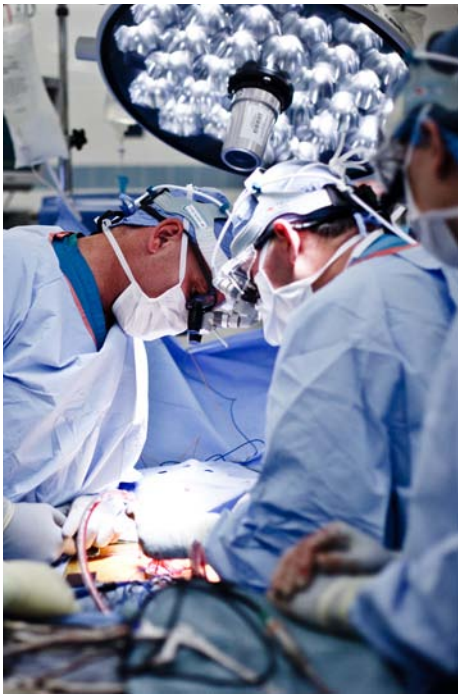
VOLUME 7, ISSUE 23 | JULY 19, 2011

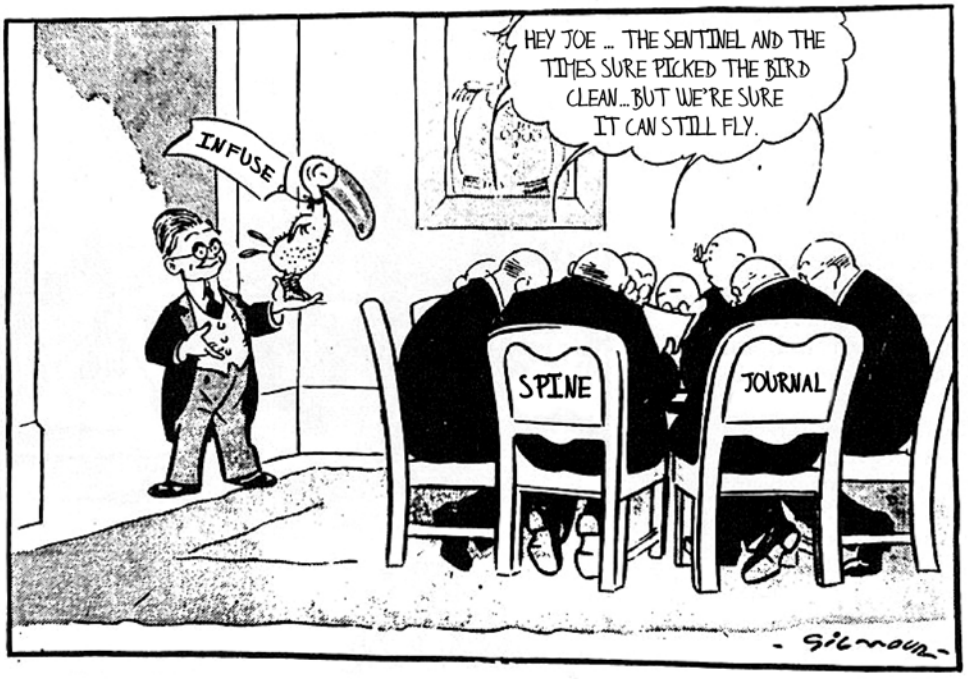
Orthopedics This Week

week in review

4 **InFuse, Part II** ◆ This week, in Part II of our review of *The Spine Journal*'s BMP issue, we tackle some of the other issues raised by the *Journal*, notably corporate funding of the InFuse studies. Then we look at the broader implications of the *Journal*'s review on innovation and self-regulation in the spine surgery community.

11 **Spine Payment Challenge in Minnesota** ◆ Spine companies and surgeons are lining up to meet the latest insurer challenge to certain fusion procedures. Blue Cross Blue Shield of Minnesota wants to exclude ALIF, AxiaLIF, XLIF and DLIF procedures from coverage. We've seen this story before. Read what the players have to say.





picture of success

24 **Dr. Dennis Devito** ◆ Dr. Dennis Devito, a pediatric orthopedic surgeon, is getting unusually good results with scoliosis patients…and he's doing it with robotic assisted surgery. He is also bringing change and hope to the lives of children and surgeons in El Salvador.

breaking news

15 **Biomet 4Q11**: Execution and Sales Challenges

Smoking Reduces **Male Arthroplasty Risk**

British Add Up **Fat Costs**

Ex-**Kyphon Manager Pleads Guilty** to Fraud

Spielberg Named **FDA Medical Products Deputy**

Breakthrough for **Ankylosing Spondylitis**

Osteoporosis and **MS**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: The current U.S. economy is a four-cylinder engine firing on just one cylinder. Consumer spending, employment and housing are all sputtering. Only the inventory cycle has turned. That's good for folks like SMA (back on the Power Ranking) but not good news for overall demand for orthopedic implants.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	14.72%	7.70%	OFIX named top small cap pick by senior Wall Street analyst Turkaly with Susquehanna Financial.
2	2	Zimmer	27.75	4.53	Wall Street's analysts recently raised their Q2 estimate by a penny. ZMH 3rd lowest priced orthopedic stock overall.
3	5	Smith & Nephew	22.8	1.85	One of Wall Street's analyst predicted that SNN picked up market share in Q2. Consensus is that SNN grew 8% last quarter.
4	6	ConMed	9.54	5.62	CNMD has delivered substantial upside surprises in recent quarters. Buyers acting as if it may happen again.
5	3	Kensey Nash	34.24	4.41	Most analysts have cut their estimates for Q2—no doubt due to recent acquisitions.
6	4	Stryker	25.23	1.07	In advance of tomorrow's release of Q2 results, the Street is betraying a case of nerves.
7	7	Exactech	8.08	3.67	If Exactech grows the top line 9%, as expected by Wall Street, conditions are in place for EPS upside surprise.
8	9	Wright Medical	8.76	7.75	This quarter should, hopefully, be much less dramatic than last quarter. Ho hum would be good.
9	8	Johnson & Johnson	26.33	1.95	While DePuy absorbs Synthes (roughly one year) there's a lot of hurry up and wait. With a 3.40% yield, the wait's not bad.
10	NR	Symmetry	7.64	6.98	SMA is due for good news. Most analysts expecting flat earnings on 8% sales growth.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	RTI Biologics Inc	RTIX	$3.09	$170	16.17%
2	CryoLife	CRY	$5.93	$166	12.74%
3	MAKO Surgical	MAKO	$31.69	$1,298	11.23%
4	Wright Medical	WMGI	$15.43	$602	7.75%
5	Orthofix	OFIX	$43.37	$791	7.70%
6	TranS1	TSON	$4.77	$100	7.43%
7	Symmetry Medical	SMA	$9.50	$346	6.98%
8	*Alphatec Holdings*	*ATEC*	*$3.53*	*$315*	*6.01%*
9	ConMed	CNMD	$27.45	$777	5.62%
10	Tornier N.V.	TRNX	$28.82	$1,125	4.91%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BONE	$2.32	$88	-31.36%
2	TiGenix	TIG.BR	$1.23	$112	-14.21%
3	NuVasive	NUVA	$31.19	$1,237	-9.59%
4	Medtronic	MDT	$37.12	$39,383	-1.48%
5	Stryker	SYK	$58.43	$22,671	1.07%
6	Zimmer Holdings	ZMH	$63.68	$12,224	1.42%
7	Orthovita	VITA	$3.89	$300	1.57%
8	Smith & Nephew	SNN	$54.06	$9,650	1.85%
9	Integra LifeSciences	IART	$47.33	$1,352	1.94%
10	Johnson & Johnson	JNJ	$67.45	$184,890	1.95%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$37.12	$39,383	11.32
2	Johnson & Johnson	JNJ	$67.45	$184,890	13.99
3	Zimmer Holdings	ZMH	$63.68	$12,224	14.06
4	Kensey Nash	KNSY	$24.86	$212	14.13
5	CryoLife	CRY	$5.93	$166	16.03

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$31.19	$1,237	37.13
2	ArthroCare	ARTC	$34.48	$942	28.97
3	Wright Medical	WMGI	$15.43	$602	23.74
4	Synthes	SYST.VX	$180.19	$21,403	23.55
5	Exactech	EXAC	$18.65	$244	21.69

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	RTI Biologics Inc	RTIX	$3.09	$170	0.96
2	Orthofix	OFIX	$43.37	$791	0.98
3	Kensey Nash	KNSY	$24.86	$212	1.05
4	NuVasive	NUVA	$31.19	$1,237	1.12
5	Exactech	EXAC	$18.65	$244	1.18

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.93	$166	3.04
2	Alphatec Holdings	ATEC	$3.53	$315	2.99
3	Johnson & Johnson	JNJ	$67.45	184,890	2.70
4	ConMed	CNMD	$27.45	$777	2.32
5	ArthroCare	ARTC	$34.48	$942	1.79

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$9.50	$346	0.96
2	RTI Biologics Inc	RTIX	$3.09	$170	1.03
3	ConMed	CNMD	$27.45	$777	1.09
4	Wright Medical	WMGI	$15.43	$602	1.16
5	Exactech	EXAC	$18.65	$244	1.28

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$1.23	$112	180.61
2	MAKO Surgical	MAKO	$31.69	$1,298	29.30
3	Synthes	SYST.VX	$180.19	$21,403	5.80
4	Tornier N.V.	TRNX	$28.82	$1,125	4.95
5	Bacterin Intl Holdings	BONE	$2.32	$88	4.73

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

InFuse Part II

By Robin Young

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In its June 2011 issue, *The Spine Journal* (*TSJ*) critically reviewed the scientific underpinnings of 13 studies of BMP-2 which had appeared in peer review journals between 2002 and 2004. One of those studies received the 2002 Volvo Award. In its review, researchers led by Eugene Carragee, M.D., found the studies suffered from "serious potential design bias" and "unpublished adverse events and internal inconsistencies."

