VOLUME 8, ISSUE 19 | JUNE 12, 2012

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: Overall the market is trying to find a platform from which to stage a rally—which is why the Spanish news was well received. Europe is still the primary external factor but a repeal of the device tax will bring long absent buyers to look for beat up ortho equities. Could ortho have a summer rally? Stay tuned.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Orthofix	16.23%	(6.76%)	Keeping OFIX #1 is a fight between emotion and logic. Logic is winning, so far.
2	2	ArthroCare	(0.67)	11.67	Someone likes ARTC at these prices—$770 million market value or 1.06x growth.
3	3	Symmetry Medical	5.29	1.62	SMA's Codman purchase is already paying off. Landed a key distributor in Japan on the basis of strong brands.
4	4	NuVasive	6.63	3.03	Valuation beginning to reach pre-collapse levels. Both P/E and P/E to growth among the highest in ortho.
5	7	Conmed	10.09	(0.80)	Most analysts are expecting a 28% rate of earnings growth. But only 6% sales growth.
6	6	Johnson & Johnson	24.93	(2.02)	Closing to acquire Synthes is imminent. Trauma unit is in Biomet's hands now. EU approval done. Synthes de-listing next.
7	9	Zimmer	24.95	(1.80)	Zimmer leads its peer group in both PSR and relative valuation. Up two spots.
8	5	Integra LifeSciences	13.34	(3.24)	6% sales growth yet only flat earnings expected by Wall Street this quarter. IART is not getting a lot of deference by the Street these days.
9	8	Stryker	23.68	(3.64)	Over the last 4 quarters SYK has had the least number of EPS surprises. Should do 10% EPS growth this quarter.
10	10	Medtronic	28.24	(1.84)	Plenty of cool technologies in the pipeline, but nothing that shows up in any analysts' estimate.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	ArthroCare	ARTC	$27.75	$768	11.67%
2	NuVasive	NUVA	$20.77	$897	3.03%
3	Symmetry Medical	SMA	$8.15	$299	1.62%
4	Bacterin Intl Holdings	BONE	$1.51	$64	1.34%
5	Kensey Nash	KNSY	$38.51	$335	0.18%
6	MAKO Surgical	MAKO	$25.94	$1,104	-0.12%
7	Conmed	CNMD	$27.30	$772	-0.80%
8	Exactech	EXAC	$16.14	$213	-1.41%
9	Zimmer Holdings	ZMH	$60.96	$10,737	-1.80%
10	Medtronic	MDT	$37.33	$38,718	-1.84%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	$2.73	$74	-23.10%
2	Alphatec Holdings	ATEC	$1.68	$151	-16.00%
3	Orthofix	OFIX	$37.25	$698	-6.76%
4	TiGenix	TIG.BR	$0.60	$55	-5.51%
5	Smith & Nephew	SNN	$46.78	$8,390	-5.13%
6	Tornier N.V.	TRNX	$20.59	$815	-4.81%
7	RTI Biologics Inc	RTIX	$3.61	$202	-4.75%
8	Wright Medical	WMGI	$20.24	$796	-3.85%
9	Stryker	SYK	$51.31	$19,546	-3.64%
10	Integra LifeSciences	IART	$34.32	$927	-3.24%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$37.33	$38,718	11.85
2	Zimmer Holdings	ZMH	$60.96	$10,737	12.56
3	Johnson & Johnson	JNJ	$62.98	$172,967	12.82
4	Orthofix	OFIX	$37.25	$698	13.96
5	Stryker	SYK	$51.31	$19,546	14.06

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$20.24	$796	51.90
2	NuVasive	NUVA	$20.77	$897	48.30
3	Symmetry Medical	SMA	$8.15	$299	32.60
4	Kensey Nash	KNSY	$38.51	$335	26.93
5	Exactech	EXAC	$16.14	$213	22.73

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$37.25	$698	0.82
2	ArthroCare	ARTC	$27.75	$768	1.30
3	RTI Biologics Inc	RTIX	$3.61	$202	1.32
4	Stryker	SYK	$51.31	$19,546	1.35
5	Zimmer Holdings	ZMH	$60.96	$10,737	1.43

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$20.24	$796	6.16
2	NuVasive	NUVA	$20.77	$897	4.98
3	CryoLife	CRY	$4.92	$136	4.39
4	Symmetry Medical	SMA	$8.15	$299	2.72
5	Medtronic	MDT	$37.33	$38,718	2.28

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.68	$151	0.82
2	Symmetry Medical	SMA	$8.15	$299	0.87
3	Exactech	EXAC	$16.14	$213	1.05
4	Conmed	CNMD	$27.30	$772	1.07
5	CryoLife	CRY	$4.92	$136	1.17

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.60	$55	47.68
2	MAKO Surgical	MAKO	$25.94	$1,104	13.07
3	Synthes	SYST.VX	$164.86	$19,582	4.93
4	Kensey Nash	KNSY	$38.51	$335	4.68
5	TranS1	TSON	$2.73	$74	3.88

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

June 6, 2012
The Scientific Journal Retraction of the Week

By Walter Eisner

Exactly one year ago Dr. Eugene Carragee devoted an entire issue of *The Spine Journal* (*TSJ*) to the issue of bias in the early studies of BMP2. Carragee's work in that now infamous June issue has been roundly criticized (from more than one podium presentation as well as in the pages of *OTW*) for several mistakes including data omissions and a *pattern* of intellectual dishonesty.

Specifically, Carragee has been accused of committing three fatal errors in his June 2011 study. They were:

1. Omissions of facts which had the potential to change the conclusions of *TSJ*'s study
2. Data used out of context
3. Errors in logic which, in turn, impugned the integrity of dozens of researchers. This, in our view, created a clear appearance of intellectual dishonesty.

Ironically enough, Carragee's primary hypothesis in that June *TSJ* issue was that studies which are supported by industry are vulnerable to bias, methodological error and omission of relevant data. In other words, he accused authors of industry sponsored research of exactly the same kind of errors that he committed in HIS study.

Truth be told, it doesn't take industry funding to trigger biased research—as Carragee himself demonstrated. So, we wondered, how prevalent is this phenomenon of academic bias in peer reviewed scientific literature? The answer, we learned, is that it is fairly common.

