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Orthopedics This Week

WEEK IN REVIEW

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: Plenty of movement within the Power Rankings as the guessing game for the 2nd quarter begins. Biomet led off with a mixed report and while some analysts may be tempted to think of BMET as a bellwether company, the reality, particularly with a DePuy/Synthes combo and with MDT building share in China, is that other companies are likely to show different sales patterns.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	29.00%	14.02%	Zimmer +Globus? It may never happen, but Biegelsen's analysis shows it is the best combination.
2	2	NuVasive	7.53	20.71	BMO downgraded NUVA since stock has had such a torrid run. Maybe premature. Q2 has yet to report.
3	4	Alphatec	(4.29)	13.28	I can visualize Dorothy clicking her ruby red slippers... there's no manager like Les, there's no manager like Les...
4	5	Wright Medical Group	6.84	11.55	Now almost a billion dollar market cap. This is a case study on how to do strategic well.
5	3	Medtronic	28.65	3.55	Stock hits 52 week high. Interesting note from recent spine surgeon survey is how high MDT rates for service.
6	7	Integra LifeSciences	12.44	4.77	The cheapest equity in orthopedics. Second lowest PE and 5th lowest PE to growth rate. Expectations are low.
7	9	Johnson & Johnson	25.58	7.46	Consensus of Wall Street's analysts is that DePuy/ Synthes sales will reach $2.5billion, up 50% from last year.
8	10	Zimmer	29.49	2.52	Stock up slightly in front of the 2nd quarter release. Consensus is a 3% rise in sales, but stronger earnings growth.
9	6	Stryker	23.68	1.60	Most analysts expect essentially flat earnings for 2Q on a 4% sales increase. If the analysts are right, then they are also expecting margin pressure.
10	8	Orthofix	19.68	(0.11)	Second quarter earnings, which are expected to be cut about in half from last year, reflect prior management.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	$26.70	$1,181	20.71%
2	CryoLife	CRY	$7.28	$200	18.37%
3	Tornier N.V.	TRNX	$18.07	$839	15.10%
4	Globus Medical	GMED	$17.40	$1,602	14.02%
5	Alphatec Holdings	ATEC	$2.18	$210	13.28%
6	Wright Medical	WMGI	$27.91	$1,303	11.55%
7	Symmetry Medical	SMA	$8.80	$328	11.25%
8	Johnson & Johnson	JNJ	$89.99	$252,772	7.46%
9	Exactech	EXAC	$19.86	$267	6.09%
10	ArthroCare	ARTC	$36.83	$1,039	5.99%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.69	$70	-24.71%
2	MiMedx Group	MDXG	$6.32	$606	-11.48%
3	RTI Biologics Inc	RTIX	$4.11	$231	-5.95%
4	Baxano Surgical Inc	BAXS	$2.07	$94	-0.48%
5	Orthofix	OFIX	$27.96	$544	-0.11%
6	Smith & Nephew	SNN	$59.00	$10,636	0.68%
7	MAKO Surgical	MAKO	$12.46	$585	1.55%
8	Stryker	SYK	$67.43	$25,430	1.60%
9	Zimmer Holdings	ZMH	$78.95	$13,292	2.52%
10	Conmed	CNMD	$33.07	$928	3.51%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$27.96	$544	10.88
2	Zimmer Holdings	ZMH	$78.95	$13,292	12.70
3	Medtronic	MDT	$53.44	$53,836	14.37
4	Smith & Nephew	SNN	$59.00	$10,636	14.59
5	Globus Medical	GMED	$17.40	$1,602	15.25

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$27.91	$1,303	121.35
2	NuVasive	NUVA	$26.70	$1,181	70.26
3	Symmetry Medical	SMA	$8.80	$328	30.34
4	RTI Biologics Inc	RTIX	$4.11	$231	24.18
5	ArthroCare	ARTC	$36.83	$1,039	23.92

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.40	$1,602	1.02
2	Zimmer Holdings	ZMH	$78.95	$13,292	1.36
3	Conmed	CNMD	$33.07	$928	1.37
4	Exactech	EXAC	$19.86	$267	1.42
5	Integra LifeSciences	IART	$37.56	$1,054	1.55

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$27.91	$1,303	11.37
2	NuVasive	NUVA	$26.70	$1,181	6.01
3	CryoLife	CRY	$7.28	$200	5.06
4	Johnson & Johnson	JNJ	$89.99	$252,772	2.95
5	Symmetry Medical	SMA	$8.80	$328	2.53

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.57	$24	0.72
2	Symmetry Medical	SMA	$8.80	$328	0.80
3	Alphatec Holdings	ATEC	$2.18	$210	1.07
4	Orthofix	OFIX	$27.96	$544	1.18
5	Exactech	EXAC	$19.86	$267	1.19

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$6.32	$606	22.41
2	TiGenix	TIG.BR	$0.69	$70	17.02
3	Baxano Surgical Inc	BAXS	$2.07	$94	6.42
4	MAKO Surgical	MAKO	$12.46	$585	5.69
5	Globus Medical	GMED	$17.40	$1,602	4.15

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

Why Is This Man Smiling?

BY ROBIN YOUNG

Fred Dinger

Fred Dinger, now that you've sold your third start-up company in ten years, what do you plan to do? Disney World? Bahamas?

None of the above. In fact, Fred's going to Austin, Texas. Which prompts the question, if that was first prize, what was second?

Fred Dinger, the former CEO of ENTrigue Surgical, Inc., C2M Medical, Inc. and OsteoBiologics, Inc. is going to go to work for Austin, Texas-based ArthroCare Corporation.

Aside from his formal title, Dinger's job will be to make sure ENTrigue's shareholders get paid on those milestone payments he just negotiated.

Three companies in ten years. And more than $150 million in payments to shareholders. Not bad for a 52-year-old executive who cut his teeth working for Jim Treace and Barry Bays at firms like Xomed, Linvatec and Concept.

ArthroCare Corporation Buys ENTrigue Medical for $45 million++

On July 1, ArthroCare announced that it had COMPLETED the purchase of ENTrigue Surgical for $45 million plus milestone payments which are based on ENTrigue's future sales. Specifically ArthroCare has committed to paying ENTrigue's shareholders a multiple of each year's annual sales growth at the following rate:

- First three years: 0.6x the increase in sales
- Year four: 1.1x the sales increase
- Year Five: 1.25x the sales increase

In many ways, this acquisition is reminiscent of Arthrocare's Opus purchase in 2004. Opus Medical was a minimally invasive surgery (MIS) technology which made repairs of the rotator cuff, the muscles and tendons surrounding the shoulder faster and easier than traditional surgery. Since becoming part of ArthroCare, Opus has become a hugely successful product category in sports medicine.

Similarly ENTrigue's MIS systems makes ENT (ears, nose and throat) repair faster and easier than traditional surgery. The specific indication for ENTrigue's systems is sinusitis. More than 30 million people in the U.S. suffer from sinusitis and, say the experts, of which approximately 500,000 are treated surgically each year.

ENTrigue MIS systems are pretty comprehensive and include implants, disposables and instruments for endoscopic sinus surgery including innovative balloon dilation. ENTrigue's lines fit well with ArthroCare's ENT products and complement ArthroCare Coblation and Rapid Rhino product lines currently being used by ENT surgeons worldwide.

Common Threads

There are two common threads to Fred Dinger's three start-up companies (OsteoBiologics, C2M and ENTrigue)—a core team that knows what to do and a reliable capital source. "Yes, the team makes all the difference" said Fred when we asked him what the secret was for launching three companies and selling three companies in ten years. "Our team members know what they are doing AND what each other are doing. And we work in dog years. We do in two months what a big company does in one year."

The Vertical Group is the other common thread. Vertical has invested and been on the board at Xomed, OsteoBiologics, C2M and, now, ENTrigue.

The Vertical Group

The Vertical Group is a Summit, New Jersey-based venture capital firm that takes a rather unconventional approach to investing. For starters, Vertical is entirely comfortable with longer term investments. Ten years is no sweat.

But, as Dinger describes them, the partners at Vertical think appropriately for each company. They adjust depending on the company, technology and market opportunity. And they are very capital efficient. In the case of Dinger's companies, Vertical didn't spend a lot of capital building sales forces. Instead, Vertical's focus was on funding quality sales—possibly smaller sales, but better sales. Sticky sales. Vertical had no problem going smaller and slower in order to make sure the product stuck in the market before going national.

For more than 30 years, The Vertical Group's principals have been hands-on investors whether as founders, early stage investors, major shareholders, or executives. Their track record is legendary.

