VOLUME 10, ISSUE 15 | MAY 13, 2014

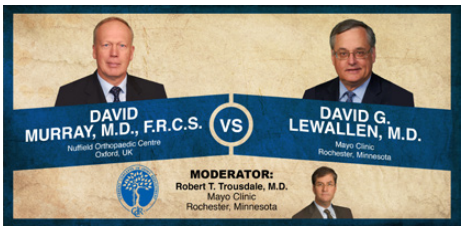
Orthopedics This Week

WEEK IN REVIEW

4 Employees of Zimmer/Biomet – What to Expect >> The dreaded euphemism—"synergy"—has griped Warsaw, Indiana. Employees of Zimmer and Biomet are wondering who stays and who goes. One of the industry's leading executive search firm leaders and former Zimmer sales rep, Drue De Angelis, has some words of advice for his former colleagues.

7 8 Million Obamacare Customers Drive $$$ >> The sign-up period to buy healthcare insurance under Obamacare has closed. Partisans spin the numbers into smoke and mirrors. The data sheds light. What does it mean for orthopedic companies? What's happening to utilization and pricing? Who is happy and sad? We got out our flashlight.

12 Implant Registries Flawed? Murray v. Lewallen >> "The data proves that registries cannot compare implant designs!" says David Murray. "Going to single surgeon or institutional efforts allow large numbers of patients to be studied very quickly," says David Lewallen. "What registry studies really do is allow us to ask interesting questions and perhaps direct the next studies."



16 New Legislation Protects Sports Medicine Doctors// Study: Try Compression Device Instead of Blood Thinners >> New bill in Congress protects sports medicine providers. New multicenter study finds compression device as effective at reducing the risk of thrombosis in hip and knee arthroplasty as blood thinners.

BREAKING NEWS

18 Nerve Damage in **Hip Surgery** Linked to Neuropathy

EOS imaging: New Installation in Japan

Medtronic Settles Some **Infuse Lawsuits** for $22 Million

Heggestad Fills **Orthofix** CFO Chair

2015 **Medicare Ortho Payments** Proposal a Mixed Bag

NASS Takes on **Milliman** and Coverage Denials

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Got yield? So long as those monthly checks are coming, nothing else seems to matter to investors these days. That's why JNJ is hitting record prices. The sector turbulence beneath the surface of the major indices is unprecedented. Large diversified ortho companies with dividend yields seem to be sailing in calm waters while innovative, fast growing companies are battling powerful headwinds.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.31%	4.12%	Zimmer's Persona knee system finalist for the 2014 Medical Design Excellence Award. Building on strengths now.
2	2	ConMed	10.19	9.12	CNMD reported 8.9% increase in earnings for Q1. And announced that buyers for the company are welcome.
3	7	Medtronic	28.84	(2.00)	Settles with 950 claimants for $22 million over Infuse product liability claims. Lawyers: big pay day. Patients: not so much.
4	4	Johnson & Johnson	26.58	1.98	Recent rise in price has pushed dividend yields to 2.60%, down significantly from the 3.30% 5-year average.
5	10	Orthofix	6.75	(5.67)	Mason putting in his new team. These last few months have been about turning the page at OFIX. Patience will be rewarded.
6	3	Smith & Nephew	20.25	1.22	SNN probably has highest dividend payout ratio in orthopedics—42% of earnings paid to shareholders. But yield is only 1.80%.
7	6	Integra LifeSciences	11.77	(2.18)	3% overall Q1 sales growth. Neurosurgery (up 39%) carrying the whole company. Spine down 6%. Extremities up 2%.
8	8	Stryker	15.71	(1.80)	While ZMH is strong in the knees, SYK is weak. Down 1% in Q1. Issue is response to DePuy's and ZMH's new knee products.
9	NR	Exactech	10.15	(10.57)	Stock pulled back. EXAC now the 3rd cheapest ortho equity—#1 in terms of expected earnings growth to price. Back on the Power Rankings.
10	9	NuVasive	6.30	(5.39)	Nice earnings beat in Q1; 11% sales growth. Top quality growth company. But the market isn't paying attention.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	ConMed	CNMD	$48.09	$1,310	9.12%
2	RTI Biologics Inc	RTIX	$4.38	$248	8.68%
3	TiGenix	TIG.BR	$0.68	$108	6.25%
4	Zimmer Holdings	ZMH	$99.98	$16,780	4.12%
5	Johnson & Johnson	JNJ	$100.91	$285,480	1.98%
6	Bacterin Intl Holdings	BONE	$0.71	$39	1.43%
7	Smith & Nephew	SNN	$77.17	$13,800	1.22%
8	ArthroCare	ARTC	$48.54	$1,670	0.75%
9	Tornier N.V.	TRNX	$20.01	$972	0.65%
10	Wright Medical	WMGI	$28.90	$1,440	-0.99%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.69	$32	-33.01%
2	Aurora Spine	ASG	$3.40	$53	-26.09%
3	Alphatec Holdings	ATEC	$1.23	$120	-16.89%
4	Symmetry Medical	SMA	$8.13	$305	-14.69%
5	CryoLife	CRY	$8.92	$251	-12.20%
6	Exactech	EXAC	$20.90	$285	-10.57%
7	MiMedx Group	MDXG	$5.42	$572	-9.06%
8	Orthofix	OFIX	$31.27	$577	-5.67%
9	NuVasive	NUVA	$33.55	$1,560	-5.39%
10	Globus Medical	GMED	$23.59	$2,200	-3.12%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	$8.92	$251	16.22
2	Medtronic	MDT	$60.17	$60,220	16.31
3	Exactech	EXAC	$20.90	$285	16.99
4	Zimmer Holdings	ZMH	$99.98	$16,780	17.15
5	Johnson & Johnson	JNJ	$100.91	$285,480	17.96

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$31.27	$577	135.96
2	NuVasive	NUVA	$33.55	$1,560	108.23
3	Symmetry Medical	SMA	$8.13	$305	73.91
4	ArthroCare	ARTC	$48.54	$1,670	33.48
5	ConMed	CNMD	$48.09	$1,310	27.17

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$20.90	$285	0.94
2	Globus Medical	GMED	$23.59	$2,200	1.51
3	Zimmer Holdings	ZMH	$99.98	$16,780	2.08
4	ConMed	CNMD	$48.09	$1,310	2.09
5	Stryker	SYK	$80.62	$30,560	2.14

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$33.55	$1,560	9.77
2	Orthofix	OFIX	$31.27	$577	7.23
3	Symmetry Medical	SMA	$8.13	$305	6.16
4	CryoLife	CRY	$8.92	$251	4.05
5	ArthroCare	ARTC	$48.54	$1,670	2.79

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.23	$120	0.59
2	Symmetry Medical	SMA	$8.13	$305	0.76
3	RTI Biologics Inc	RTIX	$4.38	$248	1.14
4	Bacterin Intl Holdings	BONE	$0.71	$39	1.17
5	Exactech	EXAC	$20.90	$285	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.68	$108	18.97
2	MiMedx Group	MDXG	$5.42	$572	8.52
3	Wright Medical	WMGI	$28.90	$1,440	5.60
4	Globus Medical	GMED	$23.59	$2,200	5.06
5	ArthroCare	ARTC	$48.54	$1,670	4.38

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

Employees of Zimmer/Biomet – What To Expect

BY DRUE DE ANGELIS

When Zimmer Holdings, Inc. announced it was buying cross-town rival Biomet, Inc., 25,000 employees and stakeholders at both companies began to wonder about their jobs and careers. As former Zimmer sales executive turned human resources expert, Drue De Angelis said: "Merger & Acquisition 101 teaches that the top brass must convey the message that, "everyone is going to be fine! Don't run away." "There's room for everyone in the New Zimmer-Biomet." "Both companies were highly profitable separately and we'll be fine as a new entity, so relax and keep your head down." But, as we all know, cuts will come. The issue is how will you maneuver in new corporate mash-up."