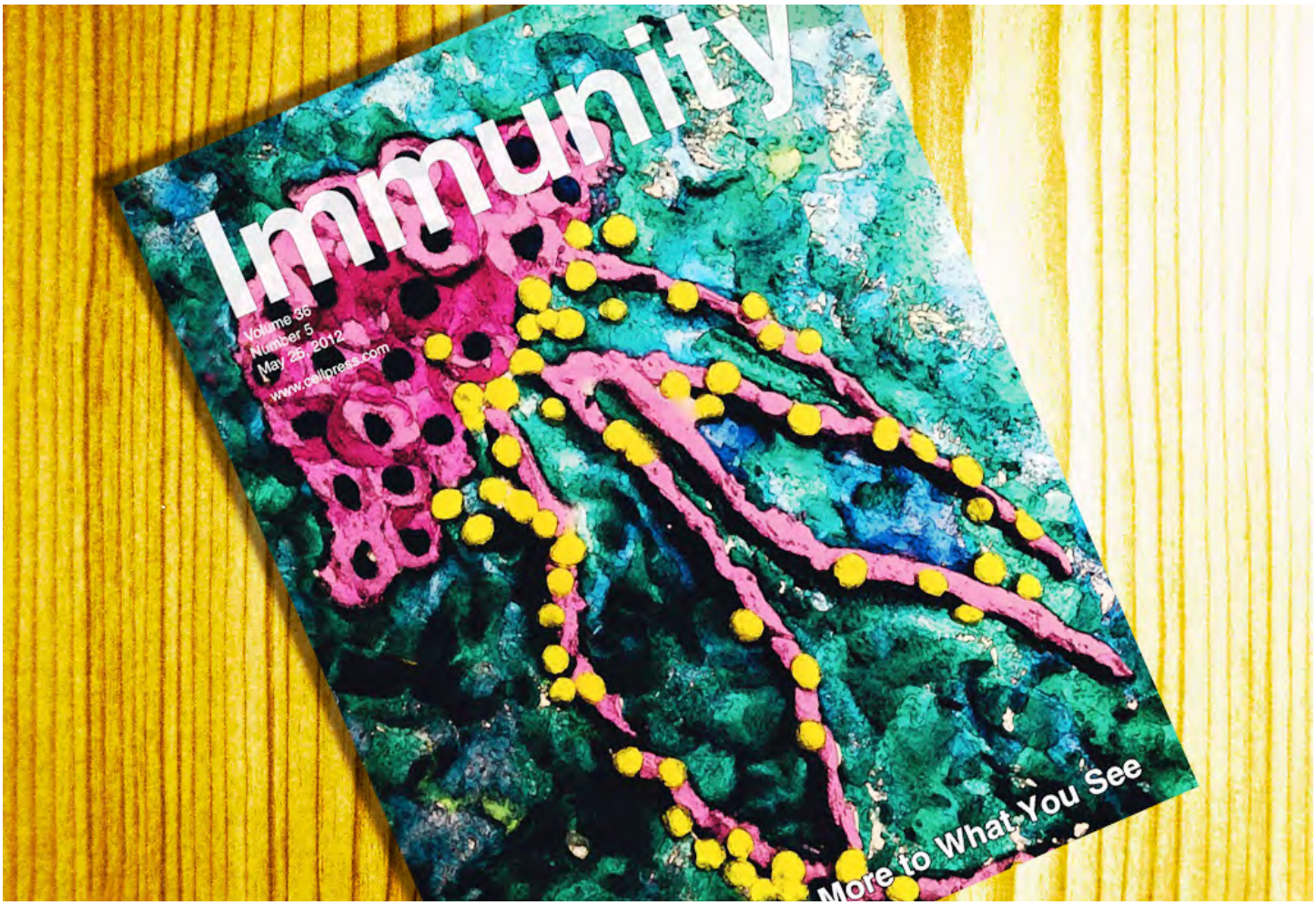
MorgueFile and jdurham

To illustrate this point, *OTW* is launching a new feature called: ***The Scientific Journal Retraction of the Week.***

Each week, *OTW* will publish a recent scientific journal retraction arising from shoddy, lazy or downright fraudulent research. These are examples of researchers who omitted or falsified data, used data out of context or employed such awful logic that they were forced to retract their study. So far, none of them were industry sponsored! These examples are collected by Retraction Watch (http://retractionwatch.wordpress.com) and we are honored to be able to present them with permission from Retraction Watch to our readers. Retraction Watch was started in 2010 by Adam Marcus and Ivan Oranksy, M.D.

Immunity - van Parijs' Falsifications

This week's dubious honor of being included in "Retraction of the Week" belongs to Dr. Luk van Parijs, a former



http://retractionwatch.files.wordpress.com/2012/05/immunity.jpg and RRY Publications

biologist at the Massachusetts Institute of Technology (MIT) who was fired in 2005 after he admitted to making up data. Dr. van Parijs' article "Autoimmunity as the Consequence of a Spontaneous Mutation in Rasgrp1": (*Immunity 19, 243–255; August 2003*) was initially published in the August 2003 journal *Immunity*. The retraction was dated May 25, 2012.

"The authors have agreed to retract the paper because of the falsification of the Western blot in Figure 6A. The figure shows a defect in Ras activation, labeled as RasGTP, following TCR engagement, in thymocytes isolated from a RasGRP1 lag mutant mouse strain. This data set is one of several that show signaling and functional deficiencies identified for cells with los[s] of function of RasGRP. The authors stand by the validity of the other figures, results, and interpretation in this paper. This matter was investigated by the Massachusetts Institute of Technology and the Office of Research Integrity at the United States Department of Health & Human Services, which found that the figure was falsified by Luk van Parijs, who is solely responsible. The authors deeply regret any inconvenience resulting from the publication of this data."

According to Thomson Scientific's Web of Knowledge, the paper was cited 44 times. Oransky writes it was among those cited by the Office of Research Integrity in its 2009 findings about the van Parisjs case:

"While at MIT, Dr. Luk van Parijs falsified figures in grant applications submitted to the National Institutes of Health (NIH), a presentation in 2003, and Fig-

ure 6A, *Immunity 19:243-255 (2003)*, by falsely claiming that the image in the figure represented an immunoprecipitation assay for Ras-GTP and a Western blot for total Ras protein, when it actually represented a Western blot for Bcl-2 and [beta]-actin in T cells, previously published as Figure 5C, *J. Immunol., 168:597-603 (2002)*."

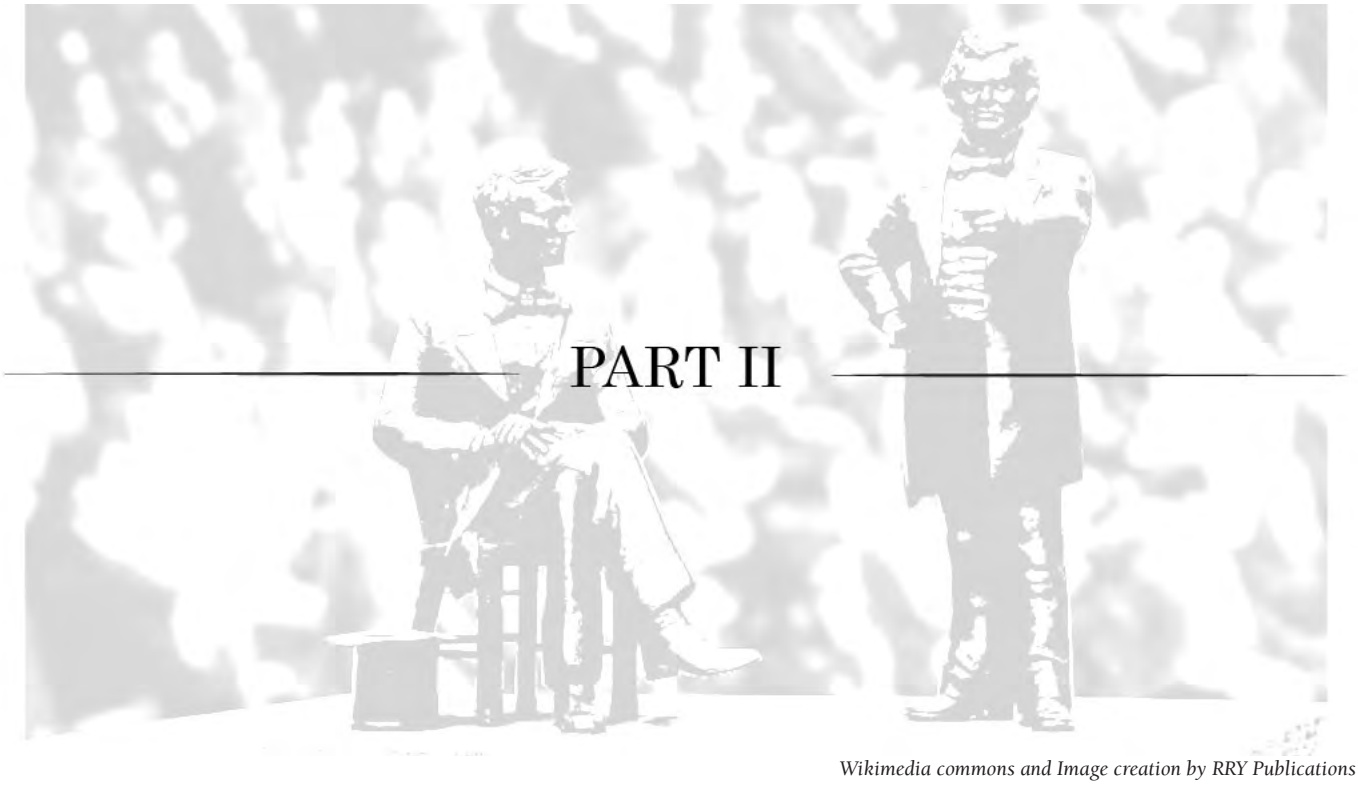
By Retraction Watch's count, it's the fifth retraction for van Parijs, who was sentenced last year to six months of house arrest.

In February 2011, the government filed criminal charges against Van Parijs in the U.S. District Court in Boston, citing his use of fake data in a 2003 grant application to the National Institutes of Health, based in Bethesda, Maryland. According to the journal, *Nature*, van Parijs entered a guilty plea, and the government asked Judge Denise Casper for a six-month jail term because of the seriousness of the fraud, which involved a $2 million grant. "We want to discourage other researchers from engaging in similar behavior," prosecutor Gregory Noonan, an assistant U.S. attorney, told *Nature*.