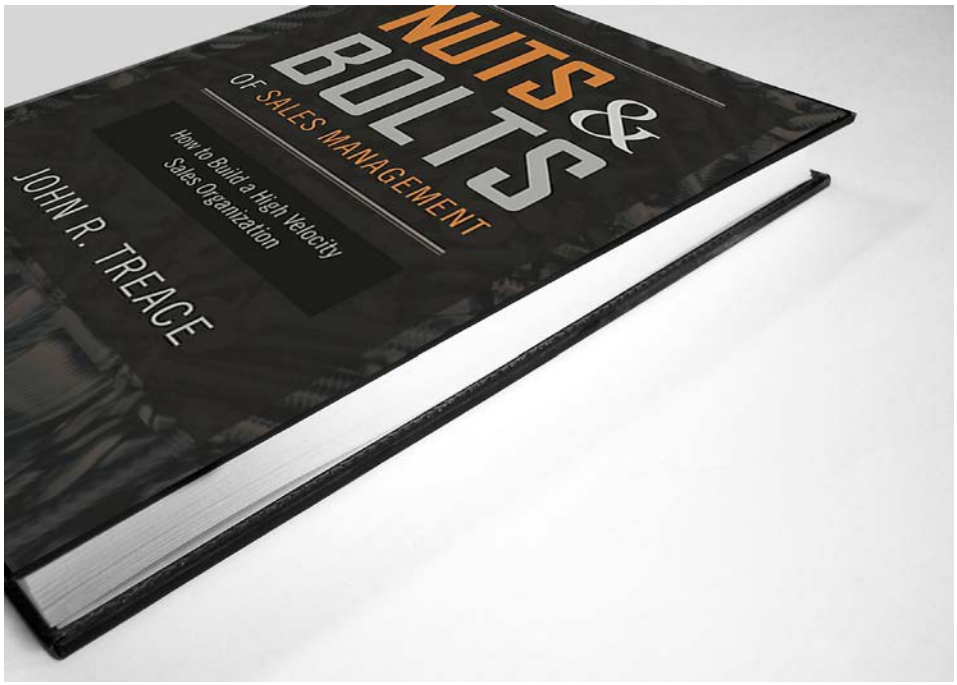
Here's just a few of Vertical's hits: American Medical Systems, Cardiovascular Imaging Systems, Cardio Thoracic Systems, EP Technologies, Intermedics, Kyphon Corporation, OEC Medical, SciMed Life Systems, Support Systems International, Ventana Medical Systems, Wright Medical Group, and Xomed Surgical Products.

The reason the founders and partners call the firm "Vertical" is because they don't limit themselves to one sector of the medical device company continuum. They will invest up or down the spectrum of companies. In their portfolio are early and late venture stage companies; private operating companies, buy-outs or corporate spin-offs and even public companies of all sizes.

Richard Emmitt is the partner working with Fred Dinger at ENTrigue Surgical. Dick's been at play in the medical device field for more than 30 years. He was originally an investment analyst with Cyrus J. Lawrence and F. Eberstadt and, today, is considered one of the leading experts on the health care industry by *Institutional Investor* magazine. He currently serves on the Boards of Directors of American Medical Systems, Inc., BioSet, ENTrigue Surgical, ev3 Inc, Galil Medical, Incumed, Tepha and Tornier. He previously served on the Boards of Directors of OsteoBiologics Inc., SciMed Life Systems, Xomed Surgical Products and Wright Medical Group.

How Dinger Does It

In many ways, the Dinger style is also the Jim Treace, Barry Bays and John Treace style—albeit with Fred's unique way of implementing and adapting.



"Nuts and Bolts of Sales Management: How to Build a High-Velocity Sales Organization" by John Treace

While we don't know when Jim Treace and Barry Bays will write their books, John Treace wrote "***Nuts and Bolts of Sales Management: How to Build a High-Velocity Sales Organization***" a couple of years back and we reviewed in early 2012.

One of the best sales tips I've ever read was in John's book. Here it is:

> Lou Holtz, famed college and NFL football coach wrote in his book ***Wins, Losses and Lessons*** that there are three questions that people mentally ask about you. These are the questions customers must answer about each sales person or company before they buy:
>
> "Can I trust you?"
> "Do you care about me?"
> "Are you committed to excellence?"

Those three questions frame up Treace's chapter on sales tips. For example, when you're a new rep in a new territory the customer has no frame of reference with which to judge you. And you're under pressure to rapidly establish a relationship with a busy, potentially antagonistic physician. It's a rough assignment. What do you do? Treace delivers with solid tips.

And, like all great coaches, Treace starts with the basics. Stuff your mother told you.

- Make a good impression. Look sharp and speak intelligently and succinctly. For good or ill, people make snap judgments so those first impressions are not only critical but entirely under your control. Don't waste it.
- Take notes. With good notes every sales rep won't forget a promise, a direction or critical piece of information and in, effect, make good on the promises of excellence and trust.
- Show you care by remembering the little stuff. Study after study of customer buying habits show that

four sales rep attributes rank higher than product price or quality—they are knowledge, helpfulness, speed and loyalty to the customer ("Do you care about me?").

Dinger, who learned a lot from his tenure at Xomed, Linvatec and by working with Bays and the Treace brothers, has added a few of his own elements to success. When asked, the first thing that Dinger talks about is finding ways to create value—not simply sales. What is building value? For Dinger it means working the kinks out of a product line before launching it. Instead of "Ready, Fire, Aim," Dinger spends a fair amount of time aiming, and testing and getting "the kinks worked out."

That's pretty much it. Get the kinks worked out. This means to figure out the indication, get the design right, get the reimbursement figured out and make it sticky. Sticky means that the product generates customer loyalty and re-orders. Once he has a sticky product with no kinks, then Dinger looks for a company—like Smith & Nephew or Tornier or ArthroCare—that has the sales and distribution to roll the product out nationally if not also internationally.

Oh yes, and then there is his posse. The people who have followed Dinger from OsteoBiologics to C2M to ENTrigue. Certain people keep showing up with Dinger at each of his companies. Two of those are Gabriele (Gabi) Niederauer, Ph.D. who has been VP of R&D and Regulatory, and Joey Oliver who has been CFO (& COO) at all three of Dinger's startup companies. Another is Jeff Wrana, a senior level orthopedics engineer who has been driving designs at OsteoBiologics, C2M and now ENTrigue.

Gabi Niederauer, Ph.D.
Source: Gabi Niederauer, Ph.D.

What's Next?

ArthroCare. For maybe the next five years. Of course, Dinger is a rare talent. And once that start-up bug bites, it's hard to give it up. Finally, big company life is not like start-up life—time, for example, gets measured in human years, not dog years. ♦

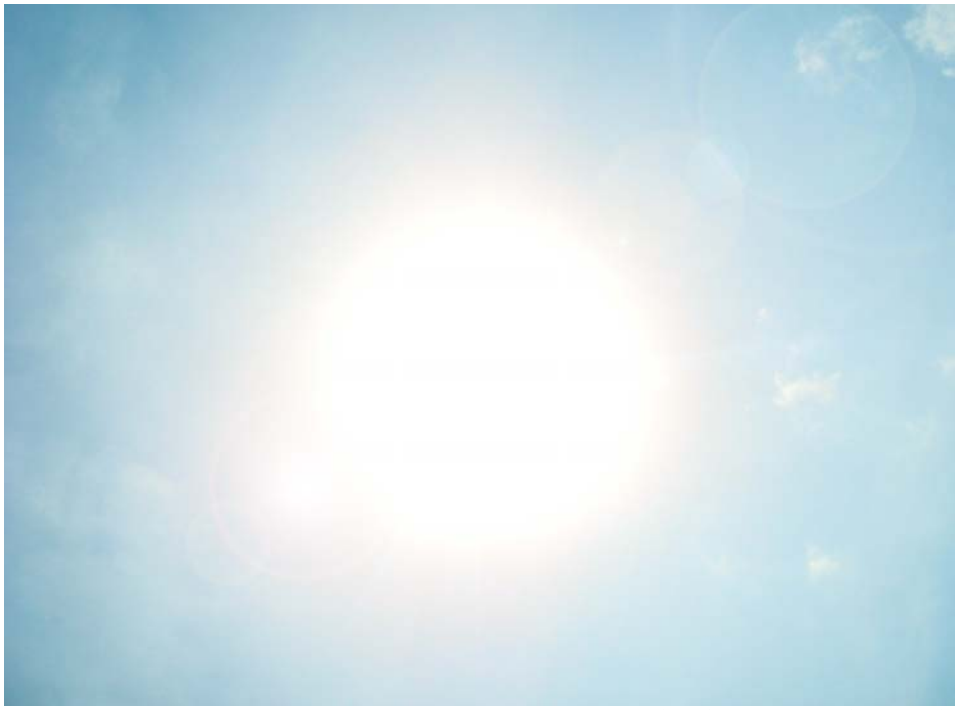
Here Comes the Sunshine Act – Is Anyone Ready?

BY WALTER EISNER

The Sunshine Act kicks in August 1, 2013. That day, device and pharmaceutical companies begin collecting data about payments to physicians and teaching hospitals. Public reporting will begin in 2014 under the National Physician Payment Transparency Program (NPPTP) for the Centers for Medicare and Medicaid Services (CMS).

