VOLUME 7, ISSUE 38 | DECEMBER 6, 2011

Orthopedics This Week

week in review

4 Are You the Victim of Monopolistic Insurers? Check This List to Find Out ◆ Physicians have been the target of antitrust prosecutions by the Justice Department and the Federal Trade Commission for years. Now the government wants to hear from physicians about potential antitrust market practices by hospitals and insurers in their communities. Read what the lawyers want you to look for.

8 Carragee for the Prosecution ◆ In the recent issue of *The Spine Journal* Eugene Carragee, MD, writes more like prosecutor-in-chief than editor-in-chief as he resumes his attack on the use of rhBMP2 and its clinical investigators. The plaintiff's bar is cheering. But NASS members are reeling. Who to believe? Read the details here.

12 Seitz vs. Burkhead in Orthopaedic Crossfire® Fixation Debate ◆ Washington Generals vs. the Harlem Globetrotters? All we know is when Buzz Burkhead and Bill Seitz debate the audience gets an entertaining education. Did Dr. Seitz cement a victory or did Dr. Burkhead press fit his advantage? You be the judge.

16 On (and Off) the Record ◆ **Chris Bono, M.D.** finds alarming differences between abstracts and manuscripts… Air Force Maj. Erik Nott, M.D is awarded the Purple Heart…**new funding program**…news on impingement… and more…

breaking news

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First Dedicated **Meniscus Transplant Center**

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Osteoporotic **Bone Screw Scores Well** in Sheep Test

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For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: CMS to require 100% prepayment medical review (up from 10%-30%) beginning January 1, 2012, for certain orthopedic DRGs. New admin burden on hospitals will not affect hip, knee, extremity, spine or trauma volumes. Ortho equities looking good.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Zimmer	27.75%	(5.63%)	Last week's sell off put ZMH's P/E at 10.39, the lowest of all orthopedic companies. Very cheap earnings and still #1.
2	2	Medtronic	28.63	1.88	Since 2006, MDT's dividend more than doubled from $0.44 / share to $0.94 / share. Almost as cheap as ZMH.
3	3	Orthofix	14.72	(4.25)	OFIX is the least expensive PEG stock in ortho. And management routinely beats EPS estimates. What's not to like?
4	6	Stryker	25.23	(0.29)	Up two spots this week. 2012 is shaping up to be strong year for ortho overall but SYK certainly.
5	9	Smith & Nephew	22.80	3.27	Up four spots. SNN's return on capital much higher than its cost of capital. SNN to be "discovered" by investors in 2012?
6	5	Johnson & Johnson	26.33	0.66	The mood is turning from safety havens to underpriced growth stocks. That's not JNJ.
7	4	Conmed	9.65	0.31	Profit margins rising at CNMD, we think, but market turning to undervalued, higher margin ortho companies.
8	10	Integra	15.38	10.49	Nice bounce this past month. Was actually the best performing ortho stock.
9	7	Exactech	7.69	(10.93)	Hit hard this past week. It's tough to be the small manufacturer in ortho these days.
10	8	Kensey Nash	34.24	0.71	Phenomenal profit margins, but middle of the pack in terms of growth expectations.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Integra LifeSciences	IART	$31.27	$839	10.49%
2	ArthroCare	ARTC	$29.62	$815	9.18%
3	TranS1	TSON	$1.72	$47	8.86%
4	Wright Medical	WMGI	$14.66	$577	3.39%
5	Smith & Nephew	SNN	$45.74	$8,173	3.27%
6	Medtronic	MDT	$34.61	$36,548	1.88%
7	Kensey Nash	KNSY	$25.70	$222	0.71%
8	Johnson & Johnson	JNJ	$63.47	$173,327	0.66%
9	Conmed	CNMD	$25.89	$723	0.31%
10	Stryker	SYK	$47.62	$18,223	-0.29%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BONE	$2.11	$86	-33.02%
2	MAKO Surgical	MAKO	$28.76	$1,198	-20.60%
3	TiGenix	TIG.BR	$0.91	$83	-17.19%
4	Symmetry Medical	SMA	$7.75	$281	-13.89%
5	NuVasive	NUVA	$12.83	$542	-11.09%
6	Exactech	EXAC	$14.10	$185	-10.93%
7	Alphatec Holdings	ATEC	$1.90	$170	-8.65%
8	RTI Biologics Inc	RTIX	$4.27	$236	-8.57%
9	Tornier N.V.	TRNX	$18.66	$733	-7.58%
10	Zimmer Holdings	ZMH	$48.92	$8,765	-5.63%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Zimmer Holdings	ZMH	$48.92	$8,765	10.39
2	Medtronic	MDT	$34.61	$36,548	10.39
3	Orthofix	OFIX	$32.20	$593	12.48
4	Smith & Nephew	SNN	$45.74	$8,173	12.57
5	Integra LifeSciences	IART	$31.27	$839	12.92

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Wright Medical	WMGI	$14.66	$577	31.19
2	RTI Biologics Inc	RTIX	$4.27	$236	26.69
3	Synthes	SYST.VX	$165.49	$19,657	20.95
4	ArthroCare	ARTC	$29.62	$815	20.71
5	NuVasive	NUVA	$12.83	$542	19.15

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$32.20	$593	0.76
2	RTI Biologics Inc	RTIX	$4.27	$236	0.94
3	Zimmer Holdings	ZMH	$48.92	$8,765	1.11
4	Stryker	SYK	$47.62	$18,223	1.23
5	Exactech	EXAC	$14.10	$185	1.27

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$12.83	$542	4.29
2	Wright Medical	WMGI	$14.66	$577	3.44
3	Kensey Nash	KNSY	$25.70	$222	3.04
4	Johnson & Johnson	JNJ	$63.47	$173,327	2.14
5	Symmetry Medical	SMA	$7.75	$281	2.00

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$7.75	$281	0.78
2	Exactech	EXAC	$14.10	$185	0.97
3	Alphatec Holdings	ATEC	$1.90	$170	0.99
4	Conmed	CNMD	$25.89	$723	1.01
5	Orthofix	OFIX	$32.20	$593	1.05

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$0.91	$83	133.64
2	MAKO Surgical	MAKO	$28.76	$1,198	27.05
3	Bacterin Intl Holdings	BONE	$2.11	$86	5.56
4	Synthes	SYST.VX	$165.49	$19,657	5.33
5	Tornier N.V.	TRNX	$18.66	$733	3.22

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

Are You the Victim of Monopolistic Insurers? Check This List to Find Out

By Walter Eisner

wicourts.gov and mncourts.gov/RRY Photo Creation

Physicians, including orthopedic surgeons, have complained for years that the Department of Justice (DOJ) and Federal Trade Commission (FTC) have targeted them for antitrust violations while hospitals and insurance companies have escaped scrutiny and prosecution as they become dominant health care players in their communities.