In June 2011, Casper opted instead for six months of home detention with electronic monitoring, plus 400 hours of community service and a payment to MIT of $61,117—restitution for the already-spent grant money that MIT had to return to the National Institutes of Health. ♦

Winners and Losers of PODs: The Great Debate Part II

By Walter Eisner



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OTW recently hosted a debate about the legality and ethics of physician-owned distributorships (PODs) and whether such ownership resulted in unnecessary surgeries.

We ended Part I of this debate with a question about the larger economic issue of who wins and loses under the current models of physician-owned distributorships. This week we bring together John Steinmann, M.D., founder of the first POD and Pat Miles, President, Global Products and Services of NuVasive, Inc.

Short-Term Gain at the Price of Innovation?

Dr. Steinmann argues that physician ownership saves the healthcare system money and makes winners of patients, payers and society. Mr. Miles argues that such ownership only brings short-term financial benefits while long-term investments in innovation—which drives long-term savings—suffer.

Pat Miles

John Steinmann, M.D.

Also joining this debate are *OTW* readers—whose comments are part of this story too.

Economic Impact of PODs

The financial and economic impact of PODS cannot be ignored. CEOs of device manufacturers frequently talk about PODs on their quarterly calls with analysts. Globus, Inc. a spine company in the midst of a public stock offering notes PODs as a risk to their business in the offering document. ***"The prolifera-***

tion of physician-owned distributorships could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships."

Wells Fargo Analyst Larry Biegelsen has reported that PODs have captured about 10% of the U.S. spine hardware market or roughly $500 million in sales.

Readers Respond

After the last debate, Ron Clark, M.D., an orthopedic surgeon from South Bend, Indiana commented:

There is an "elephant in the room" here… What does the growth in popularity of PODs tell us about the function of the industry's independent distributor? Is the value proposition for medical products distribution changing and is the distribution business model changing with it? Or is the independent distributor stubbornly holding onto an outdated model and refusing to change with the times?

Another reader added that the debate seems to have over looked a major reason that PODs are good for patients—the loss of the 30% commission paid by most companies to their distributorship. POD owners are users and trained professionals and do their own due diligence.

"The POD model allows the owners to select, train, supervise, and manage their representatives in a much more cost effective fashion. The POD orthopedic implant is sold to the hospital at a lower end user cost than the 'traditional' distributor model. The DOJ [Department of Justice] is not blind to this reality which is why the model has not been shut down," wrote the reader.

Do PODs Promote Cost Savings?

Dr. Steinmann: Physician-owned distributorships, formed with proper intent, and operated consistent with the standards of the American Association of Surgeon Distributors (AASD) absolutely promotes cost savings.

Our current system lacks effective market forces to create competitive pricing of orthopedic medical devices. Competi-

tion is based on relationships not value, negotiation is ineffective, products are purchased one at a time, device companies are at risk for large amounts of inventory, and distributors/product reps add costs disproportionate to their value.

The surgeon-owned distribution model has the necessary components to produce sustainable cost savings. Competition is based on value, negotiation is effective, product is purchased in volume, device companies are relieved of significant inventory risk and product reps are paid consistent with similar healthcare professionals.

A recent study of five distributorships operational for over one year, affiliated with Alliance Surgical Distributors, demonstrated an average 37% reduction in costs compared to non-surgeon owned distributorships.

Mr. Miles: In the short term, there is the potential for finite savings, depending upon the pricing scheme employed. *However, physician-owned distributorships typically supply only conventional products without the capacity or incentive to invest in innovation which drives more substantial healthcare system savings in the long term and delivers enhanced patient benefits.*

The question is whether we are willing to forgo innovation to recoup the short-term price differential in plates and screws. Spine surgery is constantly evolving; the suggestion that we are at a point where all service and procedures are the same is false.

Making surgery more predictable with better patient outcomes, less revision, and less rate of infection will have a much more substantive cost savings to the healthcare system. Innovation is only brought about by market forces reflective of an incentive. In the short term, mitigation of market forces results in opportunism; in the long term, higher cost."

Dr. Steinmann: Mr. Miles assertions reflect widespread misconceptions.

First, "conventional products" are generally our best and safest products.

Second, profitability is a result of innovation, not visa versa. T*o suggest that obscene profit margins are necessary to ensure innovation is frankly untrue.* It should also be pointed out that the device industry spends less than 5% of revenue on R&D while spending nearly 35% on sales, marketing and promotion.

Third, while product innovation sometimes leads to improved outcomes, it rarely, if ever, has led to lower healthcare costs.

Lastly, Mr. Miles seems to have the market force/opportunism issue backwards. Market forces exist when there is a knowledgeable customer to value the product, such as is found in the surgeon-owned distribution model. Opportunism is more clearly displayed by a company convincing a surgeon to choose their product, and then charging an obscene price because they know they have the sale.

Mr. Miles: POD's do not enhance market forces but rather introduce more conflicted interest. *Where POD affiliated surgeons deliver care and simultaneously control the delivery and pricing of goods, any savings would be short lived as the competitive market forces disappear. Cost savings becomes reliant upon the goodness of the provider; not market forces.* This scenario would create an environment that lacks incentive to create value.

Winners and Losers

OTW: Mr. Miles and Dr. Steinmann, who wins and loses when PODs are in the marketplace?

Mr. Miles: Nobody wins in the medium or long term via PODs. The healthcare system and its patient customers would lose over the longer term as innovation is replaced with minor pricing opportunism. The incentive that created minimally invasive spine procedures like XLIF is lost without the market forces to encourage innovation and make surgery better. Market forces drive value creation in immature markets and commoditization in mature markets.

In NuVasive's view, spine is NOT a mature market. We have demonstrated value through XLIF by combining service with pioneering technology to reflect better surgery for the consumer.

These same market forces must be fostered to continue the encouragement of surgical options that deliver enhanced patient benefits at reduced cost.

Dr. Steinmann: Patients, society and the U.S. healthcare system—win. Highly compensated distributors and monopoly dependent companies—lose.

Our healthcare system is twice as expensive as it should be, placing an unreasonable burden on society. Access to healthcare is threatened, individuals are bankrupted and American businesses are forced to compete globally with companies operating with far less healthcare costs.

Physicians have largely neglected the costs of the care they provide but this must change. Physicians are the most suitable group to develop a focus on value and have a responsibility to challenge cost and ensure the quality and access for their patients.

The surgeon-owned distribution model provides a mechanism for surgeons to create sustainable healthcare savings through competition, efficiency and meaningful alignment of all stakeholders.

Mr. Miles: Markets and competition are frustrated and undermined when PODs control the setting of price. This is because the incentive to compete for business and demonstrate value through better patient outcomes is taken away.

Our customers continue to derive value out of a well-trained sales force that can influence the delivery of care. They further derive value from the technological innovation we bring to surgical care, innovation that is demanded by the experienced purchasing decisions made by hospitals and surgeons who demand better surgical solutions for the benefit of patients at reduced cost.

We agree that market forces are the answer but don't believe the cynical view that furthering conflict thru short term minimal price differentials via PODs impacts value anywhere close to the way spine care is influenced by innovation.

Dr. Steinmann: Mr. Miles suggests that fair pricing and effective competition will eliminate innovation. To reiterate, there is no historical basis for the suggestion that innovation requires price protection.

The majority of implants used in orthopedics and spine, including most of Mr. Miles products have long ago reached a commodity status. It is time that we instill effective market forces to bring these products to society at fair prices.

Surgeons are, without doubt, the most suitable individuals to value products, value innovations and to distribute product in the most cost effective manner.

The U.S. healthcare system clearly wins with properly structured surgeon-owned distribution companies.

OTW: Thank you for your time and spirited conversation gentlemen.

