trip to see the doctor is a bit of a treat. It is an opportunity to leave the prison for a couple of hours…and they know that if they become difficult then they will not have that opportunity

again. The prisoners I have treated are genuinely appreciative, especially if they think that there are few people at the correctional facility who have much concern for them."

For Dr. Thompson, the sight of someone in an orange jumpsuit is not only familiar, but rather welcome. "I have taken care of prisoners since day one of my training in medical school. In those years I worked at a maximum security prison hospital; whereas many of my colleagues have VA experience, I had prison experience. That was my residency as well."

Dr. David Teuscher, an orthopedist and partner at the Beaumont Bone and Joint Institute in Beaumont, Texas, has worked with incarcerated individuals for the past 20 years. He notes, "There has been an increase in the number of local prisons built in our area over the last couple of decades. In fact, Jefferson County is unique in that it has so many correctional facilities, including county, state, federal, and youth institutions. Despite an existing contract between the state, the prisons, and the University of Texas Medical Branch at Galveston, and because of policy changes emanating from recent hurricanes, there was still a need for folks to be seen for orthopedic conditions on an expeditious basis. Since we were being asked frequently to evaluate and treat prisoners, our staff set up a system whereby the nursing staff at several local corrections facilities could routinely access our clinic."

But the inmate patient X doesn't just walk in the door and say "I'm here for Dr. Teuscher." "Our process is that when we receive a call from the nursing supervisor at a correctional facility, we then route that person through our workers compensation secretary who handles the initial paperwork, including verification of coverage. On the day of patient X's appointment our clinical coordinator checks the list of inmate patients who must be treated with a little extra protocol. In the event that the patient is a more serious offender, the correctional personnel will remain with him or her in the vehicle and then when called, proceed through a backdoor entrance to the facility. The nursing staff understands that these patients need to go directly to an exam room as opposed to the waiting room. This is largely an issue of making sure that the other patients feel safe. The prisons handle security well, and never send an inmate to our clinic without two security personnel…we have never had an issue with security."

Credit for this can also be given to the practice itself. "We have all of the understandings worked out in advance. If someone needs X-rays,

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our clinical coordinator will walk the administrative paperwork through the system. And if an inmate requires surgery, there will be a guard in sterile scrubs in the OR and one in the hallway. Again, all of this must be run in a way that makes your staff, other patients and their family comfortable."

At times, doctors can do a preliminary assessment of a prisoner's arm or leg from blocks or even miles away. "Thanks to telemedicine, we can work remotely with the facility's nursing personnel to evaluate the acuity of the injury. Then from there I must make a determination whether or not this is an offsite situation, meaning that the person should head to the ER. This is a very useful process; a doctor in a remote location can watch a nurse do a basic exam of the injury and say, for example, 'Yes, we need an X-ray.'

> "In the event that someone does want to talk about their crime, if I have a good rapport with them I may ask why they did it. The most popular answer is, 'Stupidity.' In the end, though, I'm not here to be the judge or jury; as for the inmates, they want to know that they'll be treated fairly. For anyone interested in working with incarcerated individuals, I would say, 'Don't be thrown off by their unique circumstances. They are more like everyone else than they are different.'"

Much of orthopedics is touching and feeling, so while telemedicine is a bit of an adjustment, if you watch closely and ask the appropriate questions, then it can be done well."

Then there are the questions you want to avoid, à la, "What are you in for?" "I do not inquire about the reason for the patient's incarceration. Many times, though, they bring up the subject. While I often hear, 'But I didn't do it,' I just maintain the attitude that they are eventually going to be released from the facility and that perhaps they can rebuild their lives."

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While patients "on the outside" might show up at Dr. Teuscher's office because they took a spill from a motorcycle, those who arrive with guards most commonly have been involved in physical altercations or have sports injuries. "I see a lot of hand injuries because someone has punched a wall—or someone else. Then there are the knee and other injuries that occur while the person is playing sports."

Echoing Dr. Teuscher, Dr. Thompson says, "Because these prisoners often get into fights, I see a lot of hand and wrist injuries. The athletic injuries I see are because they play a rough style of basketball and handball, which often results in ankle fractures, distal tibia fractures, ACL tears, and rotator cuff injuries."

There is basic medical care, says Dr. Teuscher, but there is no free ride for old wounds. "There is a misperception that once people go to prison they have extensive medical care and in essence get all of the 'work' done that they neglected to do 'on the outside'…

“If you are entertaining the possibility of working with prisoners, says Dr. Thompson, the main thing is to ensure that your staff and patients feel safe. “You’re going to have prisoners coming into office buildings, so all of those logistics must be worked out in detail. It may be unsettling for your average patient to see an inmate coming in with shackles surrounded by two big guys with guns and bullet proof vests. Despite what may appear visually intimidating, however, again, I have never felt threatened by incarcerated patients.”

and that it is all paid for by taxpayers' dollars. Instead, the basic question to be answered when someone is incarcerated is, 'Does this person need XYZ treatment?'"

And whatever reasonable treatment an inmate needs that is related to a *current* injury, he or she will receive. Dr. Thompson: "By law prisons must have arrangements with a practice to do a comprehensive orthopedic exam. And if, for example, someone needs a shoulder specialist, he or she will have one. Prisoners do have the right to sue if they are denied appropriate care. As for the reliability of the prison system as a payor, it is excellent."

