VOLUME 7, ISSUE 4 | FEBRUARY 1, 2011

Orthopedics This Week

week in review

picture of success

breaking news

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Zimmer reported sales growth in every sector, surprising Wall Street and, perhaps, setting the stage for a ZMH resurgence. What makes ZMH's performance even more impressive is that its two cross-town competitors (Biomet and DePuy) reported flat and declining sales. With 28% operating margins and a cash rich balance sheet, this year could be Big Blue's year.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	13.51%	0.10%	Street consensus is that OFIX will report down sales and down earnings. Management has beat Street every quarter since 2009.
2	8	Zimmer	27.69	8.16	Q4 Hip sales + 4%, Trauma +9%, Dental +13%. Third least expensive stock in ortho.
3	3	Alphatec	1.59	(10.04)	Insurer headwinds affecting all spine companies. Even so, Street consensus is that ATEC will have #1 earnings growth in 2011.
4	4	Wright Medical	6.36	(4.76)	4th lowest P/E, 5th lowest PSR. Most analysts expecting flat sales and earnings. WMGI still the best value in extremities.
5	6	Stryker	24.71	6.18	Great end of the year report—sharp contrast to Biomet and DePuy. Diversification works.
6	5	Smith & Nephew	22.83	6.18	The rumors of SNN's impending purchase don't die easily. Ironic if the rumors became self-fulfilling.
7	2	Medtronic	32.59	3.26	New buying into MDT but those concerns over spine reimbursement catch MDT more than other firms.
8	7	CONMED	9.07	(1.63)	Stryker's strong MedSurg numbers bode well for CNMD. Most analysts expecting flat results across the board.
9	9	Integra LifeSciences	15.37	(5.21)	RBC downgraded Integra—which makes no sense. IART is one of the fastest growing orthopedic companies.
10	10	Exactech	10.79	(10.20)	We're looking forward to this quarter's report. Most analysts are looking for down earnings on flat-ish sales. But EXAC can surprise.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$3.57	$75	80.3%
2	TiGenix	TIG.BR	$2.91	$90	49.3%
3	Zimmer Holdings	ZMH	$58.58	$11,500	8.2%
4	NuVasive	NUVA	$27.46	$1,080	7.8%
5	Smith & Nephew	SNN	$55.13	$9,780	6.2%
6	Stryker	SYK	$57.20	$22,570	6.2%
7	Synthes	SYST.VX	$123.54	$14,662	4.0%
8	Medtronic	MDT	$38.05	$40,850	3.3%
9	Mako Surgical	MAKO	$15.47	$527	2.3%
10	RTI Biologics Inc	RTIX	$2.59	$142	0.4%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BIHI.OB	$5.15	$185	-39.4%
2	Kensey Nash	KNSY	$23.90	$203	-15.2%
3	ArthroCare	ARTC	$27.82	$752	-11.2%
4	Exactech	EXAC	$16.82	$217	-10.2%
5	Alphatec Holdings	ATEC	$2.42	$214	-10.0%
6	CryoLife	CRY	$5.16	$145	-5.7%
7	Integra LifeSciences	IART	$46.37	$1,310	-5.2%
8	Wright Medical	WMGI	$14.82	$581	-4.8%
9	Johnson & Johnson	JNJ	$60.01	64,800	-3.3%
10	CONMED	CNMD	$26.02	$732	-1.6%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$23.90	$203	10.47
2	Medtronic	MDT	$38.05	$40,850	11.46
3	ArthroCare	ARTC	$27.82	$752	12.29
4	Wright Medical	WMGI	$14.82	$581	12.70
5	Johnson & Johnson	JNJ	$60.01	$164,800	12.92

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Alphatec Holdings	ATEC	$2.42	$214	200.87
2	Smith & Nephew	SNN	$55.13	$9,780	76.34
3	RTI Biologics Inc	RTIX	$2.59	$142	40.34
4	Symmetry Medical	SMA	$9.51	$342	28.64
5	CONMED	CNMD	$26.02	$732	20.00

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$28.78	$510	0.61
2	NuVasive	NUVA	$27.46	$1,080	0.88
3	Medtronic	MDT	$38.05	$40,850	1.29
4	Zimmer Holdings	ZMH	$58.58	$11,500	1.29
5	Stryker	SYK	$57.20	$22,570	1.43

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Kensey Nash	KNSY	$23.90	$203	3.14
2	Alphatec Holdings	ATEC	$2.42	$214	3.00
3	CONMED	CNMD	$26.02	$732	2.53
4	CryoLife	CRY	$5.16	$145	2.25
5	Johnson & Johnson	JNJ	$60.01	164,800	2.15

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	RTI Biologics Inc	RTIX	$2.59	$142	0.91
2	Orthofix	OFIX	$28.78	$510	0.94
3	Symmetry Medical	SMA	$9.51	$342	1.02
4	CONMED	CNMD	$26.02	$732	1.03
5	Wright Medical	WMGI	$14.82	$581	1.17

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.91	$90	321.16
2	Bacterin Intl Holdings	BIHI.OB	$5.15	$185	15.44
3	Mako Surgical	MAKO	$15.47	$527	14.02
4	Synthes	SYST.VX	$123.54	$14,662	8.13
5	Stryker	SYK	$57.20	$22,570	3.13

What's That Smell?

By Robin Young

Wikimedia Commons

Up until the middle of the 20th century, coal miners would take a canary into the mines. Canaries are especially sensitive to methane and carbon monoxide, which made them ideal for detecting any dangerous gas build-ups. As long as the canary in a coal mine kept singing, the miners knew their air supply was safe. A dead canary in a coal mine signaled the need for immediate action.

Wikimedia Commons

Rising Rates of Denials

We at *Orthopedics This Week* have been hearing from an increasing number of spine surgeons about rising rates of reimbursement denials for cases that, in the past, would be approved. Furthermore, the denials do NOT seem to have a scientific basis. Could these independent alerts from surgeons be a "canary in the orthopedic mine" in terms of alerting us to a toxic trend on the part of insurance companies?

For example, this professor and chief of spine surgery at a major teaching hospital in the Midwest wrote us and said "We have experienced blanket denials by Medica and others and have just about given up trying (even though this is covered by Medicare, FDA approved and used on-label). I think some of it becomes surgeon fatigue and we stop trying for approval. Perhaps this is the desired goal of the payers."

His scheduler then followed up with an email to *OTW* saying "It is my job, when a spinal fusion surgery is scheduled, to make sure these surgeries have prior authorization. In the two years I have been doing this job, I have increasingly had more denials then I have had approvals. In the past I would have sent out 15-20 pages of a patient's chart, current clinical, X-rays, MRIs, etc. Now we are at 30-60 pages due to the insurance companies wanting proof of non-operative treatments tried. Most insurance companies are

requiring physical therapy, for at least eight weeks, epidural steroid injections and physiological evaluations."

A couple months ago, Dr. Thomas Errico, the president of ISSAS, sent a note to his colleagues alerting them to the Blue Cross Blue Shield of North Carolina's proposed change in reimbursement policy for spine fusion. A literal storm of response from rank and file spine surgeons prompted nine surgeon societies to form an unprecedented collaboration to respond to the North Carolina proposal. Their letter to BCBS of North Carolina prompted that company to re-examine and change that policy.

But as the stories below illustrate, the North Carolina experience may be the start of a noxious mind set on the part of insurers.

Insurers, Denials and Milliman

Indiana:
"We have been dealing with this for over a year. The increasing rate of denials for coverage has resulted in huge frustration for our patients. We have learned that the only way to get them approved is have the patient call them daily and bug them. The insurance companies constantly lie to the patients telling them that it is our fault for not sending appropriate info, etc. This came to a head for me a few months ago when my scrub tech needed a front/back 5-1 fusion. She went through enormous hassle—constantly being lied to and harassed by the insurance company. But she was persistent-called them every day, sent literature and outcomes data. And the story has a happy ending. They finally OK'd it and she is now returned to work with no pain."