"More than 30 groups of physicians have been prosecuted over the past 14 years for alleged antitrust violations when dealing with insurers," Michael Connair, M.D. told *OTW* on November 28.

Highly Concentrated Insurance Markets

At the same time, according to an American Medical Association (AMA) study of U.S. insurance markets, 83% of the 368 metropolitan areas studied were highly concentrated. In 95% of the metropolitan areas, one or more insurers had a combined HMO+PPO market share of 30% or greater. And in 47% of the areas, at least one insurer had an HMO+PPO market share of at least 50%.

Department of Justice Seeks Input

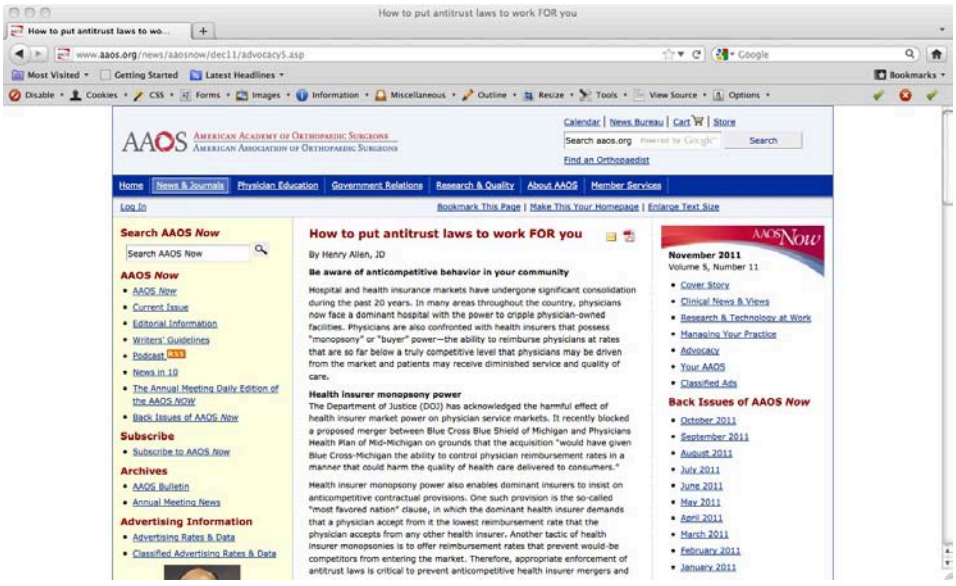
Now the DOJ is signaling that it wants help from physicians to identify anticompetitive practices by insurers and hospitals.

In a 2010 speech, then Assistant Attorney General Christine Varney told the American Bar Association/American Health Lawyers Association that it is essential that the government continue to refine and expand its understanding of market forces, structures, and dynamics in the health care industry.

She told the health care lawyers that the biggest obstacle to an insurer's entry or expansion in the small- or mid-sized-employer market is scale. New insurers cannot compete with incumbents for enrollees without provider discounts, but they cannot negotiate for discounts without a large number of enrollees. This circularity problem makes entry risky and difficult, helping to secure the position of existing incumbents.

Preventing Domination

"It is, therefore, imperative that the Division prevent mergers or acquisi-



AAOS Website

tions that will create, or even increase the size of, dominant health insurance plans, particularly in the small-group and individual markets," said Varney.

The new prosecution attitude was displayed in an October 2010 meeting between representatives of the American Medical Association, the American Academy of Orthopaedic Surgeons (AAOS) and Democratic Rep. John Conyers, Ranking Member of the U.S. House of Representatives Judiciary Committee. Conyers held a congressional hearing after the meeting with the physicians and developed a framework for physicians to use to provide information to the DOJ and FTC regarding potential antitrust activities by dominant hospitals and insurers in their areas.

In a just published article in *AAOS NOW*, Henry Allen, JD, senior attorney for marketplace advocacy for the AMA provides a list of behaviors that may be anticompetitive when conducted by market dominant health insurers and hospitals. "Accordingly, information concerning such conduct may be of interest to DOJ," said Allen.

Allen told *OTW* that there is now an appreciation by the government of the frustrations experienced by physicians on antitrust matters. Allen participated on a speaker panel at the October 2010 meeting that included a DOJ official. That official expressed a willingness to review cases forwarded by the AMA where physicians conclude they are the victims of anticompetitive conduct.

Contact the AMA

Allen made it clear that he is neither offering legal assistance nor agreeing to act as an agent or representative for any individual physician. With that understanding, he is interested in receiving information on health insurer or hospital anticompetitive conduct for possible referral to DOJ, assuming that the AMA believes the agency would consider the information important.

Hospital and health insurance markets have undergone significant consolidation during the past 20 years, says Allen. "In many areas throughout the country, physicians now face a dominant hospital with the power to cripple physician-owned facilities. Physicians are also confronted with health insurers that possess 'monopsony' or 'buyer' power—the ability to reimburse physicians at rates that are so far below a truly competitive level that physicians may be driven from the market and patients may receive diminished service and quality of care."

Health insurer monopsony power, says Allen, enables dominant insurers to insist on anticompetitive contractual provisions. "One such provision is the so-called 'most favored nation' clause, in which the dominant health insurer demands that a physician accept from it the lowest reimbursement rate that the physician accepts from any other

Henry Allen, JD

health insurer. Another tactic of health insurer monopsonies is to offer reimbursement rates that prevent would-be competitors from entering the market. Therefore, appropriate enforcement of antitrust laws is critical to prevent anticompetitive health insurer mergers and to prohibit actions that inhibit the entry of new health insurers into a market."

Allen continued that the consolidation of hospital markets has made it difficult, and sometimes impossible, for physicians to open and operate freestanding surgery centers. "Dominant hospitals have shown a willingness to use their market position to hurt physician-owned surgery centers and the physicians who work at or invest in those centers."

According to Allen, identifying anticompetitive practices by hospitals and health insurers is a critical first step in protecting orthopedic practices and physician autonomy. He summarizes the types of conduct that could indicate an anticompetitive practice. He says if your area includes a dominant hospital or health insurer, and you believe that any of these activities are occurring, you may want to share that information with him at the AMA.

Allen can be reached at Henry.Allen@ama-assn.org.

