VOLUME 6, ISSUE 27 | AUGUST 24, 2010

Orthopedics This Week

week in review

4 **510(k) Retooling-Part 2: Increased Industry Burden** ◆ FDA recommendations to retool the 510(k) program will likely add to industry's burden to bring innovative products to market. In Part Two of our three part series, law professor Ralph Hall and AAOS member Bill Mihalko, M.D., give their opinions on what these recommendations will mean for industry and physicians.

9 **Spinal Implant Sales Growth Moderating** ◆ Spinal Implant sales growth was about 1% for the second quarter although some companies, notably NuVasive, Medicrea, and Alphatec reported strong sales growth. Pricing pressures and other issues will, we expect, keep over all spine market growth at 4% in 2010. For company forecasts read on.

14 **Know Thy Patient: Psych Testing for Spine** ◆ There are some patients who are not mentally healthy enough to undergo spine surgery, say our experts. And a particular screening tool—psychological testing—is not widely used. How might such tools aid orthopedists in surgical decision making?

picture of success

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breaking news

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For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: By and large, revenue growth rates seem to be settling into a range that is somewhere between last summer and last winter. Call it a 4-6% overall orthopedic rate of sales growth. Better than the U.S. economy overall and, of course, cash flows are stronger. Demand for orthopedic products and services is basically inelastic.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	13.51%	0.20%	No company in the orthopedic universe has OFIX's combination of low valuation and rising cash flows and profitability.
2	6	Integra LifeSciences	15.37	(1.01)	Armed with nearly $600 million in new credit facilities, IART has some fresh powder to snap up cheap ortho companies.
3	2	Kensey Nash	38.72	0.48	Consensus is for 25% earnings growth on just 4% sales growth. Key for KNSY is top-line growth.
4	3	Johnson & Johnson	27.1	0.27	If this economy is truly headed for a double dip recession, JNJ is a classic haven in the storm.
5	4	Medtronic	32.48	(7.28)	The OSTE deal signals many things—including the new MDT in Memphis. The old crowd would never have bought OSTE.
6	5	CONMED	8.76	7.39	After last quarter, does CNMD have the fire power to crush earnings estimates again? Wall Street consensus is "no."
7	8	Smith & Nephew	22.83	(1.39)	Good news on the legal front from Germany. Profit margin gains are probably the key to this company's valuation.
8	7	Zimmer	27.69	(9.66)	Expectations remain low for Big Blue, but in fact conditions are improving consistently.
9	10	Stryker	24.71	(10.68)	SO glad SYK took our advice and parted with some of its cash. $1.4 billion for BSX's neuromodulation business. Up one spot.
10	9	Symmetry	11.48	(8.12)	Profitability slipped in the second quarter and suddenly, sellers came out of the woodwork. Down one spot this week.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Osteotech	OSTE	$6.39	$116	105.5%
2	Capstone Therapeutics	CAPS	$0.91	$37	26.4%
3	TiGenix	TIG.BR	$2.55	$79	14.6%
4	TranS1	TSON	$2.59	$54	13.1%
5	CONMED	CNMD	$18.61	$536	7.4%
6	Kensey Nash	KNSY	$22.86	$222	0.5%
7	Johnson & Johnson	JNJ	$58.74	$161,800	0.3%
8	Orthofix	OFIX	$29.83	$526	0.2%
9	Synthes	SYST.VX	$116.33	$13,805	-0.3%
10	Integra LifeSciences	IART	$36.18	$1,050	-1.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Alphatec Holdings	ATEC	$2.24	$196	-51.1%
2	RTI Biologics Inc	RTIX	$2.32	$127	-17.4%
3	Exactech	EXAC	$14.12	$182	-11.4%
4	Stryker	SYK	$45.81	$18,180	-10.7%
5	Mako Surgical	MAKO	$10.57	$357	-9.7%
6	Zimmer Holdings	ZMH	$49.82	$10,010	-9.7%
7	Wright Medical	WMGI	$14.58	$572	-8.8%
8	Symmetry Medical	SMA	$9.50	$341	-8.1%
9	Medtronic	MDT	$34.77	$37,650	-7.1%
10	Orthovita	VITA	$1.76	$135	-5.4%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$34.77	$37,650	10.49
2	Exactech	EXAC	$14.12	$182	11.41
3	Zimmer Holdings	ZMH	$49.82	$10,010	11.86
4	Kensey Nash	KNSY	$22.86	$222	12.41
5	Johnson & Johnson	JNJ	$58.74	161,800	12.45

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$44.60	$7,930	61.42
2	Synthes	SYST.VX	$116.33	$13,805	32.51
3	RTI Biologics Inc	RTIX	$2.32	$127	30.34
4	NuVasive	NUVA	$31.66	$1,250	26.01
5	Symmetry Medical	SMA	$9.50	$341	24.81

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$29.83	$526	0.58
2	CryoLife	CRY	$5.47	$154	0.61
3	NuVasive	NUVA	$31.66	$1,250	0.64
4	Exactech	EXAC	$14.12	$182	0.71
5	Integra LifeSciences	IART	$36.18	$1,050	1.02

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$18.61	$536	15.22
2	Johnson & Johnson	JNJ	$58.74	$161,800	1.94
3	Symmetry Medical	SMA	$9.50	$341	1.72
4	*Average*			*$10,668*	*1.70*
5	Alphatec Holdings	ATEC	$2.24	$196	1.70

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	RTI Biologics Inc	RTIX	$2.32	$127	0.75
2	CONMED	CNMD	$18.61	$536	0.75
3	Orthofix	OFIX	$29.83	$526	0.97
4	Exactech	EXAC	$14.12	$182	0.99
5	Symmetry Medical	SMA	$9.50	$341	1.03

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.55	$79	76.34
2	Mako Surgical	MAKO	$10.57	$357	10.81
3	Synthes	SYST.VX	$116.33	$13,805	7.65
4	NuVasive	NUVA	$31.66	$1,250	2.91
5	Kensey Nash	KNSY	$22.86	$222	2.76

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510(k) Retooling-Part 2: Increased Industry Burden

By Walter Eisner

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In Part One of our review of FDA recommendations to fix the 510(k) program we asked if these suggestions were a solution in search of a problem. In Part Two, our legal and medical experts offer up their views on the burdens these recommendations will add to industry and physicians.

Here's a preview: The recommendations will likely cause more industry headaches in the development of innovative device technologies.

Something's Gotta Be Done

After the ReGen Biologics fiasco, internal scientist whistleblowers and industry criticism that the 510(k) program had become unpredictable, the agency, under new leadership, decided that changes were needed.

The new Director of the Center for Device and Radiological Health (CDRH), Jeff Shuren, M.D., convened 10 internal workgroups and asked the Institute of Medicine (IOM) to conduct an external review of the program.

The internal review was completed last month and on August 3, the agency released 70 recommendations to retool the clearance program. The IOM's recommendations are expected next summer.

Shuren said the recommendations were designed to help the agency achieve three main objectives: foster innovation, increase predictability and enhance safety.

In Part One of our series, we highlighted the evidence University of Minnesota Law Professor Ralph Hall and his research team presented to the IOM earlier this year regarding the safety record of the program. Hall's research showed that during a five-year period, 99.78% of all 510(k) applications did not result in a product recall.

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"Shuren said the recommendations were designed to help the agency achieve three main objectives: foster innovation, increase predictability and enhance safety."

William Mihalko, M.D.

Viewpoints From the Lawyer and the Physician

Here in Part Two, we ask Professor Hall and AAOS (American Academy of Orthopaedic Surgeons) member William Mihalko, M.D., to give their opinions on whether or not the recommendations hit the mark of fostering innovation and making the clearance process more predictable for industry and physicians. Mihalko is one of the Academy leaders monitoring the IOM proceedings. He will have a significant voice in how the Academy responds to the agency's recommendations.

Below are CDRH Director Shuren's highlighted recommendations. After each recommendation, Dr. Mihalko offers his opinion on whether the recommendation will enhance or impede a physician's ability to provide patients with new and better medical procedures.

I. Fostering Medical Device Innovation

1. Streamline the premarket pathway for lower-risk novel devices (de novo pathway).

The de novo classification process is a regulatory pathway for novel devices that cannot be cleared through the 510(k) process because they lack a clear predicate, but do not warrant a premarket approval (PMA) level of review. This process is associated with lengthy review timeframes and nontransparent data requirements.

The FDA recommends major reforms in the implementation of the de novo process, including steps to streamline the process and clarify the Center's evidentiary expectations for de novo requests.

Mihalko: **Thumbs up**.

2. Enhance science-based professional development for CDRH staff.

The FDA recommends enhanced training and professional development for agency staff. The agency recommends these efforts include providing greater opportunities for staff to stay abreast of recent scientific developments and current clinical practice.

Mihalko: **Thumbs up**.

3. Establish a network of external experts.

The FDA recommends continued efforts to develop a network of external experts using web-based social media technology. Such a network would allow staff to leverage outside knowledge in order to answer scientific questions without requiring experts to serve in an advisory capacity.

Mihalko: "This would be difficult to predict due to the issues impeding external reviewers from accessing previous data and reports which would aid in the external review process."

II. Enhancing Predictability

4. Establishing "Class IIb."

Most concerns raised have involved the small subset of devices for which staff requested clinical information midway through a review. The submitter thus had no advance notice that such information would be needed and this has lead to avoidable delays.

The FDA recommends the development of guidance to define a subset of Class II devices called "Class IIb", for which clinical or manufacturing

information would typically be necessary to support a substantial equivalence determination.

Mihalko: **Thumbs up**. He says that in orthopedics, "multiple devices need to be reclassified and this may give an avenue for a quicker reclassification of devices from Class III." As an example he cites mobile bearing knees.

5. **Create a new "Notice to Industry" tool to communicate changes in premarket expectations.**

The FDA may need to modify premarket evidentiary expectations for certain types of devices as science evolves and new information emerges about the risks and benefits of a device type. Current law has not allowed the agency to communicate such changes in a rapid manner. Instead, manufacturers typically learn of these changes through individual engagement with the Center, often not until after they have prepared their premarket submissions.

The FDA recommends that CDRH begin to use standardized "Notice to Industry" letters to quickly communicate when the agency has changed regulatory expectations. This would apply to a particular group of devices, the general nature of the change, and the rationale for the change.