Arizona:

1.) 65-year-old female (on Ætna) had undergone successful L3-5 laminectomy and fusion for stenosis and degenerative listhesis two years ago, achieving a pain free status for over a year. She presented with severe interval degeneration at L2-3 with back pain and stooped forward posture, decreased ability to walk for distance for one year. She tried physical therapy, medications, but the back pain and stooping slowly increased. CT scan showed L2-3 stenosis, inadequate lumbar lordosis (flatback), degenerative spondylosis at L5-S1 without stenosis. I recommended hardware removal, laminectomy L2-3, TLIF L2-3 and L5-S1, Ponte osteotomies L2-3 and L5-S1 to recover her lordosis, and posterior fusion with instrumentation L2-S1. Ætna denied the surgery, stating Milliman Care Criteria.

2.) 50-year-oldmale (Ætna) underwent left L5-S1 laminotomy and diskectomy for herniation, with complete pain relief for five months. His left leg pain returned though it was most severe along the posterior thigh only, and not down the S1 dermatome. He also developed severe mechanical back pain which was improved by rest. Flexion-extension X-rays did not show instability, but only degenerative disc at L5-S1. New MRI showed typical degenerative L-S1 disc and scar in the operative area but no recurrence of herniation. He tried PT, meds, epidural steroid injections with short-term relief only.

Wikimedia Commons

I recommended fusion at L5-S1, which Ætna denied. "This case does not meet the Milliman Criteria" was the reason.

3.) 52-year-old male (Humana) with severe back pain for two years, bilateral leg pain and numbness, stooping posture, ambulatory with a quad-cane, could walk less than 1/2 block. X-rays showed 18 degrees of degenerative scoliosis L2-5 with rotational listhesis L2-3, L3-4, and flatback. He was severely out of balance in the sagittal plane (stooping forward). MRI showed severe stenosis at L4-5 with less stenosis L2-3, L3-4. I recommended L2-5 laminectomies, Ponte osteotomies to regain lordosis and correct the curve, TLIF and posterior fusion L2-3. Humana denied the surgery because the "sports medicine orthopod" that reviewed it stated that "TLIF is an experimental procedure". I pursued an appeal with someone with spine knowledge, and the reviewing neurosurgeon said "there are too many of these fusions being done". Threatened legal action finally won approval for surgery.

"In my experience, reviewing insurance company physicians hide behind the Milliman Criteria, stating they are not withholding care, but merely outlining what is covered as a benefit based on Milliman. Reviewers insist they are not defining standards of care, only covered benefits. The patient is free to have the surgery for out of pocket payment."

"The Milliman Criteria seem to be part of the problem. Today I was told by one of the Ætna reviewers that a patient with a Grade 1 isthmic spondylolisthesis with bilateral foraminal stenosis and bilateral progressive L5 EMG proven radiculopathy did not meet criteria for surgery because she did not have a Grade 2 spondy. It took significant work to get the surgery approved."

Virginia:
"The vast majority of denials that we have seen in Virginia continue to reference the Milliman guidelines as the basis for their denials."

California:
"Definitely increased denials…all very boilerplate using the same language. 'Denied based on Milliman Guidelines'."

Georgia:
"We've been struggling with the Milliman nonsense in Georgia. BCBS of Georgia (Well Point- Anthem) was the first in our area. Others have followed suit. I have a patient who is an international jazz singer. Due to L4-5, 5-S1 disc degeneration, she could no longer stand on stage. Her proposed 2-level ALIF was denied based on the Milliman Criteria (BCBS). She waited until her husband could change the insurance carrier for his business so that she could proceed with the proposed treatment. She has had an excellent outcome, and is now back touring Europe. She has indicated her willingness to share her story, as she and her husband were suitably outraged over the whole mess."

Minnesota:
"The issue that is raised here is in fact the practice of medicine. In deciding that suggested care is or is not appropriate, is a patient and fact set specific practice of medicine. It seems to me that this would fall under the same jurisdiction as legal testimony if it is

not standard of care. At a minimum these individuals could be reported to the various professional societies committees on professionalism. I think that the approach of involving the patients and providing them with information on their individual options is exactly where we will need to go."

Oregon:
"I was copied on an email this morning indicating that Regence BCBS has adopted the Milliman Guidelines, which are perhaps causing surgeons to receive increased denials for fusions for degenerative conditions in Oregon."

Massachusetts:
"I have just had a denial on a very solid gentleman in his 40's. He has had increasing pain for over 10 yrs. He has a normal lumbar MRI with the exception of prominent degenerative changes at L4-5. After exhausting conservative measures including injection therapy, he went through a discogram which confirmed L4-5 as his pain generator. After sitting with him and his wife, we decided to pursue an L4-5 fusion. The patient has been saving his vacation time and working in severe pain so that he can use those days for his recovery. MA BC/BS has denied his surgery (and denied his appeal). He will likely go on to lose the job he loves and endure pain with no end in sight. At least the executives at MA BC/BS will get their bonuses."

Involving Patients

Then one surgeon from California offered the following response tactics when confronted with a denial that is not based on either science or known reimbursement policies.

"Often, when I get a denial authored by a reviewer, I get the patient involved and suggest they do several things. Report the MD to the CA medical society for causing potentially unnecessary pain and suffering by failing to live up to the minimum standards and report the doctor to the insurance commissioner. (The patient also has the right to report the doctor to the respective specialty board.) Then I put in my report that I have suggested these things. Although the medical board never takes action, and a very few patients have actually done the reporting, it is surprising to me how many times I get approval on my appeal!"

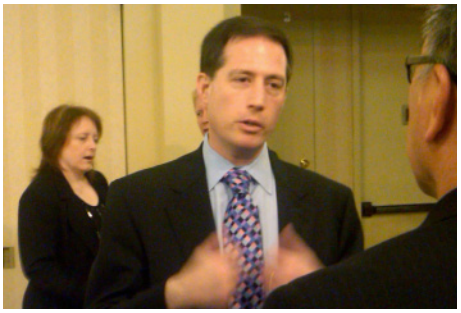
What are insurance companies doing? Clearly, there is a rising chorus of spine surgeon alerts. Could it be that the canary is sensing a more noxious environment for patients and surgeons alike? ◆

Shuren's Innovation Fix

By Walter Eisner

Jeff Shuren, M.D., J.D., the FDA's top medical device regulator, the agency itself and the President of the United States want to close a "device gap" with the EU, keep (or return, depending on your point of view) the U.S. in the lead for developing and promoting new medical technologies.

To close the gap, Shuren, on January 19 unveiled 25 changes to streamline and improve the 510(k) clearance process.



Jeff Shuren, M.D., J.D.

According to a statement from the FDA, the changes include:

- Streamlining the "de novo" review process for certain innovative, lower-risk medical devices,
- Clarifying when clinical data should be submitted in a premarket submission, guidance and thereby increase the efficiency and transparency of the review process,
- Establishing a new Center Science Council of senior FDA experts to assure timely and consistent science-based decision making.

Shuren told crowds at town hall meetings throughout the summer of 2010 that the agency has two missions: "protect and promote" public health. We know from studies that 99.8% of the devices cleared via the 510(k) process have not had reported device-specific adverse events. So, the "protect" mission has apparently been well met. Therefore, after 35 years of the existing 510(k) program, the time has come to improve the "promote" mission.

Photo manipulation by RRY Publications. Source: Wikimedia

The FDA's announcement was previewed by President Barack Obama in a *Wall Street Journal* opinion article the day before specific changes were announced. The President wrote the changes would result in "getting innovative and life-saving products to market faster."

Better, Faster and Less Confusion

Shuren told *OTW* during his press conference that the changes to the 510(k) program will "increase predictability" and "reduce uncertainty" for device developers. Such changes, said Shuren, should make the collection of data by manufacturers more efficient as FDA scientists ask more and better targeted questions. In addition, through the newly established Center Science Council, headed by Bill Maisel, M.D., M.P.H., more senior scientists will be able to rule more quickly on science questions and, Shuren hopes, will speed up the review process. In effect, Shuren promises that the FDA will get better, faster and less confusing, saving device developers time and money.