Below is Allen's summary of potential anticompetitive behaviors from the *AAOS NOW* article.

Anticompetitive Behaviors

The following behaviors indicate that a hospital and a health insurer may be working together to limit competition:

- A hospital and a health insurer in the same area refuse to deal with competing insurance plans and competing physician-owned facilities.
- A health insurer refuses to contract with a physician-owned specialty hospital or outpatient center, while permitting a dominant hospital to add new facilities to its already existing network.
- A health insurer offers reimbursement rates that discriminate against a dominant hospital's rivals.
- A dominant hospital offers bundled price discounts to insurers in exchange for an exclusive arrangement with the hospital; as a result, smaller competing hospitals or physician-owned facilities are unable to obtain a contract with the insurer.
- A hospital and insurance company merge, or one acquires the other.

Dominant Hospital

The following behaviors indicate that a dominant hospital may be abusing its market position:

- The dominant hospital conditions the granting or continuation of privileges on an agreement by physicians that they not seek privileges from other hospitals in the area.
- The dominant hospital pressures its employed physicians to not refer patients to freestanding outpatient facilities or to specialists not employed by the hospital.
- The dominant hospital gives employed physicians financial benefits if they only refer patients to other employed physicians.
- The dominant hospital initiates "sham proceedings" against another hospital, physician-owned hospital, or physician-owned outpatient center. For example, the dominant hospital knowingly submits materially false statements about the small hospital in a certificate of need application or files frivolous lawsuits against the other hospital or facility.
- The dominant hospital institutes "conflict of interest" policies that exclude physician owners of a competing specialty hospital or outpatient center from the hospital's medical staff.
- The dominant hospital refuses to enter into transfer agreements with physician-owned facilities.
- The dominant hospital requires that physicians perform a certain percentage of procedures at the hospital.
- The dominant hospital creates an alliance with staff physicians to collectively negotiate with health insurers.
- The dominant hospital negotiates an exclusive managed care contract with a critical health insurer or with several different health insurers.
- The dominant hospital merges with or acquires another hospital.

- The dominant hospital refuses to contract with a health insurer for certain services unless the health insurer agrees to use it for nonrelated services as well. For example, a dominant hospital that is the only provider of Level III neonatal care in the area refuses to allow health insurers to contract for perinatal services unless they also agree to use it for nonperinatal services.

Dominant Health Insurer

The following behaviors indicate that a dominant health insurer may be abusing its market position to hurt smaller health insurers; such conduct would ultimately hurt physicians by giving the dominant health insurer "buyer power."

- The dominant health insurer demands that a physician accept from it the lowest reimbursement rate that the physician accepts from any other health insurer ("Most Favored Nation" clause).
- The dominant health insurer threatens to terminate a physician's provider status if the physician agrees to contract with another health insurer.
- The dominant health insurer pays discriminatory reimbursement rates to physicians who work with a rival health insurer.
- The dominant health insurer insists that physicians agree to an "all-products clause," which requires them to accept all present and future insurance products and payment methods offered by the company as a condition of participating in any of the insurer's products. This can include requiring the physician to participate in an insurer's health maintenance organization.
- A dominant health insurer merges with or acquires another health insurer.

Make a Difference

The health care reform legislation, if it survives the Supreme Court challenge, will have potential anticompetitive implications for physicians as it relates to Accountable Care Organizations and insurance exchanges. The opportunity provided by AAOS and the AMA to offer direct evidence of anticompetitive insurance company and hospital market activity is one that orthopedic surgeons should take seriously.

Tell Henry Allen what you see in your community. Again, his email is Henry.Allen@ama-assn.org. ◆

Carragee for the Prosecution

By Robin Young

Eugene J. Carragee, M.D., editor in chief of *The Spine Journal* (*TSJ*), resumed his prosecutorial debating style in the journal's latest issue as he responded to a letter to the editor citing omissions from the June 2011 issue of *The Spine Journal* and his own critical review of 13 early rhBMP2 studies.

The letter to the editor in question came from six frequently published (*Journal of Bone and Joint Surgery and SPINE* among other journals) and esteemed authors concerning one of their studies which Carragee et al. had selected for criticism in the June 2011 issue of *The Spine Journal*. In their letter this group of investigators found that Carragee had omitted key, material information which might well have changed Carragee's conclusions regarding their study.

Carragee's response, published in the November issue of *TSJ*, left almost no room for further discussion and will, we expect, prove to be chilling to any other investigators who also found, as we did at *OTW*, a pattern of omission and error in the June 2011 issue of *The Spine Journal*.

The authors of the letter to the editor were Drs. Dimar, Glassman, Burkus, Pryor, Hardacker and Carreon.

Here are the citations for the two studies in question:

- Dimar JR, Glassman SD, Burkus JK, et al. *Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. J Bone Joint Surg Am 2009;91:1377–86.*
- Dimar JR, Glassman SD, Burkus KJ, Carreon LY. *Clinical outcomes and fusion success at 2 years of single-level instrumented Posterolateral fusions with recombinant human bone morphogenetic protein-2/compression resistant matrix versus iliac crest bone graft. Spine 2006;31:2534–9; discussion 2540.*

Screen shot from the movie Inherit the Wind starring Spencer Tracy, Frederick March and Harry Morgan. Courtesy Wikimedia Commons

Who to Believe?

In 2006 Dimar, Glassman, Burkus, and Carreon published, in *SPINE*, the results from their part of a prospective, randomized FDA investigational device exempt (IDE) study of a new dose of rhBMP2 in a novel, compression resistant carrier for instrumented posterolateral spine fusions. The authors enrolled 98 patients. Forty-five were randomized to the iliac crest bone graft group. Fifty-three were randomized to the BMP/compression resistant matrix group.

Two years after the last patient was enrolled, the authors published a summary of their results. The six page report offered three conclusions and a table which listed 12 categories of adverse events for both the BMP patients and the control patients. Here are the conclusions:

1. Both patient groups, the ICBG group and the rhBMP2/CRM group, improved after surgery. Specifically, the two groups exhibited similar clinical outcomes as measured by

the Short Form 36, Oswestry Low Back Pain Disability Index, leg and back pain scores at the two year mark after surgery.

2. The group receiving rhBMP2/CRM had less operative blood loss and a shorter operative time (no second surgery to harvest bone graft).
3. The rhBMP2/CRM group had a higher fusion rate based on two-year CT scans

Twelve categories of complications were listed in a table for both the rhBMP2/CRM and ICBG patients. Carragee said in his June 2011 article that the Dimar study did not mention BMP related complications. In a direct refutation of Carragee, *OTW* reproduced the Dimar et al. table in our critique of the June 2011 issue of *TSJ*.