Treatment is always a partnership, no matter if the patient is on Main Street or in Central Lockup. "The most difficult part for me," states Dr. Thompson "is that what I know is a necessary part of treatment, i.e., postoperative rehabilitation orders, tends to turn into suggestions once these patients return to prison. If, for example, you have done a complex hand reconstruction, then you must consider what access this patient will have to therapy. In a federal penitentiary they will have better access to rehabilitation services, but not at most state and local facilities. In all my years of working with prisoners, however, I have never seen a prisoner leave the facility to engage in physical therapy…it's just too much manpower and too much of a security risk."

Scheduling can also require some adjustments, says Dr. Thompson. "At times I have had inmate patients booked for surgery, but they don't show up until several weeks later. This may be because there has been a lockdown at the prison, for example, or because that particular inmate was involved in some type of altercation. On top of that, there is there a chance that while you are waiting for their surgery date to arrive they are transferred to another facility (and may fall through the cracks)."

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company

Wikimedia Commons

S&N Opens Beijing Plant

ChinaBio Today reported on May 27 that Smith & Nephew opened a manufacturing plant in Beijing at the end of May. The plant will produce surgical instruments and components of the company's artificial hip and knee replacement devices.

The manufacturing plant is a 10,000 square meter facility and replaces a smaller building which once housed Plus Orthopedics. Smith & Nephew opened a manufacturing plant last year in Suzhou, which makes wound dressing products.

According to the report, the near-term goal of the new facility is to provide products for the company's international customers. As the China market for joint replacements grows, the company will start developing joint replacement parts that are specifically designed for China's population. Smith & Nephew has previously said that its existing orthopedic facilities, which are located in Memphis, Tennessee, and Switzerland, are operating at capacity.

Education Program

The company is also planning to undertake a large education program to develop markets for the products. The plan is to train 5,000 surgeons over the next five years in advanced orthopedic techniques at four newly built education centers.

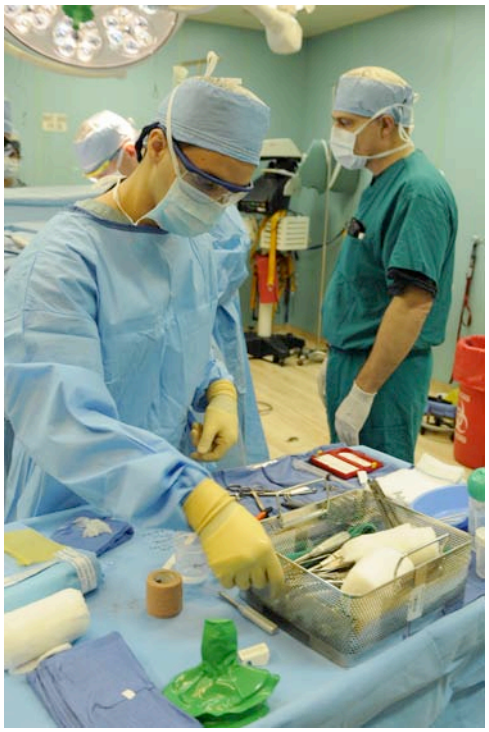
The report noted that Smith & Nephew "remains fearful" of counterfeiting of its products and will only build lower technology instruments and components in China for the time being.

—*WE (June 3, 2010)* ◆

InVivoLink Launches: Focus on Data

Knocking down communication barriers and bringing in the data…InVivoLink (IVL), a Nashville-based healthcare company whose mission is to improve medical implant procedure outcomes, has just had its official launch, and has introduced its management team. Leading the charge is Ryan Wells, Founder and CEO of InVivoLink, who previously spent 13 years at DePuy Orthopaedics.

Regarding the story behind the company's founding, Wells told *OTW,* "Throughout my career I repeatedly was reminded that the lack of communication and data was a barrier



U.S. Navy photo by Mass Communication Specialist 2nd Class Chelsea Kennedy/Wikimedia Commonst

for both the industry and providers to innovate and to become more efficient."

So what does InVivoLink do? The company indicates that it provides hospitals, physicians and medical device suppliers technology to improve clinical, financial and operational outcomes, all while enhancing patient safety. They capture clinical and financial data before, during and after implant surgeries.

"At InVivoLink, we believe there is a direct relationship between patient safety and how well the physician, the hospital and the implant manufacturer coordinate activities throughout the continuum of care," said Wells, in the news release. "We focus on providing technology to enable alignment and collaboration, benefitting everyone involved."

Surgeons gain access to reports that describe patient flow, implant utilization per patient, schedule and productivity. IVL's tools aggregate and categorize practice history and trends, allowing physicians to make informed, evidence-based choices.

The distributor portal provides for case scheduling and inventory management. Cases also can be scheduled via the physician portal, using new "active" physician preference software designed to remove steps for both the distributor and the physician's scheduling department. The hospital portal provides exposure to case and inventory data, in addition to its primary purpose of capturing data in the OR.

The resulting data is maintained by InVivoLink in de-identified form and constitutes a national implant registry. This data fills current knowledge gaps around implantable devices, ultimately increasing patient safety.

IVL indicates that medical device suppliers experience fewer errors due to improved workflows, along with enhanced case scheduling, inventory control, customer support and analytics. They can access the data, housed on a secure, Web-based platform, wherever and whenever it's needed on a variety of devices (e.g., iPhone, BlackBerry, Android).

Wells also told *OTW*, "InVivolink offers total joint surgeons a effective way to communicate implant and instrument requirements to the OR and manufacturer, while enabling a powerful dashboard reporting tool for every patient that receives a implant. Your own free registry, anytime, anyplace."