In addition, among the 25 changes to be implemented throughout 2011 and outlined below, the agency will streamline the "de novo" process to allow new devices without predicates, but deemed safe, to avoid the costly and lengthy PMA "approval" process

and be allowed to enter a new and better 510(k) process.

From his lips to God's ears.

The day before the changes were announced, we understand that the FDA informed ReGen Biologics that the company will not be allowed to enter the de novo process. Let's hope ReGen is not an example of a new and improved de novo process. The company's device was deemed safe by two separate FDA orthopedic panels.

Industry Pleased, Cautiously

Will these changes make it faster and less expensive to get new devices to patients? Will this close the device gap?

Overall, industry representatives seemed pleased with the changes. Bill Hawkins, CEO of Medtronic, reportedly said that the company was "encouraged" by the FDA's release on the actions to implement in 2011.

AdvaMed, the nation's largest medical device trade association thinks this is a move in the right direction.

David Nexon

The association's Senior Vice President David Nexon reportedly said during a call with reporters that the modifications "generally adhere to our principal that changes should be targeted, have a corresponding health benefit and support timely access treatments and cures."

Nexon warned that the changes are only the first part of what he called a "very complicated set of implementation steps.".

The Rollout

The FDA intends to roll the plan out through a process of guidance documents and proposals for new rules, both of which will be open for public comment while in development. See the timeline below.

Nexon told reporters that there will be at least eight guidance documents that the agency needs to put out over the coming year and how those come out "will make a big difference in whether the FDA continues to move in the right direction."

Many of the changes have the potential to improve the timeliness and consistency of the review process. For example, the FDA is proposing to enhance reviewer training, involve external scientific experts, improve the consistency of reviews by developing device-specific guidance documents and streamline the de novo process for medical devices without a predicate, said Nexon.

Mark Leahy, head of the Medical Device Manufacturers Association told us that his group remains concerned that FDA has deferred final decisions on key issues to the Institute of Medicine.

Industry Concession or Promoting Health?

Some "consumer" groups accused Shuren of caving in to industry interests. Diana Zuckerman, Ph.D., of the National Research Center for Women and Families said the FDA's plan suggests "industry lobbyists won, and the public lost."

"Today's FDA report gives the impression that FDA backed down on several safeguards as a result of unfavorable comments," Zuckerman said in a statement. "FDA decisions should not be based on a popularity contest, especially since lobbyists rig the results"

Even America's "business newspaper," The *Wall Street Journal* got in on the act with the headline, "FDA Makes Concessions To Industry In Device Rules." Only a tortious argument could describe steps to promote public health as a "concession" to industry.

When confronted with this accusation, Shuren told reporters, "We don't use the public as guinea pigs in the U.S."

More to Come

Nearly half of the 55 changes the agency recommended in August 2010 were temporarily taken off the table, including the most controversial such as the ability to revoke 510(k) clearances, increased post-market surveillance and the establishment of a new classification for medical devices that would require the submission of clinical evidence.

Those changes will be decided following the release of the independent Institute of Medicine review scheduled to be released this summer.

Following is a timeline of the specific changes announced by the agency:

March:

- Post Council Charter to FDA website to: oversee development of business process and SOP; promote the development of improved quality metrics; periodically audit 510(k) review decisions; establish internal team of clinical trail experts to support and advice on clinical trail design.
- Pilot program to explore the use of "assurance case" framework for 510(k) submissions.

April:

- Hold public meeting on making device photographs available in public database without disclosing proprietary information.
- Hold public meeting on the development of an online labeling repository.

June:

- Draft guidance to clarify which changes do or do not warrant sub-

mission of a new 510(k) and which modifications are eligible for a Special 510(k).
- Post initial results of 510(k) audit to FDA website.
- Determine system requirements and select the new platform for a new adverse event database.
- Post SOP (standard operating procedures) to clarify and quickly inform stakeholders when CDRH (Center for Devices and Radiological Health) has changed regulatory expectations on the bases of new scientific information.
- Complete program assessment on the root causes of existing challenges and trends in IDE (Investigational Device Exemption) decision making.
- Issue proposed regulation to permit rapid and accurate identification of devices and improve adverse event reporting and identification of device-specific problems.

July:
- Draft guidance to improve the equality and performance of clinical guidance.
- Formalize the Centers internal process for identifying staffing needs and enhance recruitment, retention and training.
- Post SOPs clarifying the guidance and regulation development process.

August:
- Develop and implement training on core competencies, including: determination of "intended use"; determining whether 510(k) raises "different questions of safety and effectiveness"; review 510(k)s that use "multiple predicates"; develop and assign product codes; interpret "least burdensome" principles; appropriate use of consensus standards.

September:
- Draft guidance to streamline the de novo classification process.
- Draft guidance to provide greater clarity regarding when clinical data should be submitted in support of 510(k); submission of photographs or schematics for internal FDA use; appropriate use of multiple predicates; the criteria for identifying "different questions of safety and effectiveness" and technological changes; resolving discrepancies between 510(k) flowchart and the Food, Drug and Cosmetic Act; the characteristics that should be included in "intended use"; the development of 510(k) summaries to assure accuracy.
- Develop a network of external experts to leverage external scientific expertise and assess best practices and develop SOPs for staff engagement with external experts.

- Complete evaluation of methods used to integrate device information into a format so it can be used by staff to make regulatory decisions.
- Post SOP of a process for regularly evaluating the list of device types eligible for third-party review and enhance the third-party reviewer training.

October:
- Draft guidance to clarify the appropriate use of census standards.
- Draft guidance to clarify the process for appealing CDRH decisions.
- Completed analysis and make results public on the apparent association between citing more than five predicates and a greater mean rate of adverse event reports.

November:
- Draft guidance to supplement available guidance on pre-IDE meetings and enhance the equality of pre-submission interactions between industry and Center staff.

December:
- Draft guidance to more consistently develop and assign unique product codes.
- Issue proposed regulation on better documentation of 510(k) transfers of ownership.
- Issue proposed regulation on clarifying the statutory listing requirements for the submission of labeling.

All the FDA documents related to these changes can be accessed at:

http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm

IRBs and *P*-Values: Your Research Team

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

You've been called in for an emergency surgery, but you know the Institutional Review Board (IRB) documentation is due today…you also know that the person you hired to handle this isn't as "on the ball" as you had hoped. These and other situations can arise in the time and resource-sensitive arena of research—especially if you don't take care to hire the right team.

Dr. Jeffrey Katz, Director of the Orthopaedics and Arthritis Center for Outcomes Research at Brigham and Women's Hospital, has experienced the gamut if not also run the gauntlet in practice of clinical research. He notes, "The principal investigator (PI) defines the research question, decides on the hypothesis, and develops a plan to test the hypothesis. But none of it is worth much if at the end of the day you don't have a team that can carry it out. Members of the research team must have the appropriate level of experience, an enthusiasm for the work, and a broad skill set. And the value of good interpersonal skills should not be underestimated. The people you hire will be interacting not only with patients, but with staff members, all of whom may have different ways of communicating. Quantitative skills and a solid comprehension of the clinical problem you are trying to address are also critical to the success of the project."

NIST Programs of the Manufacturing Engineering Laboratory/Wikimedia Commons

Dr. Katz, Professor of Medicine and Orthopaedic Surgery at Harvard Medical School, outlines the basics of a team. "Your group should include a project manager, at least one clinician, a statistician, a research assistant who is comfortable talking to patients, and a data manager."

There are enough "unknowns" that crop up during a research project… you don't want more surprises with the people you bring on board. "Ideally, you should hire someone who is a 'known quantity,' i.e., someone who already has relationships—and experience—in the world of clinical research. That way there would not be a lot of surprises because you know their strengths and weaknesses. If that isn't possible, turn to colleagues around the country to find reliable, talented people."

As there is a logical progression to research, there is also a logical progres-

"You should initially search for a project manager (PM)—someone who is able to shift their thinking from the day to day details of the study protocol to the larger picture of clinical and policy issues. You want someone who can see the forest *and* the trees because you will be conferring with them about your strategic decision making."

sion to formulating a research team. Dr. Katz: "Don't, for example, hire the research assistant first because that person doesn't have the broad view. You should initially search for a project manager (PM)—someone who is able to shift their thinking from the day to day details of the study protocol to the larger picture of clinical and policy issues. You want someone who can see the forest *and* the trees because you will be conferring with them about your strategic decision making. Additionally, the project manager should be personable and nurturing because they are often working with young people who assist with the study in various ways. While it is sometimes hard to know whether the applicant has the appropriate technical skills, you can contact someone they have already worked with to assess what they can and cannot handle."