Four years later, in July 2010, the FDA published an executive summary of the entire FDA monitored rhBMP2/CRS study—which included the Dimar et al. patients along with patients from 28 other study sites for a total of 463 patients of which 234 received the rhBMP2/CRS (now branded AMPLIFY) and 229 received ICBG.

The FDA's summary ran 69 pages.

In that FDA report, the complications associated with the broader study were reproduced in detail. Ultimately, the range, type and severity of those complications were too much for the FDA and the AMPLIFY dosage of rhBMP2 was not approved for commercial sale.

All of this information was made available for free to the general public. The FDA's conclusions were more extensive than those in the Dimar et al. study but, and this is key, they were consistent with and supported each of the three Dimar, et al. conclusions. Here is a brief list of those FDA conclusions which, like Dimar et al., looked at the 24-month outcomes.

- Investigational group (rhBMP2/CRS) and control groups (ICBG) were comparable in demographic and baseline characteristics (page 24)
- The average operative time was statistically less in the AMPLIFY patient group (page 25)
- The average blood loss was statistically less in the AMPLIFY patient group (page 25)
- At 24-month follow up, the rate of adverse events was NOT statistically significant between the two groups—87.4% of the AMPLIFY patients had an adverse event versus 87.9% of the control patients—[*emphasis added*] (page 26)
- At 24 month follow up, the AMPLIFY group had statistically lower rate of non-union adverse events—4.2% for AMPLIFY versus 10.3% for control (page 27)

But FDA Didn't Approve AMPLIFY…

The FDA's review, however, looked at data which was collected **after** the Dimar et al. study in 2006. With five-year data, the FDA decided that AMPLIFY, which has different pharmacokinetics and pharmacodynamics than InFuse, had too many safety questions to be approved for sale. Specifically, the FDA said (Under the FDA rules, ANY adverse event of any kind from any source was included):

- Of 25 categories of adverse events listed by the FDA, the AMPLIFY patients exhibited a statistically

significantly greater incidence rate of adverse event than the control group in five areas (page 30). Those five areas were:
  - o Arthritis/bursitis
  - o Back and/or leg pain
  - o Neurological adverse event
  - o Trauma
  - o Cancer
- There were a high number of serious back and/or leg pain adverse events in both groups but the rate in the AMPLIFY group was higher—10.0% versus 8.0% (page 31)
- The total number of serious adverse events was less for the AMPLIFY patients than for the control patients—52.7% versus 55.8% (page 31)
- The rate of cancer, however, tended to be higher among the AMPLIFY patients than for the control patients. Here we will quote directly from the FDA document: "Although the rates (of cancer) in the investigational group tended to be higher than those in the control, they are not statistically different at the 24 month analysis. However, statistical significance is borderline between the AMPLIFY and control groups when all cancer events though [sic] the 2010 Annual Review are considered" (page 33)
- The total number of AMPLIFY patient who reported having cancer at the 60-month follow up was 12 (out of a total population of 234) and the total number of control patients who reported cancer at the 60-month follow up was 5 (total control population of 229) (page 33)
- At 60-month follow up, the number of adverse events increased for both groups (page 27)
- At 60-month follow up, the AMPLIFY group had a lower rate of adverse events than the control group—92.9% for AMPLIFY versus 93.8% for control (page 27)

Bottom line: the FDA said: "Long-term data, although not intended as the primary outcome measure of success, suggests a less favorable profile. There is a concerning number of cancers in this study and all rhBMP-2 clinical spine studies. Recombinant BMP-2 has systemic effects, not unlike any other drug, and the medical community does not have enough information that relates to its long term pharmacological effects."

So, the System Worked?

Looking back and having read both Dimar and the FDA review, it seems to us that the six page study that was published in *SPINE* in 2006 should have been more comprehensive and could have included more information about complications.

But the Dimar study, in contrast to Carragee's work, was unemotional, data driven and when it came to conclusions, landed on three simple ones and clearly kept the door open for more study. It did NOT promote the product in any way that this reader could discern.

Carragee for the Prosecution

So we return to the question of who to believe. The problem with Carragee is that he is aggressively promoting a point of view and is omitting information which would modify his conclusions. These omissions are clearly troubling to a growing number of experienced and respected North American Spine Society (NASS) members. When an author is omitting information, the question of bias and agenda become paramount.

We have disclosed some of Carragee omissions in previous *OTW* articles.

Carragee's style of aggressive promotion has found its way into the form of argumentation that he employed in his response to the letter from Dimar et al. Simply put, Carragee is employing a prosecutorial style—which is a style we would not customarily expect to find in the pages of *The Spine Journal*.

What is a prosecutorial style of argumentation?

There are three basic elements:

1. Impugn the credibility if not integrity of any writer who would argue against the proposition

THE SPINE JOURNAL

Courtesy The Spine Journal and Elsevier

Courtesy North American Spine Society

2. Avoid ambiguity. Ignore information which might conflict with the narrative of the case
3. Find a simple storyline and hammer it home. For example: 'corrupt surgeons spin study data and therefore NASS's membership lives dangerously'

In Carragee's response to Dimar et al., these elements of the prosecutorial style were, we believe, in full view.

Examples of Carragee's Prosecutorial Style

Here, for example, is a selection from Carragee's response to the Dimar, Glassman, Burkus et al.'s letter to the editor of *The Spine Journal*; "The authors received substantial sums for consulting, royalties, and other support from Medtronic and had extensive financial ties with this manufacturer for many years before and after publication." Then, two paragraphs later, Carragee writes: "It is clear, however, that multimillion dollar corporate funding was received *to perform both of these studies,* a fact, unfortunately, omitted or denied by the original authors in both disclosures."

Clearly Carragee is accusing these authors of taking "multi-million corporate funding" to perform the studies. First of all, Carragee's comment is factually incorrect. *OTW* has been checking with these authors and so far, every one of them has told us that they received no compensation for performing the studies. None. At all. Secondly, as we documented in earlier articles, the money Carragee is referring to is for any payment made for anything at anytime paid to any single author listed in the study. Carragee made no effort to find out if any of these payments could, in fact, be reasonably connected to these studies or rhBMP2.

So, as we documented in earlier articles, a researcher (and we used Dr. Scott Boden as an example—although the same is true of other researchers mentioned by Carragee) who refused compensation for conducting the study was then credited by Carragee with receiving millions of dollars of royalties that were actually paid to an entirely different surgeon for a purpose entirely unrelated to rhBMP2 or the study in question.