Mihalko: No impact on physicians.

6. **Clarify "substantial equivalence" review standards.**

Insufficient clarity in the definition of "substantial equivalence" has contributed to inconsistency in the agency's decision making, internal and external debates, and delays in review.

The FDA recommends that CDRH more clearly define these terms in guidance and training for review staff and industry.

Mihalko: **Thumbs up**. He believes this will allow applicants to provide the necessary information upfront to reviewers and minimize the need for the FDA to ask further questions after the initial application process.

7. **Establish a Center Science Council.**

The FDA recommends the establishment of a Center Science Council, under the direction of the Deputy Center Director for Science. This body would be responsible for overseeing science-based decision making, including: premarket reviews, periodical auditing decisions and assessing program performance. It would also be in charge of and acting as a resource for staff on scientific questions, supporting greater consistency in decision making and the treatment of cross-cutting issues.

(Note: The agency has already established this Council. It is headed by Bill Maisel, M.D. Part Three of our series on the clearance program overhaul will focus on this Council and the potential impact on industry and physicians.)

Mihalko: **Thumbs down**. "More levels of review are not necessary," says Mihalko. He supports better training and retention of reviewers,

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III. Improving Patient Safety

8. Require more upfront submission of safety and effectiveness data.

The FDA recommends requiring submitters to provide a summary of all scientific information known, or that should be reasonably known, regarding the safety and/or effectiveness of the device.

Under current regulations relevant information may not be included upon initial submission, even when that information is readily available to the submitter. This would allow review staff to make decisions that consider all relevant safety and effectiveness information. Shuren says this should not present a significant additional burden for submitters.

Mihalko: **Thumbs down**. He says there is no evidence, especially in orthopedic devices, that a current safety issue exists. He says that through guidance and document development, the safety issues will become even more negligible.

9. Create a searchable online public database.

The FDA recommends the enhancement of the agency's web-based public resources to provide ready access to meaningful, up-to-date device information.

The FDA is also recommending improvements to the Center's current online database, so that it can serve as a searchable one-stop source for detailed information about cleared devices, including photographs and design schematics, summaries of FDA review decisions, and up-to-date device labeling. Such a database would allow prospective submitters to identify appropriate predicate devices and provide practitioners and patients with more comprehensive and current information to support the safe use of cleared devices.

Mihalko: **Thumbs up**.

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10. Seek rescission authority and clarify when a device should not be used as a predicate.

Concerns have been raised that current FDA regulations allow for predicate comparisons that are insufficient to provide reasonable assurance that a device is safe and effective.

The FDA recommends the development of guidance to identify situations in which a device should not be used as a predicate. In addition, the FDA recommends that CDRH consider issuing a rescission regulation.

Mihalko: **Thumbs up**.

Professor Ralph Hall

Industry Burden

Professor Hall didn't buy Shuren's highlighted list and gave us his own list, based on the ten internal task forces' agenda. Hall evaluated the potential of these recommendations increasing industry burden.

1. Predicates - Increases
2. Indications - Increases
3. New technology - Increases
4. De novo - Neutral
5. Evidence - Increases
6. Modifications - Increases
7. Standards - Neutral
8. Bundling - Increases
9. 3rd party review - Increases
10. Postmarket data - Increases

Professor Hall's main complaint is that he sees the FDA's recommendations as increasing the burden on industry without increasing the level of safety of devices in any meaningful way. "The FDA clearly focused on perceived safety issues," says Hall.

Hall adds that many of the proposals lack specific language and express ideas without details. As such, the actual impact of the proposals is not certain. As an example he notes that the FDA is proposing multiple ways to limit the availability of predicates without defining what a "bad" predicate is or what administrative process would be used to make such a determination.

For Hall, this reinforces the need for a second round of public input.

For now, we've learned the recommendations are addressing a nonexistent safety problem and will likely add a burden on innovation. That leaves recommendations to upgrade agency staff and streamline their own processes as the remaining ideas for increasing the predictability of the 510(k) process.

To read the recommendations yourself. You've got until October 4, 2010 to let the agency know what you think.

Orthopedics This Week

VOLUME 6, ISSUE 27 | AUGUST 24, 2010

Spinal Implant Sales Growth Moderating

By Matt Menze, PearlDiver Spine Analyst

GaylaLin, 2008/Wikimedia Commons

Spine industry suppliers sold $2.283 billion of products in the second quarter (2Q10), falling short of our forecast of $2.418 billion. We have therefore decreased our forecast for the year from $9.490 billion to $9.150 billion, or 4.1% year-over-year (YOY) growth. The rate of spine industry revenue growth has declined sequentially for the last four quarters. Industry revenues grew 11.1%, 9.9%, 8.6%, and 6.4%, respectively, for 2Q09, 3Q09, 4Q09 and 1Q10. This was capped by just 0.9% growth this quarter.

Three major trends, we believe, are affecting the outlook for future growth in spinal implant sales:

- *Continued hospital pricing pressure exacerbated by "me too" products*—Orthopedic manufacturers reported that prices for spinal implants declined by mid-single digits, which is consistent with last quarter's commentary. However, in contrast to last quarter, mix and procedure volumes are not offsetting price decreases and that has produced meager year-over-year revenue growth for the second quarter of 2010. Exacerbating the hospital pricing pressure is, we believe, a general lack of differentiation among products. As a result, hospitals that are attempting to cut implant costs were successfully able to switch to lower cost suppliers for some types of spinal implants.

- *NuVasive's argument on "legacy" products and open surgery*—NuVasive believes that MIS treatments for spine disorders will one day comprise 80% of the market. While 80% is a bold number, we agree that the market will continue to move decisively in that direction, and companies with product portfolios which emphasize MIS will have some greater measure of pricing and product mix power.

- *Private payer reimbursement pushback is moving beyond new technologies*—Private payers are scrutinizing traditional spine fusion/surgery claims and focusing on the "medical necessity" of the procedure before granting reimbursement. Payers may be more inclined to reimburse for spinal stenosis and spondylolisthesis cases than discogenic back pain.

Sequential Revenue Growth Declines for Four Straight Quarters

In Table 1 we list and rank our 2011 and 2012 quarterly sales estimates for each major spinal implant company. As the table illustrates, sales of spinal implants and their related biologic products rose just 9% in 2Q10, down from 11.1% growth in 2Q09. For all of 2010, we estimate that spine revenues will rise 4.1% to $9.150 billion.

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

Revenue ($ millions)	1Q 10	2Q 10	3Q 10E	4Q 10E	2010E	2011E	2012E
Medtronic	880	865	835	834	3,414	3,465	3,535
DePuy	258	260	248	248	1,014	1,074	1,128
Synthes	245	245	242	255	987	1,040	1,095
Stryker	141	140	139	156	576	602	635
Zimmer	60	58	59	64	241	254	269
Orthofix/Blackstone	72	77	73	79	300	327	357
Biomet	56	62	61	62	241	253	265
NuVasive	109	120	130	142	501	606	728
Globus	76	85	85	102	348	435	598
Alphatec	38	45	49	56	189	221	254
Pioneer Surgical	32	31	32	33	128	148	148
K2M	27	25	24	27	103	126	152
Osteotech	11	12	12	13	47	51	54
Orthovita	24	24	25	26	99	110	125
ArthroCare	4	5	4	6	19	20	22
Scient'X	15	-	-	-	-	-	-
SeaSpine	18	19	18	20	75	86	98
RTI Biologics	7	8	10	11	35	35	43
U.S. Spine	12	12	12	13	50	58	65
Integra Spine	11	12	12	12	46	52	59
Trans1	7	7	7	7	28	29	31
LDR	13	12	11	13	49	61	77
Spinal Elements	8	8	8	8	31	37	43
MEDICREA	5	6	6	7	23	30	40
Exactech (Altiva)	2	2	1	2	7	8	8
Other	150	145	150	155	600	684	773
Total Revenues	$2,281	$2,283	$2,252	$2,349	$9,150	$9,811	$10,600
Total Growth	6.3%	0.9%	3.8%	6.1%	4.1%	7.2%	8.0%

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

Table 2 displays market gains and losses for the quarter. We estimate that NuVasive and Globus gained 1.3% and 0.9%, respectively, in the quarter due to strong revenue growth. Medtronic continues to lag market growth rates and may not return to market growth until 2012.

Table 2: Market Share Changes

Company	2Q09	2Q10	Est. Market Share Δ
NuVasive	**3.9%**	**5.2%**	1.3%
Globus	2.8%	3.7%	0.9%
Alphatec	**1.4%**	**2.0%**	0.6%
Orthofix	3.1%	3.4%	0.2%
Synthes	**10.6%**	**10.7%**	0.2%
Biomet	2.7%	2.7%	0.0%
Trans1	**0.3%**	**0.3%**	0.0%
Stryker	6.2%	6.1%	(0.1%)
Zimmer	**2.8%**	**2.5%**	(0.3%)
DePuy	11.9%	11.4%	(0.5%)
Medtronic	**40.5%**	**37.9%**	(2.6%)

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

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Alphatec Spine, Inc.

Alphatec posted strong revenue growth in 2Q, but did not meet consensus expectations. On August 6, Alphatec reported that second quarter revenues grew 55% to $38.4 million (up from $29.4 million in 2Q09). Please note that Alphatec has divested in one of its Japanese subsidiaries and is reporting its operating results as discontinued operations in 2009 and 2010. Revenues grew 10% on a pro forma basis. Revenue growth was hampered by integration challenges regarding the Scient'X acquisition, an unanticipated slowdown in Europe, and continued pricing pressure (mid-single digits). Alphatec revised full-year 2010 revenue guidance to $188 million–$193 million, down from $220 million–$225 million.

For 3Q10, we estimate that sales reach $49 million and full-year revenues to be $188.9 million (10.6% YOY growth on a pro forma basis).

Biomet, Inc.