And make sure, recommends Dr. Katz, that the project manager is not uncomfortable with budgets. "Aside from the all important personality skills, the project manager needs the technical skills to help compile and manage budgets. It's not necessary that they have a financial background, but they should have the ability to learn the financial side of things."

"If you are part of a large institution there will likely be an in-house statistician whose expertise you can draw upon. If this isn't possible, contact a local public health school to determine if one of their statisticians may be qualified for the project. That being said, technical qualifications are not enough. You need someone who has a genuine interest in clinical problems…they need to be interested in the application of the numbers they are working with."

Dr. Kurt Spindler is Professor and Vice-Chairman of the Department of Orthopaedics and Rehabilitation at Vanderbilt University Medical School. An avid researcher, Dr. Spindler has also served as an ad hoc grant reviewer for NIH (National Institutes of Health) on many occasions. He states, "A pivotal team member is the research coordinator (project manager). Imagine if your project involves 80 surgeons at 40 sites. Each institution has its own IRB, so you must have a top notch person in order to handle the coordination of all of the

"When interviewing, ask questions along the lines of, 'Have you helped write IRBs? What is your experience in interacting with investigators and patients? Have you collected data from statisticians?'"

related activities and documentation. It can be challenging to find someone with experience in this area."

"Some research coordinators have Ph.D.s and some have Masters degrees; either way, the critical thing is that the person understand the concepts behind the project. Why are we conducting the study, what are the potential outcomes, what are the pitfalls, etc. In the best case scenario, the research coordinator will have some orthopedic knowledge because they will have to deal with inclusion and exclusion criteria, the clinical risks for patients, etc.

Wikimeida Commons

This person also needs to be able to get quality data from the sites—and do so in a timely manner. Lastly, they must understand the basics of data management. In my experience, you're lucky if it only takes 6 to 12 months to find such a person."

Dr. Spindler puts the primary emphasis on hiring the appropriate research coordinator. He recommends, "When interviewing, ask questions along the lines of, 'Have you helped write IRBs? What is your experience in interacting with investigators and patients? Have you collected data from statisticians?' The research coordinator—not the principal investigator—is the one interacting daily with all of these people. Get specifics on their prior involvement with data management. This is important because of all of the research steps and details involved. What if, for example, data from a research site is missing, or is not interpretable? This person needs to understand the checks and balances involved."

And while Dr. Spindler isn't advocating hiring pachyderms, he does suggest that your research coordinator have thick skin. "They have to deal with surgeons—enough said. In general, research coordinators often feel underappreciated for their many efforts. As for surgeons, they must realize that without this person the study can't be done. And the research coordinators are often

"An example of a good statistician is someone who asks the PI, 'What kind of a difference are you looking for in these two groups (one procedure versus another)? How much of a difference is important?'"

dealing with things that drive surgeons around the bend—like communicating with IRBs and completing all of their paperwork. Everyone involved in the project has pressures, but I encourage surgeons to be respectful of their fellow team members. A research coordinator is your right hand…don't cut it off."

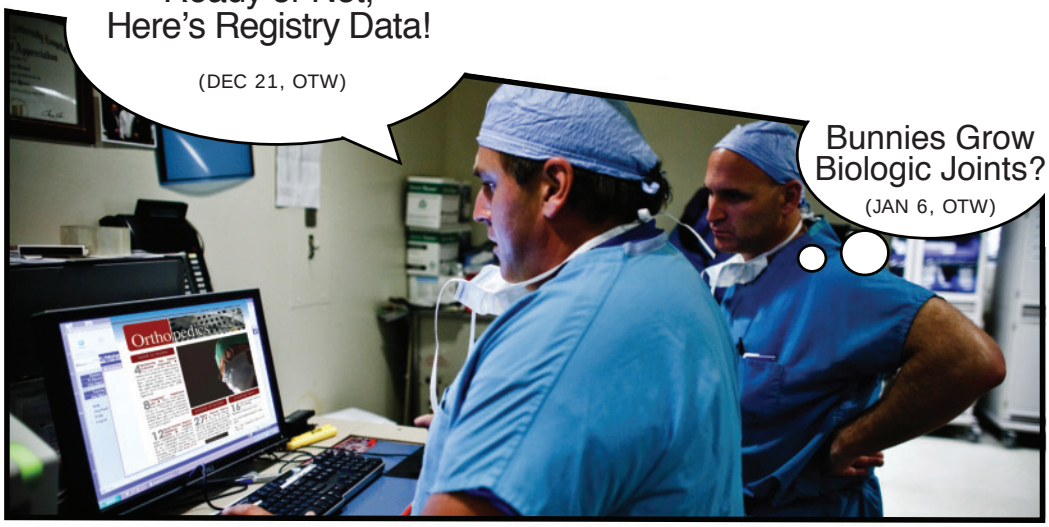
Another veteran principal investigator is Dr. Christopher Bono, Chief of Orthopaedic Spine Service at Brigham and Women's Hospital. He remarks, "If you are undertaking a clinical research project, the most critical thing is to have a clinical research coordinator who has some experience (but doesn't necessarily have a medical background). This individual will be the point person for the study, and must be familiar with the scientific process and technical writing. They need to understand that to a great extent, the job can be tedious, with a lot of computer work and perhaps not as much patient contact as the person would like. I know of problems that have arisen when a research coordinator is brought on board, but misunderstands the job description and begins crafting their own project ideas. Finally, they must be unusually organized and compulsive when it comes to record keeping."

"Red flags? The person you are interviewing tells you that the job of research coordinator is not difficult. Or they arrive late to your appointment and have a disheveled appearance. One thing you can do in the interview is to provide the person with a scenario and ask, 'If you had to do this in a day, how would you do it?'"

In hiring a statistician, says Dr. Bono, be sure that the person hasn't gotten lost in the data. "You need someone who not only has an intimate understanding of the numbers, but who comprehends the clinical goals of the study. Otherwise, that person will become distracted by the numbers. An example of a good statistician is someone who asks the PI, 'What kind of a difference are you looking for in these two groups (one procedure versus another)? How much of a difference is important?' Someone who is savvy in that way will know how to properly design and analyze your study. If, on the other hand, they only ask you about outcome measures and then say that you need X number of patients to achieve statistical significance, then that is someone who doesn't understand the whole picture."

Dr. Bono adds, "Certain projects require a research nurse, i.e., someone who conducts follow up patient examinations. This usually comes into play if the study involves a multicenter protocol for a specific exam or questionnaire (and, for example, every month each person has to undergo an exam). For this position you obviously need a 'people person' in order to encourage people to return each month…and they should be gently aggressive with regard to pursuing the participants."

So to formulate a team whose parts click well together—and do so for the entirety of the project—make sure the individuals are completely clear about the job descriptions, ask the right questions, and talk to those who have gone before you. ◆



company

Dvorak's $1 Billion Call

Call it Dvorak's $1 billion dollar conference call.

When David Dvorak took over from Ray Elliott as CEO and president of Zimmer on May Day 2007, the first few quarterly conference calls with analysts were followed by steep declines of the company's stock price. In fact, we commented that the cost of the calls were getting expensive as hundreds of millions of dollars of equity disappeared overnight.

Zimmer/Wikimedia.com

Dvorak also paid a price in the market as he disrupted and restructured consulting and financial relationships with surgeons. Slowly the company's market share began to erode.