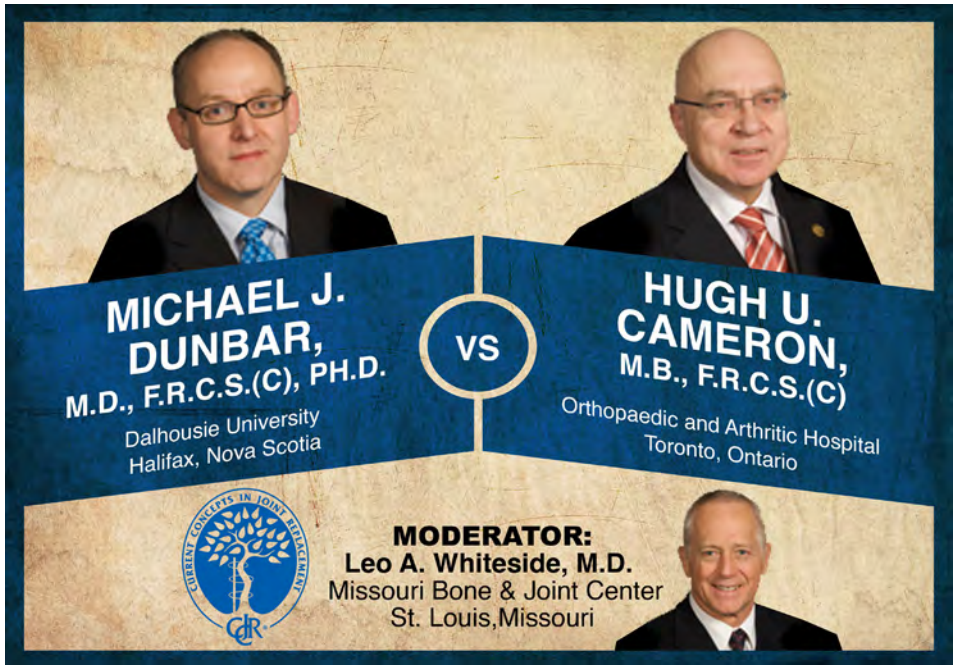
While the debate continues, the Department of Health and Human Services' Office of Inspector General is preparing a report for the U.S. Senate to assess the adequacy of the guidance that has been issued addressing the legality of PODs and other physician-owned entities under the Federal Anti-Kickback Statute. The report is expected this summer. ♦

Proximal Modular Neck in THA – Love it or Hate it?

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

"There are no advantages of modularity," says Michael Dunbar. "Come on," says Hugh Cameron "…a modular neck is like a modular head: this is love at first sight."

This week's Orthopaedic Crossfire® debate is "The Proximal Modular Neck in THA [total hip arthroplasty]: A Bridge Too Far." For the proposition was Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax, Nova Scotia. Against the proposition was Hugh U. Cameron, M.B., F.R.C.S.(C) of the Orthopaedic and Arthritic Hospital in Toronto, Ontario; moderating was Leo A. Whiteside, M.D. from the Missouri Bone & Joint Center in St. Louis.



Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Dunbar: "When we think about new technology we should understand the issues we are trying to solve. With modular necks it's stability, impingement, and some sort of effort to reconstitute leg length and offset. Let's try to cut Dr. Cameron off at the pass."

"Instability: In a good series out of London, Ontario, with 1,500+ patients they have a dislocation rate of 0.4%. So to me, it's not about the implant, it's about surgical volume, exposure, and experience or technique. There's evidence that it's the opposite with respect to the implant itself when we look at the experience from the acetabular modularity from Australia."

"When you look at the dislocation rate, reasons for revision being dislocation, the cemented cup is the baseline at 1.0x revision risk, whereas the modular uncemented cup actually has the higher dislocation rates (1.6x)."

"Impingement: it's an issue with ceramics. The easy answer? Don't use ceramics. Impingement is also related to the acetabular component. The answer? Get the cup in the right position."

"Leg length and offset: Some companies are quite ambitious when looking at modularity. One company's version for a stem—compared to their standard—changes the leg length and offset by 0.2 mm. If the patient is picking up on that it's the princess and the pea phenomenon. If you consider a terrible case…a young lupus patient…you can do a good job implanting a cemented stem and have all the advantages of the modularity. Within a continuum you can infinitely adjust the leg length and varus/valgus, and you can almost infinitely adjust the femoral version."

"So those were the advantages of modularity, of which there were none. Disadvantages. The first is that we're introducing a new mechanical construct and there could be fretting and corrosion, as well as dissociation and fracture. Second issue: long term outcomes are unknown, and there's some evidence that there will be problems with the retroverted necks. Third disadvantage: increased cost."

"We've been concerned about fretting and corrosion at the one interface; with two interfaces there's two times the fretting and corrosion potential. When

talking about a threshold with metal ions…we don't know, but stay tuned."

"There are case reports of dissociation. Even with newer stems we've had a run of these…and it means big revisions."

"Retroversion and component placement: retroverting a neck is not necessarily a benign thing. In a paper from Oxford—an RSA [Radiostereometric Analysis] study of the effect of femoral version on RSA migration patterns as a surrogate to long term failure they found that anteversion is protective if you consider the force magnifier or the lever arm that's produced by going from anteversion where you have a modest deforming force to neutral, and in fact, as you go into 30 degrees of retroversion you significantly increase the retroverting lever arm."

"Cost: I think we're going to be called to the mat soon on what we're doing in terms of innovation for the sake of innovation and the costs that are being driven up."

Dr. Cameron: "I use a modular neck for cemented stems. I don't cement that many stems, but a modular neck is like a modular head: this is love at first sight. The modular neck in most common use is the Cremascoli neck. The neck I use is different, but the principle is the same."

"I began to run into a problem with cemented stems when Richards stopped making the stem that I had used for years. When I looked at other companies' components I found that they all had proportionality…as the stem got bigger the neck got longer. Osteoporosis is an endosteal phenomenon, so as one gets older the canal gets bigger. The companies wanted me to stuff a longer neck into some little old ladies."

"The Rizzoli group in Bologna used a Cremascoli modular neck in more than 2,000 cases. They showed that without a modular neck it was not possible to recreate length and version…especially in a woman. The Cremascoli neck has a 20 year history; it has a double taper neck. Some of them do break. Modular necks make things like stubby stems possible because you can change the neck length on the version after the stem's gone in because you don't have much control over where the stem's going with stubby stems."

"Impingement…it can produce dislocation, noise, particle generation, and locking mechanism failure. To reduce dislocation you can restore the hip mechanics and reduce impingement. The ceramic-ceramic bearings have a risk of impingement, edge loading, chipping and squeaking. With metal-metal, impingement is potentially a problem. The poly sandwich cups have failed due to impingement. A chrome cobalt liner will erode a titanium neck."

"The highly cross linked polyethylenes [HCLP] have a reduced fracture toughness, so if you get impingement it may damage the locking mechanism. So don't use offset liners with HCLP. With all the newer bearings, impingement becomes potentially a major problem. The solution is if it's possible to change the version after stem insertion."

"A recent paper showed problems with a pure Morse taper neck stem. We had anticipated this and added cogs for additional rotational stability. You can also change offset and length after insertion. If you're doing a revision you can pop the neck off and access to the acetabulum is not compromised. This

makes isolated acetabular revisions easier. You have visualization, new version, and a new taper."

"I've used the thin mantle technique of cementing for the last 25 years. This means that you broach minimally and use the biggest stem possible. This means that the stem goes in to match the canal version. I insert the cup at about 20 degrees of anteversion; I now do it to 10 degrees or less. The stem goes in to best fit the femur. The position of the neck goes in for the least impingement—usually in the one or two retroverted position. For the last 25 years I've been getting slight posterior impingement with cemented stems."

"Complications: I had one fractured taper three years post-op and one neck taper dissociation; I also had one periprosthetic fracture. The easiest way to fix these is to revise the stem. With the one that broke, others had broken stems and it was immediately taken off the market. The taper strength was doubled and lengthened; it was reintroduced about five years ago. Since then I've done 156 cases with one dislocation and no other problems."

Moderator Whiteside: "Mike, if you have a patient with a very varus femur, wide offset, is it necessary to keep that as a wide offset?"

Dr. Dunbar: "If you don't pay attention to it then you're going to end up making the error of lengthening it on average. However, you don't necessarily have to put it exactly where it was because there's not a lot of evidence suggesting that's the best thing to do. Putting it too far away would be bad thing because of trochanteric bursitis, etc. You don't have to be stuck with one kind of implant for all cases; you can choose different implants with different degrees of offset built in. Some systems have multiple stems with multiple offsets. With that, and a combination of the acetabular component with offset liners you can make up for that offset."

Moderator Whiteside: "You ever tilt a femoral component to get it into varus to give yourself more offset?"

Dr. Dunbar: "You can, but I'm using cemented so, yes, but you need to be very careful because it can change the biomechanics. Pick a stem that's forgiving to that."

Moderator Whiteside: "Hugh, when you see a major offset difference do you…?"

Dr. Cameron: "I shrink it…especially in big men because those are the ones that are going to break. An even bigger problem is the tall girls with small implants."

Moderator Whiteside: "You have concerns about the strength—the mechanical bond—between the neck and the stem. If you choose a larger offset does that not apply bending loads that are unacceptable?"