Having been through a massive M&A process before, Mr. De Angelis has a unique, objective and practical view of the changes coming to employees at both Zimmer and Biomet. For example; "Unfortunately, you're not safe just because you are doing a great job in your respective role."

So Mr. De Angelis wrote an open letter to his former colleagues where he gave them some clear advice. We thought it was one of the best we'd read in a while and he allowed us to reprint it here.

Walter Eisner – Senior Writer, Orthopedics This Week

Photo Creation by RRY Publications LLC

Dear Former Colleagues:

If you are part of either Zimmer Holdings, Inc. or Biomet, Inc., as a direct employee or an independent contractor, congratulations on the big news last week. These are exciting times in orthopedics!

But, now what?

The phone calls and emails have already started coming in from people on both sides wondering what to expect. What can you expect to happen and when? No one has a crystal ball, but having been through the Stryker/Howmedica acquisition myself in 1999 and watching many others, I can provide you a little insight into what you might expect to ensue over the months ahead.

Cuts Will Come

Merger & Acquisition 101 teaches that the top brass must convey the message that, "everyone is going to be fine! Don't run away." "There's room for everyone in the New Zimmer-Biomet." "Both companies were highly profitable separately and we'll be fine as a new entity, so relax and keep your head down."

Every manager in the company on both sides will be chanting the mantra from on high as good soldiers. But know this: cuts will come. They will be deep and many will be impacted by it.

Political Players

Unfortunately, you're not safe just because you are doing a great job in your respective role. This is where, if you haven't been a good strategic "political" player, you're going to wish you had. In the end, they will pick sides. Sometimes these decisions are obvious and other

Drue De Angelis is founder of The De Angelis Group, an executive search firm in Scottsdale, Arizona.

The firm specializes in working with early stage orthopedic companies to build their leadership teams. His clients range from venture capital firms, private equity firms to boards of directors of orthopedic start-ups.

Prior to starting TDG, Drue was at Zimmer Holdings, Inc. for 10 years as a Multiple President's Club Achieving Sales Representative before being recruited by Stryker Corporation as Branch Manager of the Arizona Branch where he built an award winning team in Reconstruction, Trauma & Spine.

times they are counter intuitive. This is why Politics plays such a huge part of these decisions. Consider that there is duplication in virtually every single position in the new combined company. And even though they told you that there was room for everyone, we all know better. That never works. It's just what they tell you so that they get their pick rather than having it be made for them by someone leaving before they get to choose.

Focusing on Job Security

The simple fact is that there is not room for everyone in the new company. One of the reasons an acquisition this large works is the "Economies of Scale." Yes, you can expect another round of commission cuts as well, but for now, let's focus on your job security.

You always thought that there was greater job security in a larger company. You were wrong. An acquisition changes everything. Don't get too confident just because you work for Zimmer either. That alone will not ensure you are safe from being part of one of the RIF waves. (Reduction in Force) You're not safe. In fact, if you're not already a savvy political player, it's probably too late for you.

Engage Your Colleagues

But it isn't too late to learn that the best way to ensure that you are kept around through an acquisition is to play nice among your peers and beyond.

People wrongly believe that simply by doing a great job in their specific role, they are immune from ever losing their jobs when a downsizing happens. But they are most certainly vulnerable if they don't spend significant time and energy positively engaging with the people around them.

Companies going through the merger process benefit greatly from the goodwill of hard working people who stay focused on the prize of being part of the "chosen" in the new company. But many unsuspecting people will get their "Pink Slips" and feel betrayed because they did what they were told and didn't look out for themselves.

Learn From "Survivor"

The truth is that it is your top priority to provide for your family and the best way to do that is first by building strong relationships within your company as this is the key to survival in corporate America. You only need to watch one season of Survivor on TV to get a microcosm of what a merger of two separate companies looks like. If you have the right alliance, you might survive. But beware, because just when you thought you were in the right alliance, you've been "blindsided," and voted off the island.

Follow the Power

No one can know with total certainty what their fate will be, but there are

things you can do aside from keeping your head down and trusting that the corporation has your best interests at heart.

Brush up your resume and pay very close attention to who is making a play for power and build an alliance to the best of your ability throughout the company. The fact of the matter is that there will be multiple phases of layoffs. It happens every time there is an acquisition.

Unfortunately, it is part of the code to mislead you that everything will be fine, but it isn't. Don't be naïve and caught off guard. Because the merger won't happen until early 2015, there will be a lot of business as usual with the two companies as they merge.

Build Alliances

My advice is to start building alliances with as many people as possible, and not just the people on your side of the fence. You cannot afford to assume that your side will win regardless of the logic of the argument. You simply cannot predict who will win with any certainty. The only thing that you can be sure of is that there will be very deep cuts in the number of people in the new combined Zimmer/Biomet.

Playing politics is widely regarded negatively and I would say that if that is all you rely upon for your job security, shame on you. If, however, you are great at your job, and not a political player, that isn't enough to survive. You must be great at both. You must be proactive and effective in building rapport with all constituents within your sphere of influence.

Having said that, you'll see some people get to keep their jobs who clearly shouldn't and you'll see some outstanding talent kicked to the curb. Remember, they're only human. These people have to make some difficult decisions and many of them labor greatly over them, knowing that their decisions will hurt people.

Life After Zimmer/Biomet

Lastly, if you are one of the unfortunate ones who get laid off as part of one of the RIFs, don't take it personally and don't let it drag you down. There IS life after Zimmer/Biomet. Keep your chin up and strive toward finding a great place for you to contribute to the ongoing success of a new team. Leverage your talent and experience in a fresh environment. Godspeed!

Drue De Angelis' website is http://www.tdg-llc.com/#about ♦

8 Million Obamacare Customers Drive $$$

BY WALTER EISNER

On May 1, 2014 the U.S. Department of Health and Human Services (HHS) announced that over 8 million individuals had purchased a Qualified Health Plan (QHP) under the Affordable Care Act (ACA – a.k.a. Obamacare). Health plans are reporting that 80% or more of the enrollees have paid their premiums.

The same week the Bureau of Economic Analysis reported that healthcare spending is soaring.

Much has been made over what the new health insurance enrollees will mean to payers, physicians, hospitals and device makers. Will there be enough new customers to make up for the 2.3% medical device tax? Will there be enough physicians to serve the new enrollees? Will new enrollees pay up and what will happen to insurance premiums if enough young and healthy "Invincibles" don't enroll to dilute the risk pool of older, less healthy enrollees? What will happen to utilization and pricing rates?