Zimmer 4Q10	Sales $ in million	% Change
Net Sales	$1,130.0	up 2.5%
Reconstructive	$856.0	up 1.0%
Hips	$342.0	up 3.0%
Knees	$474.0	flat
Spine	$60.0	down 5.0%
Extremities	$10.0	up 10.0%
Trauma	$69.0	up 9.0%

Source: Zimmer Holdings

After Dvorak reported on January 27 that the company's 2010 fourth quarter revenue of $1.13 billion was up by 2.5% from the previous year, the company's stock jumped 7% and raised equity by around $1 billion. With cross-town Warsaw, Indiana, rivals Biomet flat lining and DePuy sales actually declining during the fourth quarter, the blue at the Big Blue sparkled a little brighter than usual.

That's what happens when a company exceeds expectations. Wall Street had actually anticipated lower sales for the quarter.

On a reported basis, hip sales rose 3%, knees were flat and spine declined 5%. Extremities were a really bright spot, rising 10% due, according to Dvorak, to the success of the trabecular metal reverse shoulder.

Overall Dvorak credited the results to new products launches, particularly noting the success in patient specific instrumentation in hips and knees where surgeons are able to customize treatments. In hips, he cited the Continuum Acetabular Cup system, as the market shifts away metal on metal constructs.

Like his competitors, Dvorak noted continued reimbursement and pricing challenges in spine. However, Dvorak told analysts that the company continues to see a significant long-term opportunity in spine and noted a new management team at the Minnesota spine headquarters. Dvorak didn't name names, but we've confirmed that former Disc Dynamics CEO Steven Healy, is the new head of Zimmer's spine unit.

"In the quarter, Zimmer's performance was characterized by sequential top-line growth in all geographic segments, successful product introductions and operational discipline, resulting in improved operating margins and strong cash flow," said Dvorak. "Moving into 2011, we expect to continue to strengthen our leadership position in joint reconstruction and to enhance our market share in emerging businesses and geographic markets."

Company CFO Jim Crines told analysts the company expects full-year revenues for 2011 to increase between 3% and 5% on a reported basis. Coupled with

their prediction that the orthopedic market will grow in the low middle digits, it suggests the company is expecting to gain some market share. In fact, Dvorak said he expects Zimmer to be at or above the market in hips and trauma and get back to market rate growth in knees.

With lots of cash on hand, Dvorak was asked why he thought using that cash to buy back 2 million shares of Zimmer stock and investing in orthopedics was a good bet. Dvorak said orthopedic solutions reduce costs in disease management and with the tidal wave of baby boomers still ahead, offering osteoarthritis solutions is a good investment. Even during a period of suppressed volumes, Dvorak said margins are good.

BMO Capital Market analyst Joanne Wuensch observed, "Finally, after several quarters of ceding share to its competitors, the quarter appears to have stopped the bleeding (no wonder the stock is up!)."

With a $1 billion dollar conference call and increased sales under his belt and, anticipated market share gains ahead, Dvorak may just get voted homecoming King in Warsaw this spring.

—*WE (December 28, 2010)* ◆

J&J, DePuy Stumble

There was no way to put lipstick on the results. It was an ugly fourth quarter for Johnson & Johnson (J&J) and DePuy.

Total reported sales for J&J fell 5.5% to $15.64 billion during the quarter. The company's Medical Device and Diagnostic business grew slightly by 0.2%, but DePuy, which has been pulling sales up for the giant healthcare company, was down 1.4% on an operational, or constant currency basis.

According to company management on a conference call with analysts on January 25, reported sales for hips were down 6%, knees were down 4%, and spine dropped 3%.

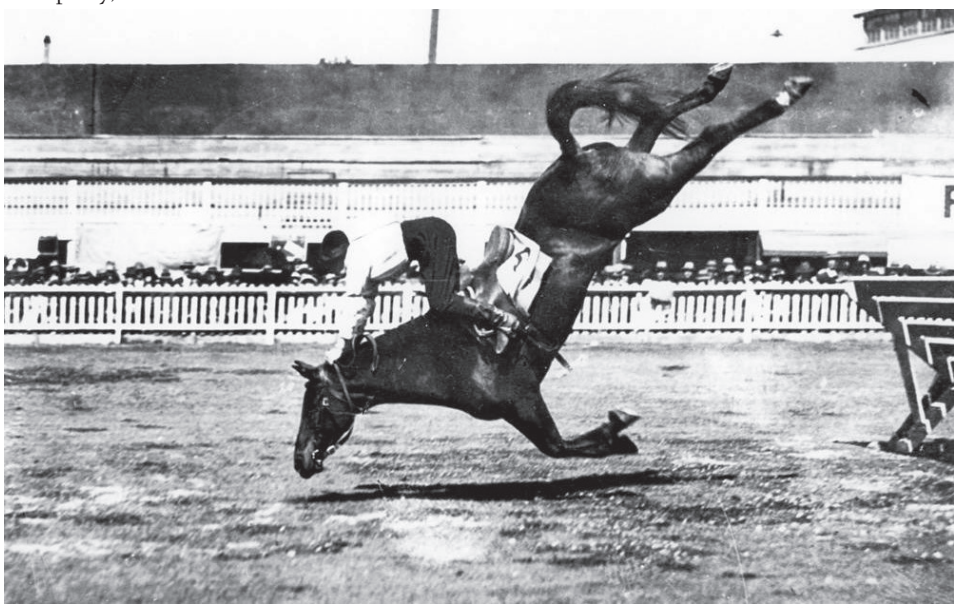
Visible Challenges

Chairman and CEO Bill Weldon didn't sugar coat it. He said the company had "visible challenges" this year with recalls and the company was going to have to "earn back trust and respect" from customers.

Weldon cited high unemployment, declining utilization, pricing pressures, consumer trade downs, govern-

DePuy 4Q10	Sales $ in million	% Change
Total Reported Sales	$1,447	down 1.8%
Hips		down 6.0%
Knees		down 4.0%
Spine		down 3.0%

Source: Johnson & Johnson Analysts call



Wikimedia Commons

ment reform and generic competition as primary reasons for the slowdown. He noted significant payer pushback in spine.

While 2010 was a tough year for the company, Weldon and his management team predicted that the company would reach sales of $64 billion in 2011, a 3.5% to 4.5% increase in reported sales.

Losing Share

Larry Biegelsen, Wells Fargo's senior device analyst, said that DePuy lagged behind its peers amidst macro level challenges.

DePuy's sales in constant currency (hips down 3.7% and knees down 1.7%) was "lower than Biomet which reported global hip and knee constant currency growth of 0.0% and 3.0%, respectively, and Stryker which reported hip and knee growth of 6.0% and 3.0%, respectively, on a constant currency basis, which implies DePuy lost share."

In the U.S., J&J's hip growth of 9.7% on a constant currency basis, was down from -1.0% last quarter due to lower volumes in the metal bearing business and pricing pressure, while O.U.S. growth of 3.3%, in constant currency, decreased from 7.0% in 3Q10.

U.S. knee growth of -1.7% in constant currency was down from 2.0% last quarter, while O.U.S. growth of -0.7% cc decreased from 4.0% cc in 3Q10.

Biegelsen said that global spine growth was lower than the combined growth for Stryker, Biomet and NuVasive in the quarter. Weldon commented that the DePuy business was pressured by macro trends which affected price and volumes partially offset by positive product mix.

While sales were ugly, cash flow was strong. Over the past year, the company increased its net cash by $6 billion to $11 billion. Free cash flow for the year was $14 billion. With all that cash in hand, it was reported in the British press that the company offered $11.2 billion for Smith & Nephew, Europe's biggest maker of hips and knees.

"Although 2010 was a challenging year, the business continued to deliver earnings growth, while investing in the future and emerging a stronger organization," said Weldon. "While we will continue to see near-term pressures on the business for 2011, we remain committed to investing in innovative products, a robust pipeline and talented people who will sustain our growth and increase our market leadership in one of the most important and rewarding industries in the world."

Fischetti Promoted

Note: A day after reporting fourth quarter results, J&J announced that Gary Fischetti has been appointed to the position of Company Group Chairman for the DePuy Family of Companies, which includes DePuy Orthopaedics, Inc., DePuy Spine, Inc., DePuy Mitek, Inc. and Codman & Shurtleff, Inc. Fischetti had been Worldwide President of DePuy Spine since 2005.

—WE (January 26, 2011) ◆

large joints

Overstriding Means Over Injuries?