Are you ready? If you're a manufacturer, do you know what you're supposed to track and how to submit the data? If you're physician, do you understand what is being tracked and reported and how you can be sure companies are reporting accurately?

The law covers meals, honoraria, travel expenses, and grants. It also requires disclosure of physician ownership in companies and investment interests in group purchasing organizations (GPOs).



Wikimedia Commons and Arivumathi

Physician/Industry Relationship

Physicians have significant relationships with industry. A 2007 study noted in a May 2013 article in the *New England Journal of Medicine* by Shantanu Agrawal, M.D., Niall Brennan, M.P.P., and Peter Budetti, M.D., J.D., said that 94% of U.S. physicians have such a relationship, with 83% receiving gifts, and 28% receiving payments for professional services such as consulting or research participation. Sixty percent of physicians with industry relationships were involved in medical education, and 40% developing clinical practice guidelines.

Industry accounts for up to 60% of the $100 billion spent annually on research and development of new drugs and devices. Industry also pays for more than a third of all continuing medical education (CME), according to the article.

Previous Disclosure Efforts

The payment disclosure requirements, part of the Affordable Care Act, aka Obamacare, come on the heels of previous efforts to increase disclosure of physician industry relationships. In 2009, the Institute of Medicine (IOM) developed recommendations to manage conflicts of interest without affecting constructive collaboration. The Medicare Payment Advisory Commission (MedPAC) has proposed a national reporting program. Medical and industry groups such as the American Medical Association, the American Academy of Orthopaedic Surgeons and AdvaMed (the Advanced Medical Technology Association) have developed voluntary codes of ethics to manage physician-industry relationships.

Various states, including Maine, Massachusetts, Minnesota and Vermont, set up their own public disclosure requirements. Various companies are also required to publicly disclose payments as a result of Corporate Integrity Agreements (CIAs) or as part of the settlement between the major orthopedic companies and former U.S. Attorney Christopher Christie. Most of those disclosures stopped as the agreements and settlements were concluded.

Reporter and Payment Requirements

"Applicable manufacturers" including foreign companies must report pay-

ments to teaching hospitals and physicians, including all doctors of medicine, osteopathy, dentistry, podiatry, optometry, and chiropractic medicine.

Payments or transfers of value worth at least $10, and transactions of less than $10 if they total $100 or more in a given calendar year, must be reported. The range of items that must be reported includes cash or a cash equivalent, in-kind items or services, stock, consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel (including the destination), education, research, charitable contributions, royalties or licenses, current or prospective ownership or investment interest, speaker compensation for CME events, and grants.

Data collection and reporting requirements fall on those making the payments, not those receiving them.

Protecting Secrets, Education and Research

Industry sources have expressed concerns that disclosure of payments to surgeons working with them to develop new products will give away proprietary information to competitors. They've also noted the Kafka-esque requirement that they collect their own evidence which could be used by the Department of Justice (DOJ) to target highly compensated physicians for investigation.

To address the competitive proprietary information concern, payments related to products in development before regulatory approval will not be published for four years or until FDA approval has been granted. Reporting of CME-related payments is restricted to cases in which the manufacturer had direct influence over the choice of speaker.

Regarding research payments in the development of devices, a separate reporting stream for research payments will clarify for consumers that a principal investigator directing a $5 million research grant from a manufacturer is

not accruing all $5 million for his or her personal use.

Physician Concerns

But physicians are concerned that reporting may lead to misleading conclusions.

Data collected from August through December 2013 will be publicly available by September 30, 2014. Subsequent reporting will be for each calendar year. Physicians will have 45 days to review and dispute any data that appear inaccurate, and manufacturers and GPOs will then be able to make necessary corrections. The data will be released online in an easily searchable form and will contain contextual information on the many appropriate reasons for which physicians and teaching hospitals maintain relationships with drug and device manufacturers.

Physician Check List

To ensure that payments are being reported accurately by companies, physicians should:

epconlane.com/checklist

- Track their own payments from industry
- Clarify with industry representatives what will be reported
- Provide companies with identifying information such as their National Provider Identifier (NPI), state licensure information, business address, and specialty
- Inquire about the source of payments they receive, since transfers of value can occur indirectly—through specialty societies, for example—when funding originates with manufacturers
- Participate in the prepublication review-and-dispute period to validate reported data and identify potential inaccuracies
- Updating NPI information or obtaining an NPI through the National Plan and Provider Enumeration System (https://npiregistry.cms.hhs.gov) is critical.

Physicians can also supply information to manufacturers and encourage its reporting to provide the appropriate context for research funding, grants, or other payments; manufacturers may not possess this information otherwise. In particular, physician groups may want to explain how payments were obtained and divided equitably among members.

Disclosure, Kickback Statute and False Claims Act

What is the relationship between Open Payments and the Federal Anti-Kickback Statute, False Claims Act or similar legislation?

According to CMS, compliance with reporting requirements does not exempt anyone from any potential liability associated with payments or other transfers of value, or ownership or investment interests under the Federal Anti-Kickback statute, False Claims Act

or similar laws. As noted in the preamble of the rule, however, the inclusion of a payment or other transfer of value or ownership or investment interest in Open Payments is not, by itself, an indicator of wrongdoing or illegal conduct.

In a recent *Financial Times* article, an official from HHS-OIG (U.S. Department of Health and Human Services-Office of Inspector General) noted that either DOJ or OIG could flag certain payments that raise concerns about possible kickbacks or other fraud violations. Either agency can take the lead in pursuing suspected violations of the Anti-kickback Statute. "As far as whether payments will be viewed as kickbacks, that is evidently a possibility," said the official.

Information posted to the CMS site would not be sufficient in and of itself to bring any kind of legal case, according to the official, but the data could be cause for further investigation. It is "certainly fair to assume that DOJ and the OIG will be taking a look" at the information, noted Andrew Van Haute, AdvaMed's associate counsel. However, he added, the sheer act of disclosure does not mean investigations are warranted.


Lewis Morris/Adelman, Sheff & Smith, LLC

Lew Morris, the OIG's former chief counsel said in the article that manufacturers and healthcare providers could face multiple sources of scrutiny. The published data will likely be of interest to "whistleblowers and investigative reporters and law enforcement," among other groups, he said.

This attention could be unjustified for those "outliers that really aren't outliers and are just a matter of information being put into the wrong category," added Morris, now an attorney at Adelman, Sheff & Smith, LLC.

Morris also said there is broad understanding that Sunshine implementation will involve some complications. Based on his conversations with the DOJ and the OIG, he said it is unlikely that enforcers "are going to be handing out traffic tickets the first day that the rule goes into effect."

CME Reporting Requirements

Are payments provided as compensation to speakers at CME events run by CME providers reportable?

Yes, according to CMS, unless the CME event is run by CME providers that are accredited or certified by one of the accreditation or certification entities identified in the law. Payments to speakers at CME events that are not run by identified CME providers are reportable payments or other transfers of value for Open Payments. The agency said it will consider modifications to this provision in possible future rulemaking.

The five accrediting/certifying bodies include:

1. The Accreditation Council for Continuing Medical Education ("ACCME")
2. The American Academy of Family Physicians ("AAFP")
3. The American Dental Association's Continuing Education Recognition Program ("ADA CERP")
4. The American Medical Association ("AMA")
5. The American Osteopathic Association ("AOA")

Payments provided to speakers, faculty, and physician attendees for travel, lodging and meals at CME programs that are not accredited by one of the five bodies are also reportable, and must be reported separately. Educational value and materials provided to physician-attendees, such as a journal reprint, would also be reportable for programs not accredited by the five bodies. CMS recommends that "[t]he value of a journal reprint should reflect the cost that an applicable manufacturer…paid to acquire the reprint from the publisher or other distributor."

Learning Disincentive?

According to the publication, *Policy and Medicine*, this strict interpretation by CMS may limit the participation of physicians in allied health educational programs supported by manufacturers. It also ignores the accreditation systems which have adopted similar standards as the ACCME for optometrists, podiatrists and chiropractors.

"These doctors will have all their faculty payments for accredited education listed as 'payments for serving in a non-accredited medical education program', 'honorarium', 'services other than consulting', 'grant' or 'charitable donation'," according to the publication.

It's a new era for disclosing the financial relationships between companies and physicians. It will undoubtedly take a long time to work out the kinks and grasp the significance of the unintended consequences of new disclosures.