This week, in part two of our review of *TSJ*'s BMP issue, we tackle some of the other issues raised by the *Journal*, notably corporate funding of the InFuse studies. We then look at the broader implications of *TSJ*'s review on innovation and self-regulation in the spine surgery community.

Correction

In part one of our review which we published last week, we created a table with information we took from *TSJ*. While we didn't check all 13 studies, we looked at two—the 2002 Burkus et al. study and the 2006 Dimar et al. study. The 2002 Burkus et al. study did not list any adverse events from using BMP. But, the Dimar study did—contrary to two tables we found in Dr. Carragee et al.'s review. According to Carragee, Dimar et al., in the 2006 study did not report any complications from the use of BMP-2. When we read the same study (n=53

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Complication	Number of Subjects With Complication: rhBMP-2/Compression Resistant Matrix	Number of Subjects With Complication: Iliac Crest Bone Graft
Gastrointestinal	9	10
Traumas	14	9
Cardio/vascular	9	6
Urogenital	6	6
Dural tears	3	5
Nonsurgical infections	6	4
Malpositioned implants	0	3
Surgical infections	0	1
Nonunions	0	2
Respiratory	0	1
Vertebral fractures	0	1
Others	14	17

Source: Spine © 2006 Lippincott Williams & Wilkins

for the BMP group) we found this table.

Corporate Funding of the Infuse Studies

In Carragee's critical review and accompanying editorial, he and his fellow authors raised the issue of corporate sponsorship of the studies and payments by Medtronic, Inc. to the study investigators. In editorial comments, which were supplied to *The Wall Street Journal* and *The New York Times* on Friday June 21—prior to being supplied to *TSJ*'s surgeon readers—the authors wrote the following:

> *"…the core of our professional faith is to first do no harm. It harms patients to have biased and corrupted research published. It harms patients to have unaccountable special interests permeate medical research. It harms patients when poor publication practices become business as usual. Yet harm has been done. And that fact creates a basic moral obligation."*

To illustrate the extent to which BMP study authors received payments from Medtronic, *TSJ* provided a Supplementary Appendix which listed the industry sponsorship and financial disclosures for all 13 peer-reviewed articles which were the subject of *TSJ*'s critical review. Here is a selection from that table.

Appendix 1: Disclosures of financial relationships between study authors and Medtronic Inc. at publication and at follow-up. (Electronic Publication only)

Article	Disclosure of Financial Relationships at Publication	Industry Supported? (in Whole, in Part, or with to Author)	Minimum Range of Total Financial Relationships of Any Type With Medtronic Inc.
Boden SD, Zdeblick TA, Sandhu HS, Heim SE. The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans: a preliminary report. Spine 2000 Feb;25(3):376-381.	Sponsored by Medtronic Sofamor Danek, Inc., Memphis TN.	Yes	$21,025,000
Boden SD, Kang J, Sandhu H, Heller JG. Use of recombinant human bone morphogenetic protein-2 to achieve posterolateral lumbar spine fusion in humans: a prospective, randomized clinical pilot trial: 2002 Volvo Award in clinical studies. Spine 2002 Dec;27(23):2662-2673.	Corporate and industry funds were received to support this work. One or more of the authors have received or will receive benefits (e.g., honoraria, gifts, consultancies) for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript.	Yes	$565,000 - $1,474,000
Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. J Spinal Disord Tech 2002 Oct;15(5):337-349.	None	Yes	$23,121,000 - $23,581,000 plus additional $1,500,000, for Burkus cited in Wall Street Journal estimates. [J. Carreyrou, Wall Street Journal, 28 June 2011]
Burkus JK, Transfeldt EE, Kitchel SH, Watkins RG, Balderston RA. Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein-2. Spine 2002 Nov;27(21):2396-2408.	This study was sponsored by Medtronic Sofamor Danek, Memphis, Tennessee. Corporate/Industry funds were received to support this work. One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript, e.g., honoraria, gifts, consultancies.	Yes	$2,532,000 - $2,592,000 plus additional $1,500,000, for Burkus cited in Wall Street Journal estimates. [J. Carreyrou, Wall Street Journal, 28 June 2011]
Burkus JK, Heim SE, Gornet MF, Zdeblick TA. Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT-CAGE lumbar tapered fusion device. J Spinal Disord Tech 2003 Apr;16(2):113-122.	None	Yes	$22,732,000 - $23,192,000 plus additional $1,500,000, for Burkus cited in Wall Street Journal estimates. [J. Carreyrou, Wall Street Journal, 28 June 2011]

Source: The Spine Journal

According to *TSJ*, as of March 2011, of the 13 original studies, one study had no information available regarding the authors financial relationship with Medtronic while in the remaining 12 studies, the median-known financial association between the authors and Medtronic was found to be approximately $12,000,000–$16,000,000 per study (range, $560,000–$23,500,000).

Clarification, Please

Payments listed in the table above were for ANY payments made ANY time for ANY thing—Carragee et al.

did not check to see if the payments occurred before or during the time the studies were published or whether the payments were related to InFuse or implants related to InFuse or anything unrelated to the studies.

In fact, upon closer inspection, it appears that Carragee et al. chose payments that were made over a 15-year period and the referred-to royalty figures were paid for intellectual property and patents that occurred years after the studies were published. None of the authors, it turns out, received royalty payments for InFuse at any point in time.

So, for example, in the first study (Boden et al., *Spine* 2000, for $21 million) mentioned in Carragee et al.'s table, Boden and his colleagues did receive a nominal hourly consulting fee from Medtronic prior to the study being published. Furthermore, Dr. Boden specifically avoided participating in stock, options and royalties during that time period in order to remove any real or perceived potential conflict of interest. This was not mentioned by the Carragee et al. review.

Thomas Zdeblick, M.D., one of the investigators listed in a couple of the studies had coincidentally written a letter to the editor of *TSJ* and took issue with Caragee's suggestion in a previous retrospective study of BMP adverse events, that conflicts of interest were poorly accounted for. Dr. Zdeblick wrote:

> *"…to suggest that the FDA trial data were somehow obscured by conflict of interest is misleading and inappropriate. No attempt was made to hide data. The results within the FDA trial concerning RE [Retrograde Ejaculation] and BMP-2 were not statistically significant, and therefore not in the initial report. Over 40 adverse events were tracked for the FDA, but did not lead to any significance, and were therefore not reported (e.g., nausea/vomiting, ileus, urinary retention). The beauty of a prospective, randomized, multicenter trial is that you get pooled concurrent data. I would rather trust this than a poorly performed historically controlled single report in making decisions regarding my patients."* Dr. Zdeblick went on to say: *"I have absolutely no financial interest in InFuse (BMP-2). At no time have I had a financial incentive related to the approval or use of InFuse. I do receive royalties for the LT Cage, which can be used with or without InFuse, was popular, and in use before InFuse."*

Dr. Carragee

Dr. Carragee shot back:

> *"This is patently incorrect: The "FDA trial" found 12 RE events in the rhBMP-2 group (7.9%) versus 1 (1.5%) in the control group. (Fisher Exact p=0.05) Dr. Zdeblick declined to publish these rates for more than 8 years. In the RCT portion of the FDA trial, the rate of RE in the BMP-2 group was more than 4 times higher than the control group (6.4% of 78 patients compared to 1/5% of 68 controls); he also declined to report these rates for more than 8 years."*

Dr. Carragee went on to write:

> *"Dr. Zdeblick's discussion regarding whether an RCT or a retrospective cohort-control trial provides more reliable evidence is also misleading. According to multiple sources on evidence-based medicine, retrospective cohort-controlled trials are most compelling as evidence when they reproduce the same effect, in direction and magnitude, as an RCT. These studies can provide strong evidence of the generalizability of an observation outside of the artificial RCT environment."*

Finally, Dr. Carragee specifically challenged Dr. Zdeblick's claim that he had no financial interest in InFuse. He noted that it was a:

> *"…fascinating denial of what, in our opinion, is an obvious and enormous conflict of interest. The old saying "follow the money" and in this case, there is plenty to follow. Specifically related to InFuse, Dr. Zdeblick receives millions of royalty dollars from the Novus LT cage. He points out in his letter that his LT cage is*

the only device tested and approved by the FDA for spinal fusion with the InFuse product." Continues Carragee : "To be clear, for the primary spinal fusion patient in the United States to receive the InFuse product in the tested and approved FDA manner promoted by Dr. Zdeblick in his letter, they must use Dr. Zdeblick's device."

The Spine Journal's Editors as Advocacy Journalists

The editors of *The Wall Street Journal* and *The New York Times* (along with many other news outlets) received an email from *TSJ* with the headline "Years of Living Dangerously" late Friday, June 21—before any of *TSJ*'s subscribers received their issue.

The Wall Street Journal is the largest circulation newspaper in the U.S. with 2.1 million readers. *The New York Times* online version is the most popular web-based newspaper in the U.S. with 30 million unique visitors each month. Combined, it is fair to say, they far out strip *TSJ*'s ability to communicate a particular story.

One effect of *TSJ*'s pre-release to such large media outlets with a hyperbolic headline was to trigger global media coverage—the effect of which was to drown out any alternative point of view. I call it the megaphone effect.