US Navy Daniel Barker/Wikimedia Commons

The speed of running is determined by two factors, the rate of the stride and the stride length. If a runner wants to run faster, he gains extra speed either by taking longer strides, by taking faster strides, or by doing a little bit of both. Runners make these adjustments unconsciously. All a runner needs to do is decide to run faster and his (or her) body decides how to do it—by increasing the stride length or the stride rate.

As runners move from a very slow jog to a full sprint, their stride rate will increase a little, but their stride length will increase much more. The reason is that the stride length way of attaining speed is more mechanically efficient than the alternative. Each runner has a certain stride rate range that is most efficient for him or her, so runners automatically stay within that range as they adjust their running speed, according to Matt Fitzgerald, author of 17 books on running.

Stride rate appears to be artificially influenced by footwear. Most runners exhibit a lower stride rate at any given speed when wearing shoes than when barefoot. Shoes cause many runners to take "unnaturally" long strides—to overstride. Overstriding is associated with greater impact forces and higher injury risk. In some cases it may be better for a runner to sacrifice efficiency by forcing himself or herself to take shorter, faster strides in order to reduce impact forces and injury risk. The other option would be to run barefoot, but this is not practical for most runners and it may increase the risk for some injuries.

Researchers at the University of Wisconsin recently studied the effects of manipulating stride rate on the level of impact forces absorbed at the knee and hip joints—two common sites of injury in runners. Forty-five runners were recruited to participate in the study. All ran on treadmills at their natural stride rate and at stride rates 5% and 10% greater and 5% and 10% lower than natural, all at a fixed, moderate speed.

The researchers found that increasing stride rate by 5% reduced impact forces absorbed at the knee, while increasing the stride rate by 10% reduced impact forces absorbed at the knee and hip. Impact forces increased substantially when stride rate was reduced by 10%.

These results fall far short of demonstrating that increasing the stride rate reduces injury risk generally, Fitzgerald notes, but they do provide some evidence that it might.

—BY (January 26, 2011) ◆

Whither Sport Medicine?

Exercise as Medicine, What to do About Concussions and The Need for Cardiovascular Screening of Athletes, are among the issues facing sport medicine in this decade, according to articles written by ten invited guest authors. The articles, which dealt with "Emerging Issues in Sport Medicine", appeared in a special issue of the January *Clinical Journal of Sport Medicine* (CJSM). The issue marks the 20th anniversary for CJSM and celebrates the development of sport medicine into an inclusive specialty involving clinicians and researchers from many backgrounds.

Duboix/morgueFile

Among the contentious issues taken up by the authors of the articles was whether cardiovascular screening of young athletes should include an electrocardiogram (ECG). They noted that current European guidelines recommend ECG screening as part of the sport pre-participation evaluation, while U.S. guidelines do not. One writer concluded that current evidence supports mandatory ECG screening.

The writers noted the media attention focused on the serious mental and physical health problems some athletes with a history of repeated concussions have experienced. Countering these reports, one writer pointed out, "[T]he scientific evidence to support these views is limited, with only a handful of cases reported." The author stated that more research is needed to determine which athletes are at highest risk. Meanwhile, he concluded, a gradual return to sport activity after concussion is "likely to be the safest option."

Another article examined the emerging concept of 'Exercise as Medicine'—a new approach to managing chronic diseases in an "increasingly sedentary" society. Sport medicine physicians have a unique role to play, according to the author, "in making exercise recommendations for patients with almost any type of health problem, and in promoting physical activity to maintain health and reduce disease risks."

Other emerging issues highlighted in the special issue are:

- The potential use of asthma medications as "doping" agents to enhance sport performance. The current international guideline permitting some medications but prohibiting others "has no foundation in pharmacological science or in clinical practice."
- The increasing use of platelet-rich plasma to treat a wide range of sport injuries.
- The growing role of ultrasound as a useful and cost-effective imaging technology for in-office evaluation of ligament and tendon injuries and other types of athletic injuries.
- Health and safety issues associated with international athletic competitions—not only travel-related concerns for athletes, but also public health issues related to such large-scale events as the 2010 Olympic Games in Vancouver.
- A condition called femoroacetabular impingement—increasingly recognized as a cause of hip pain in young athletes.

The *Clinical Journal of Sport Medicine* is an international refereed journal published for clinicians with a primary interest in sports medicine practice. CJSM is the official journal of the American Medical Society for Sports Medicine, the American Osteopathic Academy of Sports Medicine, the Australasian College of Sports Physicians, and the Canadian Academy of Sport Medicine.

—BY (January 18, 2011) ◆

reimbursement

BlueCross BlueShield Changes Direction

morgueFile.com

BlueCross BlueShield of North Carolina (BCBSNC) has reportedly revised a controversial reimbursement lumbar fusion surgery policy proposed at the end of last year.

The insurer proposed a policy to deny reimbursement in those cases, among others, where DDD (degenerative disc disease) was the sole diagnostic reason to perform lumbar spine fusion. Nine medical societies: AANS/CNS, AAOS, CNS, ISASS, NASS, POSNA, SRS and the North Carolina Neurological Society, united to convince the insurer to revise that proposed policy. The society's response was drafted by Joseph Cheng, M.D., and Chris Bono, M.D.

The insurer and the spine medical societies held a meeting in North Carolina on January 20. ISASS president Tom Errico, M.D., reported on the meeting to a group of colleagues on January 21.

Errico told his colleagues that the spine group met with two of the insurer's physicians who help direct reimbursement policy. According to Errico, the proposed policy was generated purely from the bottom line numbers of increases in expenditures related to spine surgery.

Insurer "VERY" Impressed

The insurers' physicians were, according to Errico, "VERY impressed" that nine surgical societies all signed onto one letter and that the tone of the letter was conciliatory rather than inflammatory. "They actually said it was the most polite letter they had ever received about a coverage decision," said Errico. Errico was quick to praise North Carolina surgeon, Charles Branch, M.D., for leading the presentation and Bill Mitchell, M.D. of NASS.

"Even before we started, they (the insurer) handed us a revised copy of their policy that mostly incorporated the request from the letter we signed. They also added coverage on flatback osteotomy fusions and separated peds completely from the guidelines. They stood firm on not pre-authorizing fusions in cases of iatrogenic instability created at the time of a decompression," said Errico. He said this was right because, "you don't get pre-authorization for something like this. But they stated they would be understanding on approving the fusion after the fact if it's clearly delineated in the OP report that iatrogenic instability was created necessitating the fusion."

Finally, said Errico, the insurer wouldn't budge on pure fusions for DDD but didn't close the door on approvals for that on appeal.

Evidence and Literature

"All in all it went much better than I could have hoped for and it was largely a positive meeting because we stuck to the evidence in the literature and weren't too far reaching. I think the present coalition we have created is an important one and needs to stay together and now focus on other national insurers and address what I consider to be 'industry created guidelines', the Milliman Guidelines," concluded Errico.

Added Branch, "While the BCBS change was positive, the real win here was the nine spine societies coming together to create and endorse the response letter."

It's been a good few weeks for patients in need of high quality spine care as various insurers have issued positive coverage policies for NuVasive's XLIF, Trans1's AxiaLIF and now, a successful effort in North Carolina from a united effort by the spine and surgery societies.

—WE (January 24, 2011) ◆

CIGNA/Humana to Cover XLIF

They're dropping like dominoes.

NuVasive's Chairman and CEO, Alex Lukianov, announced on January 18 that CIGNA and Humana have become the latest insurers to reverse their previous non-coverage policies about the company's extreme Lateral Interbody Fusion (XLIF) procedure.