There is a lot of partisan political heat and smoke which clouds the information needed by those making decisions about how to respond and compete in this changing healthcare landscape. We looked to some non-partisan experts to shed a little light.

Will Enrollee's Need Joint Replacements?

But first, let's take a look at the numbers and demographic data about those enrolling in the federal and state healthcare exchanges.

Photo Creation by RRY Publications/Flickr and Kara Brugman

- Those under 34 years of age comprise about 34% of the enrollees. Enrollment skews towards women 54% to 46%. Think sports medicine.

- Silver health plans comprised about 65% of total plan selections while bronze, gold, platinum and catastrophic plans made up 20%, 9%, 5%, and 2%, respectively. Approximately 85% of individuals who selected a QHP are scheduled to receive financial assistance. Over 4.8 million additional individuals were enrolled in Medicaid since the beginning of October 2013, bringing the total in Medicaid and CHIP to 64.6 million. The enrollment numbers understate total Medicaid and CHIP enrollment because not all states are reporting and the data are preliminary.

- Florida enrolled nearly 1 million people, far more than any federal exchange state—and about 250,000 more people than Texas, which has a larger population and more uninsured residents. Both Florida and Texas were among a handful of states whose enrollment doubled since March 1. Baby boomers!

- It cost the federal exchange, healthcare.gov, an average of $647 of federal tax dollars to sign up each enrollee. It cost an

average of $1,503—well over twice as much—to sign up each person in the 15 exchanges run by individual states and Washington, D.C.

Musculoskeletal Hospital Discharges

The demographics, so far, seem to point to extremities, sports medicine and back pain customers.

In 2010, according to the Centers for Disease Control and Prevention's Discharge Survey, there were 5.56 million musculoskeletal discharges from non-federal hospitals. Of those, 2.26 million were from the pre-Medicare 45-64 age group.

Total hip replacements for that age group totaled 148,000, while total knee replacements totaled 317,000. Disc excision or destruction totaled 178,000.

That leaves the remaining 1.62 million discharges for the rest of orthopedics.

Orthopedic Bump

Needham & Company analyst Mike Matson told *OTW* he estimates that within the first 12 months there would be a 0.6-0.8% increase in hip replacements, a 0.5-0.7% increase in knee replacements, and a 0.8-1.1% increase in spine fusions.

He bases that on the assumption of 3-4 million new people gaining coverage, of which half are aged 45-64 years old and the prevalence of the procedure is the same as the broad population.

Mike Matson
Analyst for Needham & Company

"In reality, the prevalence would probably be higher than the general population since there could be pent-up demand from formerly uninsured patients since many have probably deferred procedures for several years. If the prevalence was twice as high as the

broader population, this would lead to twice the increase," said Matson.

Matson would expect the numbers for sports medicine to be somewhat higher since the patient population is younger.

3 to 4 Million Newly Insured Patients

About half of ACA's enrollees are people who were previously insured and half are not, says Bob Laszewski, a health insurance consultant and publisher of the Health Care Policy and Marketplace Review. He also pointed out that more conventional polls say that repeat buyers are closer to two-thirds of the exchange enrollees. That means approximately 3 to 4 million newly insured potential patients.

When looking at the "Invincibles" Laszewski says the actuaries he talks to think this issue of average age is made to be far more important than it should be. "It is better to have a young group than an old group. But remember, the youngest people pay one-third of the premium that older people pay. The real issue is are we getting a large enough group to get the proper cross section of healthy and sick?"

Bob Laszewski
Health Policy and Strategy Associates, LLC

He adds that many people likely signed up because having insurance is the right and responsible thing to do—especially if their plan was canceled. "Many who had insurance before could now get a subsidy and sometimes a better plan for their out-of-pocket premium. Many also feared the fine. Some have health problems and they can finally get insurance."

2015 Insurance Rate Increases

Laszewski says 2015 rate increases will be about 9.9% because any rate increase of more than 10% is subject to regulatory review under federal guidelines and carriers will have very little hard claim data with which to defend increases. He notes there will be some variation in rate actions because the Obamacare enrollment outcome varies considerably among states. "Also, some carriers' rates turned out to be

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too high and others too low when compared to their competitors which will likely lead to some compression in the local markets as these outliers get closer to typical rates. This could produce a few significant increases or decreases for 2015."

Health insurers, he adds, are also protected from most underwriting losses in 2015 because of a $20 billion reinsurance scheme. "Simply, the carriers are worried about the Obamacare risk pool, they have no hard data to credibly project or defend a challenge from a regulator, and 9.9% is the most they can generally get unchallenged."

Elusive Hard Data

When will we have hard data?

"Years," says Laszewski. "In a year we will have some pretty good data on the 2014 enrollments. But, then we will have just had the 2015 open-enrollment and there will be questions about the impact these new people will have on the overall program. In addition, the 2015 open-enrollment will again have millions of relatively healthier cancelled policyholders signing up for Obamacare because their one year extensions will be running out (don't count on a lot of carriers extending these policies further)."

According to Laszewski, we won't have a good handle on Obamacare's costs until the program's enrollment stabilizes so that the group's final composition can be accurately measured, and we then get at least a year of claim data from that point. Also, at the end of 2016 "the training wheels will come off" as the $20 billion reinsurance scheme ends.

"This is going to take years to play out," cautions Laszewski.

Soaring Spending

One thing we know for sure is that healthcare spending soared during the first quarter of 2014 as millions of people obtained coverage, according to the report by the Bureau of Economic Analysis.

Spending rose by 9.9%, the largest spike since 1980. The increase was largely driven by more use of health services, prescriptions for higher-priced drugs and elective surgeries.

"The sharp increase in estimated utilization appears to have been driven by greater use of healthcare services by people who gained insurance coverage during the first quarter because of the Affordable Care Act," Jason

Furman, chairman of the Council of Economic Advisers, wrote in a White House blog post.

Increased Utilization, Stable Pricing

"It's still pretty early for most of those newly insured to access a whole lot of healthcare services, but some of them definitely are," Ceci Connolly, managing director of PricewaterhouseCoopers Health Research Institute, told *Bloomberg*. "This is definitely an increase in utilization, it appears, more than pricing."

Furman added that prices continued to increase exceptionally slowly, growing at an annual rate of just 0.5% (0.9% on a year-over-year basis), while utilization (real health care spending) rose at the 9.9% rate, following a 5.6% increase in the fourth quarter of 2014.

"The risk pool is fundamentally large and varied to support that kind of pricing…in every state," said Mike Hash, director of the office of health reform for the Health and Human Services Department. "We believe premiums will be stable."

Some analysts say other factors will continue to push up spending and costs. Faster job growth is leading to more health-related spending for many Americans who went without insurance or used few medical services while unemployed, said Dan Mendelson, CEO of the consulting firm Avalere Health LLC.

"The improved economy could result in individuals having the resources to spend on health care services," the American Hospital Association's spokeswoman told reporters.

Upward Cost Pressures

Also, Mendelson says upward pressures on healthcare costs, such as the growth of expensive high-tech treatments, are re-emerging after falling for several years. Costs had fallen because the ACA gave hospitals incentives to be more efficient, and insurance companies shifted more costs to patients, prompting many to visit doctors sparingly, he added.