OTW mentioned this to Dr. Carragee. His comment was, in effect, to say that everyone else does it including Medtronic so what's the big deal? "We used the same embargo and press release deadlines, nearly to the hour, as is used for *JAMA* and *NEJM*. That is done every week of the year for major journals. It is interesting that I have never heard this complaint when an industry-sponsored trial has the same pre-release alert with embargo to the news media."

Money Incentives and the Will to Win

There are few more powerful incentives for human behavior than money, particularly such large sums as those cited in the Carragee et al. review. Clearly, one of Dr. Carragee's principal arguments, whether expressly stated or implied, is that the bias inherent in these kinds of payments from study sponsors or product suppliers has the power to overwhelm the peer review process at scientific journals.

While the specifics and timing of the payments, as we pointed out earlier, don't match very well (if at all), with the narrative put forward by the Carragee et al. review, the point is nonetheless well taken.

In our view, it is almost impossible to underestimate the power of incentives. So the attention to this issue elicits strong sympathy from *OTW*. But getting it right is equally important.

Medicine Without Innovation

What if there had been no corporate funding of the studies? Would InFuse have been approved by the FDA?

Dr. Carragee's answer to that question was: "Absolutely, but the more important question is whether the Medtronic studies need to be performed with the multiple design flaws and internal bias identified in order to demonstrate a valuable product—I do not think those design flaws were necessary, the product has value. Second, did it need to be presented in the manner it was in the published literature as being virtually perfect in all original trials, in order to be used by surgeons? Again, no, I do not think that was necessary either."

Dr. Carragee makes several excellent points. But, in terms of the importance of corporate funding of the studies, recent trends would argue against his blanket assurance. According to an article in the January 13 issue of *JAMA*, the level of funding from the National Institutes of Health and industry has decreased by 2% in 2008, after adjustment for inflation. Subtract corporate funding and the picture is worse. "Adjusted for inflation, NIH contributions decreased by 8.6 percent from 2003 to 2007," according to the authors of the *JAMA* study.

What would life be like without research into more effective treatments,

preventative measures and new commercial products? Without funding (corporate or non-corporate), how does such research occur? This is not a trivial question.

What Does Corporate Funding Pay For?

Hopefully, with greater sensitivity to the issues raised by Carragee et al.'s review, peer-review journals in orthopedics will be ever more diligent to squeeze out all forms of bias.

But the issues at stake are greater than those raised by Carragee. Corporate funding is actually more vital and critical to all funding of biomedical research than perhaps Dr Carragee and his reviewers realize. One example in *OTW*'s backyard is Pfizer's funding for research being done in a laboratory at the University of Pennsylvania (*OTW* is based in Philly). That money goes to the institution, not into the principal investigator's pocket.

According to Dr. Elliot V. Hersch, Professor of Pharmacology at Penn: "Without research money—whether it be from industry or the federal government—hundreds, if not thousands, of jobs would be lost at an institution like the University of Pennsylvania."

For example, recently the University was awarded a $250,000 grant to do a study of a Liqui-Gel pain reliever in which each of 210 subjects, who'd had impacted wisdom teeth surgically removed, swallowed two Liqui-Gels and two caplets. (Neither the subjects nor the researchers knew who received active medication and who did not.) The study sponsor, Whitehall Pharmaceuticals (now a part of Pfizer), wrote the checks out to the Trustees of the University of Pennsylvania. About $60,000 went for indirect costs, such as for lights, heat, and use of Penn facilities.

The rest of the money was used to pay:

- Hersch's research coordinator's salary and benefits for almost two years
- Part of the salaries of Hersch and the Penn oral surgeons involved in the study
- Study participants, who spent about eight hours filling out various pain questionnaires
- And for travel to present study data at a research meeting.

But the stakes go well beyond such U.S. institutions as the University of Pennsylvania. As we illustrated earlier, medical product companies supply the largest proportion of total research spending (58%)—**U.S. only.**

Worldwide, approximately 70% to 80% of all biomedical research and development is sponsored by U.S.-based corporations, foundations and government agencies. As a proportion of total health care spending, the U.S. invests 4.5% on R&D, an amount higher than any other country in the world. U.S. spending on biomedical R&D (corporate and non corporate) supports the planet.

"Do No Harm"

> *"In surgery, as in anything else, skill, judgment and confidence are learned through experience, haltingly and humiliatingly. Like the tennis player and the oboist and the guy who fixes hard drives, we need practice to get good at what we do. There is one difference in medicine though: we practice on people." — Atul Gawande*

One casualty that may well come from the unmasking of the flaws of the early InFuse studies is that ad hoc experimentation, off-label use of, not only InFuse, but potentially, screws, plates, other biomaterials, will be deemed too dangerous to allow, if not also reimburse. That would be tragic.

One of the reasons orthopedic science experiences such rapid advances during war time is because ad hoc experimentation increases and in the process new techniques and tools are discovered. External fixation. Intermedullary nails. Pedicle screws. Even hip arthroplasty. These and thousands of other procedures and implants emerged from ad hoc experimentation by real surgeons on real patients.

There are no virgin births in medicine. All healthcare providers learn by practicing and making mistakes

on real patients. All products used to care for patients are tested and fail on real patients. Which means; to "do no harm" is also to "do no experimentation." No experimentation will mean no innovation. No innovation will do the greatest harm.

To allow for ingenuity is to allow space for failure. Innovative products (and biomaterials are no exception) are not born fully understood. Should have we waited 20-30 years before approving hip replacements in order to more fully understand wear rates? Should we have waited an additional ten years before approving InFuse in order to better understand its complications? If we had waited, how many hundreds of thousands, perhaps millions of patients would have been harmed by the omission of these products from the medical armamentarium?

Final Word

Honestly, *OTW* gives Dr. Carragee and his colleagues their due. Published clinical studies have long suffered, in our view, from poor enforcement of the disclosure rules and reported outcomes that too loosely translate into general practice. Furthermore, that view of ours is, we think, held as well by the majority of rank and file spine surgeons. Dr. Carragee's kind of critical, meticulous review gave rise to this special issue of *TSJ* and it will, we hope, raise the overall quality of peer review and financial disclosures among all scientific journals.

But Dr. Carragee and his colleagues are also advocates for a particular point of view and that prompted them to put *TSJ* into a position of campaigning for that point of view and impugning or drowning out alternative points of view. Why, for example, didn't *TSJ* use its edition to create a point/counterpoint dialogue between Dr. Carragee and his colleagues on one side and the authors of the 13 studies on the other? (Without *The Wall Street Journal* or *The New York Times* or *The Milwaukee Journal Sentinel* mucking about.)

The stakes in this debate are extremely high. How the FDA and others internalize *TSJ's* characterizations of the role of corporate funding, of experimentation and of off-label use of medical products could well determine the manner in which spine patient care progresses in the U.S. ◆

Spine Payment Challenge In Minnesota

By Walter Eisner

Photo manipulation by RRY Publications. Source: Photo by Andrew Huth

BlueCross BlueShield of Minnesota

Here we go again. Citing a "lack of evidence demonstrating an impact on improved health outcomes," Blue Cross Blue Shield of Minnesota (BCBS MN) issued a proposed coverage policy on June 24 that would exclude laparoscopic and axial anterior lumbar interbody fusion (ALIF, AxiaLIF)) and lateral interbody fusion (e.g., XLIF, DLIF) procedures from coverage.

Device makers, Wall Street analysts and medical societies quickly weighed in to assess the potential outcomes of the BCBS MN decision.

Déjà Vu

We've seen this story before.

Back in 2006, the North American Spine Society (NASS), led by Chris Bono, M.D. and Bill Mitchell, M.D., put its credibility on the line on this issue. In that year, a *SpineLine* article outlined NASS' position that the technical aspects of XLIF and DLIF are not sufficiently distinct from an ALIF to justify another code, and that XLIF and DLIF should be appropriately coded as an ALIF.

In late 2009, as NASS members began to complain about insurance carriers not approving XLIF procedures, those carriers reached out to NASS to solicit the society's input on whether or not XLIF should be considered investigational/experimental.

In response, NASS decided to make a formal statement to all the payers encouraging them to remove XLIF from their investigational/experimental lists. By 2010, Aetna, Cigna, Humana and United Healthcare had all reversed their previous positions. Apparently BCBS MN didn't get the memo.

The Blues

In fact, even within the Blues, Blue Cross Blue Shield of Texas, Oklahoma, New Mexico and Illinois proposed making XLIF investigational last year but altered their policy over the span of nine months removing any reference

to XLIF as investigational thus ensuring coverage.

BCBS MN told *OTW* in a written statement on July 13 that the revised policy, which goes into effect September 26, "clarifies that established minimally invasive procedures for anterior, posterior and transforaminal interbody lumbar fusion are covered when deemed medically necessary, while all other minimally invasive procedures are considered investigative at this time."

"We continue to monitor changes in research and clinical data. Should future studies indicate that additional minimally invasive procedures meet the same efficacy standards as those currently covered; our policy may be revised to reflect such findings.
"Also, coverage and benefits may vary according to different products. Self-insured plans administered by [BCBS MN] may design benefits unique to their organization, so there can be considerable coverage variability among these groups," concluded the statement.

It was too early for NASS to issue an official statement on the proposed coverage policy, but NASS Executive Director Eric Muehlbauer told us on July 14, "Rest assured that if it is necessary for NASS to educate the carriers, as we have with other groups, we will do so."

Industry Reaction

Industry reaction was not as reactionary as one might have expected. The BCBS MN proposal seems at first blush to be a little more nuanced than previous negative coverage proposals.