But perhaps most worrisome, as we documented previously in *OTW* (*Medtronic and Carragee on Collision Course in Court?,October 25, 2011*), one lawsuit has already been filed which cites Carragee's work as a key piece evidence *for the plaintiff*.

The fact that Carragee uses the prosecutorial style of argumentation, we believe, encourages the plaintiff's bar.

We at *OTW* are trying to apply more light than heat to this issue, but as the evidence of omissions and mistakes associated with Carragee's work continues to grow and as Carragee increasingly assumes the mantle of prosecutor if not also judge and jury, we are becoming ever more worried and concerned.

Space in this article precludes us from listing every material omission or mistake that sadly now characterizes Carragee's work in *TSJ* regarding rhBMP2 and the investigators who have studied the compound.

But, stay tuned. We are collecting examples of Carragee's omissions and errors and will be supplying them to both our readers and NASS soon. ◆

Seitz vs. Burkhead in Orthopaedic Crossfire® Fixation Debate

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

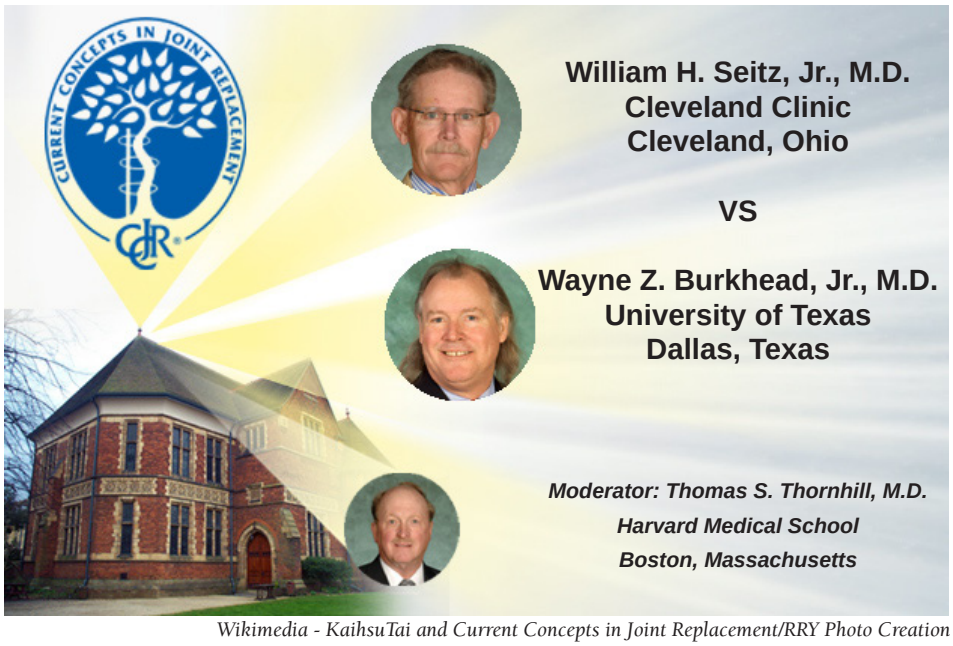
Proposition
Cemented Glenohumeral Fixation: Standard of Care

For the Proposition:
William H. Seitz, Jr., M.D.
Cleveland Clinic
Cleveland, Ohio

Against the Proposition:
Wayne Z. Burkhead, Jr., M.D.
University of Texas
Dallas, Texas

This debate was held in May 2009 at the Current Concepts in Joint Replacement™ *Spring* meeting in Las Vegas, Nevada.

Moderator:
Thomas S. Thornhill, M.D.
Harvard Medical School
Boston, Massachusetts



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

Dr. Seitz: "I'm going to talk to you about humeral fixation in joint replacement. For intramedullary stem fixation, cement has become the gold standard. The question is, 'Can a press fit implant stand the test of time?' For those that have in-growth or on-growth trabecular metal components the question is, 'Can the tip of the stem get a tight fit?'"

"Cementation is preferable to set the head height appropriately. And a trabecular metal component may help in terms of getting the tuberosity fixation. But still, head height and distal stem fit is the standard for fractures."

"For elective arthroplasty, humeral stem component fixation is affected by different surfaces. There are in-growth and on-growth surfaces. For the younger person a cup arthroplasty is preferable to a large stem if it's an elective implant."

"We've learned, after 55 years of follow-up, which press fit implants loosened and which subsided. Then we went to cement. Suddenly we have cement concerns. I think this follows the experience in the hip and knee world where putting these implants in very young patients has happened. My colleague and friend Buzz Burkhead will say that if you don't cement it the revision is easier, but that's two operations."

"Is cementless revision easier? With the new implant designs and techniques for glenoid grafting and impaction, and new techniques for later reconstruction, I think cementless has some good qualities…but the results are still too variable. Besides, if you do have good in-growth and fixation in a cementless prosthesis, a well fixed in-growth stem can be just as difficult to remove as a cemented one."

"So what does the data show? Harris and Jobe demonstrated that full cementation provided a very tight fixation—better than press fit—in reducing rotational micromotion. Peppers and Jobe demonstrated in other cadaver studies that axial micromotion was present when cementation was not done. Distal canal fill is very important in keeping the stem from rocking and subsiding. The use of a cement restrictor and gentle injection techniques are very effective in preventing this."

"In one clinical study, Torchia and Cofield showed in 89 patients implant and bone radiolucent lines in 70% of uncemented stems; 40% showed a subsidence and shift in position. In rheumatoid patients it's even worse. Two studies showed 42% and 27% radiographic loosening while cemented stems showed 0% loosening."

"Our goal is to have stable humeral fixation. When we do revisions, invariably, if it's an issue of loosening, it's not the humeral side…it's the glenoid side. "

"Our future directions? Bone in-growth, especially in implants that have trabecular metal, have a real promise in younger patients. If I must do an elective arthroplasty in a younger person I'm going to probably do a minimally invasive resurfacing. If you do have to put a stem in, then you should make sure you have a good tip fill, you have a very tight fit with meticulous canal preparation, but you should still consider that cup arthroplasty."

"When you need to use a stem, cement with a distal restrictor plug, especially if there's any questionable bone quality, whenever there is osteoporosis, in rheumatoid arthritic patients, in fractures. This will give you both rotational stability and will avoid axial micromotion."