Biomet's second quarter spinal repair and implant revenues (fiscal 4Q10) increased just 0.8% YOY to $62 million, falling short of PearlDiver estimates of $65 million. U.S. sales rose 1%. Spine was the slowest growing unit at Biomet in the quarter, lagging even the struggling dental business. The spine stimulation business grew during the quarter, but was offset by declines in the spine hardware and biologics businesses. During the conference call held on July 13, 2010, management noted that it had seen mid-single-digit price declines in spine, which were offset by increased volume and mix. However, the business did face tough year-over-year comparisons as the quarter marked the anniversary of revenue gains driven by high volume producers hired in 2009. The company expects the Polaris Deformity System, the Trivium Derotation System, and the Solitaire C system to be growth drivers in the future.

We estimate 3Q10 (Biomet's 1Q11) revenues will be $61 million (2.9% YOY revenue growth) and calendar year 2010 revenues to be $240.8 million (3.1% YOY revenue growth).

Medicrea

Medicrea, which we began covering last quarter, posted strong second quarter revenue growth. Revenues rose 36% in 2Q to €4.5 million, equating to about $5.6 million. Revenues were driven by the PASS-LP fixation system, which treats deformity. There are currently over 50 surgeons using the product, and Medicrea expects to continue gaining new surgeon users throughout the year. The company raised €2.5 million in additional capital in the second quarter as well. We forecast 37.4% revenue growth for 2010 which, we believe will equate to €18 million, or $23 million. We estimate third quarter revenues will grow 44%, to €4.47 million.

NuVasive, Inc.

NuVasive delivered strong results in the second quarter despite an overall industry slowdown and continued to gain market share. Revenues grew 35.1% to $119.6 million (versus $88.5 million in 2Q09). Management increased the low end of full-year revenue guidance to $485 million–$500 million which equates to 25%–30% revenue growth in 2011. Management commented that pricing pressure would likely continue regarding legacy spinal implants but less so in such high growth areas such as MIS, biologics, or specific areas of motion preservation. NUVA's product portfolio seems to be in the right place at the right time.

We estimate 3Q10 revenues will be $129.9 million (36.9% YOY growth). We estimate full-year revenue 2010 to be $500 million, which is a 35% YOY growth rate.

Orthofix International

Orthofix spine reported strong second quarter results with spinal repair and implant sales rising 11% to $78.7 million (up from $70.7 million in 2Q09), surpassing our estimates of $76.5 million. Spine stimulation revenue increased 12% to $44.9 million while implant and biologic revenues increased 10% to $33.8 million. Lumbar and cervical implant revenues grew 16%, and were strong contributors to overall spine growth. Key product contributors were the Firebird pedicle screw system and the PILLAR interbody device. Orthofix continues to gain share in the spine stimulation market, with this quarter marking the eleventh consecutive quarter of double-digit revenue growth.

Management believes that Orthofix is on track to earn $300 million in spine revenues for full-year 2010. We estimate 3Q10 spine revenue to rise 7.2% to $73 million and full-year 2010 spine revenues to grow 8.3% to $302.4 million.

Stryker Corporation

Stryker Spine struggled in the second quarter citing increased pricing pressure, reimbursement challenges, a slight procedural slowdown, and product roll-out delays. In 2Q10, Stryker's spinal repair and implant revenue growth was essentially flat at $140 million (vs. 9.4% growth in 2Q09). The domestic spine product business declined 3% YOY while international revenues grew 7% YOY. Stryker expects the challenges in spine to continue throughout the year. We estimate that 3Q10 revenues will be essentially flat YOY at $138.5 million. We estimate full-year 2010 revenue to be $576 million (3.1% YOY growth).

TranS1, Inc.

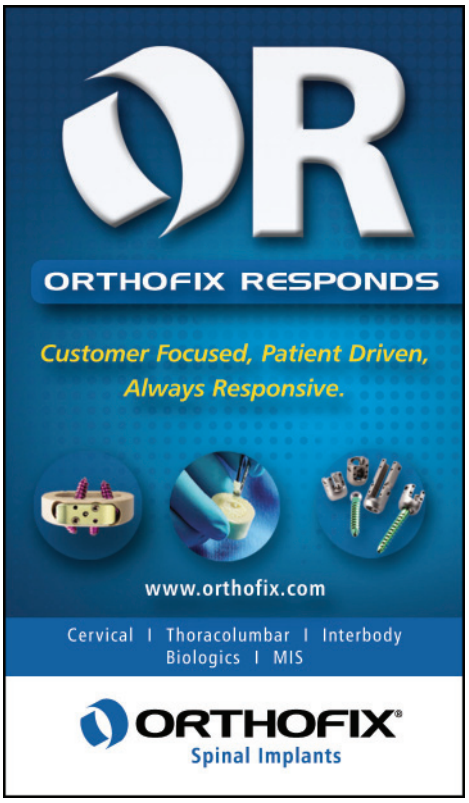
First quarter 2010 revenues declined 8.3% to $7.2 million (down from $8.8 million in 2Q09). The company reported that surgeons performed 667 Axial Lumbar Interbody Fusion (AxiaLIF) procedures worldwide (541 domestic) in the quarter (down from 671 in 2Q09). Worldwide AxiaLIF procedure growth, a key driver of revenues, decreased 16.2% YOY in the second quarter. Domestic procedure volumes actually grew sequentially in the quarter.

Physicians are encountering problems being reimbursed by payors due to the category III CPT (Current Procedural Terminology) code under which AxiLIF is being reimbursed. However, Trans1 has addressed this issue over the last several quarters, and as a result, the business is stabilizing domestically. The average selling price (ASP) of AxiaLIF was $12,100 up 13.1% from 2Q09. We estimate that 3Q10 revenues will be $6.8 million (-8.3% YOY growth).

Zimmer Inc.

Zimmer reported that spinal implant and biologic sales in 2Q10 were $57.9 million (down from $64.2 million in 2Q09) down 10% (-9% constant currency) YOY. The 10% reported revenue decline includes a negative 9% based on procedure volume/mix, no impact from pricing, and minus 1% based on foreign currency exchange. Negative volume/mix was the primary driver of the revenue shortfall. Reimbursement pressures regarding the Dynesys Dynamic Stabilization system and overall pushback from private payors continue to negatively affect revenue growth.

Management stated that they expect the domestic spine business will stabilize



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by the end of the year and they also see opportunities for international market growth. We forecast full-year 2010 revenues will decline 5% to $240.9 million, down from our previous forecast of $256.8 million. We estimate 3Q10 spine revenues to be $59 million (1% YOY growth).

Looking Forward: Spine Industry Facing Continued Headwinds

This spine industry, we believe,

Wikimedia Commons

is facing extremely challenging regulatory, reimbursement, and pricing environments. This is negatively affecting pricing, mix, and procedure volumes-the key drivers of revenue growth. Hospital pushback and reimbursement pressures are negatively impacting pricing. Regulatory challenges could slow the rate of new product introductions, which could in turn lessen the impact of new technologies on mix. Furthermore, reimbursement pressures could slow procedure volumes. However, there is hope for companies developing technologies with compelling cost propositions that improve outcomes.

To read more, click here.

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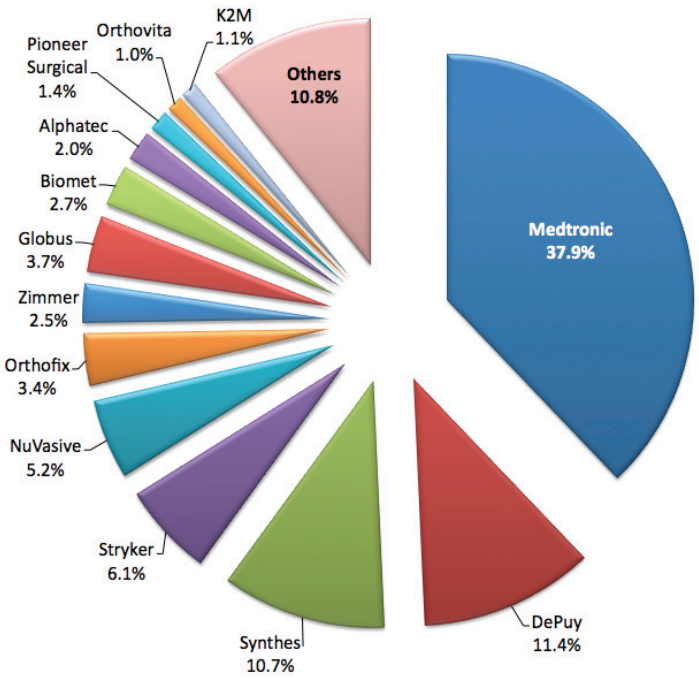
Chart 1: Spine Market Shares (2Q10)



Know Thy Patient: Psych Testing for Spine

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

Maybe your new patient seems appropriate for a discectomy… but he has a drug problem. Another patient might seem perfect for that new implant…but she has a history of sexual abuse. With the cacophony of technological advancements all around us, it can be easy to get caught up in the excitement and lose sight of the person—the whole person—you are treating. And this, say our experts, can well be the difference between post operative success or failure.

Dr. Ray Baker, President of the North American Spine Society, notes, "Data on the relationship between psychological health and surgical outcomes has been available for years; it is some of the most validated information that we have. We know, for example, that someone diagnosed with low back pain that is also unemployed, having marital difficulties, and other psychological stresses will not do as well postoperatively."

Rorschach Card/Hermann Rorschach/Wikimedia Commons

No, the average orthopedist isn't a psychologist—and Dr. Baker isn't suggesting that they add yet another responsibility to their never ending 'to do' list. "To expect a surgeon to sit down and ask if someone was abused as a child is incongruent; we should take these issues out of surgeons' hands by routinely referring distressed individuals for psychological testing. As for the payment issue, if insurers are going to invest anywhere between $20,000 and $60,000 for a surgery, they should be willing to spend a couple of hundred dollars on psych testing. The irony is, for example, that if such testing was required for lumbar fusion, there would be far fewer surgeries that insurers would have to pay for, and more successes."

Dr. Christopher Standaert, a physiatrist at the University of Washington in Seattle, expounds on the issue of pain. "We sometimes forget that you can't look at an MRI and determine if the person is in pain or distress. You must talk to the patient. If necessary, refer them to someone who can identify psychosocial

"We know, for example, that someone diagnosed with low back pain that is also unemployed, having marital difficulties, and other psychological stresses will not do as well postoperatively."

factors that can affect outcome. For example, if this person catastrophizes, that can lead to postop issues."