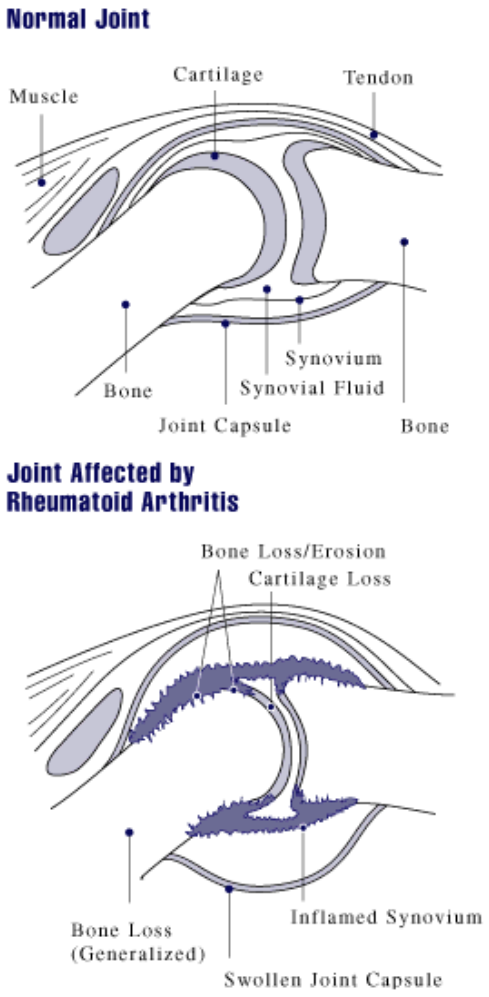
—EH (May 28, 2010) ◆

large joint

Doctor/Patient Disagreements on RA

My hand hurts. No it doesn't. OK, so it probably wasn't that extreme. But, interestingly, researchers from the University of California, San Francisco (UCSF) found that nearly one-third of rheumatoid arthritis (RA) patients differed from their physicians in assessment of their disease severity. This issue was most prevalent in patients with depressive symptoms, and those who had poor overall function. The study is the first to examine the possible association of patient language or mood with discordance, both of which can interfere with communication.

Led by Jennifer Barton, M.D., of the UCSF Department of Medicine, Rheumatology Division, the team recruited 223 participants, of which the mean age was 53. Women comprised 88% of the sample; the ethnic breakdown of participants was 45% Latino, 27% Asian/Pacific Islander, 16% Caucasian, 10% African American, 2% American Indian or other.



Rheumatoid Arthritis Joint / Wikimedia Common

"We found clinically meaningful differences between patient and physician assessments of RA disease severity in 36% of cases," confirmed Dr. Barton in the news release. "In an overwhelming majority (85%) of these discordant pairs, the physicians' assessments underscored the patients' assessments." The team found that the mean Visual Analogue Scale score for global disease severity was 46 for patients and 31 for physicians.

Depressive symptoms were common with 30% of participants exhibiting major depression, and these patients had greater odds of discordance with their physicians than those who were not depressed. Researchers noted a lower level of patient-doctor discordance in those patients who had a higher swollen joint count, but discordance persisted in those patients with poorer functional status.

Dr. Barton told *OTW*, "With respect to language, in our multivariate analysis to identify patient factors associated with positive discordance (where the patient scores his or her disease activity as higher or worse than the physician) we found that Cantonese/Mandarin language was associated with lower odds of discordance. This may in fact be a statistical artifact or related to the quality of our Cantonese/Mandarin in-person interpreter in the clinic. When we lowered the threshold of discordance from >25mm to >10mm, we did see an association of non-English language with positive discordance, as one might expect. Having language discordance (the patient and physician do not speak the same language) with one's physician is a potential barrier to effective communication."

She also commented to *OTW*, "With respect to mood, we found that for every 5-point increase in the Patient Health Questionnaire-9 (PHQ-9), subjects had a 1.62 greater odds of discordance with their physicians. Therefore, greater depressive symptoms were associated with higher odds of discordance when adjusting for age, gender, clinic site, language, HAQ score, swollen joint count and clustering by physician."

—EH (June 4, 2010) ◆

large joint

Amgen Submits BLA for Denosumab

Amgen Inc. is loading the big guns to go after tumors that spread to bone. The company has announced the submission of a Biologics License Application (BLA) to the FDA for denosumab, a subcutaneous RANK Ligand inhibitor. Included in the submission is clinical experience from nearly 6,900 patients across 18 clinical studies, including approximately 5,700 patients with advanced cancer in the three, pivotal, Phase 3, head-to-head trials versus Zometa (zoledronic acid).


Giant cell bone tumor in the head of the 4th metacarpal of the left hand / Wikimedia Commons

As indicated in the news release, cancer that reaches bone will weaken and destroy the bone around the tumor, often producing serious clinical consequences such as fractures, spinal cord compression, or the need to receive radiation or surgery to bone. The RANK/RANKL pathway is believed to play a central role in cancer-induced bone destruction, regardless of cancer type. According to Amgen, denosumab is the first therapy to target this important pathway.

"We believe that denosumab will offer substantial benefit to cancer patients suffering from bony metastases," said Roger M. Perlmutter, M.D., Ph.D., Executive VP of Research and Development at Amgen, in the news release. "Denosumab, administered monthly as a 120 mg dose subcutaneously,

large joint

demonstrated consistently similar or greater efficacy in clinical trials when compared to zolendronic acid, offering the potential to improve on the current standard of care. One potential advantage of denosumab is that dose adjustments resulting from declining renal function are not necessary."