Happy Days for Insurers

Insurance carriers are practically swooning over the new business. Humana Inc. reported that it expects revenue to grow this year as it adds hundreds of thousands of new customers to its Obamacare plans. The company expects government payments of $575 million to $775 million in 2014 to offset its outsized risk on the new clients who signed up under the healthcare law, many of whom were previously uninsured.

Humana reported it has received 700,000 applications for individual healthcare plans for 2014, putting it on track to be one of the largest players on the exchanges. Humana's rival WellPoint Inc. reported similar sized exchange enrollment last week.

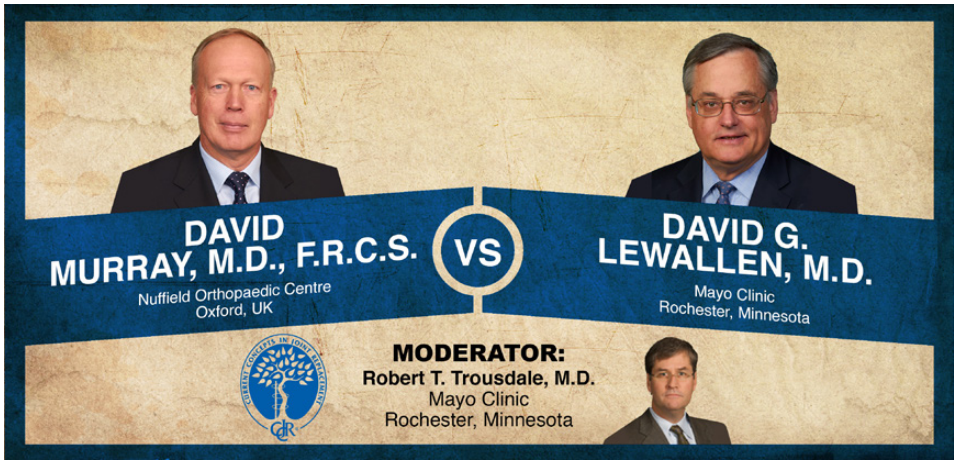
Let the Competition Begin

As Bob Laszewski warns us, it will be a long time before we have hard data to see how the ACA is impacting the healthcare system. For now we know that there are millions of newly insured healthcare customers, pricing remains stable and overall revenue for healthcare providers is rising. How the marketplace of providers, payers, device makers and hospitals compete for those customers remains an unfolding story. ◆

Implant Registries Flawed? Murray v. Lewallen

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

"The data proves that registries cannot compare implant designs!" says David Murray. "Going to single surgeon or institutional efforts allow large numbers of patients to be studied very quickly," says David Lewallen. "What registry studies really do is allow us to ask interesting questions and perhaps direct the next studies."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "The Stuff of Implant Registries: Of Limited Value." For the proposition is David Murray, M.D., F.R.C.S. from Nuffield Orthopaedic Centre in Oxford, UK; against the proposition is David G. Lewallen, M.D. from Mayo Clinic in Rochester, Minnesota. Moderating is Robert T. Trousdale, M.D. from Mayo Clinic in Rochester.

Mr. Murray: "Registries exist for three main reasons: to compare different types of joint replacement, to compare implant designs, and to provide an early warning for poor implant designs. The primary endpoint for these comparisons is revision."

"How reliable is this information? I'll give some examples from unicompartmental knee replacement. Data from a regional registry in the UK—the Trent Registry—showed 10 different total knees followed out to 15 years. Not surprisingly, most would have a survival rate of 90% at 15 years. But there is an implant with 100% survival at 15 years. Everyone who believes in registries says that is the implant you must use. It is the Sheehan Knee…a fixed hinge. I asked the people organizing why this device has a 100% survival and they said, 'Oh well, that's because you can't revise it.' So, ease or difficulty of revision is perhaps the single biggest determinant of the revision rate. In other words, what matters is the threshold for revision."

"One of the few things that all the registries agree on is that unis have a higher revision rate than totals. On the basis of this they conclude that unis have poorer results. Therefore they tell surgeons not to do unis. But is the higher revision rate because unis have poorer results, or might it be to do with thresholds? Imagine two patients come to see you in clinic. Both say they have pain worse after the operation than before, and neither has any mechanical problem. I say that if the patient had had a uni, that many of you would revise it because it's easy; whereas if they'd had a total knee most surgeons wouldn't because the results would be poor."

"The New Zealand Registry also gets outcome scores. Not surprisingly, the unis have slightly better scores than totals. What's interesting is that in New Zealand they subdivide the outcome scores into whether they're poor, fair, good or excellent. Unis have more 'excellent' results, but what is surprising is that unis have less 'poor' results than totals. So the difference in revision rate is not because of poor results. Might it be to do with this threshold?"

"The New Zealand Registry also compares the postop Oxford Score with the subsequent revision rate. Patients with an outcome score of less than 20—worse postop than preop—have a high revision rate. What this registry does not draw attention to is that the axes are different. If you plot these graphs on the same axis you see they are hugely different. If you have a total knee with a very bad outcome, 10% are revised; if you have a uni with a similarly bad outcome, 60% are revised. In other words, the difference in revision rate is a manifestation of a different threshold for revision."

"So one must conclude that registry data cannot reliably compare implant types because of different thresholds for revision. I'd even say that these comparisons are misleading because all conservative procedures—for example, unis—will have a higher revision rate even though they have better results."

"What about identification of poor implants? Data from the Swedish Registry in 1995 shows that the Oxford knee had a very high revision rate…higher than the Marmor. It was so high that the Swedish Registry thought they'd identified a poor implant, and they contacted every surgeon in Sweden telling them not to use the Oxford. Data from the Swedish Registry in 2005 show that the Oxford was then the best. I conclude that registries cannot reliably identify poor implants."

"Comparing data from the Swedish, Australian, and New Zealand registries we see that the Repicci is the worst implant in Sweden, the best implant in Australia, and is somewhere in the middle in the New Zealand registry. One can only conclude that registries cannot compare implant designs. You may say, 'Well, unis are funny things. We shouldn't do them.' I also looked at total knee replacements from three registries. The Maxim was worst in the UK, best in New Zealand, worst in Australia. Registries cannot compare implant designs!"

"Revision rate depends not only on the implant, but on the indications and technique. But registries collect little such data, so they can't adjust for this. So we can draw any conclusion we want. Registry data is important, but is frequently over-interpreted and thus results in misleading conclusions. And if David Lewallen disagrees with this, how can he justify using a cementless total hip replacement when every single registry shows that cemented hip replacements do better?"

Dr. Lewallen: "I agree that there is a tendency to over interpret data from a wide range of studies, not just registry studies. There are different registry types: single surgeon, institutional, health system, single implant, state/regional, national, multinational. What registry studies really do is allow us to ask interesting questions, and perhaps direct the next study to try and find the answers…which don't always come directly from the data."

"One study from our institution (Maradit-Kremers et al., 2013) involved more than 10,000 patients with more than 15,000 primary knees. It allowed us to prove that all poly implants were extremely durable compared to modular implants. What registries can't do is give us early detection of outlier implant performance on a national basis. They don't provide good measures of community-based experience. How it works at our institution may be different than

how it works elsewhere. It's difficult or impossible to detect surgeon or institutional volume effects without registry type information because studies typically come from high volume institutions. And comprehensive reporting of a full range of implant models and manufacturers is not possible."