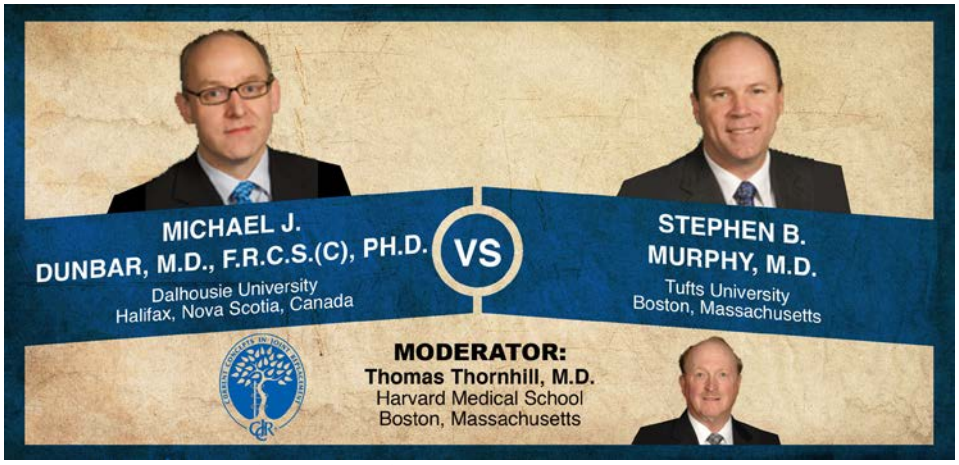
A Great Resource

CMS offers a pretty helpful website where the agency provides answers to frequently asked questions. Click here to go to the site: https://questions.cms.gov/faq.php?id=5005&rtopic=2017. ♦

Dunbar v. Murphy Debate Femoral Neck Modularity

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

Michael Dunbar contends, "Modular necks are not justified in routine primary hip arthroplasty. They increase the risk of fracture and fretting, among other things. Stephen Murphy counters, "Modular necks are associated with a very low dislocation rate, fracture is rare, and you have much better options at the time of surgery and any revision."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "Femoral Neck Modularity: A Bridge Too Far." For the proposition is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax, Nova Scotia; against the proposition is Stephen B. Murphy, M.D. from Tufts University in Boston, Massachusetts. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School.

Dr. Dunbar: "Stephen is going to tell you that you need modularity because it reduces impingement, reduces dislocation, and you can better balance the hip. Impingement can be an issue with ceramics and this is largely why modular necks were developed out of Europe—to prevent impingement on the rim of the acetabular component and subsequent fracture. My answer to that is: just don't use ceramics. Others say we need impingement to balance mal-positioning related to the acetabular component. The obvious answer to that is: get the component positioning correct."

"The other issue that arises is dislocation or instability. This can be improved, but if you use the right approach dislocation isn't the problem it used to be. In fact, it's paradoxical. Looking at reasons for revision on the Australian registry we see that dislocation is the second highest reason."

"What about fine tuning the hip? Clearly there's some ability to change your center of rotation, particularly when you've seated the femoral component and it's fixed. But if you use a cemented component you have all the same options. You can change the leg length by where you place it within the cement mantle, you can change the offset by where you put it within the cement mantle, and you can do the same thing with the version."

"Major disadvantages: There is additional mechanical interface, which increases the potential for new problems such as fretting and corrosion, as well as fractures. The midterm results with respect to these procedures are just not as good, and there is increased cost."

"As for fretting, there is a paper out of Vancouver that won the John Charnley Award that looks at metal-metal resurfacing versus total hip with another metal-metal articulation. They found a much higher incidence of urine and serum cobalt chrome levels in the total hip, not the resurfacing. The issue was the mechanical interface of the new coupling. So by adding a new interface the metal ions were increased."

"The 800 pound gorilla in the room, however, is fracture. There are numerous reports of fractures. One 2010 report is from Europe on a series of 5,000 with a fracture rate of 2.4%. Who wants that?"

"We've produced a case report at our center using the ProFemur. We have a larger series of 452 and at about six years out we have over 20 fractures. They've occurred in the long necks at about two years out. The real problem is what to do with the person's other femur."

"When you take all of these things together, it's not panning out. Modular necks have a higher revision rate… there's not an advantage to survivorship. Coming down to more subtle points, there are the biomechanics. What is really happening when we change the version of our components, particularly through the modular neck? I think it introduces a new biomechanical stress strain relationship that may be disadvantageous."

"A paper from Oxford led by Gill looked at radiostereometric data and what happens when you retrovert a femur. Think of it this way: the real issue isn't standing. It's when you're getting out of a chair or climbing stairs… we're talking about the forces that drive this component into rotation. So if you put a component into a regular anteverted position, you're offset is small in terms of your deforming forces. But just by tuning that femur back through the neck you're actually increasing the biomechanical lever arm, and you're putting substantially more rotational forces on the femoral component."

"There are increased costs, which are coming at a time when markets are tanking. We can't afford these premium products without improved outcomes. Would the money have been better spent on surgical technique/training? Yes!"

"Another moral hazard is metal ion concerns at the taper. Do I live with the risk of toxicity or do I undergo a complicated revision? This is happening with data that we don't know a lot about; few people know what is going on with MARS-MRIs and ion levels. So in conclusion the use of modular necks is not justified in routine primary hip arthroplasty."

Dr. Murphy: "I think we can agree that control at the neck shaft junction is the primary biomechanical control that we have, both in joint preserving surgery and in total hip arthroplasty."

"There are certainly many advantages to modularity, already outlined by Michael. Variation in native femoral anatomy is quite wide: 60 degrees or more. I think that fixed necks have some difficulty in controlling and correcting these variables properly. You can use a cemented component, and cement more or less in anteversion; a canal filling component has great difficulty doing that. If you fail to correct the anteversion properly that leads to impingement, dislocation, polyethylene fracture, and potentially, revision."

"If you have significant rotational problems you can burrow away some bone and put a fixed neck in a different direction…or use a component that has free control of anteversion. But these all lack the potential revision opportunities of being able to remove and replace a modular neck."

"Our personal experience of titanium neck on titanium stem is with 792 patients and a minimum of 3 – 10 years follow up. There were two neck fractures in this group (0.25%), however there were four revisions that were much easier because of the presence of a modular neck. We saw no adverse local tissue reaction, and had a 0.25% dislocation rate. There is a 19-fold difference in the fracture rate we had compared to the fracture rate that Michael just quoted—using the exact same neck. If you look at those stems they had variable wall thickness, and a very thin wall thickness in one area. The stems we used had a more uniform wall thickness, which may affect the fretting. And assembly force is the greatest single force affecting fretting, corrosion, and fracture resistance."

"Looking at our cobalt chrome neck on titanium stem experience, we had 559 patients with no neck fractures, no dislocations, one revision that was made easier because of the presence of a modular neck, and one patient with a metal allergy and elevated cobalt chrome level (and fluid collection around his greater trochanter)."

"I would like to discuss the recalled Stryker Rejuvenate modular neck stems. That is totally different than the other stems: it's a cobalt chrome neck on a beta titanium alloy, which is made of TMZF. There were a number of these stems used in our institution with pseudotumors, and I think that's a corrosion/fretting issue which may be metallurgical in its origin."

"Control of that junction is the right way to go, but it's a question of designing things so that they are successful."

Moderator Thornhill: "Michael, Steve says the reason you have trouble when it's breaking is because you're using the wrong implant and you're too weak to assemble it."

Dr. Dunbar: "That's my point. We're not the best surgeons in the world, but we're not the worst…and these things pop up. Total hip is the golden goose of arthroplasty; all of a sudden we bring in a new variable and our golden goose starts laying lead."

Moderator Thornhill: "Steve, if you need to change the modular neck at five years do you have concerns about the female side on the stem in terms of taking a new neck?"

Dr. Murphy: "This is not risk free. Let's say you had an unstable patient with a femoral anteversion problem…and you had a choice of removing that entire component that was well fixed and potentially extensively porously coated, versus popping a neck off, changing the angle and putting it back on. Well, the risk tradeoff is strongly in favor of putting another neck on, compared to an extended trochanteric osteotomy."

Moderator Thornhill: "When I run into trouble it's either developmental dysplasia of the hip where I have too much anteversion, or a femoroacetabular impingement with femoral retroversion. I tend to use a modular implant. Mike, can I be less worried about that articulation of that modularity versus the neck?"

Dr. Dunbar: "I assume you're referring to a prosthesis that's been around a long time. I agree with Stephen that the future will be balancing the hip. But why did we release all these things in such large numbers and then find out after that depending on how you impact this taper may make a difference?"

Moderator Thornhill: "Steve, how much can you change in terms of anteversion, retroversion, and offset with your modular necks? And are the extremes of that putting more risk on that couple?"

Dr. Murphy: "You have a 30 degree range in anteversion, retroversion, and a 16 degree range in varus/valgus. Regarding femoral anteversion, I think the concept of combined anteversion is very important, but it's greatly oversimplified and overused. If you take a femur with 60 degrees of anteversion and you decrease it to 20 degrees then the patient will dislocate posteriorly. If you take a femur with 0 degrees of anteversion and increase it to 25 degrees the risk would be anterior dislocation. I think the change in anteversion from what the patient had to what you set it to is a much more important variable than absolute number of anteversion. I think that's one of the reasons why, in the Australian registry, they had a higher dislocation rate…because they had the ability to overcorrect."