Dr. Burkhead: "Seth always picks his favorite guy, like Bill Seitz, and puts me up against him because he knows I'm not that smart. I'm like the Washington Generals up here every year…against the Harlem Globetrotters."

"Debates are fun at meetings, but in the real world you have to individualize each patient. Sometimes you do need cement, but not all porous coated components and porous coatings are alike. And all the data that Bill showed you is old data using a component that was designed for cement in a cementless fashion. I'll try to bring you up to date."

"Charlie Neer's first implant was a cementless component, and the reason that some of these osteoarthritic patients failed wasn't because of implant failure…it was because of glenoid wear. In fractures the goal is to create a milieu favorable for tuberosity healing, so using a little cement is probably reasonable. But you want porous coating that will attract in-growth of the tuberosities to the implant as well as promote healing to the shaft. So avoid lots of cement."

"You also have to look at the design of humeral implants. I've always favored a trapezoidal type shape to gain fill in the promixal component. I'm not worried much about distal stem fill."

"So there is data out there…long term results of uncemented humeral components in shoulder arthroplasty. In 2007 Verborgt showed that these patients did extremely well, and even though radiographically some of them appeared to be at risk at an average of about nine years, none of these patients had been revised."

"The surface replacements now are all used in a cementless fashion, so you should consider using those in younger patients with osteonecrosis. The fact that cemented components never loosen is a fallacy as well. This data from January 2009 from Mayo Clinic (Cil) involved 38 revision arthroplasties. The humeral components were cemented in 29 of those, with in-growth implants used in nine cases."

"Rational uses of cementless fixation? Surface replacement or hemiarthro-

plasty in the young patient; hemiarthroplasty or total shoulder arthroplasty in older individuals. Sometimes the cement can be quite cardiotoxic, so use a small amount in older patients; with a minimal amount of cement in fractures—just enough to get stability; and then obviously the glenosphere in a reverse is cementless currently."

"So if you don't believe me, Bill, and you don't believe Rick Matsen or Bob Coffield, maybe one of my patients can convince you [showing video]. I was telling him that JP Warner at Harvard couldn't get a good result with this operation. Patient: 'I had my right shoulder done in November '94, so that would be 14 years this November. It's been fantastic…pain free. The left shoulder was done six months ago and it too is totally pain free. Now I don't know what's wrong with those *&^%$ up at Harvard, but you got to work at it to get it better baby.'"

Patient drops and does pushups…says, "Don't mess with Texas."

Moderator Thornhill: "Buzz, you obviously didn't look on the schedule to see where the moderator was from."

Dr. Burkhead: "Oh, I absolutely knew where he was from. He's talking about your patients, not the faculty at Harvard."

Dr. Seitz: "That was an impressive video. The only thing is that I didn't see any scars on his shoulder. You're a really fine surgeon."

Dr. Burkhead: "Well he does and I am. Thank you."

Moderator Thornhill: "Bill, many years ago we looked at our rheumatoid patients and found that uncemented humeral components worked well. These were plasma spray, no in-growth; a little bit of subsidence… not much loosening…this was on the humeral side. In hips we started with all cemented implants, then hybrids. Most hips of type A and type B bone are uncemented…so you're telling me now that I should start cementing my total shoulders on the humerus?"

Dr. Seitz: "If you look at the rheumatoid patients that you looked at 23 years ago they're very different than the surgical rheumatoid patients today. Those patients tended to be very low demand, very sedentary. Today's rheumatoid patients have a lot of disease modifying drugs…by the time they get their shoulder they still have a fair amount of activity and they frequently have better soft tissues. They should be cemented. I don't think that you should cement everybody. Obviously, Seth gives us a charge to take a passionate stand, but I think that in anybody where there is a question of bone stock, then I would cement them. And a hip is very different than a shoulder in terms of the forces on it."

Moderator Thornhill: "But our rheumatoids also have better bone quality, with their DMARDs [Disease-Modifying Anti-Rheumatic Drugs] so it may go both ways. Buzz, you said that doing an uncemented will prevent cardiotoxicity of the cement. Do you really believe that?"

Dr. Burkhead: "In an older patient with a four part fracture—when I used to do hip surgery, I had two intraoperative cardiovascular events using cement, so yes I absolutely believe it."

Moderator Thornhill: "Because it turns out that the monomer itself probably doesn't give it enough quantity to do it. It may be just the embolization of marrow elements and fat that is the cardiotoxicity."

Dr. Burkhead: "But the monomer has been shown to be cardiotoxic, hasn't it?"

Moderator Thornhill: "In massive doses injected on its own. Um, Bill, cement restrictors…Alan Boyd looked up a group of our periprosthetic fractures and they frequently occurred at the junction right between the bone and the end of the cement restrictor. One of the suggestions from that was that maybe it would be better not to have it because they didn't loosen and you didn't want to have that sharp demarcation. Is that a bunch of baloney?"

Dr. Seitz: "The technique of cement injection in a humerus is different than that in a hip. In general we don't use as much pressurization in a humerus…

there's a transition point. The issue is that you don't want the cement which is injected to dribble down the intramedullary canal. So I use a cement restrictor, but I can think of two patients of my own who have had periprosthetic fractures…in both of them it was well below that…they were in the supracondylar area."

Moderator Thornhill: "When you have to remove cement that is well fixed in the humerus, what is your preferred technique?"

Dr. Seitz: "My preferred technique is to get the implant out first. If it's really good, hard bone then I will try to fragment it and remove it with ribbon osteotomes and power. I don't use ultrasound. If I have to slot the bone I will, especially if it's weaker bone."

Dr. Burkhead: "I usually use an episiotomy—single split—and then advancing sized drills into the deeper part of the cement mantle after you get past the implant. I want to make one point on the fractures: these two events that I had were hips that were fractured, but people that come in with fractured shoulders also can be hypovolemic. If they have a big metaphyseal split they can also put a lot of blood into their arm, just like somebody can put into their thigh. And that was really the point…that if you have somebody that's in extremis it's a good idea to skip the cement and go to an uncemented component."

Moderator Thornhill: "Thanks to both speakers." ◆

Please visit www.CCJR.com to register for the upcoming 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.