"An example of hip related information comes from another Mayo Clinic study (Howard et al., 2011) giving us 20 years of experience, and it shows a difference in performance with different designs. The question is, 'Could we have known earlier about some of those that did not perform well?' Perhaps if we had been looking. If you look back after 15 years you will learn these lessons too late to avoid the implants that weren't doing well. You need larger numbers to be able to detect these changes quickly."

"National registries have given us surveillance of implant performance. Also, removal of selected devices that have been proven to be inferior…not because of a single registry data point, but because it focused attention on that design and allowed questions to be asked about what's going on. So more important than the answers provided are the questions. We don't have the resources to study everything in detail and put the necessary effort into the surveillance of new designs."

"I agree with the comments about ease of revisability and the fact that they get a bad rap because of that. But this just shows the kind of thing that can be done with studies looking at low and high volume instances. Higher volume improves the results of some of these implants, showing us some that are excellent devices, but are more demanding…others that are more forgiving where lower volume surgeons can get better results with less experience… and then poorly designed implants that fail in everyone's hands."

"We don't have the personnel to track every single arthroplasty patient through the years. We may be able to use patient reported outcomes to decide who needs follow-up and who we can leave alone. Registries can do a lot of things we can get done with single institutional efforts."

Moderator Trousdale: "David Murray, I take issue with your statement that it doesn't allow us to compare implants. What they don't tell us is 'why.' So the benefit of the Marmor experience is that where it had a high failure rate it

allows those surgeons to explore why it had that high rate in their hands versus someone else's."

Mr. Murray: "I agree. So the registry data is of limited value. Many trainees coming up to their exams—who used to learn the literature and now learn the registry—quote it. In Australia the trainees learn that the Repicci is the best performing uni in Australia and they will go with that."

Moderator Trousdale: "Your issue is how people interpret the data."

Mr. Murray: "People think it's the truth because the numbers are so large and the *p*-values so small."

Moderator Trousdale: "David Lewallen, is it the best way to monitor new innovation?"

Dr. Lewallen: "It's certainly not the only way. There are a variety of things that should be done with new technology, such as RSA studies. But at some point the decision has to be made to release the implant for general usage."

Moderator Trousdale: "Tell us about the finances of the American Registry and the ownership of that data."

Dr. Lewallen: "Individual surgeons and hospitals, etc., have access to their own data, and will have a very sophisticated technique available online for being able to review. It's a not-for-profit organization with multiple stakeholders that is supported by all of the organizations that have a stake in this. There is also representation from the hospitals, private payers, a patient advisory board…so this is owned by the community."

Mr. Murray: "I don't know one implant that's been identified as a poor implant by a registry before it's been identified by surgeons. The problem is that manufacturers tend not to listen to surgeons. Also, in the UK we were led to believe that our data wouldn't become public. Now the government is forcing us to make all the revision data from all surgeons freely available."

Moderator Trousdale: "So what happens in a suburb of London with a surgeon who is doing unicompartmental knee replacement with severe patellofemoral arthritis and he's got a 20% failure rate at 10 years? How does the UK handle that surgeon?"

Mr. Murray: "In the UK they identify outliers—three standard deviations above what you would expect. They report that to the surgeon and the surgeon should do something about it. It's now being reported to the managers, which is unjustifiably changing surgical practice. In the future it's going to be reported generally. I support the registries giving surgeons their data and reinforcing if they are outliers. The Swedish experience shows that this is what works. That's why the revision rate is so low in Sweden…because data is fed back to the surgeons. If all the data goes public then surgical practice will change. Surgeons won't want to operate on difficult cases and they won't use conservative procedures, so you must be careful with this data."

Moderator Trousdale: "Thank you." ♦

New Legislation Protects Sports Medicine Doctors// Study: Try Compression Device Instead of Blood Thinners

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Frederick M. Azar, M.D. Discusses Bill to Protect Sports Medicine Specialists A team doctor accompanies athletes across state lines to cover a game. When the excitement of the game passes, however, he or she learns that they are at risk for a lawsuit. But things are changing with the introduction of a new bill in Congress that would provide licensure clarity for sports medicine professionals. Dr. Frederick Azar, M.D., President of the American Association of Orthopaedic Surgeons (AAOS), tells *OTW*, "Sports medicine doctors often travel across state lines with their teams, and there are a lot of injuries during the game that require rapid evaluation. The team doctor is then faced with an unenviable dilemma: either deny their patient continuity of care from their own doctor who knows the athlete and his or her medical history, or treat their patient at significant professional and legal risk."

"In the absence of licensure clarity, team doctors risk civil and criminal liability when they treat athletes and staff at away games, and their malpractice carriers would likely not cover the civil portion if there was an issue in a different state. Moreover, things have been rather ambiguous because of the differences in state laws. Thanks to this bill, doctors will not have to choose between their patient's care and their ability to effectively practice medicine."

Wikimedia Commons and Carlos Delgado

Eureka! Decrease DVT Risk Without Blood Thinners A multicenter study has found that a new compression device is just as effective at reducing the risk of thrombosis in hip and knee arthroplasty as any of the available drug protocols. Clifford Colwell, M.D. is an orthopedic surgeon with the Scripps Clinic in La Jolla, California. He tells *OTW*, "Hospitals have used compression devices for many years, but the

motors were cumbersome and patients could not take them home. Therefore, physicians have relied on drug therapy; but drugs are met with bleeding issues."

"The ActiveCare+S.F.T., which coordinates with a patient's respiration phase, ensures the best blood flow to the right heart, also takes into consideration the compliance issue: the manufacturer put a LCD on front of the device to record hours of use. We enrolled over 3,000 patients and found that the DVT (deep vein thrombosis) rates based on clinical outcomes were the same as those of those patients who took blood thinners—under 1%—and there was no bleeding."

"Once you get the risk down to that degree, your chances of changing those numbers for the better are low. The next target is to get companies to compete in order to drive down costs. About three companies are trying to put out a portable device, so that will happen. This device costs about $200-$300 for the home use component if the insurance company does not pay. Medicare will not pay for prophylaxis, but this device could be considered more than prophylaxis because we're treating an *impending* clot. It would be difficult to improve on the incidence of clots below the 1% level, but it could be done less expensively."

Note: Dr. Colwell indicates that he was compensated to organize the trial, but that he has no financial interest in the product.

James Jagger, M.D. Wins SEC Team Physician of the Year Team doctors are on a roll in Kentucky. Dr. James Jagger, an assistant professor in the University of Kentucky (UK) Department of Orthopaedic Surgery and Sports Medicine of the, has been named Southeastern Conference Team Physician of the Year. In 2013, it was UK's Darren Johnson, M.D. who earned the prestigious honor.

Dr. Jagger also serves as the UK chief of athletic medicine and head team physician for all UK sports. A graduate of the University of Cincinnati, Dr. Jagger is in his 14th year at Kentucky and has been a vital asset to the UK sports teams.