Moderator Thornhill: "Is it fair to say that the relationship between the final construct of the femur and the acetabular isn't critical for stability?"

Dr. Murphy: "It is critical. I think that using rigid numbers, and not keeping track of what it was compared to what it is, is the problem."

Moderator Thornhill: "Mike, you used the term 'moral hazard.' To me that means that you make a decision where the results of that don't impact you. You were discussing fracture and ions. I'd think that wouldn't be a moral hazard because it would impact the patient and surgeon."

Dr. Dunbar: "This is the point. We are falling into traps."

Moderator Thornhill: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

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Treating the Boston Marathon Bombing Victims… Scrambling to Get Ready for ACA…Finally! An Effective Way to Measure Arthroscopy Technique

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

Wikimedia Commons and Aaron "tango" Tang

Scrambling to Get Ready for ACA

It's hard to say which party is sweating the impending insurance changes most. Some are doing their best to plan. Ted Miclau, M.D. is an an orthopedic surgeon with San Francisco General Hospital. Dr. Miclau, who is also past president of the Orthopaedic Research Society, tells *OTW,* "I work in a public hospital, and my vantage point in looking at the changes emanating from the Affordable Care Act is one that is shared by many of my colleagues in similar systems. Like many of our 'sister' public hospitals in the U.S., our hospital is scrambling to figure out how our facility will fit in to the bigger picture. Part of the problem is that we are having to make assumptions; while the rules are clear, how they will play out are not."

"For example, in San Francisco we have roughly 60,000 uninsured patients enrolled in a city-supported system. Two-thirds of these patients will be eligible for some type of coverage. Some of these patients will elect not to have coverage, and we are estimating that about half of these patients will continue to be uninsured. The question is, 'Will those who have a choice stay in the system or sign up for coverage with another organization?' Further, will those from other systems in other counties choose to migrate to our system. So, the planning and budgeting in this era of new health care changes is extremely challenging."

"In our system and others, one of the deciding factors that will likely influence individuals' choices will be whether they have a primary care provider in their system. In San Francisco, for example, nearly 20,000 of our uninsured patients currently have a medical home, and it is quite likely that they will remain in the system. However, for those who do not have a medical home with the Department of Public Health, they will likely be more motivated to look for other options. We therefore have to be ready to adapt and compete."

Asked what advice he might give to his colleagues in other public hospitals, Dr. Miclau told *OTW*, "I recommend that physicians and their public health departments make a strong effort to work together, and this includes the specialists. Complete health care systems,

which include primary and subspecialty care, are more likely to provide the kind of network that would be attractive to individuals who become covered in these new insurance exchanges. For those who are not engaged in a system, such as sole practitioners, the challenge for them will be to become integrated into a system. You can see where these new changes would be anxiety-provoking for those in the health care industry at many levels."

Treating the Marathon Bombing Victims: What It Was Like Trauma is what John Kwon, M.D. is used to. What was unusual about that April day in Boston was *how much* trauma there was. Dr. Kwon, a foot and ankle and orthopedic trauma surgeon at Massachusetts General Hospital, was there when the patients began to appear in the wake of the recent bombing. He tells *OTW*, "First of all, the outcome would have been very different if the bomb had gone off at the starting point. Because it was at the finish line, there were substantial medical providers in the area, as is typically the case with such an event. It was also helpful that the square is centrally located amongst all of the level one trauma centers; patients went to many of these facilities, namely Massachusetts General, Boston Medical Center, Brigham and Women's Hospital, Beth Israel Deaconess Medical Center, and Boston Children's Hospital."

"From the time the bombs went off the first injuries arrived at our facility within 20 minutes. While these are the type of injuries we see on a daily basis, it was the volume of injuries that made it unique. There was quite a lot of careful triaging between the orthopedic trauma team and the other surgical services such as general surgery, vascular, burns and plastic surgery. We had the first patient in the OR within 40 minutes of the first bomb blast; by approximately 11:00 pm on the first day we were done operating. Afterwards, we dealt with smaller lacerations and shrapnel injuries that came in over next couple days…then the burn service and plastic surgery took over. It was amazingly seamless—as it should be."

"Any level one trauma center must be prepared for this type of disaster—a concrete disaster plan is required. Here at Mass General we called up extra nurses, and were fortunate that most surgeons were available. Everyone knew his or her role; we activated

the disaster plan, and used the algorithms in place (who is in charge, what do they do, who's next in line, what do they do, etc.)."

Finally…A Way to Measure Arthroscopy Proficiency How do we know that surgeons are doing arthroscopy well? Gregg Nicandri, M.D., assistant professor in the Department of Orthopaedics and Rehabilitation at the University of Rochester Medical Center, set out to learn more. He told *OTW*, "In the world of surgical training it's been the 'see one, do one, teach one' model for years and in general, orthopaedic residents that complete a five-year program and are deemed competent to perform the core surgical procedures of that specialty. Clearly, there must a better way to educate and evaluate the skills of our residents. It has been recognized that not all training needs to take place in the presence of patients and newer curricula which incorporate simulated surgery are being developed."

"Currently there is no objective way of evaluating a resident's proficiency with arthroscopy, and as a result it is difficult to determine whether your curriculum is appropriate or whether arthroscopic surgical skills labs are achieving their purpose. The Arthroscopic Surgery Skill Evaluation Tool (ASSET) allows for the assessment of a surgeons arthroscopic skill level. As a result we will be able to determine whether a certain curriculum or method of training (virtual reality simulation for instance) actually improves a surgeons arthroscopic proficiency and to what extent. Hopefully this will result in more effective and efficient training."

"The tool is valid for construct; we had residents perform diagnostic knee arthroscopy and found that the ASSET score did correlate with experience (novices achieved lower scores than those with intermediate experience and individuals with intermediate experience recieved lower scores than those with advanced experience). The tool also demonstrates quite a high level of intraobserver reliability when compared to other similar evaluations; we had two raters review videos of residents performing diagnostic knee arthroscopy and then assign a score and the level of agreement was very high between the two scores. The next step is seeing how we might apply the ASSET to other procedures such as ACL reconstruction, shoulder arthroscopy, and menisectomy. We also want to see if residents can perform as well in a live environment as they do in the lab and use the tool to assess skill transfer from one environment to the other. There is a lot of promise here. There is increasing pressure on residency programs and certifying bodies to more rigorously evaluate procedural competency and the ASSET is one tool which may help to satisfy that need."

Reverse Shoulder Arthroplasty: How Many? Who Is Doing Them? Orthopedic surgeons are using reverse shoulder arthroplasty for complex fractures and cuff arthropathy with increasing frequency these days. A team at the Rothman Institute, including Joseph Abboud, M.D., wanted clarification on this very statement and hence they have been studying these questions. The team looked at how many reverse shoulder arthroplasties are being performed yearly and who is performing these procedures. Dr. Abboud told *OTW*, "In our first study we used the Medicare database to examine the volume of arthroplasty (total shoulders versus reverse shoulder arthroplasty). What we have found was that the volume of arthroplasty being performed is nearly evenly split between a standard arthroplasty and a reverse shoulder arthroplasty. We also looked at volume by surgeon and found that there was indeed a fairly significant percentage of reverses being done by lower volume surgeons. This is somewhat surprising since this is an advanced procedure with a relatively high complication rate even in the hands of high volume surgeons."

"Our second study involved new graduates performing reverse shoulder arthroplasty for fractures during their boards collection period. While hemi arthroplasty is still a more common procedure there is definitely an uptick in those surgeons taking step two of the boards who are utilizing reverse shoulder arthroplasty for these fractures. While in many instances this is the best option for the patient, we have to continue to emphasize the indications and technique to continue to optimize outcomes and minimize complications." ♦

COMPANY

Biomet Recon Sales Stall, Extremities and Trauma Rise

Biomet, Inc.'s net sales for the company's fourth quarter rose 6% to approximately $784 million.

Biomet, Inc./Corporate Headquarters

Sports Medicine, Extremities and Trauma

According to a July 11, 2013 company press release, Sports Medicine, Extremities and Trauma (S.E.T.) sales of $160 million were up 62.1% over the previous year. The large increase was due to the acquisition of Johnson & Johnson's trauma business last year. Excluding the acquisition, S.E.T. sales rose 6.4%.

Extremities sales increased 22.3% on a constant currency basis, including a 28.2% rise in the U.S. BMO Capital Market analyst Joanne Wuensch said Biomet has now had 22 quarters of double-digit extremities growth. She credited the company's number one market leading shoulder franchise as well as a healthy market.

Hip and Knee Weakness

Reported hip and knee revenue declined during the quarter as knee sales were down 1.4% and hip sales dropped 0.3%. Overall reported large joint sales declined 1%.