According to Dr. Standaert, if you're asking, "Hmm, what is the right implant for this person?" then you should reverse the order of the question. "Pain is not just about the effects of pain on the individual, but about the individual himself. The fact is that we don't spend enough time finding the right patient. Someone has to tease out the 'chicken and egg' issues, i.e., did this person develop psychological problems because of the pain or were the issues there beforehand? Let's say there were two people riding in a car that was rear ended. One person reports physical pain and one doesn't. Much of the difference is related to coping style, someone's experience with pain in the past, substance abuse, etc. For instance, someone with a passive coping style tends to do poorly with pain."

While inexpensive, noninvasive psychological screening would seem to be a more rational option, a patient's response to stressful situations can act as a surrogate screening method. "That is one of the reasons that I can detect patients who will fare poorly with surgery within a few minutes of starting an interventional procedure," says Dr. Baker.

Dr. Baker has often made psychological issues concrete to surgeons who are ready to hit the OR by having them observe injections on their patients. "I remember one occasion when a world renowned spine surgeon was observing a discogram on one of his patients. He really felt that this person was solid, but after observing how the patient responded to the infiltration of local anesthetic even before the discography, he was astounded. He told me that I needn't go any further…that there was no way he would operate on the patient. It was a real eye opener."

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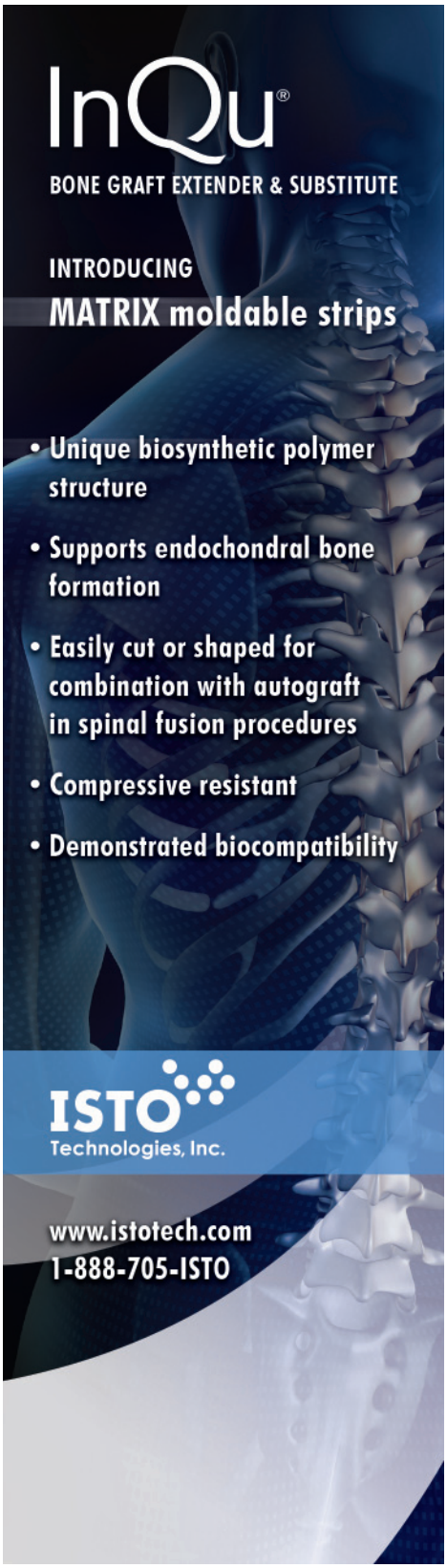
Dr. Baker is also the kind of physician you want talking to the person who needs preop psychological treatment. "When addressing psych issues with patients I use myself as an example. I say, 'For 12 years I have had chronic neck and arm pain emanating from my spine. Pain is a barometer for my life. When my life is out of control and I am stressed, my arm hurts more. Does this mean I am crazy? No.' They begin to think, 'If he is admitting to stress affecting pain, then I can too.' Many patients shake their heads vigorously and say, for example, 'You know, I never thought about it, but my pain started shortly after I lost my job three months ago. And now my husband's job is on the line, etc.' Getting to some of the underlying core stresses that a patient is experiencing is not only compassionate…it helps you move their treatment forward."

And if someone's test scores recommend against surgery? Dr. Standaert: "Patients who are denied surgery often say, 'Things are a mess for me now, but if I can just have this surgery then I can put my life back together.' I do my best to convince them that this isn't true, and that if they can address their life issues non-operatively (counseling, eating better, sleeping better, etc.), then there is a good chance that they won't need surgery. There is evidence in the literature showing that patients treated with comprehensive multidisciplinary non-operative care seem to do just as well as those who undergo lumbar fusion."

And, says Dr. Baker, patients aren't the only ones engaging in magical thinking.



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"Physicians often say, 'This patient is on high dose chronic opiates, but if they detox then surgery will be successful.' My point is that it's what led to their taking opiates in the first place that makes them a bad surgical candidate. It's not just the physical pain…it's that you can't turn a psychological train wreck into a good surgical candidate."

Although the doctor is pulling for the patient, there are other forces going in the opposite direction. Dr. Baker notes, "I have helped design several IDE [investigational device exemption] trials in which psychological tests were a part of the screening; as it turned out, the test scores were off the charts for many subjects in these trials. The response I used to get from the companies was, 'We cannot afford to slow enrollment; you must exclude the results of those tests.' Now, companies are listening. Manufacturers realize that if only a small percentage of patients do well with their implant then their time on the market will be very limited. If they can increase their success rate to 60-70%, then the likelihood that their time on the market—and market share—will be improved."

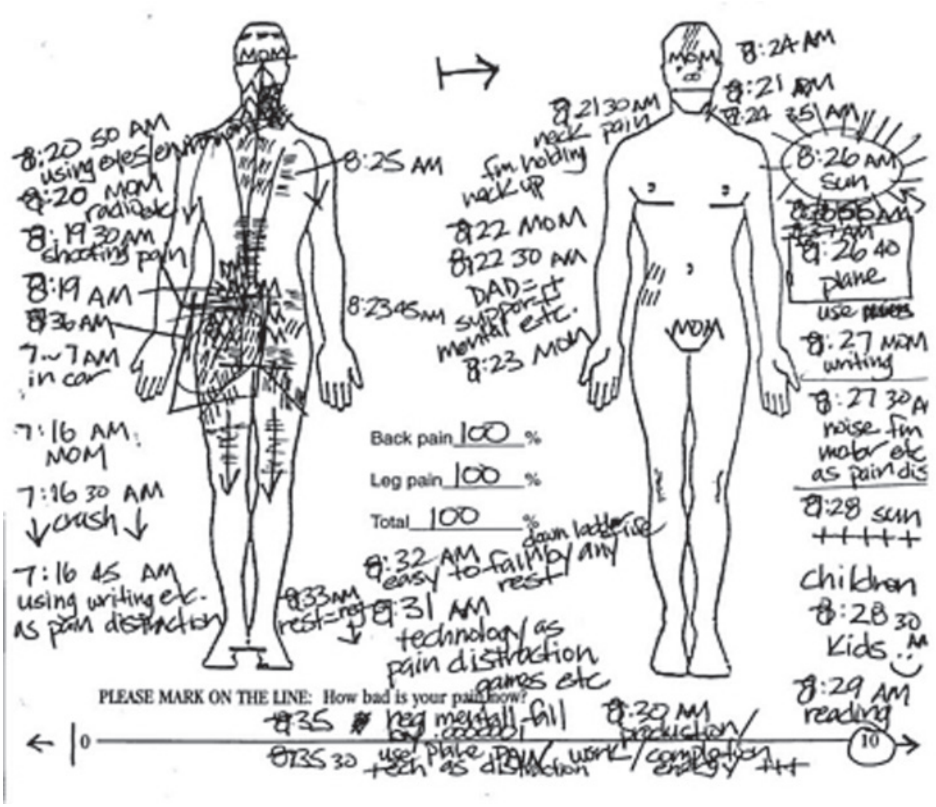
Dr. William Deardorff, Assistant Clinical Professor at the UCLA School of Medicine, is the co-author of The Psychology of Spine Surgery. He explains, "Preoperative testing is a tool to help surgeons with surgical decision making…it is a piece of the puzzle that we can give surgeons to ensure they have a complete picture of their patients. And a patient may certainly have an alternative to an elective surgery. There are several large, randomized studies where half of the patients underwent fusion and half went through a nonoperative program involving intense exercise and pain coping education. The authors found that two years out there was no difference between the two treatment groups."

So what does Dr. Deardorff tell surgeons who are interested in the value of such testing? "Although some surgeons believe that they are unilaterally able to identify patients with psychological problems, the research suggests otherwise. Subtle, yet impactful psychosocial variables, are those that can only be picked up with the appropriate testing. The most effective spine surgery decision making approach is collaborative biopsychosocial evaluation, beginning with an astute spine surgeon who begins the process."

Look for discrepancies, recommends Dr. Deardorff, and expect the unexpected. "We have to wonder how much symptom amplification is going on. This is not necessarily conscious—these people aren't faking. But for whatever reason there are discrepancies between what they say and what we see on tests. For example, the MRI findings are at one level but the patient is complaining of pain at a different level. Or the person is complaining of pain that is way out of proportion to what might be expected (given the MRI results). At that point, you have to ask, 'What else is going on?'"

"I recently interviewed a 24-year-old woman who was taking 10 pain pills daily; her surgeon was considering obtaining a discogram but was perceptive enough to get a psychological screening. She hadn't told anyone that she was in the process of a difficult divorce, however, and no one asked about that because she was so young. It was clear that she

"By conducting preoperative psychological testing, and working collaboratively with spine surgeons, we can improve outcomes and help prevent situations where we have a technical success but a clinical failure."



Pain drawing by patient not cleared for surgery/Dr. William Deardorff

was primarily using the medication to manage her emotional distress."

And, says Dr. Deardorff, a brief, no-cost screening measure is available that can help assess these types of issues. "Surgeons are welcome to visit my website, where they can access a screening tool that can be used as a 'first cut.' This can help them determine with more accuracy what might be a 'problem' case. Using a screening tool doesn't mean that the surgery can't proceed, but it can at least help the physician make better decisions with regard to preparing the patient and delivering the appropriate postoperative care."