The Team Physician of the Year award is chosen by the athletic training staffs at Southeastern Conference (SEC) member institutions and is given annually to recognize a team physician who has contributed greatly to both his or her school's teams and to the SEC sports community. ♦

COMPANY

EOS imaging: New Installation in Japan

EOS imaging has announced the installation of the EOS imaging system in Japan's leading spine medical center at Meijo Hospital in Nagoya. The installation is one of the four installations of EOS in Japan since the equipment has received market clearance.

Japanese adoption of the EOS system began in December 2013 with a first installation at Niigata Spine Surgery Center (NSSC) following regulatory approval by the Japanese authorities. The current installation at the Meijo Hospital, affiliated to the Nagoya University Hospital, underscores the adoption of EOS by the best Japanese institutions for spine surgery. Meijo Hospital has the highest volume of deformative spine surgeries in Japan.

Professor Noriaki Kawakami, director of orthopedic surgery at Meijo Hospital, said in the April 22, 2014 news release, "Our hospital performs a vital role providing community health services throughout Japan. The installation of EOS in our facilities and throughout Japan is an important step in ensuring that our patients have access to the most beneficial imaging technology available."

EOS imaging

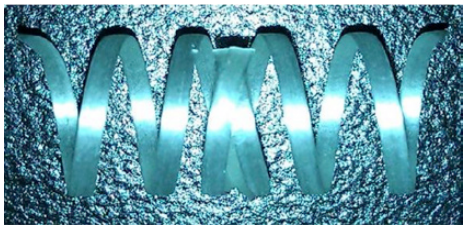
Marie Meynadier, CEO of EOS imaging, said, "We are happy to report rapid adoption of the EOS system in Japan. The Meijo hospital and more globally our four installations demonstrate the positive results from our ongoing market development strategy in the Asia-Pacific region. We are confident that EOS adoption will continue in Japan, and throughout the region, as other physicians see the value of our technology demonstrated at these hospitals."

Meynadier told *OTW*, "As we develop our sales organization and begin to deploy our technology in the Asia-Pacific region, we are simultaneously intensifying our marketing, clinical and applicative support initiatives in countries where EOS is approved. EOS will be present for several major Asian orthopedic meetings in 2014, and we also have EOS symposia planned in China, Korea and Japan. These symposia will allow U.S. and European EOS users to share their positive experiences with our technology with new and potential Asian customers."

—EH (May 7, 2014)

TissueGen: Patent for Self-Expanding Device for Drug Elusion

TissueGen, Inc. has announced that it has been issued a patent from U.S. Patent and Trademark Office for a self-expanding medical device capable of drug elusion within the body. TissueGen's patented product meets the market's need for devices that are self-expanding and can stay in place when implanted in tubular organs of the human body.



TissueGen, Inc.

TissueGen's latest patent applies to the invention of a helical coil comprising multiple reversing sense helical coil units that are capable of drug elution and provide all the benefits of a small closed-cell stent design while maintaining high flexibility, high radial force and crush resistance. The resulting device is well-suited for the peripheral vascular system, but can really benefit most applications where a device is required to maintain position within any tubular anatomical structure.

Definitive testing supports the strength of TissueGen's helical coil-containing device compared to other stents, even bare metal stents. This self-expanding device corrects the issues of previous generations of coil-based stents, which have typically had limited clinical success.

"Helical coil stents have long been a good idea in theory but were prone to migrating in the artery and caus-

ing complications; in some scenarios the end-user patient could even end up with a narrower artery than they started with," said Kevin Nelson, Ph.D., company CSO, in the April 29, 2014 news release. "TissueGen's device has a unique design which allows it to be self-anchoring and prevents tissue prolapse. Another improvement over existing products is that ours reduces the time and effort required by the surgeon to implant the device."

Dr. Nelson told *OTW*, "TissueGen is focused upon licensing this patented design to medical device companies to add value to existing products and enable new innovations that may improve patients' lives."

—*EH (May 6, 2014)*

LEGAL

NuVasive Settles Neuromonitoring Litigation With Cadwell Labs

NuVasive, Inc. announced on May 6, 2014 that the company reached a settlement agreement with Cadwell Laboratories, Inc., in a lawsuit involving NuVasive's patented neuromonitoring technology.

NuVasive sued Cadwell in 2012 over alleged infringement of NuVasive's technology, including the integration of nerve monitoring technology during lateral approach spine surgery. As part of the settlement reached between the parties, Cadwell has agreed to exit the lateral spine surgery market, and to no longer provide products, services, or support for lateral approach spine fusion surgeries. In addition, certain of Cadwell's future products (that rely on NuVasive patented technology) may be required to openly attribute intellectual property ownership to NuVasive and may require a 5% fee paid to NuVasive.

NuVasive, Inc.

According to the NuVasive press release, the company's proprietary monitoring platform is the only technology that can deliver real-time information and has been clinically validated for more than 10 years and in eight peer-reviewed publications.

The company's neuromonitoring technology was previously validated in litigation between NuVasive and Medtronic, Inc. In 2011 a jury verdict awarded monetary damages and back royalty payments to NuVasive in favor of the company's claim that Medtronic's NIM-Eclipse System infringed upon NuVasive's neuromonitoring technology patent. The jury awarded NuVasive $660,000.

This isn't the only neuromonitoring litigation in which NuVasive has been involved. Another jury returned a $30 million verdict against NuVasive on April 3, 2014 in a second trial in the company's ongoing litigation with Neurovision Medical Products over the right to use the trademark, "NeuroVision."

"At NuVasive, we take immense pride in the investments we have made to be a dominant innovator in the spine market, and we intend to aggressively protect those investments. Our neuromonitoring technology is best in class and is central to the facilitation of surgical reproducibility and safety in less invasive spine procedures. I am exceptionally pleased that the solid intellectual property that surrounds our neuromonitoring technology has once again been validated," Chairman & CEO Alex Lukianov added in prepared remarks.

—*WE (May 9, 2014)*

Medtronic Settles Some Infuse Lawsuits for $22 Million

Medtronic, Inc. has agreed to pay $22 million to settle Infuse liability claims with 950 claimants. That averages out to about $23,000 per case.

The announcement on May 6, 2014, stated that approximately 750 filed cases brought by approximately 1,200 individual plaintiffs remain pending in various courts throughout the U.S. The majority of these cases are still in the early procedural stages and none have resulted in a finding of liability against Medtronic. As previously disclosed in Medtronic`s SEC filings, certain law firms have advised the company that they may bring a large number of similar claims against the company in the future. The company estimates those law firms represent approximately 2,600 additional unfiled claimants.

Potential Liability

If there are over 3,000 remaining and potential unfiled claimants and the benchmark is $23,000 per claim, Medtronic could be on the hook for another $77 million.

Earlier this month, on the eve of trial and after several days of pretrial motions, a California trial judge entered summary judgment in favor of Medtronic in the first Infuse case scheduled to go to trial.

The Allegations

As we have previously reported, most of the lawsuits include allegations that Medtronic improperly promoted off-label uses of Infuse. Plaintiff's lawyers are trying to prove those allegations by presenting testimony of former Medtronic employees regarding off-label promotion in a shareholder derivative action, undisclosed payments to opinion leaders, letters from U.S. Senators regarding promotion and marketing of Infuse, the June 1, 2011 issue of *The Spine Journal* and the October 25, 2012 U.S. Senate Committee on Finance "Report on Medtronic's Manipulation of the Infuse Studies and Close Financial Ties with Researchers."