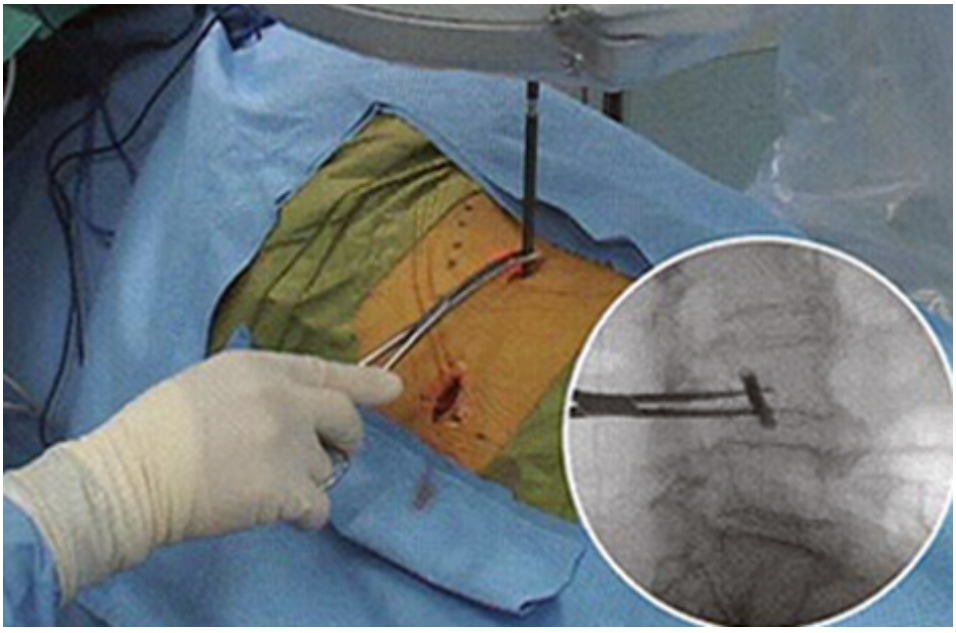
"We are very pleased with the recent coverage decisions by both CIGNA and Humana. We applaud the efforts of surgeons, surgical societies and the insurance companies to ensure beneficial technologies, like our XLIF procedure, are available to those patients suffering from spine related issues. We look forward to future collaborations on spine surgery guidelines in order to provide patients access to appropriate physician recommended treatments," said Lukianov.

According to the company, all of the major commercial insurance providers that once had non-coverage policies for XLIF have reversed their positions. The list includes Aetna, United Healthcare, Health Care Services Corporation, Humana and most recently CIGNA.

This news follows Trans1's announcement on January 7 that Humana will now reimburse providers for that company's pre-sacral AxiaLIF approach.

While these two companies have won coverage decisions, (NuVasive with the assistance of the North American Spine Society), the major spine societies are working together to convince Blue Cross and Blue Shield of North Carolina to modify that insurer's proposed policy changes that will make it more difficult for patients to get reimbursement for the treatment of lower back pain caused by degenerative disc disease (DDD).

—WE (January 18, 2011) ◆



XLIF Procedure/Spine Institute of San Diego

people

Woman Orthopedist Keys Steelers' Super Bowl Run

Super Bowl rings are not just for the guys. Dr. Robin West, Associate

Dr. Robin West/University of Pittsburgh Medical Center

Professor of Orthopedic Surgery at the University of Pittsburgh Medical Center, has one. Hers may be smaller than the men's but the design is the same and the ring has the requisite number of diamonds. West is the Assistant Orthopedic Surgeon for the Pittsburgh Steelers—one of two female NFL team orthopedists, according to Stephania Bell of ESPN W. The other woman is Dr. Leigh Ann Curl, head orthopedic surgeon for the Baltimore Ravens.

West who has been with the Steelers since 2003, assists injured players on the sidelines, in the operating room, and is considered not only a regular member of the team but the essential piece that kept players on the field and now in the Super Bowl.

When West, while a student at Johns Hopkins, was sidelined with mononucleosis her sophomore year, she began working as a student athletic trainer, an activity that ultimately led to medical school. Upon completion of a sports medicine fellowship at the University of Pittsburgh, Dr. Jim Bradley, the Steeler's chief orthopedic surgeon, offered West a position. Bradley says simply, "She was the best candidate for the job."

In addition to her work with the Steelers, West serves as the head team physician for Carnegie Mellon University as well as the University of Pittsburgh's men's basketball team.

West believes that a factor in her acceptance by members of the Steelers football team may be because many of the athletes identify a woman, such as a mother or grandmother, as the strongest force in their personal lives. West applauds the Rooney family and the Steelers organization for being open-minded in its hiring processes. She also credits Ariko Iso, the only female athletic trainer in the NFL who has been with the Steelers since 2002, with establishing respect for women professionals among the medical staff prior to her arrival.

—BY (January 26, 2011) ◆

Vaters Promoted, Rewarded at Orthofix

Bob Vaters has been recognized and promoted for his good work at Orthofix International.

Orthofix President and CEO Alan Milinazzo announced on January 10 that Vaters is, effective immediately, the company's new Executive Vice President and Chief Operating Officer.

"Since joining Orthofix, Bob has had a positive impact on key drivers of the company. This promotion recognizes his contribution to our success over the last two years and we look forward to his continued success with his new responsibilities," said Milinazzo.

The recognition came with some concrete rewards. An SEC filing on January 14 stated that the company's Board of Directors approved a one-time promotion bonus of $115,000 and increased his base salary to $456,500 per year. Vaters will now be responsible for the operations of the company and continue to report to Milinazzo.

When Vaters joined Orthofix in September 2008, the company had experienced a challenging year in the financial markets and saw its stock downgraded by some analysts. In addition, the company's spine division had failed to meet management's expectations. At the time of his hiring, Milinazzo told *OTW* that Vaters' experience in providing financial leadership for global companies and his knowledge of the medical device industry "will be valuable assets as we continue to focus on strengthening our legacy businesses while executing the strategy for our emerging spine business."

Bob Vaters/Orthofix International

Today, Orthofix sits atop the *OTW* Power Rankings. Said *OTW* Publisher Robin Young, "So interesting how Orthofix tamps down expectations then routinely exceeds them each quarter."

Brian McCollum, Interim CFO

Vaters was the company's Chief Financial Officer. That position has been filled, in the interim, with the promotion of Brian McCollum to the CFO spot.

McCollum has been with Orthofix since 2001, most recently as Senior Vice President of Finance since August 2010. From December 2008 until August 2010, he was VP International Finance and Group Treasurer; from July 2006 to December 2008, he was VP Finance, The Americas; and from May 2001 to July 2006 he held various other finance-related positions at the company.

McCollum will be responsible for all financial activities of the company including investor relations. His salary is being increased to $300,000 per year.

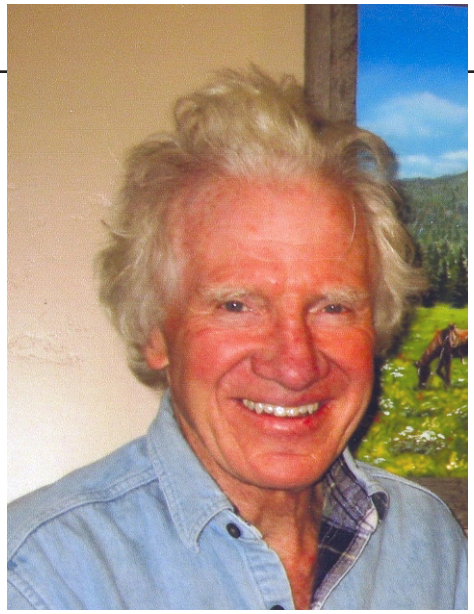
The company also announced that Eric Brown, who had previously held the position of President, Spine Stimulation will "cease to serve as an employee of the company on January 31, 2011."

—WE (January 17, 2011) ◆

THE PICTURE OF SUCCESS

Dr. Charles Hamlin

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



Dr. Charles Hamlin

Some of his epiphanies hit him aboard a freighter in the Atlantic… some came to light on the analyst's couch. No matter…Charles Hamlin was gaining insight into himself and the world—and how he wanted to contribute to society. And contribute he did… he changed a nation.

Now a retired hand surgeon, in 2001 Dr. Hamlin was honored with the American Academy of Orthopaedic Surgeons (AAOS) Humanitarian Award for providing years of expert care to the Navajo Nation—all at no cost to the patients. For this work Dr. Hamlin was also presented with the Navajo Indian Health Service Directors Award.