A NuVasive, Inc. (XLIF) representative confirmed knowledge of the proposed coverage change. He told *OTW* on July 13, "This proposal is not unlike prior policy proposals which were successfully overturned over the last year or so. NuVasive is well versed in the process of collaborating with the insurance providers to educate them on the clinical merits of XLIF and will continue to fully support the surgical societies in their lead role of working with the insurance providers to ensure access for their patients."

RRY Publications

A Medtronic, Inc. (DLIF) spokesperson told us that the company also was aware of the proposal and was in the process of evaluating the proposed policy.

Ken Reali, president and CEO of Trans1 (AxiaLIF), sent us an email on July 14 that said, "AxiaLIF has been regarded as investigational by BCBS of MN since inception of our category III code in 2009. So this is not new. The AxiaLIF procedure is another interbody fusion with a different access point to the spine (the pre-sacral approach) but once the spine is accessed it is similar to any other interbody fusion procedure."

Continued Reali, "Our message to payors will continue to be that access to the spine is not as relevant as the fusion itself, as long as that access is proven safe. For AxiaLIF this is further bolstered by recent and upcoming publications in peer reviewed journals that demonstrate the safety of the pre-sacral access route and the efficacy of the fusion."

Other industry insiders we spoke to are of the opinion that proposed changes like the one from BCBS MN will probably continue to surface from time to time as there is a much larger macro issue at hand. Over the last six-nine months, spine companies have openly acknowledged stricter guidelines for any lumber fusion surgery. This, say the insiders, is just another attempt to slow down the utilization of lumbar fusions in their plans.

Wall Street: "Don't Hold Your Breath"

Some Wall Street analysts doubt that BCBS MN will be able to make their proposed policy change stick.

On July 12, BMO Capital analyst Joanne Wuensch, who brought the pol-

icy to our attention, wrote that BCBS MN is the latest insurance company to propose a policy that would exclude NuVasive's XLIF and Medtronic's DLIF from coverage on the basis that they are investigational devices. "As a reminder," wrote Wuensch, "Aetna, Cigna, Humana and United Healthcare labeled XLIF as experimental and had non-coverage policies in place in December 2009. NASS responded fiercely in support of the procedure, and NuVasive offered additional clinical studies validating the outcomes of its products, and by January 2011, all of these major providers had reversed their decisions."

Wuensch says XLIF and DLIF have strong support in the physician community and believes there is substantial clinical evidence showing improved health outcomes, and given past experience, doubts that BCBS MN will be successful in implementing the proposed policy.

"What is more likely," wrote Wuensch, "is that BCBS MN implements a more restrictive set of requirements and a more rigorous approval process for the procedures, similar to that implemented by Blue Cross and Blue Shield of North Carolina in January of this year. Such changes have already become common in the U.S."

A William Blair report on July 13 stated, "We anticipate more of these proposed coverage decisions will appear in the coming quarters (the Blue plans are independent and do not correspond with each other on these policies) but do not expect they will be implemented and will not affect current or future procedural volumes for either NuVasive or Medtronic.

The Blair report stated their analysts spoke with NuVasive's management, who indicated that there has been no disruption to case volumes as a result of this proposed policy.

"We view all the recent reimbursement pushback surrounding lateral interbody fusion as part of the evolution process for this emerging surgical approach to spinal fusion and believe that eventually all payers will comprehend the clinical and cost benefits asso-

ciated with this technique," concluded the Blair report.

Waiting for NASS

Surgical societies and industry are formulating responses to the BCBS MN proposal. Industry is clearly waiting for NASS to take the lead. Based on past actions, it is likely that NASS will be putting its reputation on the line again to assure coverage and access for patients and payments for their members.

It is also almost certain that NASS, as was the case in 2010, will issue their statement without input from industry representatives, including NuVasive, or any consultant surgeons. In 2010, the authors of the NASS statement had no conflicts with NuVasive or similar companies and devices.

Below is the text of the proposed policy:

http://notes.bluecrossmn.com/web/medpolman.nsf/8c1a3acbf6f126e1862574ea0050a7f2/f44dc8215d542943862578b9005d4c19?OpenDocument ♦

Minimally Invasive Lumbar Interbody Fusion

The policy title has been revised from "Axial (Percutaneous) Lumbar Interbody Fusion (ALIF)" to "Minimally Invasive Lumbar Interbody Fusion."

Minimally invasive interbody fusion of the lumbar spine may be considered medically necessary when one of the following approaches are used AND when the patient has met the criteria for lumbar fusion as defined in Medical Policy #IV-87, Spinal Fusion:Lumbar:

- Anterior lumbar interbody fusion (ALIF);
- Posterior lumbar interbody fusion (PLIF);
- Transforaminal lumbar interbody fusion (TLIF).

All other minimally invasive procedures for lumbar interbody fusion are considered investigative, including, but not limited to the following, due to a lack of evidence demonstrating an impact on improved health outcomes:

- Laparoscopic anterior lumbar interbody fusion (ALIF);
- Axial anterior lumbar interbody fusion (AxiaLIF);
- Lateral interbody fusion (e.g., XLIF, DLIF). Prior authorization: Yes, only for anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF).

Prior authorization: Not applicable for laparoscopic anterior lumbar interbody fusion (ALIF), axial anterior lumbar interbody fusion (AxiaLIF), and lateral interbody fusion (e.g., XLIF, DLIF).

Any procedures (e.g., spinal fusion, allograft, instrumentation) performed in conjunction with the investigative procedures identified above, will not be covered. This includes, but is not limited to, professional, facility and anesthesia services as well as supplies.

company

Biomet 4Q11: Execution and Sales Challenges

Biomet, Inc. reported a 2% rise in total revenue to $715.2 million for the company's fourth quarter of 2011.

The Struggle, based on Zainul Abedin's painting of the same name: Wikimedia Commons

While reported sales rose, so did losses as the company reported a loss of $847.3 million compared to a profit of $83.3 million a year earlier. Excluding merger-related depreciation and amortization and other special items, Biomet's adjusted earnings came in at $216.3 million for the quarter.

Jeff Binder, the company's president and CEO stated, "Our sales results continued to be challenged by industry volume and price pressures that affected our sales throughout fiscal 2011. In addition, we have not been executing to our standard of above-market growth in most of our businesses. We are working hard to return to that standard as quickly as possible."

Commenting in an investor note on July 12, Joanne Wuensch, BMO Capital Market analyst, wrote that the results were "remarkably similar to FY3Q11, and there was not much of a deviation from the current orthopedic script." Jeffries analyst Raj Denhoy wrote the results were no worse, but also no better from the previous year's quarter: "While specific company growth rates are quite divergent in orthopedics of late, Biomet's results point to any recovery in orthopedics still being a ways out."

Biomet 4Q11	Sales ($ in millions)	% Change
Net Sales	$715.2	2%
Reconstructive		4%
Hips		3%
Knees		2%
Spine		down 10%
Extremities		17%

Source: Biomet

Hips, Knees, Spine

In hips, Wuensch said metal-on-metal products continue to face a steady decline in demand, dipping below 20% of total hip sales from more than 50%. She suspects that Zimmer and Stryker will continue to be hip market share beneficiaries.

For knees, Wuensch noted the return of the company's Signature Personalized Patient Care custom knee was returning to market more slowly than expected and likely responsible for share losses. She believes Smith & Nephew will be the net share recipient.

While spine sales were tough, the company's 3% spine share, the lack of meaningful product differentiation, and the loss of certain accounts make the spine read-through tough, added Wuensch.

Reported gross debt as of May 31, 2011 was $6.020 billion and cash and cash equivalents totaled $361 million. As industry consolidation continues, Biomet's competitors have bigger war chests and less debt on their books. However, Biomet's Wall Street private equity owners, led by the Blackstone Capital Partners, have deep pockets of their own.

—WE (July 15, 2011)

legal

Ex-Kyphon Manager Pleads Guilty to Fraud

Wikimedia Commons and Sarah Morris

A former senior marketing manager for Kyphon, Inc., pled guilty in federal court on July 7 to ripping off Medtronic, Inc. for at least $2.1 million.

Jennifer Rutherford was responsible for selecting vendors to supply marketing merchandise that company reps could distribute at trades shows and industry conferences. The merchandise included such items as key chains, baseball caps, and tee-shirts. Rutherford admitted to creating three shell companies from June 2004 to June 2009 and pretending to buy merchandise from those companies. She'd then submit the invoices to Medtronic for merchandise that didn't exist.

Rutherford's admission didn't specify how much merchandise the $2.1 million would have bought, but that's gotta be a lot of tee-shirts.

A press release from the U.S. Attorney's Office in Minnesota announced the guilty plea and noted that Rutherford faces a potential maximum penalty of 20 years in prison. The federal judge will determine her sentence at a future hearing, yet to be scheduled.

Medtronic bought Kyphon in 2007. Medtronic has since paid $75 million to settle allegations that Kyphon, before being purchased by Medtronic, caused the submission of false claims to Medicare. The hospitals who submitted the false claims have also paid tens of millions to the government to settle the allegations.

—WE (July 11, 2011)

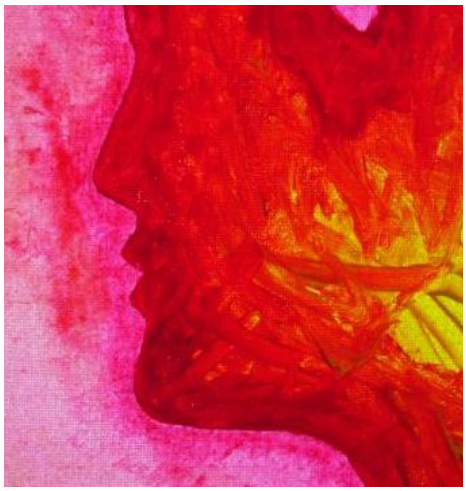
biologics

PRP – Any Good For Pain?