Elucidating the importance of being thorough preoperatively, Dr. Deardorff states, "I once met with a 22-year-old who was scheduled for spine surgery. While it was my job to prepare him for the procedure, the clinical interview determined that he was showing symptoms of a first time schizophrenic episode. The physician cancelled the surgery and the patient was referred for the appropriate psychiatric treatment."

Dr. Deardorff summarizes the goals of testing as follows: "By conducting preoperative psychological testing, and working collaboratively with spine surgeons, we can improve outcomes and help prevent situations where we have a technical success but a clinical failure."

For more information on preoperative screening, please visit: http://www.behavioralhealthce.com/ ◆

Advertisement

company

SBi: Small Bones, Big Revenue Growth

Small Bone Innovations (SBi), the S.T.A.R. ankle and small bone and joint company announced a 35% growth in revenue for the first half of 2010.

Revenue at the privately held company increased 45% in the first quarter and 26% in the second quarter.

Anthony Viscogliosi, Chairman and CEO of SBi, noted on August 17 that the financial performance was especially noteworthy given that global orthopedic revenue growth has been slowing in the second quarter as elective surgeries are down due to a soft economy.

Revenue in North America grew 44% in the first quarter, 33% in the second quarter and 38% in the first half of 2010. International revenue rose 47% in the first quarter, 15% in the second quarter and 30% for the first half of the year.

Growth Drivers

Viscogliosi said the growth rates can be attributed to the company's fast growing upper and lower limb product systems, highlighted by the S.T.A.R., total ankle replacement system that has been implanted in more than 17,000 patients worldwide. According to Viscogliosi, SBi has trained more than 500 foot and ankle surgeons throughout the world during the introduction and phased launch of the S.T.A.R. in North America and the re-launch of the S.T.A.R. under the SBi brand name in international markets.

Ortho Financing Bright Spot

The company was a bright spot for the orthopedics industry during the worst of the Great Recession when the company announced raising $144 million in funding last year from a host of investors including: Goldman, Sachs & Co.; Khazanah Nasional Berhad (the investment firm of the Government of Malaysia); Malaysian Technology Development Corporation (MTDC), an integrated Malaysian-based venture capital company; The Family Office of Bahrain; Viscogliosi Brothers, LLC; Trevi Health Ventures; NGN Capital; 3i Group; and TGap Ventures, among others.

SBi closed on $12 million in Series E funding from Olympus Corporation in March 2010. In November 2009, the company secured a $30 million debt facility from Fortress Investment Group to fund accelerated business expansion and refinance existing indebtedness.

Outlook

Looking ahead, Viscogliosi said, "I am also happy to note that we anticipate that at least 10 of our product systems will each generate well in excess of $1 million in revenues this year."

The company was founded in 2004 by Viscogliosi Brothers, LLC as the first company to focus purely on small bones and joints. Today, SBi has facilities in New York, New York, Morrisville, Pennsylvania, Bourg-en-Bresse, France, Donaueschingen, Germany, and Kuala Lumpur, Malaysia.

—WE (August 20, 2010) ◆

It's Official: Biomet Expands

Biomet is adding almost 300 jobs and investing $26 million in the company's facilities in Warsaw, Indiana.

Despite a looming device tax which Biomet CEO Jeff Binder called a tax that would, "create the worst of all possible situations: escalating costs on the newest technology and reduced capital to invest in jobs and R&D," the company is forging ahead.

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Tax Incentives

Biomet moved forward on the expansion after the Kosciusko County Council approved 10-year real and personal property tax abatements. The Indiana Economic Development Corp. offered Biomet up to $2.75 million in tax credits and up to $200,000 in training grants.

Gaining Market Share

Biomet has good reason to expand. Wells Fargo analyst Mike Matson wrote recently that Biomet gained the most market share in the second quarter of 2010 in the hip and knee market.

Matson wrote that Biomet gained 0.8% in reconstructive market share, winning in knees, gaining 1.2% share and tying with DePuy in hips, gaining 0.5% share

So as the federal government increases its tax on the company, local taxpayers decided to give the growing local company a break in exchange for more jobs.

Kosciusko Council President Harold Jones previously reported that Biomet's project has four components:

- Manufacturing
- Distribution
- Technology
- Research and Development

The plan is to renovate existing property and add new equipment. The jobs will be added over a two-year period and pay more than $50,000 a year on average, he said.

Congratulations to all the employees of Biomet.

—*WE (August 20, 2010)* ◆

Stryker Buying Elliott's Pain Management?

When we reported a Ray Elliott sighting in May, it was over Boston Scientific Corp's enrollment of patients in a clinical trial to compare spinal cord stimulation (SCS) for patients whose first back surgeries failed. Elliott is, of course, the CEO of Boston Scientific and the former head of Zimmer.

Ray Elliott, CEO Boston Scientific

We wondered if he was longing to get back into spine.

We were wrong.

It was reported by Bloomberg on August 17 that a former Elliott competitor, Stryker Holdings, was in advanced talks to buy Elliot's pain management device (neuromodulation) unit for $1.5 billion. Bloomberg reporters wrote that their information came from "three people with knowledge of the transaction."

The "people" said the deal may be announced next week and that Stryker would probably pay all cash.

Analyst Bill Plovanic of Canaccord told Bloomberg that the acquisition made sense from a distribution standpoint for pain management physicians currently serviced by Stryker.

Boston Scientific put the neuro business up for sale earlier this year.

Stryker has a ton of cash and has obtained a $1 billion senior unsecured credit line, due in August 2013. According to Wells Fargo analyst Mike Matson, Stryker has $4 billion in cash for mergers and acquisitions.

Too bad, it would have been fun to keep writing about Ray Elliott and pain management. Former orthopedic competitors of Elliott's are probably happy to watch the Canadian-born Elliott skate by and off the ice.

—*WE (August 17, 2010)* ◆

legal

FDA Hauls Regenexx Into Court

RRY Publications/Source: Regenexx

Are cultured adult stem cells from a patient's own body drugs or body parts when used in a medical practice?

That question may get answered after the FDA filed an injunction in federal court on August 6 against Regenerative Sciences (Regenexx), citing violations of "current good manufacturing practice that cause its cultured cell product to be adulterated." The agency claims the product is also "misbranded due to the lack of adequate directions for use and the failure to bear the 'Rx only' symbol."

The FDA wants Regenexx to stop offering the company's novel stem cell therapy for orthopedic problems. The company has agreed to stop the practice until a court decides on the issue.

Cultured Cell Product

The company's cultured cell product is derived from a patient's own bone marrow or fluid surrounding the patient's joints (synovial fluid). The cells are grown, processed, and mixed with drug products outside the body before being injected back into the patient.

The FDA says the product is not approved and "no adequate and well-controlled studies have been done to demonstrate its safety or effectiveness for any indication."

Body Parts or Drugs?

John Schultz, M.D., a company founder stated in an email to *OTW*, "We have published a study with 227 patients and are submitting another with 339, that shows that our stem cell based procedure is dramatically safer than the more invasive surgical procedures it helps many patients avoid. So while FDA mentions lack of adherence to drug factory guidelines, we don't make drugs, but treat patients."

"FDA recognizes the importance of the development of novel and promising new therapies," said Karen Midthun, M.D., acting director of FDA's Center for Biologics Evaluation and Research. "However, when companies like Regenerative Sciences fail to comply with FDA laws and regulations, they put the public's health at risk."

Christopher Centeno, M.D., medical director of Regenexx's clinic told *OTW*, "The FDA's position on the patient's own stem cells is that they are drugs. Making these cells drugs isn't going to make them any safer or help patients any sooner."

The company has sued the agency four times to try to bring this disagreement to a conclusion.

Centeno added," We have been trying to force the agency into court for two years and they have refused to discuss why a medical clinic practicing medicine using a patient's own tissue is producing a drug that is regulated by the FDCA.

"They [FDA] will now be forced to show up and answer these questions. We welcome the opportunity to have this critical issue decided: Are our patients' stem cells, when used in our medical practice, body parts or drugs?"

The entire stem cell industry will welcome an answer.

—*WE (August 18, 2010)*◆

FDA Warns Biomet

Biomet received a warning letter from the FDA on July 27 regarding the company's Signature Personalized Patient Care System.

Signature Personalized Patient Care System/Biomet

The system, in a nutshell, is a Magnetic Resonance Image (MRI) generated roadmap of a patient's anatomy that is used by a surgeon to preplan and navigate proper placement for a knee replacement.

Disagreement

The FDA says Biomet is marketing the system without marketing clearance or approval.

Biomet responded on August 3 with a letter to the FDA explaining why the company believes the system has been appropriately marketed under a

510(k) premarket clearance. The FDA has not responded to the company's explanation.

The company issued a statement saying Biomet "is committed to working with the FDA to resolve the issue in the best interest of patients and their doctors without disruption to patient treatment."

It should be noted that the company has not had a warning letter in eight years and this warning does not allege any harm to patients.

The System

According to Biomet, the system utilizes the MRI information to "personalize [a] total knee replacement procedure. The MRI creates a three-dimensional image of the patient's joint anatomy, enabling the surgeon to preoperatively plan the patient's knee replacement. The three-dimensional MRI is also used to create custom positioning guides for the patient's total joint replacement implants. In the past, surgeon planning has typically been based off of two-dimensional X-rays."

Traditional total knee replacement, according to the company, sometimes uses instruments placed inside the femur and/or tibia (shinbone) to assist with implant alignment.

In the Signature system, positioning guides are placed directly onto the patient's femur and tibia, and therefore do not require instrumentation of the bone canal, allowing for a potentially less invasive procedure. With the MRI and Signature personalized positioning guides, surgeons have access to a greater level of detail and precision for implant position and alignment before the procedure. This allows for personalized implant positioning and may help enhance surgical efficiency.

Industry Impact?

Biomet is not the only company to utilize a personalized system for knee replacement. DePuy offers the TruMatch Personalized Solutions System and Stryker offers customizable instrumentation after acquiring OtisMed in 2008.

Clearly Biomet did not forget about the FDA when it began marketing the product. We don't know whether this disagreement with the FDA will have an impact on other companies with personalized surgery systems. Biomet is the only company that has received a warning about marketing.