Raised in a "stern" New England household, Charles and his brothers were expected to "do something" with their lives—but for awhile they would find their way without paternal guidance. "My father was a neurosurgeon who at one point joined the WWII effort and went to the Pacific for three years. Sometimes when I reflect on my work with the Navajo I get a chill up my spine. When I 'lost' my dad to the Pacific, in an eerie way it's like the Navajo code talkers—whose war contributions were immeasurable—were responsible for bringing him back alive."

Most college graduates are itching to get on with their lives. The itch that Charles Hamlin felt after completing Yale undergraduate, however, was one that whispered to him, "seek solitude." "I boarded a freighter for Spain by myself and began to reflect on what it was like to be alone. In nine months of walking the streets of Europe and reading, my thoughts coalesced. From Geneva I phoned the Dean of Freshman at Yale and asked for a job as a freshman counselor, my plan being to take up the sciences and enter a life of medicine. In my time alone I had actually discovered that I quite enjoyed the company of others, and that the best way to be with people was to help them solve important life problems. Perhaps because of my unusual experiences, I was accepted to medical school before my grades even came out. I chose Dartmouth."

While medical school brought challenges, the most significant obstacle of his young life was in the personal arena. "I married a classmate at Dartmouth, but the marriage didn't survive. We both tried our best, but ended up on separate paths professionally and personally. During this time, my wife, a psychoanalyst, convinced me that I should undergo a full Freudian analysis. I saw the merit in this, and so four times a week for nearly five years I took my motor bike and headed to 'the couch.' In fact, this experience was invaluable, and has made me a much more astute physician. In particular, I am able to sense the messages that patients are trying to send me, but are not verbalizing. This experience, as well as my time studying the humanities, has given me

"During this time, my wife, a psychoanalyst, convinced me that I should undergo a full Freudian analysis. I saw the merit in this, and so four times a week for nearly five years I took my motor bike and headed to 'the couch.' In fact, this experience was invaluable, and has made me a much more astute physician. In particular, I am able to sense the messages that patients are trying to send me, but are not verbalizing."

the ability to form trusting relationships with my patients."

And the experience in his career that has changed him the most? "It's a combination of two things. The first is the excellent training I received at Roosevelt Hospital in New York, Hospital for Special Surgery, and Columbia. Additionally, the grounding experience of undergoing psychoanalysis gave me a willingness to accept myself and kept me from being restless or bitter. These two things permitted me to work like hell, enjoy it, and see the richness of life."

With such a foundation, Dr. Hamlin was well positioned to set about "selling" his thoughts on the necessity of hand clinics. "One of my most significant accomplishments was the establishment of a hand clinic at Craig Hospital in Denver (where they only do spinal cord injury and traumatic injuries). I approached the administration about starting a hand clinic in the late 1970s. While the hospital was somewhat skeptical, they gave the approval, and we built a stellar program. I derived a great deal of satisfaction from working with these patients. So much had been taken away from them…they had lost so much independence that to be able to help them regain some of that was tremendous."

A trip with a Craig Hospital medical team would lead to the expansion of Dr. Hamlin's world—and the expansion of life possibilities for the Navajo people. "On occasion, the Craig team went to the Four Corners area to evaluate quadriplegic patients. One look at this high Colorado plateau and something struck me. After some convincing of the local people in charge, I started a volunteer hand service there in 1994. We now hold 18 clinics a year, and treat the Navajo Nation (population: 350,000 people), the Hopi, and the Zuni. While these are not complex hand problems the point is that we are solving them. For example, the people cook with wood, something that often leads to a child or adult getting a bad burn on the hand. Traditionally, any sophisticated treatment was unavailable. You might also have situations where patients cut tendons or nerves in the upper extremity, leading to significant functional loss. Because of our clinics, repair or reconstruction leads to a return to full activity."

In between trips to the Four Corners, Dr. Hamlin was in a thriving group practice in Denver. To keep the staff, the patients, and the practice thriving, he established something rather unheard-of in the world of private practice. "My brother was a professor at Yale, and had just returned (quite refreshed) from a sabbatical. During an office meeting one day I announced that our practice should start a sabbatical program. The idea gained ground, and we established it such that after seven years—and then every five years—a doctor has three months off with financial support. He or she can write poems or visit some mysterious place, etc. The idea is not to produce a body of work (as in academia), but to go refresh oneself. For those who are hesitant to take time off

I say, 'First of all, no one will probably notice that you're gone. If they do, they won't miss you…*and,* you will be just as busy when you return.' During my sabbaticals my wife and I have traveled to Italy, New Zealand, Australia, East Africa, New Guinea…and we just missed meeting Nelson Mandela in South Africa. I fully support the idea that in a forty year career one should occasionally take a side road. Our sabbatical program exists to this day."

In pondering what has brought him this far in life, Dr. Hamlin notes, "I accept the fact that I have not been able to solve every problem that I have

"After some convincing of the local people in charge, I started a volunteer hand service there in 1994. We now hold 18 clinics a year, and treat the Navajo Nation (population: 350,000 people), the Hopi, and the Zuni."

encountered. Yet I also believe that we physicians can at least make a start in solving some problems. I think it's also been helpful that I never took my intellect as seriously as I took my energy. I put the time into working rather than thinking that my idea was going to be a dominant solution in the field."

Dr. Hamlin does have a tendency to be the master of his ego. And it was a stormy Colorado night—and a very large cow—that led him further down this path…and into retirement. "One rain-soaked night three years ago I was returning from our mountain house when my car hit a 1200 pound black angus cow. Two weeks before I had been listening to Virgil's epic poem, 'The Aeneid' on tape and was struck by a certain passage where the warrior asks, 'Bless me in battle.' Hercules responds: 'Each man has his day and life is short and does not come again. But to take action, that is true courage.' Fast forward and I'm stuck in a coffin of a car when a truck arrives. The driver looks in and says, 'You're Dr. Hamlin. You took care of my Pa.' He put the cow out of his misery, pushed my car into the ditch, and drove me four hours to my front door in Denver. The words, 'Each man has his day…' were never far from me during that drive. I took this experience to mean that for me, courage through action would be my retirement by my 70th birthday."

Dr. Hamlin, who says he is gifted with rose colored glasses, looks through them and sees a world of innovation coming down the pike. "We are in an enlarging frontier of vascular and nerve surgery. With the unraveling of the genome, we may well see the manipulation or regenerative growth of damaged cartilage. This will affect not only the diseases we get but our response to them. For example, let's say that someone develops an inflammatory condition—perhaps rheumatoid arthritis or some kind of infection. We might eventually be able to program the environment and orchestrate its response to such problems. I am also excited about the acceptance and advancement of stem cell research to help tissue regenerate. The recently launched Geron project in this country is beginning trials using embryonic stem cells in the freshly injured spinal cord. This could give us great insight into how we can help the central nervous system heal."

There is always change, imperfection, and, if we're fortunate, great growth. "Study the humanities," says Dr. Hamlin to young surgeons. Medicine is an imperfect human endeavor where the landscape is always changing. "Read a book, look at a painting. You will better comprehend the landscape of your patients."

Dr. Charles Hamlin…bringing the family of man into his heart and light into so many lives. ◆

PearlDiver analysts:

- **Attend surgeon meetings**
- **Listen to company analyst calls**
- **Prepare bottom-up forecasts**
- **Bake the latest regulatory, technology and capital markets news into their 5-year forecasts!**

pearldiverinc.com

PearlDiver co-founder Robin Young has been at the forefront of virtually every major technology trend in orthopedics. He organized PearlDiver's research to give senior marketing executives the most actionable market data possible.

Detailed market analysis (in spreadsheets) from $1,950.

Specific indication analysis (in pdf) from $950.

For unfathomably deep and useful medical market research, call the Data Guys at PearlDiver-Scott or Heather at 260-469-4161 or dataguys@pearldverinc.com.

PearlDiver
unfathomably deep data retrieval

Orthopedics This Week | RRY Publications LLC

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

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

Walter Eisner
Senior Writer
walter@ryortho.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Biloine W. Young
Writer
bgwy@msn.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

Main Contact Information:
RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-877-817-6450
Fax: 610-260-6451