No Admission of Liability

A company statement said the settlement agreement is a compromise of disputed claims and is not in any way an admission of liability or validity of any defense in the litigation by Medtronic. The company continues to stand behind the product, which has been utilized in more than one million patients since it was approved more than ten years ago, and will vigorously defend the product and company actions in the remaining cases.

—*WE (May 6, 2014)*

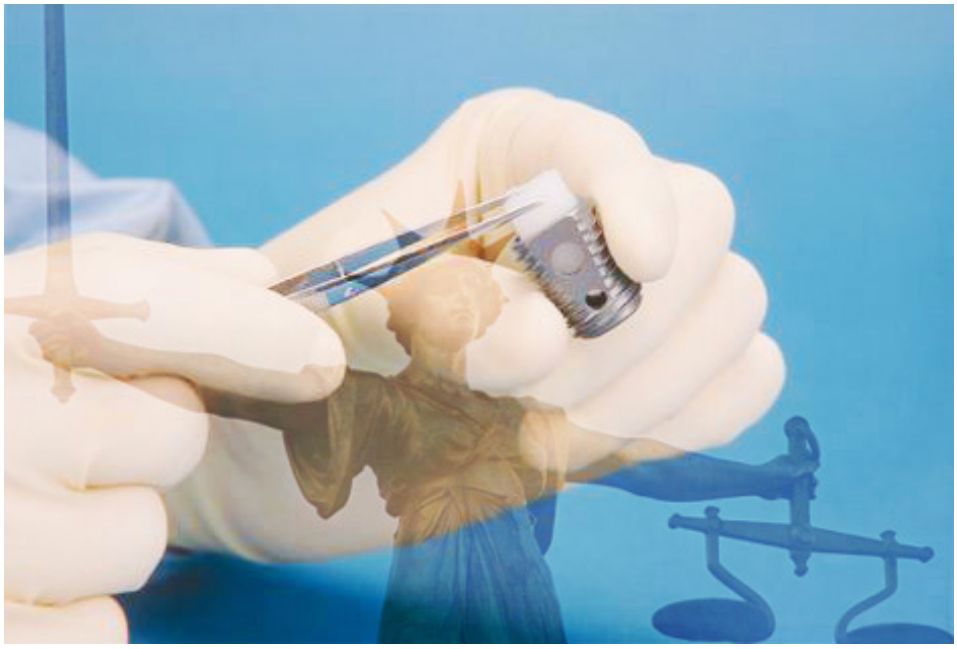


Photo creation by RRY Publications/Infuse product courtesy of Medtronic, Inc.

LARGE JOINT

Nerve Damage in Hip Surgery Linked to Neuropathy

Neurologists from Mayo Clinic are reporting new findings that link some nerve damage after hip surgery to inflammatory neuropathy. Historically, nerve damage from hip surgery has been attributed to mechanical factors caused by anesthesiologists or surgeons, such as positioning of the patient during surgery or direct surgical injury of the nerves.

In this retrospective case series, researchers examined patients who developed inflammatory neuropathies, where the immune system attacks the nerves, leading to weakness and pain. Inflammatory neuropathies may be treated with immunotherapy.

"Neuropathy after surgery can significantly affect postsurgical outcomes," says Nathan Staff, M.D., Ph.D., Mayo Clinic neurologist, in the May 5, 2014 news release. "The good news is that if we're able to identify patients experiencing postsurgical inflammatory neuropathy, rather than damage caused by a mechanical process, we may be able to provide treatment immediately to mitigate pain and improve overall outcomes."

The study included patients who developed pain and weakness in a limb after undergoing hip surgery where there was no documented direct or traction injury during surgery. Nerve biopsy demonstrated an inflammatory neuropathy in all patients.

Dr. Staff says it is important that physicians understand that nerve damage may be related to an inflammatory issue, and there are some telltale signs for physicians to look for:

- Patient's neuropathy isn't immediate, but rather it develops over time
- Severe pain
- Neuropathy progresses
- Different anatomical distribution than expected

"We know new or worsened weakness after hip surgery can be attributed to surgical factors, such as stretching, compression, contusion, hematoma or even transection of the nerve. But now we know that this weakness may be attributed to an inflammatory issue, and it's important that physicians look for this cause, too," says Dr. Staff.

—EH (May 9, 2014)

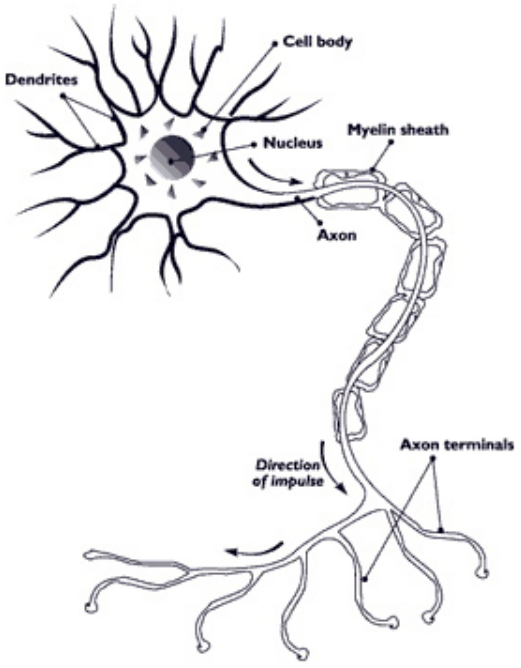


Diagram of nerve cell/Wikimedia Commons

EXTREMITIES

Nextremity Solutions Launches Re+Line Bunion System

Propelled by the positive results of the limited commercial release of its second proprietary product line, Nextremity Solutions, Inc. announces the full launch of the Re+Line Bunion Correction System in the United States.

Nextremity Solutions, Inc.

Rod K. Mayer, company president and CEO, commented in the April 29, 2014 news release, "We are very pleased by the overwhelmingly favorable surgeon feedback on the versatility and stable fixation characteristics of Re+Line. This is important to us given the multiple techniques utilized by forefoot surgeons in bunion correction surgery today. Consequently, we anticipate that Re+Line's unique, low-profile, tension-band plate design will to continue to expand in its applications as we gain more market experience."

William von Brendel, EVP Global Marketing and International Sales of Nextremity Solutions, remarked, "The combination of Nextra and Re+Line provides us a highly differentiated product

presence in the two largest and fastest growing forefoot surgery segments. Additionally, the high rates of combined hammertoe and bunion surgery will provide important synergy to our growing best-in-class product portfolio."

Rod K. Mayer told *OTW*, "It is our goal that one year from now, the Re+Line Bunion Correction System will be recognized as a unique solution for bunion surgery. The Re+Line plate's unique, low-profile 4-point fixation was designed to provide superior stability with multiple osteotomy techniques. This is what forefoot surgeons require to achieve an excellent and enduring surgical outcome with minimum patient downtime. Re+Line will take its place side-by-side with the Nextra Hammertoe Correction System as industry leading implant systems in the hi-growth forefoot surgery market."