—WE (August 18, 2010) ◆

Advertisement

large joints

Calcium and Heart Attack Risk

Check your medicine cabinets… calcium may be a culprit. A new study from researchers at the University of Auckland in Australia have found that calcium supplements, frequently taken for osteoporosis, are associated with an increased risk of a heart attack. The authors indicate that a reassessment of the role of calcium supplements in osteoporosis management is needed.

The international team of researchers analyzed the results of 11 randomized controlled trials of calcium supplements (without co-administered vitamin D) involving 12,000 patients. Differences in study design and quality were taken into account to minimize bias.

Ragesoss/Wikimedia Commons

Their findings? That calcium supplements were associated with about a 30% increased risk of heart attack and smaller, non-significant, increases in the risk of stroke and mortality. The findings were consistent across trials and were independent of age, sex, and type of supplement. The authors indicate that despite the increase in risk being a modest one, the widespread use of calcium supplements means that even a small increase might translate into a large burden of disease in the population. Previous studies have found no increased cardiovascular risks with higher dietary calcium intake, suggesting that the risks are restricted to supplements.

Co-author on the study, Dr. Ian Reid, told *OTW*, "We weren't really surprised by the results of this study since they confirmed what we had published two years ago, and are consistent with the evidence of adverse effects of calcium supplements in people with kidney disease. We have further work in progress looking at the effects of Ca plus vitamin D. At present, we think it is wise to be much more cautious in the use of calcium supplements, and use other ways of reducing fracture risk."

In an accompanying editorial, Professor John Cleland (of the department of cardiology at Hull York Medical School in the UK) and colleagues suggest that while uncertainty exists about whether the increase in heart attack and stroke is real, there are also doubts about the efficacy of calcium supplements in reducing fractures. On the basis of the limited evidence available, they say, patients with osteoporosis should generally not be treated with calcium supplements, either alone or combined with vitamin D, unless they are also receiving an effective treatment for osteoporosis for a recognized indication. They also believe that research on whether such supplements are needed as an adjunct to effective agents is urgently required.

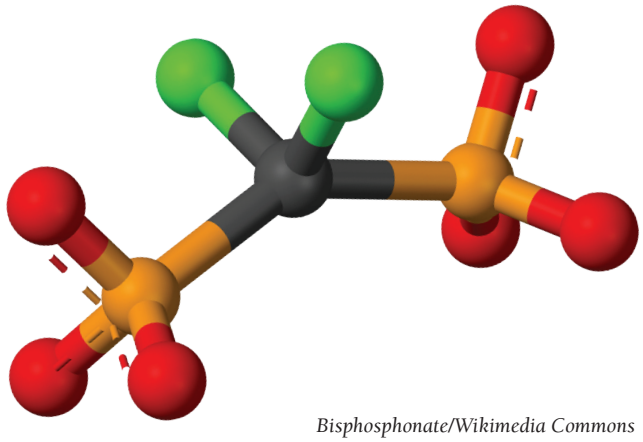
—EH (August 19, 2010)◆

Bisphosphonates and Esophageal Cancer: No Link

It's nice to rule out a serious potential issue related to taking a drug…especially when the drug is so widely administered. A study from the UK that included more than 80,000 patients has found that use of oral bisphosphonates was not significantly associated with new cases of esophageal or gastric cancer. This is good news for the multitudes of osteoporosis sufferers who take bisphosphonates.

Chris R. Cardwell, Ph.D., of Queen's University Belfast, United Kingdom, and colleagues investigated the association between bisphosphonate use and esophageal cancer by extracting data from the UK General Practice Research Database (GPRD) of patients treated with oral bisphosphonates, along with a group of patients not treated with these drugs (control cohort), between January 1996 and December 2006.

There were 41,826 members in each group (81% women; average age, 70.0 years). One hundred sixteen esophageal or gastric cancers occurred in the bisphosphonate cohort and 115 in the control cohort. Analysis of the incidence of these cancers among the bisphosphonate and control groups found no difference in risk of esophageal and gastric cancer combined between the cohorts for any bisphosphonate use or risk of esophageal cancer only. There also was no difference in risk of esophageal or gastric cancer by duration of bisphosphonate intake.



Bisphosphonate/Wikimedia Commons

"In conclusion, in the UK GPRD patient population we found no evidence for a substantially increased risk of esophageal (or gastric) cancer in persons using oral bisphosphonates. These drugs should not be withheld, on the basis of possible esophageal cancer risk, from patients with a genuine clinical indication for their use," say the authors.

Dr. Cardwell told *OTW*, "Although there seemed a plausible hypothesis for a bisphosphonate esophageal cancer association, and case reports were suggestive, we went into the study very open minded and weren't really surprised that our study did not find any association. Although our study is the largest to date, it contained few people who were very long-term bisphosphonate users (for instance with over 10 years usage) so I suppose there remains the possibility that in these long-term users there could be some association. Also, in our study there were weaknesses in the recording of information on the characteristics of individuals (such as BMI and alcohol intake, etc.). I think a study which recorded this information more completely, and therefore could account for these characteristics better, would provide further reassurances."

—*EH (August 18, 2010)* ◆

AAOS and Haiti

After the horrific earthquake in Haiti earlier this year, the American Academy of Orthopaedic Surgeons (AAOS) leapt into action to come to the aid of those in need. Immediate assistance was provided in the form of AAOS members who donated their time to perform numerous surgeries under very difficult conditions. There has also been an effort to help Haiti move forward with its efforts to create/rebuild an orthopedic infrastructure.

Lynne Dowling, the Director of the International Department at AAOS, told *OTW*, "We are working with the Pediatric Orthopaedic Society of North America (POSNA) and the Orthopaedic Trauma Association (OTA) in an effort to determine how we can help with the ongoing training of doctors in Haiti. It's pretty difficult in the current situation, with 60% of the government offices destroyed, governmental disarray, and most of hospitals demolished. There are a mere 39 orthopedic surgeons in Haiti, but only 15 of them are actually practicing. Those 15 surgeons have scattered throughout the country trying to find work, meaning that there is no centralized effort to work together."

AAOS

As for the future of orthopedic training, Dowling indicates that there is not significant motivation for people to select orthopedics as a specialty. She continued, "The field is not well reimbursed and is not well recognized; if people have the proper skill sets they tend to leave the country. Those who know Haiti well are advising that we can't try to establish a U.S.-type residency program of five years in length. And, because the governmental agencies are in such disarray it is unclear where orthopedic training fits in with everything else that needs to be done."

One thing the AAOS/POSNA/OTA team doesn't want is a duplication of effort. Dowling commented to *OTW*, "The AAOS project team is listening to Haitians and doing a needs assessment alongside them. The team is meeting mid-September to put together a plan that we hope to implement early next year. One of our goals is to identify younger people who will be the future of the profession. We are beginning to connect some of the AAOS members with these young surgeons so that when our members go to Haiti the younger surgeons can join them in the OR. This will have to suffice until a more formal training program is established."

The good news? This is an opportune time for Haiti to begin to establish a formal, quality orthopedic training program.

The call? Lynne Dowling: "We are in dire need for orthopedic surgeons to continue helping out in Haiti. If you are in a position to volunteer, please see www.aaos.org/haiti or call 847-384-4170."

—*EH (August 17, 2010)* ◆

extremities

Amputee Youth Camp a Success

Canoeing, archery, and more…The Amputee Coalition of America (ACA) has reached its goal to send 100 campers to the Amputee Coalition of America's Paddy Rossbach Youth Camp in Clarksville, Ohio. More than $180,000 was raised by the ACA to send the children, ages 10-17, to the five-day camp.

"We have had tremendous success raising funds for the camp this year. People have given generously after seeing the difference the camp makes for these children. By working with children's hospitals, industry partners, ACA members, support groups and other healthcare providers, the youth camp is currently at 100 percent capacity this summer. This doubles our enrollment from last year," said Marshall J. Cohen, chairman of the Amputee Coalition's Board of Directors, in the news release. "Our Pebble Parties across the country have raised many of the funds, and we thank all those who donated."

Elaborating to *OTW* was Derrick R. Stowell, Development Coordinator for the Youth Camp Program. He said,"A Pebble Party is an event where the hosts focus on the mission of the Amputee Coalition and how it fulfills its purpose. People invited to a Pebble Party have an interest in the cause and learning more about the organization. Attendees learn firsthand what impact their support will have and are encouraged to make direct donations. Pebble Parties can be hosted to raise funds for various programs of the Amputee Coalition of America. The first two Pebble Parties were hosted to raise funds for the Paddy Rossbach Youth Camp."

Campers have access to activities that include fishing, swimming, zip lining, canoeing, and archery. Campers are not accompanied by their parents, which, says the ACA, inspires campers to take on new challenges, be independent, and build new friendships.

Amputee Coalition of America

As for how the ACA plans to grow the camp, Stowell told *OTW*, "It is our desire to continue to be able to reach out to more youth with limb loss and limb difference from around the nation. Our goal next year is to raise enough funds to be able to bring 100 more youth to camp in 2011. In order to accomplish this goal we will need the support of many individuals, corporations, and sponsors."

If you would like to support the ACA's efforts, please visit: www.amputee-coalition.org/donate. To host a fundraising event or Pebble Party contact Derrick Stowell, Development Coordinator at dstowell@amputee-coalition.org, or 888/267-5669, ext. 8130.

—EH (August 20, 2010) ◆

Hand Therapy After Surgery

Just out of the OR? You've only just begun…A new literature review, published in the August 2010 issue of *The Journal of the American Academy of Orthopaedic Surgeons* (JAAOS), indicates that hand therapy is one of the most vital treatment steps in recovery from hand injury surgery.

"Hand therapy is the critical link between certain surgeries on the hand and a good outcome," said Erik Dorf, M.D., in the news release. Dr. Dorf, an orthopedic surgeon and upper extremity specialist at Vail Summit Orthopaedics in Vail, and Frisco, Colorado, and a co-author of the review, added, "Collaboration and cooperation between the patient, the therapist, and the orthopaedic surgeon is critical."

The review found that hand therapy addresses factors such as range of

Tom Watanabe, U.S. Navy/Wikimedia Commons

motion, strengthening of the hand, and work conditioning. Different modalities used by hand therapists to include fluidotherapy (a dry heat treatment that helps range of motion), paraffin therapy (a warm wax bath that helps range of motion), electrical stimulation (decreases fluid in the hand and accelerates wound healing).