On (and Off) the Record By Elizabeth Hofheinz

Dear *OTW* Reader: **Chris Bono, M.D.** finds alarming differences between abstracts and manuscripts… Air Force Major Erik Nott, M.D is awarded the Purple Heart…**new funding program**…news on impingement…and more…

Abstracts Not Matching Manuscripts Christopher Bono, M.D., chief of spine at Brigham and Women's Hospital, and Deputy Editor of *The Spine Journal* is up to some eye opening research. He tells *OTW*, "Last year I had one of our fellows—Jeff Lehmen, M.D. —do an evaluation of all randomized controlled trials for lumbar spine that have been done in the last ten years. We were looking for inconsistencies between the abstracts and the manuscripts...we found an alarmingly high rate of inconsistencies. And these were not necessarily industry sponsored studies—some were government sponsored. Regardless, however, we found many studies that failed to include pertinent negatives and positives in the abstracts--apparently in an effort to slant some results in one way or another. Our work has just now been accepted as a poster at the International Spine Intervention Society. The solution? It all comes down to journals and reviewers ensuring that the abstract completely reflects the information in the article itself. Sometimes the abstract's conclusions are quite a ways away from what the data showed."

Casts for Injured Fashionistas If you're going to suffer, do so in style… CastMedic Designs has a new line of swanky accessories for medical walking boots. It all began last summer when Christina Daves, founder of CastMedic

CastMedic Designs

CastMedic Designs

Designs, broke her foot and had to use a walking medical boot for eight weeks. She scoured the Internet for anything to "dress-up" her boot but came up empty handed. Now, she has created over 60 products including faux-fur wraps, decorative socks, flowers, and themed buttons for children. With decorating the boots and making people feel happy and fun while wearing them, CastMedic Designs is hoping its products can help in the healing process and if not, at least put a smile on someone's face.

New President for PA Orthopaedic Society Dr. Greg Gallant of Doylestown has been named president of the Pennsylvania Orthopaedic Society, a professional medical specialty organization representing more than 1,000 orthopedic surgeons in Pennsylvania. Gallant is a former president of the Bucks County Medical Society, a fellow of the American Academy of Orthopaedic Surgeons and immediate past president of Doylestown Hospital's medical staff. He serves various clinical instructor roles and is team physician for Delaware Valley College.

Foot and Ankle Popularity on the Rise Scott Ellis, M.D., director of research for the foot and ankle service at Hospital for Special Surgery, tells *OTW*, "I'm thrilled that foot and ankle is gaining popularity; actually, this is the first year that we have more applicants to foot and ankle fellowships than there are spots. More and more people are realizing the draw of the specialty—namely, that not only is it fun and varied, but there are many jobs to be had. Sports medicine and foot and ankle are still working out their 'overlaps,' and there are a lot of surgeons who do sports medicine and foot and ankle. Overall, there is more arthroscopy in foot and ankle now because we doing more training in arthroscopy and people are pioneering its use in the specialty. People are realizing that foot and ankle surgeons encounter so many different issues, and there are so many bones and joints in the foot, that they will never be bored. In addition, there is ample room to contribute to the research arena because this is a relatively young field."

NASS: Outstanding Paper Award in Basic Science Dr. Steven Leckie, a fifth-year orthopedic surgery resident at the University of Pittsburgh, and his colleagues from the Ferguson Laboratory, received the prestigious Outstanding Paper Award in Basic Science at the recent North American Spine Society (NASS) Annual Meeting. Their paper entitled "Injection of AAV2-BMP2 and AAV2-TIMP1 into the Nucleus Pulposus Slows the Course of Intervertebral Disc Degeneration in an in vivo Rabbit Model," will be published in *The Spine Journal* December 2011 issue.

New Orthopedic Hospital in the Philippines The Tim Tebow Foundation and CURE International have announced plans to build a children's hospital in the Philippines, the country where Tebow, the starting quarterback for the Denver Broncos and a Heisman Trophy winner at the University of Florida, was born. The Tebow CURE Hospital in Davao City will be a 30-bed

surgical facility focusing primarily on orthopedics; the hospital is expected to open in mid-2013.

The hospital, which is CURE's first in the Philippines and 12th worldwide, will be on the island of Mindanao, a particularly poor area of the Philippines. About one-third of the children treated at the hospital are expected to be charity cases. The hospital will house a Timmy's Playroom, which will provide faith, hope and love to children before and after their surgeries.

OREF, NREF Announce Grant Program Two flagship foundations for advancing spine care through support for research, the Neurosurgery Research and Education Foundation (NREF) and the Orthopaedic Research and Education Foundation (OREF), have announced a collaborative grant program that will broadly cultivate multidisciplinary clinical spine research. The jointly establish Collaborative Spine Research Foundation (CSRF) will focus on advancing the science and practice of the highest quality spine care. The CSRF board of directors, comprising equal numbers of neurosurgeons and orthopedic surgeons, will oversee the establishment of grant and award criteria; the establishment and enforcement of conflict-of-interest standards; the recruitment of qualified, independent peer-review teams; and the development of strategies to secure financial support from spine-care stakeholders.

Thomas Lowe New VP at Millstone Medical Outsourcing—an entity providing advanced inspection, clean room packaging, loaner kit processing, and distribution services—has announced that the company has hired Thomas C. Lowe as Vice President of Business Development. Located in Warsaw, Mr. Lowe will be responsible for developing key accounts and supporting Millstone's medical device manufacturing customers. Lowe's background includes more than 18 years of generating new business. Prior to Millstone, he spent 14 years with a Tier 1 supplier to the medical device industry, where he was primarily responsible for identifying, building, and managing strategic accounts.

Biomechanics News on Impingement Tom Brown, Ph.D., the Richard and Janice Johnston Chair of Orthopaedic Biomechanics at the University of Iowa, tells *OTW,* "The most interesting research here at the moment involves the impingement and dislocation of hard-on-hard total hips. There are various adverse metal on metal engagements associated with edge loading, some of which comes from impingement. We are doing finite element

computer modeling, looking at adverse engagements of hard-on-hard materials and the shedding of metal debris. The effects of curvature of the lips of metal acetabular components are proving intriguing…you might think that if lips are gently curved then that would reduce high contact stress, but we are finding that the large radii of the lips means reduced acetabular coverage of the head…and more tendency to sublux and edge-load. We were very surprised at the severity of the effect; orthopedists need to know that if they have patients who are likely to impinge, then large lip curvature may not be such a good thing."