Amgen plans to follow up this move with marketing applications in the European Union, Switzerland, Canada and Australia, and also in Japan, working with its licensing partner, Daiichi-Sankyo.

This BLA represents the second marketing application for denosumab that has been submitted to FDA; denosumab is currently being reviewed under the trade name Prolia for conditions related to bone loss. For that application, the FDA has set a corresponding Prescription Drug User Fee Act action date of July 25, 2010.

Commenting to *OTW* was Roy Baynes, M.D., Ph.D., VP of Global Development at Amgen, who noted, "Bone metastases occur in more than 1.5 million patients with cancer worldwide and frequently result in significant morbidity. Results of the denosumab phase 3 studies show that denosumab can reduce or delay the serious complications of bone metastases in patients with advanced cancer as well as or better than the current standard of care. Denosumab is administered as a convenient subcutaneous injection, and in the pivotal studies was also generally well tolerated."

—EH (June 3, 2010) ◆

Tweeting From the OR

Just about a year since a hospital in India was the first to broadcast a knee replacement surgery on Twitter, one by one, hospitals in the U.S. are jumping on the bandwagon and each new month seems to find another hospital becoming "the first in its region" to share a surgery over this social medium.

Just recently St. Joseph's Hospital Health Center in Syracuse, New York, for example earned the distinction for being the first hospital in Central New York to "tweet" in the OR. Orthopedic surgeon Dr. Seth Greenky performed a total knee replacement surgery that also included the use of platelet-rich plasma. His brother, Dr. Brett Greenky, also an orthopedic surgeon observed and manned the laptop, providing constant updates…in of course 140 characters or less. Many of the tweets included play-by-play photos via TwitPics.

Here's just a few of the tweets that were broadcast during this surgery:

The thing that looks like a gun is a pulse irrigator--like a power washer for your car--which allows us to wash and suck the fluid & debris.

Actual implant now in place & bone cement being cleaned out of way. Next pic is of cement on femur. Looks like dollups of icing on cake.

Upcoming pic is of component box which shows implant . This is a gender specific or "girl" version of the implant.

The doctors believe this is an excellent medium for patient education and can give the general public access to real-time surgical procedures, something they'd rarely have an opportunity for otherwise. But with warnings about the graphic nature of some of the gorier pictures, maybe hospital PR people should wonder whether this is effective marketing or shock therapy. Afterall, do we really need to see the garage shop-looking instrument that the surgeon is wielding? Or the green putty that's needed to affix a replacement knee?

(Twitter Logo/Knee Replacement Surgery/Wikimedia Commons)

On the flipside, viewers seem to be having mixed reactions, with many comments voicing concern over the surgeons' ability to concentrate. But most of the physicians that Tweet surgeries reassure viewers that only the doctors and assisting staff who are not working on the patient at the time post comments. Still what happens when the semi-private event of surgery joins the public forum of social media? Will a new class of celebrity doctors arise? Will doctors be looking for their close-up in the operating room, or is this just the next technological advancement beyond the well-worn surgical theater?

Obviously many hospitals are betting on social media's power, with some estimates showing over 500 hospitals with Twitter accounts, which makes this the most popular of the social media giants for the medical field, followed closely by Facebook and then distantly by YouTube and blogging respectively.

—JR (June 1, 2010) ◆

large joint

Compression Device Cuts VTE Risk

After promising data was unveiled just prior to this year's AAOS conference, Medical Compression Systems is riding the wave of interest in its ActiveCare+S.F.T compression device and positioning it in health centers for the prevention of VTE after orthopedic surgeries.

The Israeli-based Medical Compression Systems, Inc. (MCS) recently announced that its ActiveCare + Synchronized Flow Technology (S.F.T.) compression device will now be offered at four major U.S. medical centers for orthopedic procedures. The centers, located in Missouri, Ohio, Oregon, and Minnesota are the latest to begin using the device for the prevention of venous thromboembolism (VTE).


(ActiveCare+Synchronized Flow Technology/Medical Compression Systems, Inc.)

MCS is reporting that it expects its penetration rate to reach 20% for the first year of introduction at these sites. And the company is looking to gain a foot in the door at other medical centers as well, with MCS' CEO Adi Dagan pointing out the excellent timing of their study data release just before the 2010 AAOS (American Academy of Orthopaedic Surgeons) conference, helping to generate significant buzz.

The multicenter, prospective, randomized, controlled study

looked at 410 patients and showed ActiveCare+S.F.T used alone to be just as effecting as enoxaparin injections. The study appeared as the lead article in the March 2010 issue of *Journal of Bone and Joint Surgery,* also showing the additional benefit of a decrease in bleeding, when compared with Lovenox injections in hip arthroplasty.

Ambaw Bellete, President of MCS, Inc., says that one of the key benefits to the product is that it is much more user friendly for the patient than injections. "There's very little education needed compared to injection therapies and there aren't the bruising and inflammation issues."

But Bellete says there are also perks for the orthopedic surgeon, who can clearly tell precisely how the device is being used by the patient, thanks to a data storage system within the device. "It can track compliance and will tell you what percentage of time the patient used the device. So nurses, patients and physicians can all have access to this information very easily."