"If therapy is not part of the overall treatment plan, the long-term consequences can include ongoing pain, decreased range of motion, decreased strength, and difficulty with fine motor tasks," added Dr. Dorf. "The activities of daily life can become very difficult."

When asked about some issues that arise with hand therapy, Dr. Dorf told *OTW*, "Therapy after hand injury follows a fairly predictable course that progresses from pain reduction and swelling control to range of motion, strengthening and finally, focused work, or sport-related activities. As patients progress through this spectrum of treatment they typically increase the demand on the injured hand. Arresting this process at any particular time point may result in an inability to perform at this increased demand level. This can result in either a prolonged healing time, or simply a result that has not been optimized and that results in some sort of permanent impairment of hand function."

As for how directive the surgeon should be with regard to therapy, Dr. Dorf commented to *OTW*, "The physician's involvement in therapy varies significantly based upon the injury, the time since the injury, and the relationship the doctor has with the therapist. Some injuries require weekly follow-up, with consistent direction from the doctor, and communication with the therapist. Other injuries, or injuries that may have occurred in the more distant past require less direct physician intervention."

—*EH (August 17, 2010)* ◆

spine

Welsh Aid Helps Launch Bone Substitute

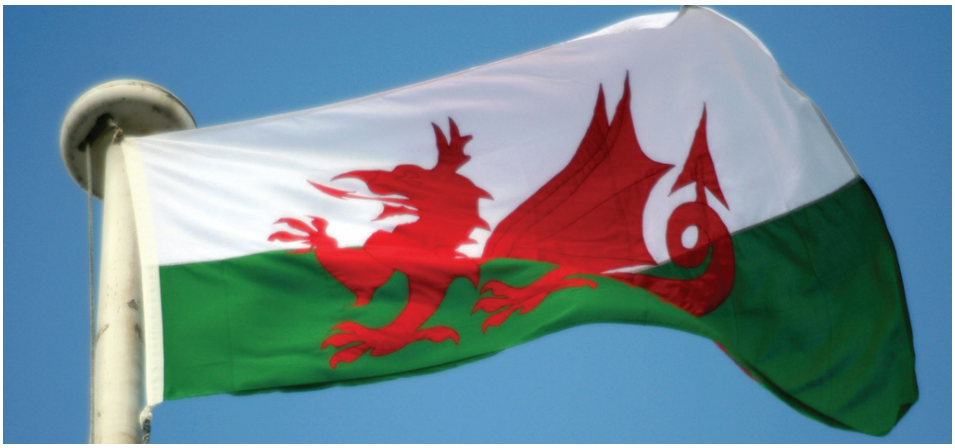
The announcement of a new bone substitute by Welsh-based medical technology company Orthos isn't just a story about new innovation. It also has some big names in the business behind it, with larger plans in the works.

A new bone substitute is being launch by Cwmbran, Wales-based Orthos. But it couldn't have happened without a lending hand from some Welsh institutions.

The focus of the Orthos product is on skeletal injuries and this new bone substitute is supposed to offer many advantages. Aside from being having the consistency to be molded by hand, it is a material that according to the manufacturer minimizes the risk of infection that is related to bone implant surgery. Specifically the bone substitute will focused on the treatment of spinal bone defects.

The aforementioned help came from a combination of sources, broken down here:

- £500,000 equity investment from Finance Wales
- £60,000 business angel follow-on investment
- £275,000 from the Welsh Assembly Government fund



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This combined funding has helped to bring this ßGel synthetic bone substitute to the market. And an impressive market it is. Synthetic bone products in Western Europe alone add up to an estimated $60 million a year with significant growth forecasted at over 10% in the next few years. Internationally the market for bone grafts is valued at around $200 million with more than half of this total coming from the spinal surgery market. This new bone substitute will take its place next to Orthos' other products such as OsteoBoost, a bone marrow aspiration kit.

As a 12-year old company, Orthos focuses on skeletal defect repair and spinal fusion. And much has been happening recently for the Welsh company. Aside from this launch, a new management team has been installed, including Robert Welsh (former managing director of Corin Limited) as chief executive and Prof. Christina Doyle (previously at Stryker and chief executive at Xeno Medical) as non-executive director. Doyle brings the authority of being a highly respected leader in the fields of artificial bone, vertebroplasty and orthobiologics.

The recent investments in the company will allow for further innovation with this new team and enable the company to target new markets, including entering the fertile vertebral compression fracture market that is blossoming due to the correlation to osteoporosis spurred on by an aging population. And the Welsh Government hopes its investment will not only help this native company, but have a ripple effect on the regional economy. It just goes to show all you need is a little help from your friends.

—JR August 15, 2010 ◆

biologics

No Assembly Required Nanodevices

A device that's one billionth of a meter in scale and can spring into shape at the exact right moment around specifically targeted cells? No we aren't talking science fiction anymore!

Self-assembling nanodevices can be a real stretch for the imagination to conceive. First of all we are talking about the realm of the extreme microscopic, billionths of a meter in size. If that's not enough, this concept combines biology with architecture.

But perhaps the best way to conceptualize this breakthrough technology that centers around the idea of tensegrity (a structure with an integrity based on a balance between tension and compression components) is to focus on the common task of rigging a tent. Think of how tethers pull at the tent's poles to pop the tent into form. This is the same act demonstrated in tensegrity and can be used in nanodevices to allow an implant to be compressed and spring into action when it is in the right location.

In the research project from Harvard's Wyss Institute for Biologically Inspired Engineering, Harvard Medical School and Dana-Farber Cancer Institute, each device is made of a circular, single-stranded DNA molecule. But here's where things get interesting. Once this molecule mixes with shorter pieces of complementary DNA, the device self-assembles. Another analogy could be a ship in the bottle, constructed in a compressed state that, with a single tug blooms into a pre-set design. The double helices of the nanodevice form rigid struts through interwoven single strands of DNA, which pull the struts up like the string connecting the miniature ships masts.

This formation makes for a strong and stable design, with forces of compression and tension equally distributed and balanced by the structure.

It's a concept that many buildings, mobiles and art structures operate under. Tensegrity can also be witnessed in systems of organisms, from large scale examples, like bones connecting

to tendons and ligaments to the shape of individual cells.

So where might this spring-action nanotechnology apply? Nanodevices could deliver drugs directly at a pinpointed site, such as diseased cells. The device would be activated to open by responding to a specific signal, whether chemical or mechanical, so that it would be released only at the proper spot.

This is an especially exciting idea if you think that the nanodevice could be teamed up with stem cell technology. That's because stem cells are influenced by their environment to grow into various parts of the body. So a nanodevice could be sent to stem cells to create an extracellular matrix that sends the signal for bone growth.

Funded by the Wyss Institute for Biologically Inspired Engineering at Harvard University, National Institutes of Health, Deutscher Akademischer Austauschdienst Fellowship, Swedish Science Council Fellowship and the Claudia Adams Barr Program Investigator award, this certainly will not be the last we hear about tensegrity and self-assembling nanodevices.

Ship in Bottle/Creative Commons

The project's authors Tim Liedl, professor at Ludwig-Maximilians-Universität in Munich, Germany and lead investigator, William Shih, Wyss core faculty member and associate professor of biological chemistry and molecular pharmacology at HMS and Dana-Farber Cancer Institute published their findings in *Nature Nanotechnology*. Shih describes the structure as having the versatility of a Swiss Army knife and the biological replication capability of a copy machine. And because they are based in DNA, the devices should be according to Shih, relatively easy and efficient to produce.

—*JR (August 12, 2010)* ◆

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THE PICTURE OF SUCCESS

Dr. Thomas Faciszewski

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

Dr. Thomas Faciszewski

"Tom, you have two choices in life. You can be a priest or a doctor—but you must serve mankind. There is no greater reward."

Tom Faciszewski was at a crossroads and the man offering advice was his grandfather. The words struck a chord in the 15 year-old...either pathway would have rewards that go beyond any paycheck.

Born in Columbus, Ohio, Tom Faciszewski's parents moved the family abroad for three years. "My dad, a mechanical engineer, accepted a position in Germany; while there we traveled to over 21 countries, among them Tunisia, where I saw extremely difficult living conditions that were completely new to me. It was striking how the rest of the world was not necessarily focused on American values. This 'flavored' my view of the world at a young age, informed my practice of medicine, and years later would influence me as President of NASS. Those early experiences gave me the backdrop that whatever we as individuals are working on professionally 'it' must be more than just about us. Our work is bigger than we are, especially in healthcare…and it is easy to lose that focus."

Dr. Tom Faciszewski, a spine surgeon with the Marshfield Clinic in Wisconsin is this week's Picture of Success not because of any accolade from his peers or because he has served in the leadership of NASS and other societies, but because he exemplifies the dictum of service to patients and colleagues. No, he didn't choose the frock ('I didn't think I was cut out for the priesthood') but he did choose a comparably profound way to heal.

After completing Grinnell College in 1982, Tom Faciszewski began medical school at the University of Colorado. "I thrived on my rotations at the Denver General county hospital, and developed a love for the West. Given my affinity for this region, I decided to attend the University of Utah for residency. It was a challenging and rewarding experience, with call every other night—not to mention that we had a two week old baby at home. While it was like taking a drink from a fire hose, I also had the attitude of, 'Wow, it's too bad I'm missing the cases on those other nights.'"

It was not only the pace that was new, it was a certain mentor's approach to the OR. "The most memorable person from my residency was Dr. Sherman Coleman, a founding member of the Pediatric Orthopaedic Society of North America (POSNA). He forever changed the way I think about how to perform in the operating room. Dr. Coleman's philosophy was that a surgeon should

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have no wasted motion in the OR. Your movements should be fluid and your thoughts should be a running stream, as opposed to things being 'stop and start.' This requires having mastered human anatomy and applying that knowledge in the art of surgery. I emphasize these points with all of my residents and fellows today."

Beginning in residency, life—and sometimes death—are at your doorstep…and certain days will never let go of you. Dr. Faciszewski: "In residency you are introduced to this progression where you go from being the one who is taught to the one whose name is on a patient's armband. You are introduced to the tragedy of human life—up close. I recall a 15 year old who had undergone surgery elsewhere and was not doing well. We took X-rays and found that he had an osteosarcoma that had gone unrecognized; he was dead three months later. That is burned in my memory."