Doctors have been using platelet-rich plasma (PRP) for years to promote healing after surgery. But is PRP any good for pain? Doctors at Rush University Medical Center, Chicago, are trying to find out if PRP can relieve knee pain in patients with mild to moderate osteoarthritis. PRP contains growth factors that promote cell proliferation and is prepared from the patient's own blood and tissue.

PRP has received popular attention because of its recent use treating injuries in professional athletes. No one is sure that the treatment is effective.

"There have been few controlled clinical trials, and results are inconsistent, but data so far suggests that it could be a promising treatment for healing in a variety of tissues," said Dr. Brian Cole, orthopedic surgeon, head of the cartilage restoration center at Rush and


Morguefile and grietgriet

head team physician for the Chicago Bulls. "The therapy will not be a cure for osteoarthritis, but it could help put off the day when a patient will need to get a knee implant."

The standard of care, at present, is either corticosteroid injections, which may provide relief for about three months, or synthetic lubricants containing hyaluronic acid, which can last for up to a year.

In the double-blind, randomized, controlled study, 100 patients will receive either hyaluronic acid or PRP prepared from 10 millimeters of the patient's own blood. The blood will be spun in a centrifuge to separate the platelets from the red and white blood cells and then injected into the knee joint using ultrasound imaging to guide placement.

Patients will receive three injections over three weeks and, in periodic clinical exams, will be monitored for two years. In addition, a teaspoon-size sample will be taken of the synovial fluid around the knee joint to test for molecular changes that may indicate a shift in the balance of anabolic factors that increase the buildup of tissue and catabolic factors that break it down. An imbalance in these factors has been implicated in the deterioration of cartilage that leads to osteoarthritis.

Rush is a not-for-profit academic medical center comprising Rush University Medical Center, Rush University, Rush Oak Park Hospital and Rush Health.

—BY (July 14, 2011)

large joints

British Add Up Fat Costs

British National Health Service

The British National Health Service (NHS) is adding up the cost of obesity. The service reports that one in four adults in East Lancashire is obese, costing the health service $51 million each year (converted to U.S. dollars). That is eight times more money than the combined cost of all the hip replacement operations, knee replacement surgeries and cataract treatments paid for by the National Health Service East Lancashire last year.

Health officials report that, last year, 565 people in East Lancashire received new hips. The estimated cost of obesity by 2050 could fund an additional 11,500 hip operations. Last year doctors performed almost 200 cataract surgeries at an average cost of $1,126 each. Health officials estimate that money expected to be spent on treating obesity-related conditions could fund cataract removal surgery in East Lancashire for the next 42 years.

Dr. Mike Ions, chairman of NHS East Lancashire's Professional Executive Committee, warned of the economic and emotional effects of rising obesity: "Aside from the money spent on treating people with obesity-related illnesses such as diabetes, heart disease and immobility, the emotional effect will be devastating, as obese people will generally have a poorer quality of life. It's vital people empower themselves to improve their health."

—BY (July 14, 2011)

large joints

Smoking Reduces Male Arthroplasty Risk

Being overweight increases the chances, for men, that they will undergo total joint replacement surgery—one of the most common elective surgeries performed in the United States. However, surprisingly, men who smoke appear to have less risk of undergoing total joint replacement surgery than those who never smoked.

This is according to a study published in the July 8 issue of *Arthritis & Rheumatism*, a journal of the American College of Rheumatology. Patients cited severe osteoarthritis (OA) as the most frequent cause for undergoing the procedure. OA, the most common form of arthritis, causes pain and stiffness in the joints, with studies indicating that older age, female gender, and obesity increase the risk.

Researchers examined the associations of smoking, body mass index (BMI), and physical activity as they relate to the risk of joint replacement surgery in men. They selected 857 male study participants who had joint replacement surgery. Of those having surgery, 59% had total knee replacement and 41% had total hip replacement. The subjects were categorized into three age groups: 65-69 years, 70-74 years, and 75 or more years of age.

Analysis showed that being overweight independently increased total joint replacement risk, while smoking lowered the risk. This was most evident after 23 years of smoking exposure. Men who smoked for 48 years or more were up to 51% less likely to undergo total joint replacements than those who never smoked. The researchers also reported that vigorous exercise increased the risk of joint replacement in men in the 70-74 year age group.

"Our study is the first to demonstrate a strong inverse correlation between smoking duration and risk of total joint replacement. The independent inverse associations of smoking with risk of total joint replacement were evident also accounting for the competing mortality risk in this elderly cohort of men," George Mnatzaganian, a Ph.D. student from the University of Adelaide in Australia, said. "Further investigation is needed to determine how smoking impacts the development of OA."

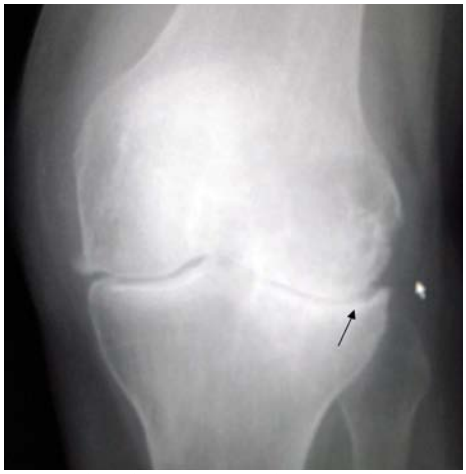
—BY (July 14, 2011)

Wikimedia Commons and Gary Stevens

Knee OA and ROM

Say it with me…Range of Motion! A new study—recently presented at the annual meeting of the American Orthopaedic Society for Sports Medicine—is showing that the onset of osteoarthritis (OA) may be related to a loss of knee motion after reconstructive ACL surgery. The team found that patients who showed motion limitations after surgery were more likely to develop arthritic changes in the knee.

"Our research shows that patients given rehabilitation that emphasizes full motion be obtained and maintained throughout time after surgery have more favorable results on X-rays than patients who lose motion," said lead researcher K. Donald Shelbourne, M.D., founder, Shelbourne Knee Center in the July 9, 2011 news release.



Wikimedia Commons and James Heilman, M.D.

The study examined data from 780 patients who were at least five years after ACL reconstruction with a patellar tendon graft. In individual follow-ups, patients were evaluated and rated based on knee range of motion (ROM) tests and radiographs. The percentage of patients with normal radiographs (no arthritic changes in the knee) was 71% in patients with normal range of motion

compared to 55% of patients who showed deficits in motion. In patients who had similar meniscus removal, OA was observed more in patients who had motion deficits.

"Something like osteoarthritis can be debilitating," said Shelbourne, "and our goal is to continually find new ways to help patients avoid such a problem."

Dr. Shelbourne told *OTW*, "The first thing clinicians need to do to is be able to recognize subtle differences in ROM between knees. ROM should be critically examined and the involved knee should be compared to the non-involved knee, to include an evaluation of knee hyperextension. Many clinicians consider ROM of zero degrees neutral to 135 degrees of flexion as normal. If the patient has 5 degrees of hyperextension and 145 degrees of flexion in the non-involved knee, then ROM in the involved knee of zero extension to 135 degrees of flexion means the patient has ROM loss that could increase their change of having osteoarthritis after surgery."

—EH (July 13, 2011)

Successful Hip Impingement Arthroscopic Surgery

Researchers at the Hospital for Special Surgery (HSS) have found that in comparison to open surgery, "arthroscopic treatment of a common hip problem that leads to arthritis produces similar outcomes in terms of repairing structural problems in most patients." Their study will be published in the July 2011 TK issue of the *American Journal of Sports Medicine*.

The hip problem known as femoro-acetabular impingement (FAI) or hip impingement has become widely recognized as the most common cause of early osteoarthritis in patients who don't have arthritis caused by dysplasia (a shallow socket). In some people a bony bump on the upper thigh bone produces a situation where there is inadequate space for the hip bone to move freely in the socket. The result is damage to the socket rim and the cartilage that lines the bones, which can lead to hip arthritis.


Andrew Huth and RRY Publications LLC

Arthroscopy Equals Open Surgery Results

According to a July 8 press release from HSS, this condition can be treated by structural correction of the bone through open surgery or arthroscopic surgery. Surgeons have been regularly using the latter technique since roughly 2003. Studies comparing arthroscopy against open surgery to treat FAI have shown that the two produce similar outcomes in terms of improving symptoms and returning athletes to their sport of choice. "Studies have not, however, examined whether the two surgeries are equal when it comes to achieving structural or mechanical corrections," continued the release.

The Study

Investigators enrolled 60 male patients under 40 years of age who had symptomatic FAI. Thirty consecutive patients

were treated with open surgery and 30 consecutive patients were treated with arthroscopy. X-rays were taken both before and after surgery. The researchers analyzed angles in the X-rays that determine the roundness of the femoral head, the ball of the thigh bone, and found that for the most part, both surgeries repaired sphericity similarly. They found that the two surgeries also similarly repaired the degree of separation between the sphere of the femoral head and the edge of the socket.

Bryan T. Kelly, M.D., co-director of the Center for Hip Pain and Preservation at HSS said the long-term goal of surgery is, "to improve mechanics across the joint so that the cartilage wears at a slower rate and the health of the joint is preserved longer. The ability of the procedure to do that is really based upon precise structural correction. This is the first study in patients to show that we can achieve similar mechanical correction arthroscopically."