Dr. Cameron: "Absolutely. Some companies advise…the implant box says that this high offset neck must not be used in heavy patients."

Moderator Whiteside: "Do you use this modular neck primarily now for retroversion/anteversion management?"

Dr. Cameron: "I started off primarily because of length problems. The problem was that you go to put a big stem in and find you've got a big, long neck in this little old lady. Then I was surprised in the changes in offset."

Moderator Whiteside: "Mike, what do you do with a severely retroverted hip?"

Dr. Dunbar: "It's a combination of acetabular side and femoral side so I'd be more concerned with a retroverted acetabulum. But assuming you can work on some osteophytes and get the cup where you go, you've got a lot of liberty to put that stem in a neutral position… maybe slightly retroverted. But you need to be careful considering the RSA data, and you need to choose a stem that's forgiving to torsional resistance in that plane."

Moderator Whiteside: "How do you manage fretting, and even fracture of the neck?"

Dr. Cameron: "It worried me initially—still does a bit—especially when you've got a big man who wants more offset. What has changed for me is that for the first time I can truly center the head and the acetabulum. If I can stop impingement—even if it's with polyethylene—I'm cutting down on the number of polyethylene particles available, cutting down possibly on my dislocation rate. And it's not so important for the hard/soft bearings, but crucial for the hard/hard bearings."

Moderator Whiteside: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

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Cowboys Need Not Apply: The New Disaster Certification Course

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

Take away the nice, big sterile operating rooms with a team you know and a stepwise process…step into a tent…100 degree temperature…add a line of desperate, traumatized patients demanding treatment…throw in general chaos. What do you have?

A disaster…a Haiti, a Katrina.

What do you have to work with? Look in the mirror—it's you, your talent and ingenuity as an orthopedic surgeon and, most of all, your training from the new Disaster Certification Course.

In the face of disasters like Haiti or Katrina, what's really needed, the experts say, is a cadre of orthopedists specially trained to function appropriately in such extreme situations.

The American Academy of Orthopaedic Surgeons (AAOS), the Orthopaedic Trauma Association (OTA), and the Society of Military Orthopaedic Surgeons (SOMOS) are making this happen.

For those who aspire to join this extraordinary team, there is now an official *Disaster Certification Program*.

Lynne Dowling, director of the International Department at AAOS, is leading the charge. "This certification program is a direct result of the Haitian earthquake in 2010. Our board recognized that we didn't have a disaster plan in place that would help members better respond to future events. So, we created a joint project team with the OTA and SOMOS and developed a disaster preparedness plan for AAOS. The plan includes training pathways for members to become certified as 'AAOS registered disaster responders.' At this point we have a database with approximately 120 orthopedic surgeons who have been through the program."

"While there were already programs in existence, such as the National Disaster Medical System, and a program

Wikimedia Commons and U.S. Navy's Mass Communication Specialist 3rd Class Cory Rose

through the Department of Health and Human Services, we have streamlined the training pathway. For example, we have made a disaster response course a mandatory training requirement for all three responder types—surge, acute responders, and those in the sustaining phase of a disaster."

"Our database contains details of which surgeons have received exactly what kind of training. This includes what other certifications they have, such as from the Department of Health and Human Services—or if they are registered to work with Doctors Without Borders, etc. The main thing is that our members get certified in how to work in an austere environment—and that is what our disaster response course does."

COL Tad Gerlinger, M.D. is the president of the Society of Military Orthopaedic Surgeons. Having gleaned extraordinary lessons from the wartime practice of orthopedics, Dr. Gerlinger and his colleagues were determined that this important knowledge not fade away. "At SOMOS our big 'push' has been that these lessons not be lost to time. So much of what we have seen and learned in conflict is useful for disaster situations. This includes crush injuries, explosions, blasts, etc. To preserve this knowledge, SOMOS, OTA and the AAOS came together to create the Disaster Response Course in an effort to prepare orthopedic surgeons to care for the victims of war and disaster in an austere environment."

"This course is designed for people who are accustomed to the comforts, equipment and facilities of the modern day U.S. hospital. They learn how to function in an environment with limited resources where they may be in some type of danger. We teach them how to conduct surgery safely, how to triage effectively based on resources, and how to treat specific wounds without the customary resources."

"We prepare orthopedic surgeons for disasters abroad, as well as here in the U.S. At our last meeting we had a physician who was at the Reno airshow disaster. He came to the course because he was inspired to know and do more. My biggest take home message is this: at some point disasters occur in every community…they are everybody's business."

COL James Ficke, M.D. is Orthopaedic Surgery Consultant to the U.S. Army Surgeon General. He co-chaired the military focus of expertise—the Extremity War Injuries symposium for 6 years. "I am working with Lieutenant Colonel Warren Kadrmas from the Air Force and Navy Captains Daniel Unger and Eric Hofmeister to facilitate a coordinated military and civilian program. The military is interested in an organized civilian response, and to that end we have been working to see where orthopedic surgeons as a community can contribute. If an orthopedic surgeon responds to a disaster outside the U.S., we want to ensure that there is the appropriate security, as well as platforms where they can work."

"As orthopedic surgeons we have to understand the concepts of damage control orthopedics—external fixation, adequate wound debridement, assessment of soft tissue viability. And because we must be creative when working in austere environments, orthopedists need a good comfort level with their surgical skills. We have to provide safe surgery without the luxury of a C-arm or antibiotics…and we need to know how to do a definitive reconstruction yet leave a limb functional. Think about this: 'How does an orthopedic surgeon contribute when you can't take six hours to do a definitive reconstruction because there is a long line of patients waiting?' That is triage…the kind of thing we teach in this course."

Christopher Born, M.D. is chair of the Disaster Management and Emergency Preparedness committee for the Orthopaedic Trauma Association. He has been a co-director of the disaster response course since the program's inception. "We have so many well-meaning orthopedic surgeons who are moved to help in the face of a dire situation. The fact is, however, that if you have never worked in a humanitarian/disaster situation then you most likely will have a lot to learn about how to function in these

environments. You may be asked to do things you don't normally do, such as move patients around; you may have to act as a general medical practitioner or assist other surgical subspecialists such as OB/GYN or general surgery."

"Ethical situations are omnipresent… you can't just come into a disaster situation and do what you want. We must remember that we are dealing with human beings and even if they are different from you, they should still be afforded the same considerations as the patients you usually treat. An example of a mistake would be doing an operation on a patient that is semi-emergent, and not using an interpreter to tell the patient what you are going to do and what they can expect. Sometimes, you may not have a choice—but you must continue to hold yourself to the highest ethical standards possible."

"You should not, for example, perform amputations if you have never done that before. And if you are a sports medicine specialist you probably should not do open fracture debridements if you haven't done them in many years. We also cannot do ill-advised operations, such as internal fixation where sterility is questionable because this will increase the chance of infection. In the disaster response course, we cover what other options surgeons have in situations such as this."

Surgeons are people of action. But, says Dr. Born, in disasters you just may have to sit back and wait. "It's imperative that surgeons understand that they are only one component of a larger system that they may not fully appreciate. If you are part of a government team or an NGO that's coming into a country, you should understand that a lot of organizational work goes on behind the scenes. Cowboys need not apply. Take Haiti, for example. U.S. government teams arrived, but couldn't be deployed immediately because a supply chain had to be established and permission from the Haitian government to practice medicine needed to be obtained. We also had to find a secure facility in which to work. Setting up a surgical treatment center in an open soccer field where you are surrounded by overwhelmed, hungry people is not a good solution."

Paul Girard, M.D. has also "been there." A former Lieutenant Commander in the Navy, Dr. Girard was deployed to Iraq and has served on the USS Comfort. He has led a seminar—Extremity Fractures in an Austere Environment—at the disaster response course on several occasions. "There are two significant clinical lessons that need to be transferred to civilian orthopedic surgeons. First is the management of soft tissue injuries. This is arguably more important than the management of bone injuries. The second thing is conceptual: the management of bone injuries requires a high degree of flexibility—and we surgeons can be a rigid bunch at times. The severity of the wounds and the austerity of the environment require that you account for the personality of the injury in the context of your surroundings and the regional culture when developing treatment plans in this type of setting."

"We are used to nice, big sterile operating rooms with a team we know and a stepwise process. In an austere environment you have little, if any control over where you work—it could be a tent, or outside—either way it might be 100 degrees. It is imperative to understand that you should not try to utilize the same techniques to manage these patients that you use every day in your hometown. If I normally stabilize a fracture with a rod or plate, in an austere environment I may need to do debridement, cleaning, dressing, and a splint or cast instead of trying to fix it. You have to be prepared to broaden your view to all possible treatment options and think like a resident again."