Bellete says that the ActiveCare + Synchronized Flow Technology works in a cascade process in synch with the patient's breathing. "On the exhale, compression happens and there is a sensor in the sleeve and pressure is applied at just the right moment." Because of the timing the pressure is significantly low, Bellete even compares it to a light touch someone on a playground swing might feel when they are at the highest point in their upswing. And with the device weighing in at just under a pound and a half, hospitals and patients are also seeing perks in mobility features another benefit that contributes to better compliance rates compared with injections.

—JR (May 27, 2010) ◆

large joint

Vertebral Fractures, Hospitalization, and QoL

Osteoporosis can change your lifestyle, for sure. But being hospitalized for an osteoporotic vertebral fracture, well, that may be another issue entirely. There is new research from the Karolinska Institutet in Sweden regarding the ongoing project known as The International Costs and Utilities Related to Osteoporotic Fractures Study (ICUROS). The study, recently presented at the World Congress on Osteoporosis 2010, found that patients who were hospitalized as a result of their vertebral fractures had a significantly larger quality of life reduction than non-hospitalized patients. The results support the previously reported large decrease in quality of life that occurs as a result of vertebral fractures.

Vertebral fracture/Wikimedia Commons

The reasons for this need further exploration, however according to Fredrik Borgström, Ph.D., who said in the news release, "The existence of co-morbidities among the hospitalised fracture group and higher severity of fractures are likely reasons."

Dr. Borgström told *OTW*, "The purpose of ICUROS is to investigate the consequences of osteoporosis-related fractures in terms of costs and health related quality of life (QoL) from an international perspective. Patients that have sustained an osteoporosis related fracture (primarily hip, wrist and vertebral) are included and followed for 18 months. During this period information regarding costs and QoL are collected. Currently, 10 countries are including patients and about 3,000 patients have been included so far. The aim is to collect about 600 fractures per country. More information can be found on the study web site (www.icuros.org)."

Dr. Borgström also commented to *OTW,* "The results presented at the conference were based on an interim analysis. The findings and its reasons will be further analysed when the full data set from the ICUROS is available."

—EH (May 27, 2010) ◆

extremities

Statins and Tendon Ruptures

Inflated cholesterol and inflamed tendons…both are problematic for many Americans. Researchers from Michigan State University are looking into the role that statins, widely taken by patients trying to lower their cholesterol, play in causing disabling tendon ruptures.

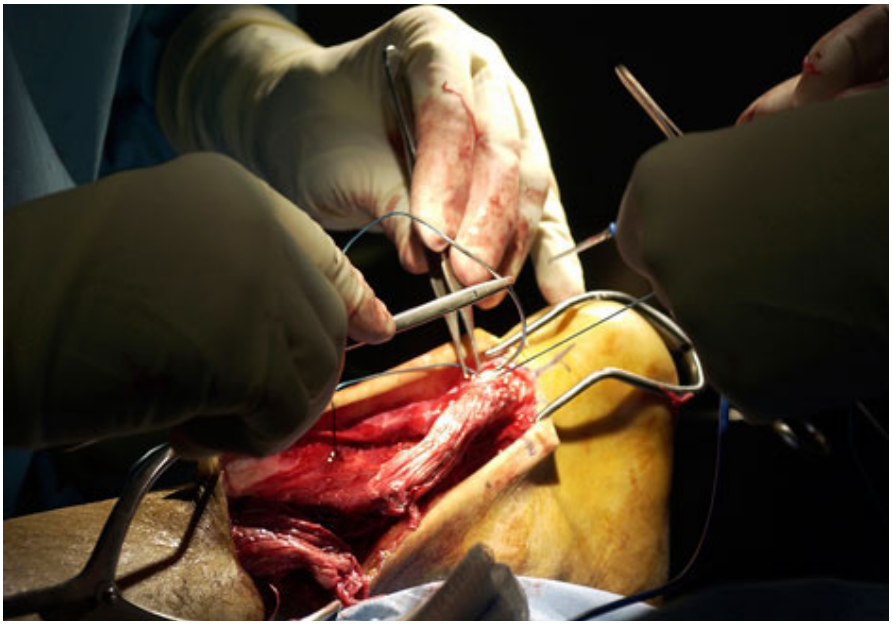
The study, funded by a grant from the Blue Cross Blue Shield of Michigan Foundation, is being led by Francesca Dwamena, M.D., an Associate Professor in the College of Human Medicine's Department of Medicine.

"Statins are such commonly prescribed medications, and the number of statin-users is on the rise," Dwamena said in the news release. "It is important for physicians and patients to be aware of all the risks. We need to find out definitively if statins predispose patients to this disabling complication."

Dwamena, who noted that statins inhibit certain proteins that are required for remodeling of tendons, set out with her team to confirm the results from a pilot study that found increased tendon ruptures in women. With a large population-based outlook, the researchers also will assess the effects of dose, duration and type of statin on tendon rupture.

Ultimately, more than 100,000 Blue Care Network enrollees between 2000 and 2009 will be included. The analysis is expected to take about one year.

Dr. Dwamena told *OTW*, "We will compare rates of tendon rupture in ~30,000 BCN enrollees who were prescribed statin rupture during the study period (2003 – 2009) to rates in 60,000 age-, sex-, date of enrollment- matched controls to ascertain whether statin use increases the risk of tendon rupture."



Repair of the ruptured achilles tendon /Wikimedia Commons

She also commented to *OTW*, "If findings from our preliminary study are confirmed, orthopedists will need to consider the possibility of statin as a cause of tendon ruptures. They may also need to advise patients who are taking statins and their primary care providers on how to prevent both spontaneous and traumatic tendon ruptures."