Kelly said the study did find that one particular angle, called the anteroposterior (AP) alpha angle, was better repaired with open surgery. The AP alpha angle was reduced by 25.7% in the open surgery group and 16.8% in the arthroscopic procedure. This angle also involves the sphericity of the femoral head.

Dr. Kelly said that if doctors determine a patient has a large AP alpha angle, that patient might be better suited for open surgery. "People who have large alpha angles on their AP on the front view X-ray are ones that you might consider alternative surgical techniques to arthroscopy. That is one particular location that is hard to get to."

Other investigators involved in the study include Asheesh Bedi, M.D., former HSS fellow now at the University of Michigan; Ira Zaltz, M.D., William Beaumont Hospital, Royal Oak, Michigan.; and Katrina De La Torre, R.N., M.Sc., from Hospital for Special Surgery.

—WE (July 12, 2011)

trauma

Osteoporosis and MS

Those in early stages of multiple sclerosis (MS) need to take extra care to prevent osteoporosis, says a new study published in the July 12, 2011, print issue of *Neurology*. Researchers from Norway studied 99 people with an average age of 37 who were recently diagnosed with MS or clinically isolated syndrome, which means they had a first episode of symptoms like those in MS but have not yet been diagnosed with the disease.


Wikimedia Commons and Senseiwa

"We've known that people who have had MS for a long time are at a greater risk of low bone density and broken bones, but we didn't know whether this was happening soon after the onset of MS and if it was caused by factors such as their lack of exercise due to lack of mobility, or their medications or reduced vitamin D from lack of sun exposure," said study author Stine Marit Moen, M.D., of Oslo University Hospital Ulleval in Norway, in the July 11, 2011 news release.

Low vitamin D levels are associated with an increased risk of MS. Low vitamin D levels can lead to reduced calcium absorption and bone mineralization, or the process the body uses to turn minerals into bone structure.

"Our hypothesis was that if vitamin D exerts a major effect on the risk of MS, then the effects of low vitamin D levels on bone density would be apparent soon after the onset of MS," Moen said.

The participants had bone density tests an average of 1.6 years after the first time they had any symptoms suggestive of MS. Their tests were compared to bone tests of 159 people of similar age, gender and ethnicity who did not have the disease.

A total of 51% of those with MS had either osteoporosis or osteopenia, compared to 37% of those who did not have the disease. The results remained the same after researchers adjusted for other factors that can affect bone density, such as smoking, alcohol use and hormone treatment.

"These results suggest that people in the early stages of MS and their doctors need to consider steps to prevent osteoporosis and maintain good bone health," Moen added. "This could include changing their diet to ensure adequate vitamin D and calcium levels, starting or increasing weight-bearing activities and taking medications."

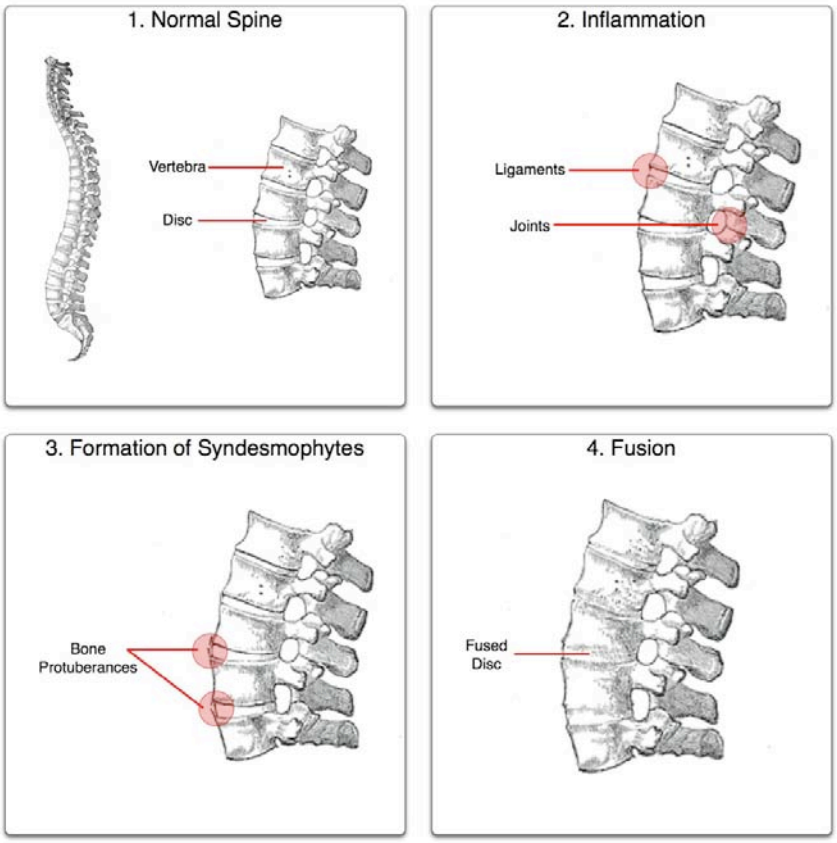
—EH (July 15, 2011)

Breakthrough for Ankylosing Spondylitis

Researchers at The University of Queensland Diamantina Institute (UQDI) in Australia have made a major breakthrough in the understanding of the molecular mechanisms underlying ankylosing spondylitis (AS), a form of arthritis that results in bone growth and can consequently cause the spine and or pelvis become fused into a fixed position.

Headed by Professor Matt Brown, UQDI scientists formed an international consortium with research groups in the UK, the U.S. and Canada to embark upon the largest study in history into the genetic causes of AS. Their research has identified eight new genes that help clarify previously unexplained aspects of AS. In particular, these genes help explain why bone formation occurs and why some AS patients also develop the conditions inflammatory bowel disease and/or psoriasis.

Professor Brown said the findings shed light on a 40-year-old genetic mystery. In the 1970s it was discovered that nearly all AS patients carried a particular gene called HLA-B27. Professor Brown said in the July 11, 2011 news release, "the link between AS and



Wikimedia Commons and Armin Kübelbeck

HLA-B27 is one of the strongest known genetic associations of any common disease. However, the precise role this gene plays in AS has never been clear until now." He and his colleagues have discovered that a mutation in a second gene, ERAP1, only appears in HLA-B27 positive AS patients.

"These crucial findings provide the first confirmation that in humans, as has been shown in plant and other animal species, interaction between genes is important in influencing disease risk," Professor Brown said.

Professor Brown told *OTW*, "We were surprised to see that although HLA-B27 positive and negative AS cases were associated with the same genes, only HLA-B27 positive cases were associated with ERAP1. We then showed that the protective variants of ERAP1 reduced the risk of AS by producing less peptide for HLA-B27 to work with. This really narrows the possibilities down about how HLA-B27, which increases the risk of AS by about 80 times, operates to cause the disease."

He also commented to *OTW*, "We showed association with several new genes and AS, some of which are potential therapeutic targets. Following our previous finding that variants of IL23R are involved in AS, pharmaceutical trials of compounds targeting the IL23R pathway have commenced, and early results show that this is a very effective approach. This study identified other genes in the same pathway that are also involved in AS, strengthening the case for treatments targeting the pathway. Other potential therapeutic targets were also identified. A particularly interesting finding was that variation in the gene PTGER4, which encodes a receptor for prostaglandin E2, influences AS risk. This pathway is involved both in causing inflammation and in driving bone formation: AS is characterized by inflammation-induced bone formation. Therefore inhibiting this pathway may be effective in both reducing inflammation AND slowing the bony formation which causes most of the long term problems in this disease."

—EH (July 11, 2011)

people

Spielberg Named FDA Medical Products Deputy

The FDA's top device regulator, Jeff Shuren, M.D., has a new boss.

According to a ***Reuters*** story on July 13, former Dartmouth Medical School Dean Stephen P. Spielberg, M.D. has been named to a newly created FDA position of deputy commissioner for medical products and tobacco.

Dr. Stephen P. Spielberg/Dartmouth.edu

In a letter sent to FDA staff and obtained by ***Reuters,*** FDA Commissioner Margaret Hamburg, M.D., said, "The new organizational alignments more accurately reflect the agency's responsibilities, subject matter expertise and mandates in an ever more complex world, where products and services do not fit into a single category.... In this role, Dr. Spielberg will serve as both advocate and a support for center directors in their important work for FDA."

Hamburg also promoted Deborah Autor, currently a director of the agency's compliance office, to the job of deputy commissioner for global regulatory operations and policy.

An FDA spokesperson told *OTW* on July 15 that Shuren will report to the new deputy commission, but still have access to Commissioner Hamburg.

In addition to his academic background, Spielberg, who most recently served as director of personalized medicine at Children's Mercy Hospital in Kansas City, also previously worked with Johnson & Johnson and Merck & Co.

David Nierenberg, doctor of pharmacology at the Dartmouth Hitchcock Medical Center, told ***The Dartmouth*** in an interview on July 15 that he thinks Spielberg will be "terrific" in his new post. Spielberg has many qualities that make him well suited for his recent FDA appointment, Nierenberg said. "He has very strong ties to industry, and they respect him." He's fair, he's balanced and he's respected in academia."

Spielberg "really knows the ins and outs of drug development and testing for safety, especially in kids," which will be particularly useful for his future work with the FDA, Nierenberg said. He added that Spielberg's previous

work experience will help him in his new role.

"Since Dr. Spielberg has spent years with Johnson & Johnson, a well-respected drug and device company, he's perfect for the job," Nierenberg told *The Dartmouth*.