Shedding light on how one's thinking must evolve to participate in disaster response, Dr. Girard says, "An orthopedic surgeon in the audience asked about the use of different types of plates and screws. I let him know that the course isn't about XYZ implant. He was seeing the trees as opposed to the forest. Let's say you put in a plate and screws and they remain in the patient for the month you are in the area volunteering. When you leave, another provider from the local area will likely assume care and be responsible for managing that patient's needs. If the patient develops an infection, you have made the care of that patient that much more challenging if the next surgeon does not have the appropriate instruments to remove the implant. Any care we provide must be reversible by the host nation physicians if things turn sour. The way to think and act when responding to a disaster or humanitarian relief effort is different and not intuitive, and therefore must be passed on and learned."

Thanks to the dedication of these and other individuals, there is now a way to do just that. ♦

For additional information on the AAOS/OTA/SOMOS disaster course, please visit www.aaos.org.

company

Stryker Offers Feds $33 Million to Settle OtisKnee Investigation

Stryker Corporation disclosed in a June 5 SEC filing that the company has offered the Department of Justice a $33 million olive branch to reach a "consensual resolution" over allegations of violations of "Federal laws related to sales of a device not cleared by the [FDA]".

The Justice Department issued a subpoena to Stryker in 2010 related to the sales and marketing of the OtisKnee device. The government has looked hard at customized instrumentation devices at other companies. There was

Wikimedia Commons and Eugenio Hansen/Dove With Olive Branch

no word from the government if they would take the money to settle the investigation.

The company said it will record a non-tax deductible charge for the second quarter of 2012 and reduce reported diluted net earnings per share by approximately $0.09.

Stryker acquired the OtisMed Corporation, the developer of the OtisKnee device, in 2009.

Custom devices and instruments have caused FDA regulators to look extra hard at the clearance process. ConforMIS was the first company to receive 510(k) clearance to market its iTotal CR Knee Replacement System in early 2011, following a lengthy review period. In 2010, Biomet received an FDA warning letter regarding its Signacre customized cutting guides for total knee replacement, and the company temporarily suspended marketing of the device until it was cleared by the agency in February 2011. Stryker received 510(k) clearance in May last year for the Shapematch, which it acquired when it purchased OtisMed.

The Shapematch system is a customized jig system for the Triathlon knee , the combination of which is called the Triathlon CustomFit Knee.

—WE (June 6, 2012)

Orthofix Teams With Brainlab

Orthofix International N.V. and German-based Brainlab AG introduced a partnership at the recently completed SpineWeek Meeting in Amsterdam for the integration of Orthofix's Phoenix MIS and Firebird Pedicle Screw System into the latest generation of Brainlab Spinal navigation systems.

The agreement allows for the integration and co-marketing of the technologies, which permits preoperative planning and real-time positioning of spinal fixation devices in technically challenging spinal fusions procedures.

Brainlab develops, manufactures and markets software-driven medical technology that supports targeted, less-invasive treatment. Core products are image-guided systems and software that provide real-time information used for surgical navigation and radiosurgical planning and delivery. The privately held company was founded in 1989 and has more than 5,000 systems installed in over 80 countries. Based in Munich, Germany, Brainlab employs 1,020 people in 17 offices worldwide.

Orthofix International N.V./Firebird Pedicle Screw System

"We believe that the combination of our navigation technology with minimally invasive surgical instrumentation can change the way spinal procedures are done today. It will not only increase the accuracy of the implant placement but also provide a better orientation during surgery and has the potential to reduce the intra-operative radiation exposure. We are very excited to add the Orthofix products to our supported portfolio for minimally invasive spinal navigation," said Martin Immerz, Global Product Line Director Orthopedics of Brainlab.

Bob Vaters, Orthofix's president and CEO, said he and his colleagues are excited to promote the intra-operative advantages of Brainlab's' different image-guided surgery platforms when used with the Phoenix and Firebird systems.

—WE (June 5, 2012)

Expanding Orthopedics and Advanced Medical Systems

Ciao Italia! Expanding Orthopedics has entered into an exclusive distribution agreement with Advanced Medical Systems (AMS Group S.P.A.) for the distribution of its unique XPED Expanding Pedicle Screw System in Italy.

Mauro Vendrami, President and CEO of AMS, said in the May 29, 2012 news release: "AMS is committed to bringing the most innovative and advanced technologies to the Italian market and we are convinced that the XPED system has great potential here. Initial feedback from Italian surgeons shows that there is a clinical need for a pedicle screw system with enhanced anchoring capabilities in compromised bone. We look forward to establishing reference centers with Key Opinion Leaders in Italy in order to establish XPED as the standard of advanced care. AMS's expertise in partnering with physicians is a key to therapeutic success and that its success in developing innovation in treatments has contributed in improving patient care."

Ofer Bokobza, CEO of Expanding Orthopedics, added, "We are very pleased to add AMS as a business partner, adding a top-notch company to our distribution network. Their reputation for successfully introducing advanced medical devices is well known. Italy, as the 4th largest market in Europe, is a major target for us. The extensive sales and service network of Mr. Vendrami and his team will allow Italian surgeons the ability to provide patients with an optimal fixation solution."

Ofer Bokobza commented to *OTW*, "AMS has set up a dedicated spine team of product specialists and territory managers that combines a long-term personal relationship with the Italian spine surgeons with an in-depth technical and clinical knowledge and understanding of the therapeutic needs and technological solutions. When a new product is introduced by AMS, this dedicated team first learns the product in depth and then supports and mentors the direct sales people and distributors/agent network during the first months of the product launching and introduction."

—EH (June 5, 2012)

Wikimedia Commons and Tobias Wolter

legal

The Device Tax's Political Kabuki Theater

An effort to repeal a 2.3% medical device excise tax is heating up in Congress. But for now it's all for show.

Republicans on the U.S. House of Representatives' Ways & Means Committee voted to repeal the excise tax included in the Affordable Care Act on May 31. Two Democrats joined Republicans in the 23-11 vote. The full House is expected to take up the bill June 7 or 8. The tax is expected to raise $29 billion starting in 2013 to help pay for insurance for the uninsured.

Democrats criticized Republicans for not finding cuts in the budget to make up for the $29 billion that would be lost in revenue to the U.S. Treasury and add to the national debt. Republicans say they will offer ways to pay for the lost revenue before a full House debate. Interestingly, one of the proposed ways to pay for excising the tax may end up pitting physicians who want a permanent "doc fix" against their uninsured patients. More on that later.

Senate to Ignore House

The bill is expected to pass the full House, but not in the Senate, where parallel legislation introduced by Republican Senators Orrin Hatch and Scott Brown lacks bipartisan authors. Democrats control the Senate and even if 60 bipartisan filibuster-busting votes could be rounded up, the President could still veto the bill.

"Of course we're not going to bring it up," said Adam Jentleson, spokesman for Senate Majority Leader Harry Reid of Nevada.

The Supreme Court may render all political debate about the Act moot, when it announces a decision about the constitutionality of the Act. The Court has already voted on the outcome and is expected to announce the results sometime before the 4th of July.

Device Tax Debate

Democrats say the device industry can afford the new tax because they'll get to sell more products to tens of millions of new customer who will now have health insurance coverage. Republicans, and some Democrats from heavy medical device manufacturing states like Massachusetts and Minnesota, say we shouldn't put new taxes on the nation's $130 billion-a-year medical device industry which exports products overseas and keeps jobs at home. Supporters of the tax note that imported devices would be subject to the tax, while devices made for export would not.

Minnesota's two Democratic senators, Al Franken and Amy Klobuchar, say they favor eliminating the tax as has Democrat Elizabeth Warren, who is challenging Brown in Massachusetts.

"Doc Fix" or Insurance Coverage

The Star Tribune in Minnesota reported on June 4 that Republican sources told them that Republican leaders will pay for the tax cut by trimming health insurance subsidies for low- and middle-income taxpayers. Their $43.9 billion plan would "recapture" overpayments under a new health insurance tax credit. Those taxpayers would have to fully reimburse excess tax credits they would receive under the new law's government-sponsored insurance exchanges. Currently, eligibility can be based on a two-year-old tax return. There is a cap on liability for overpayments.

But others have had their eye on those potential savings. Some Democrats in the Senate have voted in the past to limit excess subsidy payments to pay for the "doc fix."