—EH (June 3, 2010) ◆

legal & regulatory

FDA Announces Innovation Workshop

The FDA is planning a public meeting on June 24, 2010, to get input on identifying the most important unmet public health needs and to determine what barriers exist to the development of medical devices that can address those unmet needs.

Council on Medical Device Innovation

A May 27 announcement from the FDA's Center for Devices and Radiological Health (CDRH), says the Center wants to, "facilitate device innovation through loosening of regulatory practices, establishing a Council on Medical Device Innovation to identify unmet public health needs and obstructions to medical device development where action by the federal government can have an effect."

This continues an FDA offensive to show the agency is not becoming overly risk adverse and takes its mission of promoting medical innovation for the benefit of patients as seriously as it takes its mission of protecting public health.

The announcement noted that "unnecessary barriers to market may exist either due to market failures or regulatory inefficiencies" and that those barriers may be "out of proportion to what is warranted based on the public health needs."

The workshop will run from 8 a.m. to 5 p.m. at the Hilton Washington DC/North Gaithersburg, Maryland.

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Persons interested in attending the meeting must register by 5 p.m. on June 10, 2010. You've got until July 23, 2010 to submit electronic or written comments.

Registration

To register, go to: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm and select the appropriate meeting from the list.

Oral Presentation

If you want to make an oral presentation at the workshop, you must indicate this at the time of registration. You should identify which discussion topic you wish to address in your presentation and you must submit a brief statement that describes your experience and/or expertise relevant to your proposed presentation.

Participants are asked to provide their perspectives on priority areas in which medical device innovations can have the highest positive impact on public health. Participants will also be encouraged to comment on devices not being developed or redesigned due to barriers that the Federal Covernment can and should directly or indirectly remove or minimize.

The FDA contact person is Melanie Fleming, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5407, Silver Spring, MD 20993, 301-796-5424, FAX: 301-847-8510, melanie.fleming@fda.hhs.gov.

We've dealt with Melanie. She's very responsive.

—WE (June 3, 2010) ◆

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Idaho Orthopods Settle With DOJ

The Department of Justice (DOJ) reached a proposed settlement on May 28 with the Idaho Orthopaedic Society, an orthopedic practice group and five orthopedists that will, according to a DOJ press release, "prohibit them from conspiring with competing physicians in the Boise, Idaho, area to deny medical care to injured workers and to engage in group boycotts to obtain higher fees."

"Conspiracy To Gain Favorable Fees"

The Justice Department alleged that the defendants, "conspired to gain more favorable fees and other contractual terms by agreeing to coordinate their actions, including denying medical care to injured workers and threatening to withdraw from healthcare plans offered by Blue Cross of Idaho."

The government filed a civil antitrust lawsuit in Idaho against the Idaho Orthopaedic Society, Idaho Sports Medicine Institute and five individual orthopedists—Timothy Doerr, Jeffrey Hessing, John Kloss, David Lamey and Troy Watkins. At the same time, the department and the Idaho Attorney General's office filed a proposed settlement that, if approved by the court, would resolve the lawsuit.

According to the complaint, the conspiring orthopedists allegedly engaged in two antitrust conspiracies, which took place from 2006 to 2008.

In the first conspiracy, through a series of meetings and other communications, the orthopedists agreed not to treat most patients covered by workers' compensation insurance. They entered into a group boycott in order to force the Idaho Industrial Commission to increase the rates at which orthopedists were paid for treating injured workers. The Idaho Industrial Commission sets the fee schedule that determines the amount that orthopedists and other healthcare providers usually receive for treating patients covered by workers' compensation insurance. The boycott resulted in a shortage of orthopedists willing to treat workers' compensation patients, causing higher rates for orthopedic services.

Federal Courthouse - Boise, Idaho

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In the second conspiracy, all of the defendants, except David Lamey, and other conspiring orthopedists agreed to threaten to terminate their contracts with Blue Cross of Idaho. They jointly threatened to terminate their contracts to force Blue Cross of Idaho to offer better contract terms to orthopedists.

The proposed settlement will be published in the Federal Register. Any person may submit written comments concerning the proposed settlement within 60 days of its publication to Joshua H. Soven, Chief, Litigation I Section, Antitrust Division, U. S. Department of Justice, 450 Fifth St. N.W., Suite 4100, Washington, D.C. 20530. At the conclusion of the 60-day comment period, the court may enter the final judgment upon a finding that it serves the public interest.

Collaboration Lesson

This action should serve as a lesson for physician societies which have made veiled threats that physicians will drop out of the Medicare program if the Medicare physician reimbursement rate is not fixed. There may be a fine line between "reporting" on member surveys that show that physicians will drop out of the program and "conspiring" to cause such a boycott.

This is yet another example of physicians being treated differently than other citizens when it comes to the constitutional right of equal protection of the laws. There is no exemption of physicians in the Bill of Rights.

—WE (June 3, 2010) ◆

Medtronic Discloses Payments

Medtronic has begun voluntary posting of annual physician payments and disclosed that it paid more than $15.7 million in royalties and consulting fees to U.S. physicians in the first quarter.

Of that amount, $14.2 million went to orthopedic specialists and orthopedic surgeons. $13.9 million were for royalty payments. An additional $512,000 went to vascular and cardiac specialists, $495,000 to heart-rhythm doctors and $473,000 to neurosurgeons and neurologists.