Wuensch attributed much of the weakness the company's knee segment, where sales were up only 0.1% on a constant currency basis, including flat growth in the U.S. She noted that Biomet management citing a stable market, but possible market share losses as physicians trialed several new competitive products. Specifically she pointed to Johnson & Johnson's Attune Knee System, Zimmer Holdings, Inc.'s Persona Personalized Knee system, and Smith & Nephew's Journey II BCS Knee System.

Biomet 4Q 2013	Sales $ in million	% Change
Total Reported Sales	**783.9**	**6%***
Large Joints	435.2	down 1%
Knees		down 1.4%
Hips		down 0.3%
Sports, Extremities, Trauma	159.2	61.2%*
Spine & Bone Healing	67.0	down 18.2
Dental	68.5	down 1%
Other	54.0	6.7%

Source: Biomet, Inc.
** Includes DePuy Trauma acquisition*

PiperJaffray analyst Matt Miksic said knee sales were driven by the Oxford partial knee with Signature. The company also rolled out their DTC (direct-to-consumer) campaign in the U.S., and the company continued the commercial launch of the Vanguard 360 Revision System.

It looks like the company held hip market share during the quarter, according to Wuensch, with a 1.8% revenue increase on a constant currency basis with a 2.2% increase in the U.S. She added that pricing pressure remained at low single-digit declines.

Key growth drivers in the quarter included the Taperloc Complete Systems. The company also continued the early global commercialization of their next generation Acetabular system, the G7 Acetabular cup.

Wells Fargo analyst Larry Biegelsen said he believes that Biomet's slowing large joint growth was company specific and not a good read through for the other large ortho players like Zimmer and Stryker Corp.

—WE (July 12, 2013)

Millstone Installs High Powered Equipment

Millstone Medical Outsourcing has announced that the company has welcomed a variety of advanced equipment to its mechanical inspection cells in both Fall River, Massachusetts and Olive Branch, Mississippi facilities.

Millstone has added another high speed, high accuracy coordinate measuring machine, the Zeiss Contura G2, and a CCP CC-14 digital optical comparator to its fleet of equipment in Fall River. Alongside Millstone's Brown & Sharpe measuring systems, the Zeiss Contura, featuring VAST scanning technology accommodating lateral styli up to 65 millimeters, enhances the timeliness and precision of inspection processes, getting OEM's product to market faster. Housing various brands of equipment, Millstone can now provide OEMs the option to utilize sharable programs while ensuring the number of rejected parts is reduced and production quality is at its absolute best.

In Olive Branch, a 14" Jones and Lamson EPIC-114P Comparator and Phase II 900-372 Rockwell Twin Hardness Tester have been added to the inspection cell to certify all products meet hardness standards and all product measurements fall within designated tolerance limits during inspection. These additions heighten the productivity and accuracy of Millstone's mechanical inspection line and enhance all processes throughout the entire Olive Branch facility.

Millstone Medical Outsourcing

"As the advanced mechanical inspection needs of our customers continue to grow, we improve our processes and equipment simultaneously in order to deliver the most efficient, highest quality services possible," said Kelly Lucenti, president of Millstone Medical Outsourcing, in the July 5, 2013 news release. "The additions to both of our locations ensure both facilities are well-equipped with the necessary inspection tools to remove measurement obstacles for our customers, meet their rapidly increasing demands, and get their products to market faster and more efficiently."

Lucenti told *OTW*, "By adding these machines to our facilities, Millstone now has the ability to inspect more products in less time and at higher accuracy levels. We have increased the capacity of our inspection departments by 33% and reduced the cycle time in inspection by 50%."

—EH (July 12, 2013)

SpineNet Warned by FDA

SpineNet, LLC of Winter Park, Florida, was warned by the FDA on May 31, 2013, that the company's products are adulterated.

FDA/Enforcement Actions

The company, founded in 2007, is the developer of the SpineNet ACC (anterior cervical cage) System; an importer/repacker/relabeler of Apollon and Vane Pedicle Screw Systems; and a relabeler/distributor of the SpineNet Bone Marrow Aspiration Needle Kit.

After an inspection that lasted from January 29, 2013 through February 1, 2013, the agency issued a Warning Letter that said the products were adulterated because, "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice (CGMP) requirements."

The company responded to the inspection observations on February 22, 2013, but the agency remains unsatisfied.

The alleged violations include:

- Failure to adequately ensure, when the results of a process cannot be fully verified by subsequent inspection and test, that the process shall be validated with a high degree of assurance and approved according to established procedure. The agency said the firm failed to provide a copy of its validation procedures; failed to indicate why these sterilization cycles were not validated; and failed to provide evidence that the firm has implemented a corrective action to ensure that this does not recur.

- Failure to establish and maintain adequate procedures to ensure all purchased or otherwise received product and services conform to specified requirements.

- Failure to maintain adequate procedures for acceptance of incoming product. During the inspection the company confirmed that it failed to establish acceptance activities to address incoming inspection of components, instrumentation, finished implants, and returned goods.

- Failure to adequately establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. The firm does not have a complaint procedure to ensure timely processing of complaints, investigation of complaint, and Medical Device Reporting (MDR) review of complaints.

- For example, a complaint dated June 15, 2012, references a doctor trying to get an Apollon rod (part of the Apollon Pedicle Screw System) to go thru an offset construct and torqued the rod, breaking it. The firm did not document whether the rod tip broke inside the patient or if the tip was required to be retrieved from inside the patient to facilitate MDR review. Another complaint dated January 18, 2013, referenced a Vane Crosslink that opened on one side of the hook during initial surgery. The firm did not document an MDR review of this complaint and told the FDA the complaint investigation was closed.

FDA/Enforcement Actions

- Failure to establish adequate procedures for quality audits.

- Failure to adequately establish and maintain procedures for implementing corrective and preventive action (CAPA).

- Failure to establish and maintain adequate procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

Reporting, Off-Label Promotion and Mislabeling

The inspection also revealed that the firm failed or refused to furnish material or information respecting the devices that is required by or under the Medical Device Reporting Regulation. For example, there were no definitions of what the firm will consider to be a reportable event.

The inspection also revealed that the SpineNet Bone Marrow Aspiration Needle Kit, which contains the Bone Marrow Aspiration Needle, is adulterated because the firm does not have an approved application for premarket approval (PMA) in effect, or an approved application for an investigational device exemption.

A review of the materials determined that the firm is promoting and marketing the kit for uses with new performance claims and specifications and for a use that does not have FDA clearance or approval.

The agency acknowledged that the firm voluntarily recalled the product until it has validated that is has the proper clearance for the needle.

Finally, the inspection revealed that the Vane and Apollon Pedicle Screw System devices are misbranded, in that the devices were not included in a list required by law.

—WE (July 10, 2013)

Zimmer Exclusive Distributor of SpineCraft's APEX

Zimmer Spine, Inc. is now the exclusive distributor of SpineCraft, LLC's APEX Spine System in the U.S., Canada, Australia and New Zealand.

The system is a pedicle screw fixation system that provides immobilization and stabilization in the thoracic, lumbar and sacral spine regions, in the surgical treatment of acute and chronic spinal instabilities and deformities. Designed for skeletally mature patients as an adjunct to spinal fusion, the system consists of longitudinal rods, pedicle screws, hooks, lateral connectors and cross connectors. With a comprehensive range of component sizes, and addresses a broad range of spinal pathologies with a low-profile design that allows surgeons to maximize bone graft.

The system's custom deformity-correction instruments, according to a July 10, 2013 company announcement, are designed to shorten surgery time while enabling safer, more controlled correction of spinal deformities.

Steve Healy, Zimmer Spine's president, said the system represents a true union of intuitive design and engineering excellence. "These innovative implants and instrumentation offer powerful correction capabilities with excellent intraoperative flexibility. This state-of-the-art pedicle fixation system represents a natural fit for Zimmer Spine's expanding portfolio, enabling surgeons to meet the unique needs of their complex spine and deformity patients, as well as patients with degenerative pathologies."

The APEX system was designed by a team of spine surgeons practicing in the Chicago area. SpineCraft received FDA 510(k) clearance in 2006 and, to date, the system has been used in over 3,500 clinical cases.

SpineCraft was founded by a business team and U.S. spine surgeons in 2004. The company's Advisory Board includes: Kamal Ibrahim, M.D., Steven Mardjetko, M.D., Steven Mather, M.D., Anis Mekhail, M.D., and Youssry El-Hawary, M.D.

—WE (July 10, 2013)

APEX Spine System by Zimmer

Biomet's Single-Use Delivery System for Fractures

Promising to reduce costs, Biomet, Inc. released the ePAK single-use delivery system for internal fracture fixation on July 9, 2013.

"We are excited to be the first orthopedic company to release a device in this category that addresses the needs of the orthopedic surgeon, patient, and the hospital system," said Wil Boren, president of Biomet Sports Medicine, Extremities and Trauma (SET).