The Wall Street Journal reported that Spielberg will oversee the bulk of the FDA's operations, including the centers for drugs, medical devices and biological products, as well as the relatively new tobacco center. The one major area over which he won't have primary authority is food regulation, which will continue to be overseen by Deputy Commissioner Michael Taylor.

—WE (July 15, 2011)

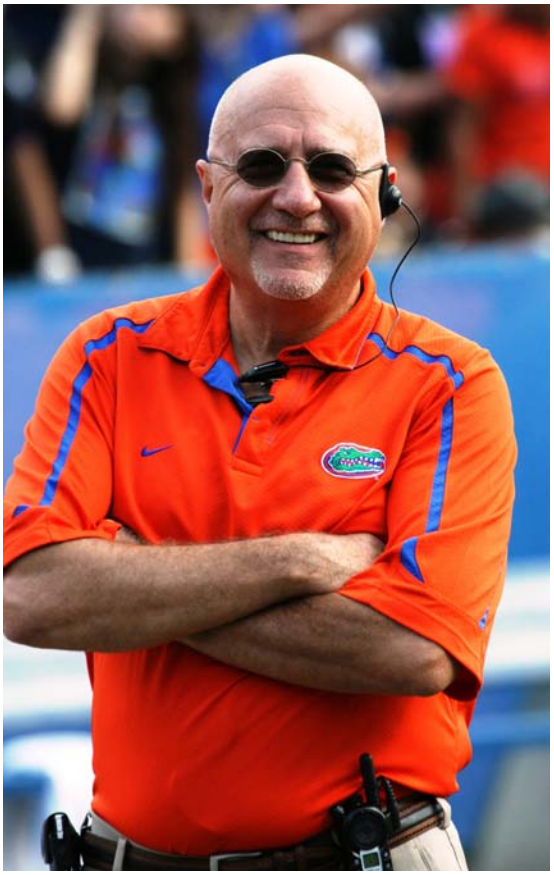
New AOSSM President: Dr. Peter Indelicato

Peter A. Indelicato, M.D., Wayne Huizenga Professor and Chief of Sports Medicine for the Department of Orthopaedic Surgery and Rehabilitation at the University of Florida has been installed as the 40th president of the American Orthopaedic Society for Sports Medicine (AOSSM). Dr. Indelicato was the associate team physician for the Miami Dolphins from 1988-1996 and recently retired as the head team physician for the University of Florida, a position he had held since 1977.

Dr. Indelicato attended New York Medical College and received his medical degree in 1969 then went on to complete his orthopedic residency training at New York University. Following residency, he spent two years in the U.S. Navy as a staff orthopedic surgeon at NAS Corpus Christi, Texas. Upon completion of his Naval service, he went on to serve as a sports medicine fellow at the well-known Kerlan-Jobe Orthopaedic Clinic and had the opportunity to care for members of the Los Angeles Rams, Lakers, Dodgers and Kings.

He has been an active member of AOSSM having served on the Board of Directors and multiple other committees since his membership began in 1983. He is also a member of the American Academy of Orthopaedic Surgeons, Herodicus Society (President 2007-2008), Florida Orthopaedic Society, National Athletic Trainers' Association, Magellan Orthopaedic Society, Medical Advisory Committee-UF Athletic Association.

Dr. Indelicato has lectured extensively around the country on the recognition and management of athletic knee and shoulder injuries. In addition, he has been an invited speaker at more than 35 conferences internationally.



Dr. Peter Indelicato

Asked about his goals as president, Dr. Indelicato told *OTW*, "My first priority is to continue to grow the STOP (Sports Trauma and Overuse Prevention) program. Specifically, I would like to enhance the level of grassroots involvement of the AOSSM membership, as well as continue to strengthen the relationship between the organization and the National Athletic Trainers Association. My other goal is to improve international relationships with other sports medicine societies around the world. We already have solid relationship with groups in Europe, the Pacific Rim, and South America, and are seeking to establish relationships with societies in Eastern Europe and the Middle East."

Dr. Indelicato added, "I am retiring at the end of August so I will be in a position going to devote a large portion of time to the society. I look forward to consulting my colleagues and getting their input as I move forward."

For more *OTW* profile of Dr. Indelicato, please see our December 7, 2010 Picture of Success.

http://ryortho.com/12_07_10_EH_DrPeterIndelicato.pdf

—EH (July 14, 2011)

THE PICTURE OF SUCCESS

Dr. Dennis Devito

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

Dr. Dennis Devito

Ask most spine surgeons how their profession will advance, and they will talk about the commitment to gathering the best available evidence, to using the scientific method and then applying a double-blind, randomized controlled trial to the problem. But then there are those cases where you don't need to do a study…you just ***know.***

For Dr. Dennis Devito that moment came in the form of an 11 year old girl from El Salvador in the summer of 1996. Unfortunately, there was no gray area, no uncertainty and as the young girl with her twisted spine looked into the eyes of Dr. Dennis Devito she did not find hope. Dr. Devito, a pediatric orthopedic surgeon at Children's Healthcare of Atlanta at Scottish Rite, is a recognized expert on scoliosis…but despite his capabilities there was nothing he could do. "I was incredibly frustrated and saddened," says Dr. Devito.

Modern spine surgery can trace its roots to a similar moment for Dr. Paul Harrington in the 1950s, a frustration which was the impetus behind the Harrington rod for treating spinal deformities. Despite fifty years of dazzling progress, the room for error in complex spine scoliosis surgery – as in the case of Dr. Devito's 11 year old patient, remains infinitesimally low.

Scoliosis surgery is difficult to teach. Getting the angles right is tricky. Surgeons have to master both the axial and compressive forces and anticipate where instrumentation may ultimately deliver symmetry ***as the child grows.***

The question facing every scoliosis surgeon is: can I see all the dimensions of this case now and for the next decade? We're talking 4D vision.

Looking at problems multi-dimensionally is something Dr. Devito started developing even before medical school. "My mother was a Renaissance woman…an artist, a writer, and a teacher. One summer in middle school I took an art class and decided that I would try working in stone. My mom took me to a local quarry and I became fixated on a certain stone. I began to envision it as a woman's head, and developed ideas about how to 'bring it to life.'"

It was his early days of creating, and following the flow of stone that laid the foundations for Dr. Devito's understanding of art, symmetry, and balance. "Doing scoliosis surgery on children means that I am taking something deformed and envisioning how to change it, i.e., using a sense of artistry to help decide how to make the patient's spine look a certain way. My background in art helps me line things up; you are looking at a uni-dimensional image but you must understand it as 3D object. This is normal for me now, and I don't get upset if I go into a case where things are unclear and you have to go with flow. I actually thrive on that because I know that it means that my mind is free to be creative."

That is, if the window for treatment is open far enough. In the case of the 11 year old girl from El Salvador, the window for surgery had shut. What was needed was a new kind of tool – something to make near perfection almost routine. Something that could, in other words, open up surgery for the more afflicted patients. "Four years ago I was approached by a robotics company that

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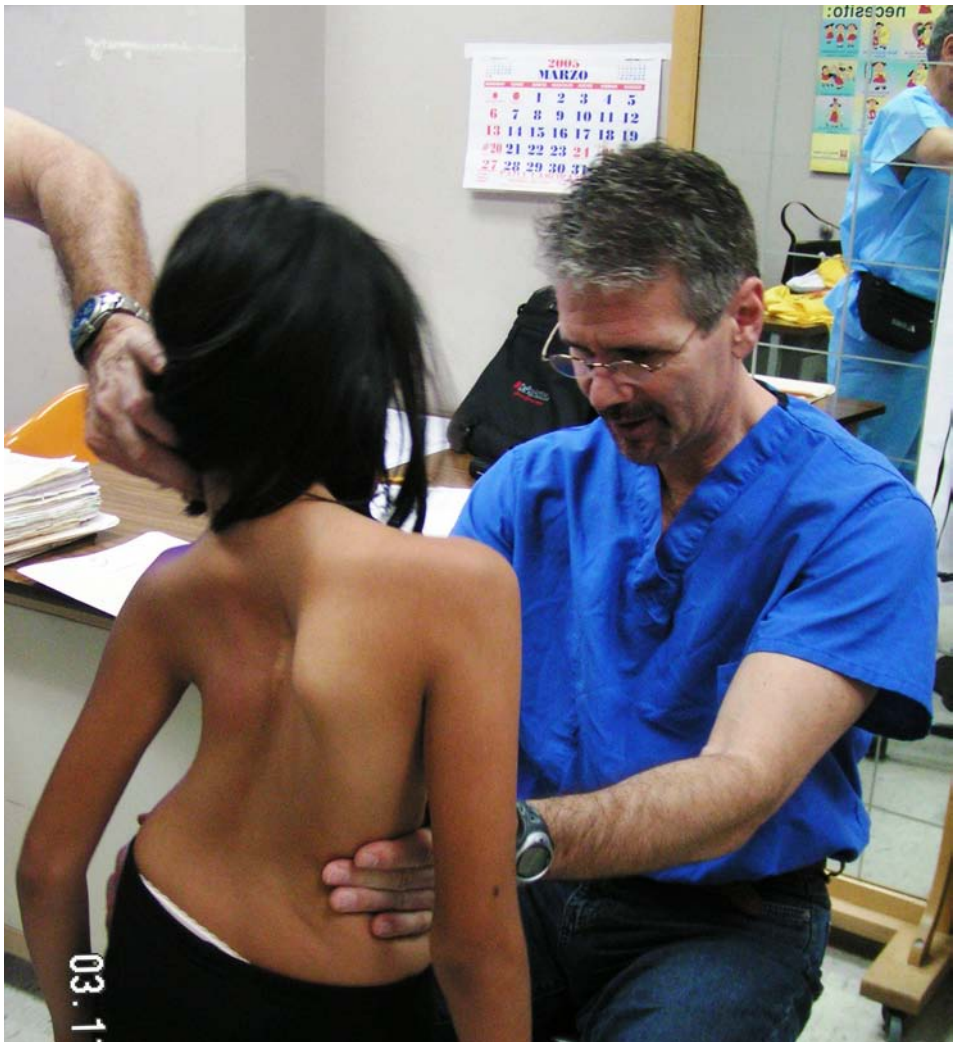
wanted me to help them develop or apply their system for scoliosis surgery to children. My challenge to them was, 'Let's make something that provides better outcomes than I can get without such a program.' I worked with their engineers and software people over many sessions until we made it happen."