—WE (June 5, 2012)

house.gov/U.S. House Committee

Do "Sunshine" Physician Payment Laws Work?

Do existing sunshine laws impact physicians' behavior?

The early evidence suggests that laws requiring drug company disclosure of payments to physicians do not influence prescription behaviors.

A study led by Kavita Nair, Ph.D., an associate professor at University of Colorado School of Pharmacy in Aurora, found that physician choices of which drugs to prescribe in states with sunshine laws did not differ much from their peers in states without a disclosure law.

In letter to the May 28, 2012, *Archives of Internal Medicine*, Nair's team said they decided to look at the experiences of Maine and West Virginia—states that each enacted sunshine laws in 2004.

Using information on insurance claims made between July 2003 and March 2009, the researchers analyzed how many prescriptions were written in each state for brand-name cholesterol-lowering statin drugs and brand-name selective serotonin reuptake inhibitor (SSRI) antidepressants.

For comparison, they did the same for demographically similar states without sunshine laws. New Hampshire and Rhode Island were compared to Maine, while Kentucky and Delaware were compared to West Virginia.

The researchers note that patients can get cheaper, generic versions of statins and SSRIs, and drug companies rely on marketing to increase the number of prescriptions written for the brand-name versions.

Overall, "there were negligible to small effects of the disclosure laws in Maine and West Virginia for both statins and SSRIs," Nair's group concluded.

Critics of the study claimed that since the disclosure of the information was to state agencies, not the general public, the laws were less likely to influence physicians' behaviors.

The researchers acknowledge to *Reuters Health* that several limitations in their study, including that other factors could influence the results, the comparison states may be different in other ways and looking at brand-name prescriptions may not be a means to detect the benefits of the laws.

"This doesn't even present a bird's-eye view," Charles Ornstein told *Reuters Health*. Orenstein has looked at the issue of payments to doctors at *ProPublica*, a non-profit investigative news organization in New York.

Ornstein also said that both Maine and West Virginia do not make their disclosures available online. And, he added, companies did not start disclosing how much they paid doctors until 2009.

The Affordable Care Act includes a provision that requires companies to report certain payments made to physicians. Those disclosures will be available to the general public and will include medical device companies.

—WE (August 30, 2011)

National Cancer Institute and Linda Bartlett

biologics

Stem Cells + Crushed Bone =Repaired Hips

All forms of arthritis are unfortunate ailments to have, but one form, osteonecrosis, a condition where poor blood supply causes significant damage to the bone, is particularly outrageous. Doctors at Southhampton General Hospital, UK, have mounted an assault on osteonecrosis in cases where the bone has been damaged leaving affected patients in need of hip repair.

To make the repair, doctors extract stem cells from the bone marrow of patients whose hips have been damaged by osteonecrosis and mix them with cleaned, crushed bone from a patient who has had his own hip replaced. They use this mixture, like a cement, to fill the holes made by surgeons who have removed dead and damaged tissue from the hip joint.

Doug Dunlop, M.D., a consultant orthopedic surgeon at Southampton General Hospital, and Professor Richard Oreffo, a specialist in musculoskeletal science at the University of Southampton, developed the procedure.

"Although this work is still ongoing, several patients who have had the procedure have reacted very well and, if we get the results we are hoping for, these patients won't need to have their hip joints replaced—they should be fixed completely," said Dunlop in the May 29 press release.

Oreffo added: "By using stem cells to send out chemical signals to blood vessels, we hope the body will continue to create new vessels in the hip which supply enough nutrients to maintain bone strength."

Osteonecrosis is one of the three main causes of arthritis alongside osteoarthritis and rheumatoid arthritis. The doctors say that the ailment is on the rise in the UK with around 4,000 cases a year. Arthritis in general affects one in five people in the UK.

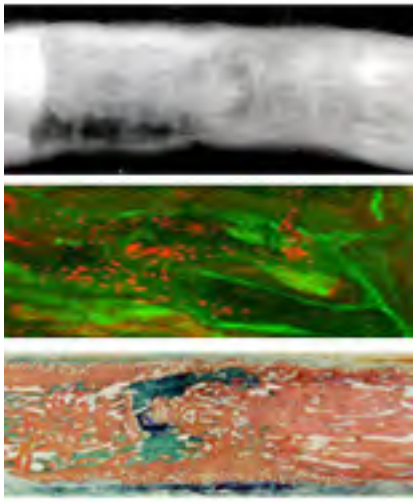
—BY (June 4, 2012)

Caption: Radiography of total avascular necrosis of right humeral head Source: Wikipedia Commons and jmarchn

Osiris Stem Cells Treat Flesh-Eating Bacteria

Collaboration between the stem cell company Osiris Therapeutics, Inc. and Spencer Misner, a Georgia M.D., has resulted in the "regrowing" of Bobby Rice's right foot. The incident is reported by Charles Oliver, writing in the *Dalton Daily Citizen*. Misner credits emerging stem cell treatments for saving Rice's right foot and leg.

It all began when Rice, who has diabetes, cut his foot on a piece of glass. When it became infected, Rice went to Dalton's Hamilton Medical Center emergency room where doctors discovered that Rice had contracted a necrotizing fasciitis—flesh-eating bacteria. To save his life, doctors amputated one toe and carved off much of the flesh from his foot and along his ankle.



Courtesy of Osiris Therapeutics, Inc.

Oliver quotes Misner as saying, "We did what we had to do. We got the infection out. We saved his life. But what do you do next? We'd normally say all you can do now is cut off his leg so he can get on with his life."

Before taking that step, Misner contacted Ed Fickey, a sales representative for Osiris Therapeutics, and asked if he could use the company's new stem cell technologies in an attempt to rebuild Rice's (who was indigent) foot and ankle.

The company, which had never had a case of this magnitude before according to Misner, agreed to provide two products, called Grafix and Ovation, which are made from adult stem cells derived from donated placentas. When Misner asked for guidelines on how to use the products, he said that the company basically told him "You let us know what the guidelines are because we do not have a record of anything like this being done before."

Misner started the treatments in November 2011. The company representative Fickey remembers, "He (Misner) had a syringe, and he was looking for some tissue to push it into. But there was nothing but bone there," he said. "Now, there's a whole fleshy foot."

Misner has now applied nine stem cell treatments and describes the foot as being more than 90% healed. He expects to do approximately three more stem cell treatments before the foot has completely regenerated.

Fickey told the writer Oliver that Osiris has been watching "the Dalton foot" very closely. "Each time we do an application, I send the latest pictures back. They (company officials) wanted to see if there has been muscle growth and the answer has been yes. They wanted to see if there has been vascularization, blood flow, and there has been. The most impressive thing is that Bobby has feeling back. This is what we want to see."

Rice said he never dreamed he would regain his foot. "I know what it looked like. I expected he would just have to take it off. To see where it is today is just amazing," he said.

—BY (June 4, 2012)

large joints

Tailored RA Biologic Treatments Reduces Costs

Data from a Dutch study has demonstrated that tailoring biologic treatment to individual patients with rheumatoid arthritis (RA) can reduce total costs by €2,595,557 ($3,239,514) per 272 patients over three years, at the same time increasing effectiveness by an average of 3.67 quality-adjusted life years. The research, presented recently at the Annual Congress of the European League Against Rheumatism (EULAR), found that the cost savings were mostly related to medications.

A total of 272 RA patients taking adalimumab treatment were measured for DAS28 (Disease Activity Score), HAQ DI (Health Assessment Questionnaire – Disease Index), and biologic use over three years. A treatment protocol for personalized care was defined in which EULAR response and adalimumab serum drug level test results at six months determined whether adalimumab treatment was continued or discontinued, dosing was altered or, in case of non-response, another biological treatment was started.

Charlotte Krieckaert from the Jan van Breemen Research Institute, Reade, The Netherlands and lead author of the study stated in the June 7, 2012 news release, "Governments and health authorities around the world are looking to save money by cutting costs and providing reduced access to more expensive treatments. This study demonstrates that with careful monitoring and testing disease activity at six months, costs for RA treatment can be reduced and treatment effectiveness can actually increase."

In total, €2,562,494 ($3,198,248) was saved on biological drug costs and testing costs amounted to €10,872 ($13,569), resulting in an average incremental cost-effectiveness ratio of -€707,236 per QALY* gained.

*QALY (quality-adjusted life year) is a measure of how many extra months or years of life of a reasonable quality a person might gain as a result of treatment.