Physicians Named

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There were 227 doctors and doctor groups that received consulting or royalty payments exceeding an aggregate $5,000 in the first quarter.

Tennessee neurosurgeon Kevin Foley, M.D. was one of the largest recipients and was paid $3.97 million in the quarter for a range of surgical plates, rods and screws used in spine surgery. A Louisville orthopedic surgery practice including Steven Glassman, M.D, received $2.38 million for spine-surgery products. St. Louis orthopedic surgeon Lawrence Lenke, M.D., was paid $832,000 for various spine-surgery products.

Foley reportedly told the *Wall Street Journal* that all the royalties were for spine-surgery inventions. Glassman reportedly said members of his group "were the primary developers of one of Medtronic's biggest products."

Medtronic chairman and CEO Bill Hawkins said, "Collaboration between physicians and industry remains crucial to innovation in the medical technology industry...it [collaboration] must be based on solid principles, in order to avoid the potential for real or perceived conflicts of interest. As an industry leader, Medtronic wants to be at the forefront of helping to establish best practices that will enhance patient and public confidence in the collaborative model."

Wisconsin U.S. Senator Herb Kohl, Chairman of the Senate Special Committee on Aging and a principal architect of the physician payment disclosure provisions in the health care bill said, "I appreciate Medtronic's voluntary decision to stay ahead of the transparency curve."

New Policies

The company also announced that it has developed a set of policies and procedures relating to physician collaboration and transparency that it is

implementing across all of its businesses and multiple physician specialty areas.

The policies include:

- A standardized needs-assessment process that verifies and documents the precise business need for specific physician services;
- Imposing limitations on the involvement of royalty-earning physicians in clinical studies, and on the total annual payments that can be made to individual physicians for providing services to the company.
- A services agreement, standardized across businesses, that documents in advance services to be provided by physicians and the fair market value payment to be made for the services;
- Systems linking each of these steps with documentation that the services have been satisfactorily completed and invoiced prior to payment.

The payments can be seen on Medtronic's physician registry at http://www.medtronic.com/about-medtronic/physician-collaboration/physician-registry/index.htm

—WE (June 2, 2010)◆

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Stryker/Wright Kiss and Make Up

Stryker and Wright Medical have been at each other's throats for ten years over Stryker's allegation that Wright's Advance knee implants infringed on an old Howmedica patent.

MassDevice reported on May 28 that the two companies have now asked a New Jersey federal judge to let them kiss and make up.

The federal court ruled last November that Stryker's original Howmedica patent was invalid. Wright then accused Stryker of "inequitable conduct" for failing to disclose the invalidating patent.

According to the report, the companies have asked Judge Garrett Brown Jr. of the U.S. District Court for New Jersey to dismiss the case with prejudice, subject to the terms of a licensing and settlement agreement, according to court documents. As part of the deal Wright agreed to drop the inequitable conduct charge and each side will pay its own legal fees.

To dismiss a case with prejudice means that a party's legal rights have been determined and lost.

Babies Myspace Graphics

—WE (May 28, 2010) ◆

THE PICTURE OF SUCCESS

Dr. James Gladstone

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

Dr. James Gladstone

He shrank from the sight of blood and at one point was a bit more European than American. Dr. James Gladstone, Co-Chief of Sports Medicine at Mount Sinai School of Medicine in New York, has led an intriguing life indeed.

Born in Geneva, Switzerland, to American parents, James Gladstone was accustomed to hearing "Bonjour" and "Gutentag." "My dad specialized in international labor law and established programs for African and South American countries. My mom, who was American-trained, was the first dental hygienist in Switzerland; she juggled work and bringing up two kids. The school I attended had students from 80 countries, so it was an environment where being broadminded was the norm. After living in Geneva for 18 years I decided that it was time to experience life in the U.S. Although I had always considered myself to be an American and had visited the U.S., I wanted to 'dig into' my native culture. The benefit to all of this internationalism? Things that may seem odd to some people just don't bother me as much. In fact, I feel that having such a broad exposure to different cultures has added an extraordinary dimension to my life."

But he had no such love for the study of mass and matter. "I was drawn to biology, but just detested physics… and hated the sight of blood. While I entered Dartmouth College in 1980 thinking about law, I kept returning to the idea that I wanted to work with people in a way that held some social benefit."

"Medical school was whispering in my ear, but I wasn't ready…I had to prepare for the time and dedication that it was going to require. I took my cold feet and worked at a biotech company for two years as a market researcher and product manager. One day I was on the phone selling and realized that I couldn't care less whether or not this individual made a purchase. I hung up and knew I was ready for medical school."

A twist of fate—and an extremity—would lead Dr. Gladstone toward orthopedics. "Between my first and second year at Tufts University School of Medicine I broke my ankle, went to the school's orthopedic clinic, and ended up meeting Dr. John Richmond, the head of sports medicine for Tufts. He is 100% the reason I am where I am today. I did research with him, and also got a chance to witness the incredible rapport he had with patients. At that point I could see a light into the future."

It was a future that would include certain aspects of his past. "While in medical school I went to Swaziland to work at a missionary hospital. Unfortunately, the people running the facility had created an 'us versus them' mentality and isolated themselves from the local populace. I had envisaged going there and being part of the community, but it didn't work out that way. Nonetheless, I quickly realized the desperate need for medical care so many people in this world have, and how much one can do with relatively few resources."