And make it happen he did. In a study that included 120 scoliosis patients and 2,000 pedicle screw placements, Dr. Devito demonstrated that with robotic assistance, a scoliosis surgeon could get results that are an order of magnitude better. Dr. Devito: "The existing literature showed that even the best studies were saddled with a 10% misplaced screw rate. I am extremely proud to say that ours was a mere 0.3% (but even those did not involve complications). When I recently presented these results at a national meeting there were hardly any comments. People just said, 'Well, you can't argue with 99.7% accuracy.'"

While this precision is not at the expense of OR time, it is—in a budgetary sense—costly. First, the good news: "Robotic assisted surgery is a reliable, safe, and accurate procedure that can produce better outcomes and make an institution more attractive to patients. And it saves time as well. Pedicle screw placement is the most difficult part of scoliosis surgery, and you really have an unknown element when there is a small deformed pedicle involved. And, because of the challenging anatomy, it can sometimes take over 20 minutes to get this right. With robotics it is more routine and can be done in less than three minutes."

The price of precision can be high. Dr. Devito says, "The technology can run an institution between $500,000 and one million dollars. Can a facility survive without it? Yes. But I go back to the old saying that it only takes one poorly placed screw to make you wish that you had had something to prevent that. I don't know how you put a price on that."



Dr. Devito in examining young patient

Indeed, the price is too high for many of Dr. Devito's patients. But they do have the benefit of his unusual spatial abilities. "One day, after that experience of not being able to help that little girl, the mission team coordinator showed up at my door and said, 'Everyone has backed out of the next trip to El Salvador. Will you please come?' I said 'yes' immediately. What I saw there was more severe pathology than I had ever encountered, coupled with a paucity of resources. They do not have a lot of the special equipment necessary to perform these surgeries, so I bring everything… including my 3D instinct."

Also accompanying Dr. Devito on his now regular trips to El Salvador are some residents and fellows who have to set aside what they are accustomed to and learn something else…they must learn to trust their own hands and eyes. "The younger surgeons often 'squawk' because we don't have the equipment that we are used to. They have not learned about—and are not comfortable with—using their innate abilities to assess 3D and spatial issues. They are not comfortable when there is no set plan, and sometimes they get upset—never a good thing in the OR. I tell them, 'This is what real surgery is like and you get to learn it here.'"

"For example, say we have to realign a hip and must cut the bone, turn it, and point it toward the hip socket. In the U.S. we would bring in the fluoroscope, make the adjustments, realign things, put in the plates and screws, and take another image. That is not readily available in El Salvador. The trainees must learn to stick their finger in there, conceptualize the angle they just made, and implant the plates and screws by tapping and feeling the depth."

Dr. Devito is also ensuring that his orthopedic colleagues in El Salvador have the capacity to help their own people. "My initial mission was that within five years I would have taught the surgeons there how to do spine surgery. This was partially successful but the instrument and implant technology is just too expensive for their medical system. This is especially true because while they are capable surgeons who learn fast, the cases they are doing are not routine…they are 'off the wall' difficult. So I altered my mission, and began focusing on teaching the orthopedists there to recognize scoliosis early on, i.e., before it gets severe."

Citing his attention to detail as a reason for his success, Dr. Devito states, "Take patient contact as an example—literally, contact. Physicians don't seem to touch patients as much anymore, and instead are often tempted to derive their answers from various tests. I'm not just bemoaning the loss of patient/doctor connection…there is a practical, clinical side to this as well. For example, the beauty of treating children is that while they can't always tell you what is happening with them, if you rely on your hands and others senses you can feel any stiffness, and/or tightness or resistance to movement that might indicate a painful area. Whether working in the U.S. or El Salvador, that diligence and attention to detail has given me an edge and makes me a much better physician."

And then sometimes, doctors have other reasons not to touch patients. "When I first went to El Salvador someone said, 'Just so you know, these kids don't live in the most sanitary conditions.' The first thing I did when I arrived at the clinic was give each child a big hug.

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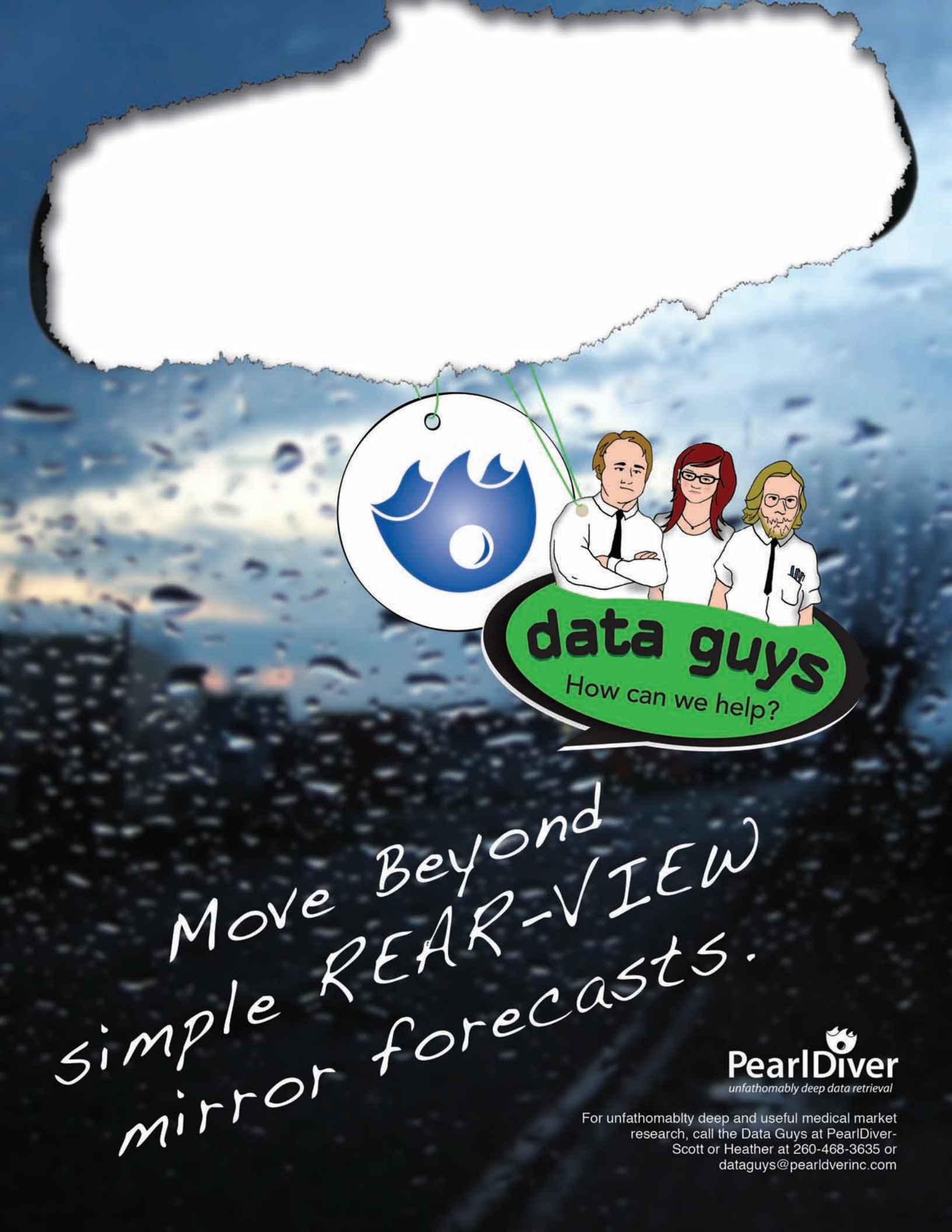
They were thrilled…they could feel that I'm gentle and was going to do my best to help them."

Patient care is unquestionably the center of Dr. Devito's career life. "I began in academic medicine at Vanderbilt, but was dismayed to find that the academic life wasn't what I was looking for. I altered course, and dedicated myself to being the best practitioner I could be. My biggest legacy is having trained a number of talented surgeons, and I'm glad to say that I still get calls from former fellows who have questions about tough cases."

This legacy is based on not being a "one man show." Dr. Devito states, "Years ago I realized that the fact that I had skills meant that I was here for a purpose. As a surgeon you do the pedigree thing, building your career and focusing on yourself. I came to see that it's not about me…I have to use my energy to give what I have. I can do nothing better than to pass on my knowledge to future generations."

His next generation involves four children and two grandchildren. "And there's my wife," says Dr. Devito, "who is my biggest supporter, and says I have 'too much energy.' This is likely because I did Ironman competitions for 18 years. I enjoy pushing myself to the limit; I mainly do a lot of bike riding now, something that makes it easier to stand in the OR all day."

Dr. Dennis Devito…multi-dimensional innovator, teacher and humanitarian. ◆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