A company statement said the system is a pre-sterilized, single-use procedure pack designed to add value by addressing the productivity needs of the operating room in one complete package that is designed to help save time, reduce cost, improve efficiency, and ultimately increase productivity.

The system addresses distal radius fractures and features Biomet's DVR Crosslock implant and instrumentation. "With over 10 years of clinical heritage in treating distal radius fractures using the volar approach, the DVR plate and instrumentation continue to refine fracture fixation," said the statement.

Excluding the DePuy Trauma acquisition last year, Biomet's SET division increased quarterly sales by 8% to $161.4 million for the latest quarter reported by the company. The increase was driven by significant Extremities growth of 22% globally and 29% in the U.S. on a constant currency basis.

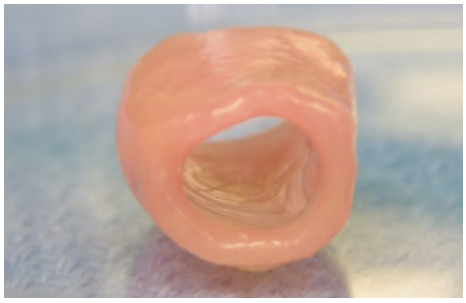
—WE (July 10, 2013)

Biomet, Inc./ePAK Single-Use Delivery System

BIOLOGICS

Can Stem Cells Heal Cartilage? Texas Doc to Find Out

Will stem cells from a patient's own fat tissue aid in healing cartilage after knee surgery? Damaged knee cartilage is hard to treat and, untreated, can lead to constant pain and disability. More than four million knee arthroscopies are performed worldwide each year, according to the American Orthopaedic Society for Sports Medicine. To test the potential of stem cells to deal with this problem, Robert Burke, M.D. an orthopedic surgeon with Fondren Orthopedic Group in Houston, Texas, and InGeneron, Inc. are joining to launch a clinical trial to find out if cells from adult adipose tissue can help heal their damaged cartilage.



Tubular Cartilaginous From Amniotic Mesenchymal Stem Cells / Source: Wikimedia Commons

The study will utilize InGeneron's patented Transpose RT system to prepare regenerative cells from the patient's own fat tissue. The Fondren Orthopedic Group is recruiting qualified patients for the study. Adults age 18 to 68 in the Houston area are invited to apply for enrollment.

"Articular cartilage, the smooth surface covering the joints at the ends of bones,

has no good way of healing on its own," Burke told the *Herald OnLine* reporter. "The body doesn't create enough new cartilage of the same type to repair the damage." He believes that better treatments would use ways to help the body make new cartilage. "Stem cells and other regenerative cells that we can obtain from fat have the potential to do that," he said.

Burke will perform identical surgery, one that is commonly used for treating cartilage damage, on all patients in the study. One group will have only the surgery. A second group, selected randomly, will have a small amount of fat removed from under their skin and processed using the InGeneron Transpose RT System to separate out the regenerative cells. The separated cells will then immediately be placed into the area of damaged cartilage during knee surgery. Once inside the knee, Burke hopes that the cells will divide to make new cartilage cells. Burke plans to monitor both groups for 12 months after the surgery to see if adding cells improves cartilage healing.

Burke says that this sort of biological activity has been seen in laboratory studies and veterinary medicine. His study will be one of the first to test the technology for treating cartilage damage in humans. The treatment is not currently licensed for human use in the United States but is registered and used in Europe, Mexico, and other countries. Burke says that he will be following the Texas Medical Board's rules about using adult stem cells for treatment. The study is being conducted under the supervision of the research review board at Texas Orthopedic Hospital, where all of the surgeries will take place.

—BY (July 9, 2013)

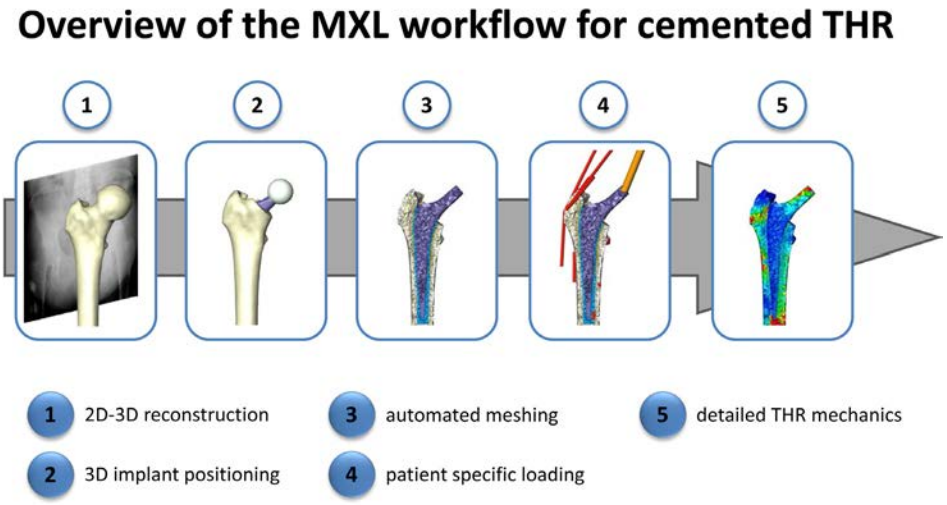
LARGE JOINTS

Extending the Lives of Joints

Researchers at the University of Southampton have completed a project that will enable surgeons to fit joint replacements with longer, optimized lifespans. The MXL project uses computational modeling to define the mechanics of an artificial joint to ensure successful surgery and longer lifespans of the prosthetic joints.

In the July 8, 2013 news release Professor Heller said, "We developed a 3D musculoskeletal model, with data on the variations in bone shape and tissue density, which has enabled advanced biomechanical assessment of the joint reconstruction. The development of this specialised software allows the automated positioning of implants and allows us to modify implant size and position, to address individual patient needs. The intention is, that this technology will lead to increased patient safety and improved lifespan of joint replacement prosthetics."

Professor Heller told *OTW*, "The key challenge we faced here was to not only develop an Information and Communication Technologies (ICT) framework to enable cost effective prosthesis designs and support surgeon decision making by quantitative data on those aspects of joint biomechanics that critically define the outcome of joint surgery, but to also validate its individual components, and finally demonstrate the predictive capabilities of an integrated system. To meet this challenge we brought together a distinguished consortium of leading partners from across Europe: academic experts with biomechanical engineering, but also medical image processing and visualisation expertise and industrial partners,



University of Southampton

which provided innovative solutions to challenging problems, also supported by clinical opinion leaders."

"I am particularly proud that we managed to integrate the various tools and components of the MXL workflow and demonstrate the ability to predict joint mechanics and predict failures in considerable sized clinical cohorts. Here, the Southampton team together with our clinical partners succeeded to deliver that proof for hip stems, but also for knee replacements. This clinical demonstration of the predictive power of these tools will certainly be instrumental for the translation of the technology to implant development and clinical practice alike."

Asked how long before this work could actually help patients, Dr. Heller stated, "We are already actively translating results of our work together with partners from industry. This includes the reliable measurement of anatomical parameters through a EPSRC funded Knowledge Transfer Secondment with Simpleware (Exeter, UK), to be offered through their world-leading software for the conversion of 3D image data into high-quality CAD and Finite Element models. In a similar way, the bespoke motion analysis techniques that we have demonstrated to be effective in identifying even more subtle deficits in dynamic function after cruciate ligament injury are currently being integrated with a world leading system to track and analyse motion (Vicon Motion Systems, Oxford, UK)."

"Moreover, the unique framework to consider variation in patient anatomy and loading conditions is already being used to better identify suitable indications of existing implants as well as the development of new devices."

—EH (July 10, 2013)

Watching Cricket During Surgery?

Patients in the United Kingdom are watching cricket matches while getting a new hip or knee, according to Judy Hobson, writing in the *Daily Mail*. Patients who are not likely to become upset by the sounds of hammering and sawing can opt for a spinal block that numbs sensation from the waist down for four to five hours instead of general anesthetic. Patients who make that choice are fully alert during the procedure.

Jeannette Griffin, 68, was having her right hip replaced and wanted to follow her favorite cricket team on the radio. The anesthetist lent her his iPad so she could watch the game. "I could hear some hammering in the background but I was prepared for that. I was conscious my body was being pulled around slightly, but it didn't disturb me and I had no pain whatsoever," she told Hobson.

The UK doctors have noted that patients who have a spinal block need less pain medication following the surgery and have a lower risk of a deep vein thrombosis. It is also a better option for patients with severe respiratory disease.

The anesthetist who cared for Griffin said, "'I see patients before surgery and reassure them that with a spinal block they won't feel anything from the waist down. If they feel anxious, they can also be given intravenous sedation to relax them. And if surgery takes longer than expected a general anesthetic can still be used. A general would also be offered if someone undergoing hip surgery felt they couldn't lie in one position—not moving their upper body—during the operation."