During his fellowship in spine surgery at the Minnesota Spine Center in 1992-93, Dr. Faciszewski would be influenced by some of the best surgeons in the world. He relates how their trust, dedication to education, and ultimate confidence in him helped shape his career. "In one of my first few days of fellowship working with Dr. Bob Winter, a deformity specialist, we had a patient from Russia with a 110 degree thoracic scoliosis. Dr. Winter left me in the OR and said, 'Call me when you get the exposure completed.' I must have turned pale because his nurse looked at me and said, 'We'll get through this.' Another talented surgeon, Dr. Francis Denis, was very supportive, saying, 'You'll be better than any one of us attendings. You will take away the knowledge from each of us and combine it into the surgeon that any one of us could never be."

Hoping he would be someone who could move the field forward, Dr. Faciszewski accepted a position at the Marshfield Clinic in Wisconsin. "I could see that the physicians here were all pulling in the same direction…in the direction of their patients. It's hard to get physicians to agree on many things, and yet to see 350 physicians on the same page regarding the mission of their organization is rare indeed. I was also enamored of Marshfield because they allowed me time to become involved in efforts such as NASS and time to conduct research. Their dedication to endeavors other than, say, Relative Value Units (RVUs) is unique and one of the strengths of the Marshfield Clinic system."

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"While it is thrilling to encounter such a variety of spinal disorders, anatomical issues and pathology, it is fulfilling to be in a place where I can take the time to address patient fears and psychosocial issues. Increasingly, the push in medicine is to quickly 'fix' the patient's problem, which sometimes leads to leaving other medical or psychosocial issues untreated."

Dr. Faciszewski is also grateful to be in an environment where the big picture includes the *whole* patient. "While it is thrilling to encounter such a variety of spinal disorders, anatomical issues and pathology, it is fulfilling to be in a place where I can take the time to address patient fears and psychosocial issues. Increasingly, the push in medicine is to quickly 'fix' the patient's problem, which sometimes leads to leaving other medical or psychosocial issues untreated. You take a normal person who gets injured and they are often bewildered by what is going on with them physically. They are in pain and often have a component of disability. We must devote time and energy to help them understand where they are in the injury and healing process and what they can expect. Fortunately, at Marshfield Clinic we have a full complement of folks on staff, including physical therapists, psychiatrists, psychologists, occupational medicine personnel, etc."

By reflecting on his time at the helm of NASS, Dr. Faciszewski can peer into the future. "I was introduced to NASS because of the research that I had done while in fellowship regarding the coding of spinal procedures. In 1992, while I was in fellowship the RVRBS system of physician work RVUs was introduced. I had written several papers regarding the accuracy of database coding as it related to spinal surgery, complications and diagnosis. The problem then, as it is now, is that the databases are flawed regarding the accuracy of coding. The limitations in these administrative databases are all too commonly dismissed."

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And, says Dr. Faciszewski, the information gleaned from administrative databases may have untoward effects on patient care. "The government (Medicare) and others are using administrative databases to develop scorecards comparing hospitals to each other and Dr. X to Dr. Y. The outcome is that you have newspaper articles saying, 'Hospital X has a higher mortality rate or other clinical outcome than hospital Y.' However, this may not accurately reflect the situation, for example, if hospital X is caring for much sicker patients and/or more complicated patients (which isn't reflected in the database coding). The incentive for doctors is to say, 'Why would I take the sicker patients? They're going to ruin my scorecard.' This can unfortunately affect access to care."

Regarding healthcare expenditures, Dr. Faciszewski is concerned. "Politicians and the government are telling the public that services will stay the same for our Medicare patients, but the fact is that no one can study the financial

"We must work harder to find more economically viable solutions for common spinal disorders. We must help patients understand what the medical field is facing in terms of the rapidly rising age of the population and their increased medical needs."

aspects of healthcare today and come up with the answer that nothing is going to change. Expenditures will likely increase if we can't control costs for those over 65—or there will be rationed healthcare. Exciting new innovations reduce suffering for patients, improve function and generally increase the quality of life for patients. As our population ages, more and more patients will be asking for help from surgeons and physicians. We must work harder to find more economically viable solutions for common spinal disorders. We must help patients understand what the medical field is facing in terms of the rapidly rising age of the population and their increased medical needs. This is a challenge and an opportunity. As an example, the Marshfield Clinic has participated in pay for performance programs sponsored by Medicare to improve illness prevention treatment. These sorts of programs are clearly needed as we go forward into the future."

Dr. Faciszewski has ample time to consider these and other issues in the field when he is pounding the pavement…for 26 miles or more. "My entire family participates in endurance events; I have been doing triathlons for 13 years, and have just set a goal of doing an ultramarathon (50 miles). My wife and I also enjoy big game hunting for elk, deer, and bear; we process the meat and make our own sausage. I also love working on cars, and restoring four wheel drive trucks."

Dr. Thomas Faciszewski…living and teaching the true rewards of service to his fellow man. ◆

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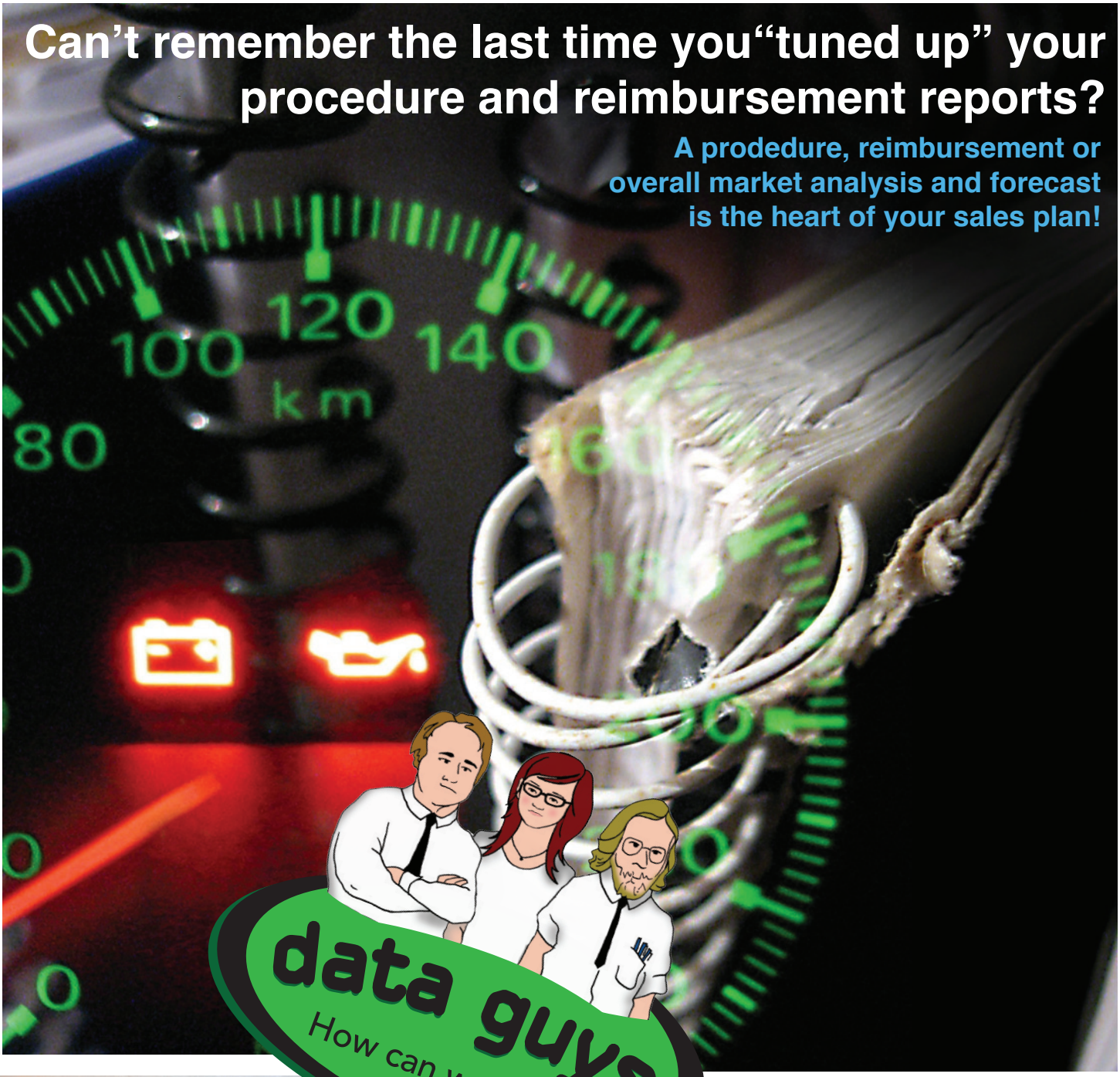

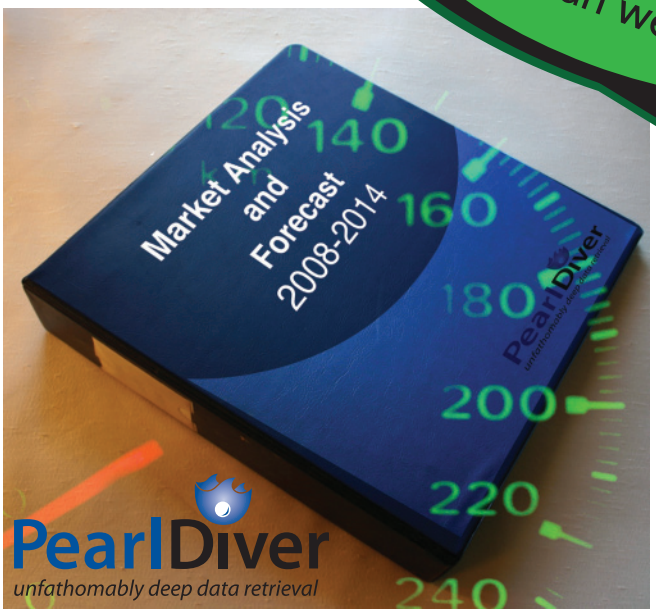

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