—EH (May 5, 2014)

REIMBURSEMENT

2015 Medicare Ortho Payments Proposal a Mixed Bag

The proposed 2015 Inpatient Prospective Payment System (IPPS) for Medicare services paid to hospitals was released by Centers for Medicare and Medicaid Services (CMS) on April 30, 2014. Comments will be taken by agency until June 30, 2014, with a final rule issued by August 1. With more surgeons becoming employees of hospitals, these proposed payments take on added importance for those surgeons.

Orthopedic related DRGs (Diagnostic Related Groups) are up 2.2% vs 5.5% in 2014.

BMO Capital Markets analyst Joanne Wuensch says with the device industry facing stable pricing pressures, the proposed reimbursement changes for hospitals are mixed for certain orthopedic procedures:

- Lower extremity joint replacement (including hip and knee) w/MCC* decreases 0.3% and w/o MCC decreases 0.5%.
- Upper extremity joint replacement (e.g., shoulders) w/ CC/MCC decreases 7.1%.
- Hip or knee revision procedures w/ MCC decrease 1.0%, w/CC increases 0.2%, and w/o CC/MCC are up 1.2%.
- Spine procedure reimbursement w/MCC increases 4.4%.

**Major Complications*

Spine

Overall spine reimbursements were up 2.4%, with artificial discs up 5.3% and vertebroplasty/kyphoplasty up 3.6%. Wells Fargo analyst Larry Biegelsen said companies with the most U.S. exposure to spine are NuVasive, Inc. (89% of total sales), Globus Medical, Inc. (90%), LDR (78%), Orthofix International N.V. (18%) and Medtronic, Inc. (12%).

Hips, Knees and Extremities

Hip and knee replacement DRGs were down 0.6%. Biegelsen said Zimmer Holdings, Inc. has the most exposure as 38% of total sales come from U.S. hip and knee replacements, while Stryker Corporation has 18%, Smith and Nephew 17% and DePuy Synthes 2%. Extremities were up 3.9%. Tornier, Inc. (78% revenues), Wright Medical (72%), Zimmer (4%) and Stryker (3%) are most exposed to extremities.

DRG Changes

CMS is proposing to collapse two upper extremity replacement codes (483 & 484) into the 483 code. CMS is also proposing to create three new DRGs (518,519,520) for cervical discs and deleting existing cervical disc DRGs 490 & 491. CMS rejected code reassignments for total ankle replacement.

—WE (May 7, 2014)

Photo creation by RRY Publications LLC

SPINE

NASS Takes On Milliman and Coverage Denials

The North American Spine Society (NASS) is taking on the Milliman Care Guidelines and inappropriate insurance coverage denials by issuing its first of 13 coverage recommendations for spine procedures.

The recommendations are being distributed to other medical societies and 152 insurance entities.

This is the society's first attempt to proactively write coverage recommendations to counter Milliman or any other such guidelines and give payers a reasonable policy to adopt. To gain credibility with payers, the society has taken conservative, evidence-based approaches to coverage matters over the last several years—sometimes being criticized by some of its members for not being aggressive enough with payers.

The society is likely to get one shot with payers, so this looks like a strategic move to begin with a narrow recommendation and put the best arguments forward. Later the society can begin to chip away at other restrictive policies.

NASS President William Watters III, M.D., told his members in a May 1, 2014 letter that the society has largely been reactive, responding to shortcomings and issues with coverage policies on a case-by-case basis. Watters said it's the society's "strong intent and vision" that payers will use these coverage recommendations to deny "inappropriate denial of quality spine care."

Current Coverage Topics

After an extensive review of available literature, NASS Coverage Task Force members led by Christopher Bono, M.D., developed coverage recommendations to share with payers, patients and spine care providers on the following topics:

- Cervical artificial disc replacement
- Endoscopic discectomy
- Epidural cervical spinal injections
- Interspinous device without fusion
- Interspinous fixation with fusion
- Laser spine surgery
- Lumbar artificial disc replacement
- Lumbar discectomy
- Lumbar fusion
- Lumbar laminotomy
- Lumbar spinal injections
- Percutaneous thoracolumbar stabilization
- Recombinant human bone morphogenetic protein (rhBMP-2)

Future Coverage Topics

The task force will continue to develop additional coverage recommendations. Future coverage policy recommendations include treatments, imaging/diagnostics and surgical augments for:

- Annular repair
- Cervical and Lumbar radiofrequency neurotomy
- Cervical fusion
- Cervical laminectomy
- Cervical laminoplasty
- Facet joint blocks (therapeutic and diagnostic), both cervical and lumbar intradiscal coblation treatments
- Lumbar laminectomy
- Minimally invasive lumbar fusion
- Percutaneous laminectomy (e.g. MILD)
- SI joint fusion
- SI joint injections (therapeutic and diagnostic)
- DNA-based scoliosis test
- Electrical stimulation for bone healing

NASS will revise its coverage recommendations periodically based on the availability of new evidence-based literature and the feedback received from members, patients and insurance entities. NASS strongly encourages interested parties to contact the society with any feedback and suggestions for topics for future consideration by the task force at: coverage@spine.org.

The coverage recommendations can be viewed at: https://www.spine.org/Pages/PolicyPractice/Coverage/CoverageRecommendations.aspx

Image Credit: North American Spine Society

—WE (May 9, 2014)

PEOPLE

Heggestad Fills Orthofix CFO Chair

Mark Heggestad is taking over the books at Orthofix International N.V.

Heggestad will replace the Interim CFO David Ziegler on May 9, 2014. Ziegler has been the company's interim CFO since April 21, 2014. Ziegler succeeded Emily Buxton who voluntarily resigned from the company. Buxton had been named interim CFO in October 2012 and given the permanent role in April 2013.

The company recently emerged from a protracted internal financial review which resulted in restatement of previous revenue. He's got a clean deck.

Brad Mason, the company's president and CEO since March 2013, said there is a "lot to do" in the next few years to "become best in class" in the company's finance and business processes. "I believe Mark will be a great partner to the executive team and me in leading these efforts and that he will keep the company focused on the key initiatives that will drive shareholder value."

Mark Heggestad/Orthofix International N.V.

Before joining Orthofix, Heggestad served as executive vice president and CFO at American Medical Systems Holdings, Inc. (AMS) where his supervisory responsibilities included finance and accounting, investor relations, internal auditing, IT, business development and strategic planning among others. He is no stranger to disruption as he was at American Medical Systems (AMS) during a time when the company CEO left after missing revenue expectations and a difficult merger and acquisition.

Prior to AMS he held a variety of executive and management roles at Medtronic, Inc., including vice president of finance and IT for the cardiac surgery business, vice president of corporate audit & compliance assurance and vice president of corporate finance, assistant controller. Before joining Medtronic, he was as an audit manager for KPMG.

As an inducement to join the company, Heggestad has been granted stock options to purchase 32,000 shares of the company's common stock, as well as 33,000 restricted shares of common stock. The exercise price of the stock options will be the closing price of the stock on May 5, 2014, the date he became an employee. The stock options and restricted shares of common stock will each vest in one-fourth annual increments beginning on the first anniversary of his first date of employment.

—*WE (May 6, 2014)*

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