Entering residency in 1991 at Columbia-Presbyterian Medical Center's New York Orthopaedic Hospital, Dr. Gladstone found an environment of camaraderie and talent. "Our residency class was large—eight people—and we got along tremendously well. One of those who was instrumental in shaping what I did and how I did it was Dr.

David Roye, a pediatric orthopedist who just last year won the AAOS [American Academy of Orthopaedic Surgeons] Humanitarian Award. Watching him communicate with parents was amazing, and I learned, for example, how to put both a three-year old and his parents at ease. Dr. Mel Rosenwasser, Chief of Trauma, was another mentor, and was known for his availability and compassion. He never rushed anyone and was 100% dedicated to his patients. Dr. Evan Flatow, now my Chair, also made a tremendous impression on me with his encyclopedic knowledge of the shoulder joint and his love for discussing it."

"During residency I realized that I felt most comfortable having in depth knowledge in one particular area rather than being a generalist, something that goes along with my somewhat obsessive personality. Besides having been a lifelong athlete, the dynamic and constantly evolving field of sports medicine attracted me the most."

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In 1995 Dr. Gladstone was accepted into the Rolls Royce of sports medicine fellowships. "I was very fortunate to get the acceptance call from the American Sports Medicine Institute in Birmingham, Alabama, where I learned from the esteemed Drs. James Andrews and William Clancy. Dr. Andrews gave me the ability to get to the heart of the issue when assessing injuries. He insisted that we know how to distinguish patients who require surgery from those who just need more physical therapy. Dr. Clancy wowed me with his remarkable mind…he understands what he is teaching to an incredible degree."

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In 1996 Dr. Gladstone joined the Department of Orthopaedics at Mount Sinai as an assistant professor and specialist in sports medicine. Since then he has had a challenge familiar to those in academic medicine. "Balancing the clinical side of things—the part that runs the engine and pays the bills—with the need to have sufficient time for research, is an ongoing issue. Unfortunately, research takes place in the evenings and on weekends."

The research that Dr. Gladstone is most proud of involves a part of the shoulder that serves as a stabilizer—the rotator cuff. "My team and I looked at rotator cuff repairs from the point of view of the muscle. The traditional approach is to reattach the tendon to the bone, but we took a different course of action. If you think of the tendon as a cable, then if the muscle doesn't work it doesn't matter what happens to the cable. We took MRIs and looked at the condition of the muscle before the rotator cuff repair and then took MRIs a year later to determine what happened to the repair and to the muscle. Specifically, we are assessing muscle atrophy, as well as fatty infiltration (meaning that fat has developed within the muscle fibers). We found a direct correlation between muscle atrophy and fatty

infiltration and whether the repair did or did not hold. That has evolved as a real factor as to whether the rotator cuff should be repaired; it also has led to more preop patient counseling where we emphasize setting proper expectations of surgery."

His time in the lab now is dedicated to something that will enhance cartilage healing…cellular repair. "I am working with ProChon Biotech, an Israeli company, on a phase II FDA approved clinical trial (I have no financial interest in the project). ProChon's technology puts cells into a biologic scaffold and then we implant that into a defect in the knee. The idea is that you're not putting the cells into a hole and hoping to create a cartilage base over time…you're putting them into a 3-dimensional structure that the body can accept and convert into cartilage. The product, known as Biocart, incorporates into the scaffold a fibroblast derived growth factor. That, in turn, allows the patient to grow new cells in their own blood, a process supported by the fibroblast platform. This technology grows cells at a much faster rate; also critical is that this medium potentiates healthier cells to grow preferentially."

He continues, "ProChon has also developed a biologic sponge that is a combination of fibrin and Hyaluronate. The sponge is a latticework with micropores so the cells get distributed throughout the sponge in a 3D fashion…then each cell begins creating an extracellular matrix. The product's stickiness means that it adheres itself to the defect; it's also very easy to manipulate (push around, snip with scissors, etc.)."

Such advanced technology wasn't available on his recent mission to Haiti, however. There, it was low tech, save limbs, save lives. "The head of the ICU at Mt. Sinai is Dr. Ernest Benjamin, who is originally from Haiti. He went down right away, then called the Mt. Sinai administration and told them of the chaos 'on the ground.' The administration sent out an email asking for assistance and 70 healthcare providers and logistics personnel responded 'yes.'"

"We were glad to be under the auspices of the seasoned folks at Partners in Health because, when we arrived, we found that the hospital in Port-au-Prince was completely disorganized. Loaded with 2,500 lbs of supplies we were met with no running water, occasional electricity and no way to sterilize equipment. We settled on a policy of using as few instruments as possible to minimize the danger of injury. I recall one patient with a dislocated hip…every time we put it back in place, unless we kept it abducted it would fall out again. Normally you'd have a splint or brace, but we had to make do with two short leg casts and a broom stick. We took a broom, cut the handle, and incorporated that with the plaster into the casts. Every day we saw situations that were life threatening, something unusual in the world of orthopedics."

Whether returning from his Upper East Side practice or Port-au-Prince, Dr. Gladstone has a loving family to welcome him. "My wife Kate and I have two children who adore our family trips. I am so pleased the kids have a mother who dedicates her time to helping others. Kate manages programs in Africa for Malaria No More, a wonderful non-profit organization that saves lives every day. On the less serious, stress relieving side of things, our family enjoys hitting the ski slopes together and decompressing."

Dr. James Gladstone…embracing the global challenges and rewards of healing with both the heart and the mind.

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