With a spinal block, a needle is threaded through a gap between the bones in the lower back and the physician injects local anesthetic into the area to numb it. Having a spinal block when a patient is having a hip or knee replaced is becoming increasingly common in the UK, according to Elis Hughes, M.D., and a consultant anesthetist at the Robert Jones and Agnes Hunt Orthopaedic Hospital in Oswestry.

He told Hobson, "In 2003, I anaesthetized 43 hip patients and only 6 had spinal blocks. This year I've done 42 so far and all of them had a block. The majority opted to stay fully awake throughout the procedure."

Patients' biggest concern is the noise—all the sawing, hammering and drilling—that goes on during the procedure, says Hughes. "Many of them bring in MP3 players so they can listen to their favorite music."

—BY (July 10, 2013)

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Program Cuts TKA/ THA Costs 19%

In a pilot program designed to control costs, the California Public Employees Retirement System (CalPERS) announced last year that its top payment to a hospital for a member's knee replacement would be $30,000. The CalPERS organization gave its members a list of 46 hospitals which, investigators had ascertained, provided quality joint replacement care and charged less than $30,000 for the procedure. Members had a choice. They could either choose one of the 46 facilities on the list, which would result in their paying little to no out-of-pocket costs beyond deductible or co-insurance, or else pay the difference if they used a costlier facility that was not on the list.

The result? The price of members' hip and knee replacement surgeries dropped by 19% in one year—from $35,408 to $28,695, per surgical-related admission. And patients experienced improved outcomes.

"We are pleased to see this program resulted in both substantial savings for CalPERS, and, on several measures, with higher quality outcomes for its members," said Sam Nussbaum, M.D. "Our programs demonstrate the power of innovative product design, aligned financial incentives and better informed decision-making."

Ann Boynton, deputy executive officer for Benefit Programs Policy and Planning for the California Public Employees' Retirement System, which has 356,543 members in California served by WellPoint's affiliated health plan, said, "This program was an effective tool in managing costs as we all know that current spending levels are not sustainable if we're going to provide benefits that are affordable now and into the future."

An analysis of the program found that the use of designated facilities increased by 21% by CalPERS members, member out-of-pocket costs remained relatively flat from 2011 to 2012, outcomes were either equivalent or better in the group using the designated facilities, and CalPERS members had significantly lower 30-day general infection rates than did non-CalPERS members.

The writer of "Money & Co", published by the *Los Angeles Times*, commented that the CalPERS findings could motivate other employers to cap prices to encourage competition and reduce health costs.

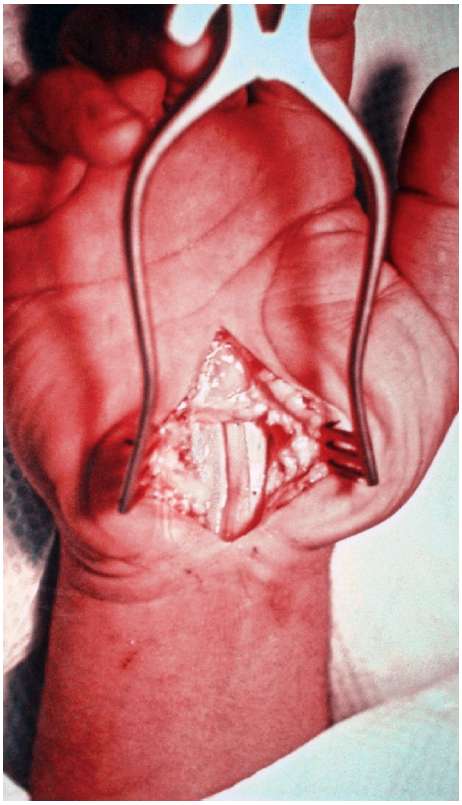
—BY (July 8, 2013)

Morguefile and imelenchon

EXTREMITIES

Carpal Tunnel Release Surgery a Winner

It is good news when patients remain symptom-free and report satisfaction 13 years after undergoing a procedure.



Wikimedia Commons and Dr. Harry Gouvas

That is the case with most patients who underwent open carpal tunnel release, according to a study published in the June issue of *The Journal of Bone and Joint Surgery*.

Dexter L. Louie, from Brigham and Women's Hospital in Boston, and colleagues assessed the functional and symptomatic outcomes of 113 patients who underwent open carpal tunnel release from 1996 to 2000. The pro-

cedure on all of the patients was performed by the same surgeon. The follow-up was conducted at an average of 13 years after surgery, using validated, self-administered questionnaires. Levine-Katz symptom and function scores ranged from 1 point (best) to 5 points (worst).

The researchers found that the mean Levine-Katz symptom score was 1.3 points. The most common symptom-related complaint was weakness in the hand, followed by diurnal pain, numbness, and tingling. Nocturnal pain and tenderness at the incision were the least common symptoms. The majority of patients (88%) were completely or very satisfied with the surgery, with 74% reporting complete resolution of symptoms. More men than women had poor function (33% versus 23%) and two patients had repeat surgery.

The authors wrote, "Our results suggest that the long-term results of open carpal tunnel release are excellent, with patients experiencing consistent pain relief over 10 to 15 years."

—BY (July 9, 2013)

SPINE

Anand Spine Group Tests Biologic Disc Therapy

Will the injection of young cartilage cells into the lower back regenerate pain generating spinal discs? To find out, the Anand Spine Group of Los Angeles will participate in a Phase II clinical trial studying the efficacy and safety of ISTO's NuQu cell-based therapy. The Anand Spine Group, lead by orthopedic spine surgeon and medical director Neel Anand, M.D., is one of a group of spine centers throughout the United States that are taking part in the study. NuQu is comprised of young cartilage cells that the physician delivers through a needle during a short, one-time procedure. Study participants may go home about one hour after receiving the injection.

"We are very excited to be selected as investigators in the NuQu study because it offers a unique opportunity for volunteers who meet the study's criteria to potentially participate in research for low back pain and disability caused by spinal disc disease," said Anand.

ISTO estimates that each year there are approximately 500,000 patients in the U.S. who suffer with discogenic back pain who do not respond to standard-of-care treatment. There are currently no FDA approved disc nucleus regeneration or repair products on the market, according to ISTO officials.

Researchers estimate that, on average, 297 million restricted work days and 87 million disability days are lost each year due to back pain, the leading source of which is intervertebral disc disease or degeneration. In a study released in 2004 from the Medical Expenditure Panel Survey, Duke University Medical Center researchers found that patients in the U.S. suffering from back pain consume more than $90 billion annually in health care expenses, with approximately $26 billion of that amount directly attributable to the treatment of back pain.

"There are countless numbers of people suffering from debilitating low back pain caused by degenerated discs that must either manage the pain through physical therapy and injections or undergo surgery," said Anand. "We hope that this study will provide us the scientific data needed to support the continued use of this investigational technology."

Study participants must have had low back pain for at least six months and have never had previous surgery on their lower back. ISTO does not recommend NuQu for smokers or women who are pregnant or currently breast-feeding. Patients can learn more about the NuQu study at The Anand Spine Group by contacting Anand's clinical coordinator Cece Bruce at (310) 423-9209.

—BY (July 10, 2013)

Courtesy of The Anand Spine Group

PEEK Tops Titanium in Seven-Year Test

A seven-year long clinical study comparing the PEEK polymer spinal cage with titanium in the surgical treatment of multilevel cervical spondylotic myelopathy (CSM) has come down on the side of the PEEK polymer, according to a news release by *PRWeb*.

The study concluded that a cage made of the high performance PEEK polymer is superior to a titanium cage in maintenance of intervertebral height and cervical lordosis in surgical treatment of CSM.

Chen Y, M.D., and colleagues from the Department of Spine Surgery, Changzhen Hospital, Shanghai, designed the study to compare outcomes of titanium and PEEK cages. A total of 80 patients with 3-level CSM were randomized in a 1:1 ratio into two groups between November 2002 and December 2004. The overall follow-up period of the patients ranged from 86 to 116 months. The average was 99.7 months.

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Among the tests used in the evaluation were the JOA (Japanese Orthopedic Association) score and the NDI (Neck Disability Index). Both indicated that patients benefit from cages made of implantable PEEK polymer.

Here are the comments made by the research team as noted by *PRWeb*: "Although fusion was observed in all patients of two groups at the final follow-up, the titanium group demonstrated significantly inferior clinical outcomes compared to the PEEK group. More loss of the Cobb angles, measurement of spine curvature, and the intervertebral height was observed in the titanium group, resulting in the radiological parameters in the titanium group becoming inferior to the PEEK group at the final follow-up. Cage subsidence rates were 34.5 % in the titanium and 5.4 % in the PEEK group. The higher modulus of the titanium material properties is the likely cause of this," they said.

—BY (July 8, 2013)

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