—EH (June 8, 2012)

Caption: X-ray of the hand and wrist joints in a patient with rheumatoid arthritis/ National Institutes of Health

Unconventional Surgeon Gets 4x Better TJR Outcomes

Patients who go to Crovetti Orthopedics and Coronado Surgical Recovery Suites, in Henderson, Nevada, expecting to get a little rest along with a new hip or knee, are in for a surprise. Founder and orthopedic surgeon Michael Crovetti, M.D., has a distinctive approach to recovery that he would like to see in place nationwide.

Following surgery and after recovery, nurses wheel Crovetti's patients to a private suite where they will spend the next two days learning to regain their physical abilities with the help of their own family members and the staff. Therapists transfer the patients to a Murphy bed which is folded up after breakfast to encourage the patients to move. Nearby restaurants or an on-site deli send in food. Patients stay for only two days after their surgery and a family member stays with them, in this way learning precisely what will be needed for the patient's care after their discharge. Crovette says, "The family members know exactly what to do (for the patient) when they leave."

The key to Crovette's program is the 50 foot long hallway outside the rooms. The floor is painted green with football yard line markings on it and there are touchdown goal posts on each end. On the ceiling is a stabilization device known as a Secure Track. With the help of the Secure Track, which replaces traditional metal frame walkers, physical therapists guide patients up and down the hallway. Patients can put as little or as much weight on the system as they need. Physical therapists and the device guide patients up and down the 50-foot-long hallway. "I don't care where you live in the world," said Crovetti, a one-time college quarterback. "You know when someone scores a touchdown, it's a good thing. I want people to score a lot of touchdowns."

Courtesy of Crovetti Orthopedics

Crovetti sees his work as restoring complete physical ability without pain and the only way to accomplish that, he believes, is to get his patients moving. The average number of feet Crovetti's first 150 hip replacement patients have walked on the day of their surgery is 356 feet. Knee replacement patients walked an average of 310 feet on the same day as their surgery.

On day one following replacement surgery, hip patients average 998 feet walked and knee patients average 706 feet. Crovetti notes that in a conventional hospital, it is common to only walk about 250 feet total. He adds that the patient's movements also prevent blood clots and embolisms, common problems after joint replacement surgeries.

When it comes to hip replacements, in particular, Crovetti says he uses a much smaller incision and thus disturbs less tissue overall. He follows a strict operating room routine and has used the same two anesthesiologists for years. Crovetti says the surgeries and movement afterward come with a dramatic and quick reduction in pain. Pain scores register at 9 or 10 (on a 10-point scale, 10 being the highest) prior to surgery and are cut in half after surgery. They are generally minimal by three weeks, he says.

According to Brian Sodoma writing in May 28 the *Las Vegas Sun*, Crovetti's idea originally met with resistance from Nevada officials who did not believe his idea would work. He received clearance from health examiners in November 2010. Crovetti describes Nevada's health and regulatory system as being one "that didn't understand the model," but whose oversight and concerns were well meaning and required.

What is pushing the recovery suite model forward is Crovetti's data collection for the past year and a half. Patients sign forms giving permission for their progress to be used for data collection to check how the model is working or where changes need to be made. Crovetti now has more than 200 surgeries done under the model. He told Sodoma, "The biggest reason companies fail with stuff like this is a lack of data."

—BY (June 4, 2012)

trauma

AAOS Wins Award for Decide to Drive!

AAOS...they pulled out all the stops to put a stop to distracted driving. And now, the ASAE Marketing, Membership and Communications Conference (MMCC), has awarded the American Academy of Orthopaedic Surgeons its 2012 *Council's Choice Award* for the "Decide to Drive" campaign. From print ads to public service announcements, the "Decide to Drive" campaign—a partnership among the AAOS, the Orthopaedic Trauma Association (OTA) and the Alliance of Automobile Manufacturers—has done its all to bring attention to the dangers of distraction behind the wheel.

"We are honored to receive this award from ASAE," said AAOS CEO Karen L. Hackett, FACHE, FASAE, CAE in the May 30, 2012 news release. "There are so many dangers with distracted driving, and we wanted to raise peoples' awareness through a creative, multimedia campaign, which turned out to be very successful. I'm extremely proud of our PR team in how they created and implemented this campaign, and we hope it will make a difference in saving lives on the road."

The national campaign includes TV, radio and print public service advertisements (PSAs), a media relations program, educational materials for children and drivers of all ages, a public-participation website (www.decidetodrive.org), patient-education initiatives, and a cohesive social media component. There have been PR efforts that reached airports, shopping malls, buses and bus shelters, as well as broadcast across the country. The campaign has also included a national Harris Interactive Survey on drivers' behaviors and perceptions of distracted driving, a television PSA called "Froggy" that depicts a young mother who is woefully distracted by her toddlers dropped toy and eerily suggests a tragic outcome from that brief lack of attention to the road, a radio PSA called "Spoken Word" that uses poetry-slam style delivery to convey the message that no one can "get away" with distraction behind the wheel, and other initiatives.

Sandy Gordon / Courtesy: AAOS

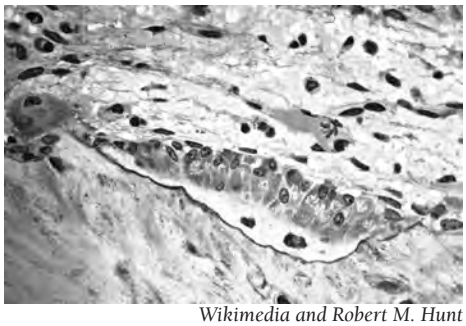
In 2012, the "Decide to Drive" initiative continues its success by holding a series of public events stressing the importance of driving the conversation home about distraction—with your parent, your teen, your spouse, your cab/bus driver or anyone else behind the wheel who is succumbing to distraction.

Sandra Gordon, director of Public Relations for AAOS, told *OTW*, "We have heard from so many people that are grateful we are doing this campaign. And our members have been very involved with and enthusiastic about these efforts."

—EH (June 7, 2012)

NASA, ASU Collaborate on Bone Loss

Scientists at Arizona State University (ASU) are working with NASA to develop and apply a technique that originated in the Earth sciences. In a new study, this technique was more sensitive in detecting bone loss than the X-ray method used today.



Wikimedia and Robert M. Hunt

Ariel Anbar, Ph.D. a professor in ASU's Department of Chemistry and Biochemistry and the School of Earth and

Space Exploration, is senior author of the study. In the May 29, 2012 news release he stated, "Bone loss also occurs in a number of cancers in their advanced stages. By the time these changes can be detected by X-rays, as a loss of bone density, significant damage has already occurred. Also, X-rays aren't risk-free. We think there might be a better way."

The team assessed bone loss by carefully analyzing the isotopes of the chemical element calcium that are naturally present in urine. Patients do not need to ingest any artificial tracers and are not exposed to any radiation, so there is virtually no risk, the authors noted.

"The paper suggests an exciting new approach to the problem," said Rafael Fonseca, M.D., chair of the Department of Medicine at the Mayo Clinic in Arizona, and a specialist in the bone-destroying disease multiple myeloma. Dr. Fonseca was not associated with the study but is partnering with the ASU team on collaborative research based on the findings.

Fifteen years ago, corresponding author Joseph Skulan, now an adjunct professor at ASU, combined all the factors into a mathematical model that predicted that calcium isotope ratios in blood and urine should be extremely sensitive to bone mineral balance.

The new study, funded by NASA, examined calcium isotopes in the urine of a dozen healthy subjects confined to bed ("bed rest") for 30 days at the University of Texas Medical Branch at Galveston's Institute for Translational Sciences–Clinical Research Center. Whenever a person lies down, the weight-bearing bones of the body, such as those in the spine and leg, are relieved of their burden, a condition known as "skeletal unloading." With skeletal unloading, bones start to deteriorate due to increased destruction. Extended periods of bed rest induce bone loss similar to that experienced by osteoporosis patients, and astronauts.

The new technique can detect bone loss after as little as one week of bed rest, long before changes in bone density are detectable by the conventional approach, dual-energy X-ray absorptiometry (DEXA). Importantly, say the authors, it is the only method, other than DEXA, that directly measures net bone loss.

Dr. Anbar told *OTW*, "One of our next steps is to collaborate with biomedical researchers who have archived urine and blood samples of patients known to have suffered from bone loss to determine if the Ca isotope technique detects the known bone loss in these patients."

—EH (June 4, 2012)

And he reads Orthopedics This Week.

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