Purple Heart for Orthopedic Surgeon Air Force Major Erik Nott, M.D., an orthopedic surgeon with Saint Louis University (SLU), received the Purple Heart on November 7, 2011 after being wounded in Afghanistan last May. Dr. Nott is a member of an elite, eight-person medical operations unit that provides close support for military troops on special missions. That fateful day, as the military medical personnel walked away from their most recent patient, gunshots rang out. Under enemy attack, Dr. Nott recognized the severity of the situation and grabbed two of his teammates, sending them into the nearest structure as the marine special operations team and special forces snipers returned fire. During the past four years, Dr. Nott has been on missions in Afghanistan, Haiti, Croatia and Africa. When not deployed, Dr. Nott teaches residents and medical school students at SLU and cares for patients at Saint Louis University Hospital. ◆

company

Infuse Hurts 2Q12 Medtronic Spine Sales

Medtronic, Inc. reported a 6% increase in revenue to $4.1 billion during its second fiscal quarter.

"I'm pleased we delivered another quarter of consistent growth in a difficult environment," said Omar Ishrak, Medtronic's new chairman and CEO in a November 22 press release. "A majority of our businesses, and nearly all of our geographies, contributed to this growth. As we continue to focus on innovation, globalization, and execution, I see tremendous opportunities for growth in the future."

Infuse Controversy

The Spinal franchise continued to struggle as sales of Infuse fell 16% after the North American Spine Society's (NASS) official publication, *The Spine Journal*, accused researchers of failing to report complications due to payments from the company. The company has provided funding to Yale University to review all the published literature and report their independent findings.

Spinal Revenue

Overall reported Spinal revenue of $839 million declined 1%. International reported sales for the Spinal business increased 17%. Core Spinal revenue of $631 million, which includes core metal constructs, interspinous process decompression devices (IPDs), and balloon kyphoplasty (BKP) products, declined 3% on a constant currency basis. Biologics revenue of $208 million declined 4% on a constant currency basis, driven by the decline in Infuse sales, but partially offset by revenue growth from other biologics products.

Overall, the company said the Core Metal Constructs business saw sequential growth of 5% during the quarter. Garry Ellis, the company's CFO attributed the growth to new products such as Solera. He expects the spine business to decline in the low single digits on a constant currency basis for the remainder of the company's 2012 fiscal year.

Medtronic Spine 2Q12	Sales ($ in millions)	% Change
Total Reported Sales	**$839.0**	**down 3%***
Core Spinal	$631.0	down 3%*
Biologics	$208.0	down 4%*

** Constant currency basis*
Source: Medtronic, Inc

Wells Fargo analyst Larry Biegelsen said the weak spine sales were not "as bad as expected," and beat consensus by $17 million. He believes Infuse sales will decline further based on the negative commentary and data presented at the NASS meeting in early November. "In addition, the ongoing Department of Justice (DOJ) investigation into the off-label promotion of Infuse could create additional headline risk."

Ishrak: "Depending on Yale"

During a question and answer session with Wall Street analysts on November 22, Ishrak said that aside from the financials, the company's position on Infuse is that, "we always put patient safety and quality first. We believe in the clinical data that we submitted to the FDA, and we know that, that data supports safe use in the indicated areas. We're depending on the Yale study to look at the data transparently and we will take action resulting from whatever we find in Yale study.... Integrity, patient safety and quality are our highest priorities and that will continue to be so, irrespective of what financial sort of consequences we have here."

—WE (November 30, 2011)

Medtronic, Inc. HQ/Wikimedia Commons and Bobak Ha'Eri

legal

Former Synthes Execs Jailed

The sad journey of Huggins, Higgins and Walsh has come to an end with prison sentences imposed on them by a federal judge in Philadelphia.

U.S. District Judge Legrome D. Davis sentenced the three former Synthes Inc. executives to prison on November 21 after they pled guilty to conducting unapproved medical trials for a bone cement. Three people died during those unapproved trials. No evidence directly linked the deaths to the use of the product.

A fourth defendant Richard Bohner's sentencing was postponed after his attorney collapsed at the hearing. The attorney had just made a statement that Synthes Board Chair Hansjörg Wyss was the undisputed leader of the company. "He [Wyss] made some of the very critical decisions that put the trials on the ultimate pathway," said the attorney."

Michael Huggins was president of Synthes North America during the time of the trials, while Thomas Higgins was a senior vice president. Each defendant received nine months in jail with three months probation and a $100,000 fine. John Walsh, who was the director of regulatory affairs of the company, received a five-month prison term.

David Sell of the *Philadelphia Inquirer* reported that Judge Davis said Huggins showed a "knowing disregard" for the safety of patients.

"You are being punished for the decisions you made and personally participated in," Judge Davis told Huggins and the packed court room at the Federal Courthouse at 6th and Market Streets.

The patients died on the operating table when their blood pressure dropped precipitously, shortly after surgeons injected bone cements SRS, with barium sulfate, or XR into their vertebrae. The bone cements were produced by Norian, a wholly owned subsidiary of Synthes.

Synthes did not have approval from the FDA to use the cement to treat vertebral compression fractures.

The defendants were sentenced under the responsible corporate officer doctrine. That doctrine holds executives responsible if illegal activity happened on their watch and if they did nothing to stop the activity upon learning of it. Sell reported that Wyss was not charged and that prosecutors declined to say why.

"The government is pleased with the sentences," reportedly said lead prosecutor Mary Crawley, of the U.S. Attorney's Office in Philadelphia. "We believe it sends the right message to medical-device and drug companies that lying to the FDA and disregarding patient safety has consequences."

Huggins was immediately taken into custody. Judge Davis, according to the *Inquirer* story, gave Higgins two weeks to report to prison so he can arrange for extra medical care for his wife. Davis gave Walsh until November 28 to report because the 22nd was his young daughter's birthday.

Synthes previously agreed to plead guilty, sell the Norian unit and pay a $23.5 million fine to settle the case. The agreement allowed the company to keep operating in the U.S. without its products being banned from Medicare reimbursement programs.

—WE (November 21, 2011)

morguefile.com and kconnors

large joints

First Dedicated Meniscus Transplant Center

They have left no stone unturned in looking for a solution to meniscus pain…OK, lame joke aside, there is news from The Stone Clinic in San Francisco. They are announcing the opening of the world's first dedicated meniscus transplant center.

In 2010, The Stone Research Foundation reported on long-term results of meniscus transplantation in arthritic knees with a 79% success rate at improving pain and function. Their peer-reviewed, prospective study in the *Journal of Bone and Joint Surgery* (Br) proved that a meniscus transplant combined with an articular cartilage stem cell paste graft procedure can delay knee replacement for an average of 9.9 years, even in the presence of arthritis.

"Many arthritic, bone-on-bone patients, often younger than 60, are told to sit at home and wait for their knee replacement; however, the technology and expertise exists that can return them to their activities and keep them from having a knee replacement for an average of approximately ten years," stated Dr. Stone in the November 29, 2011 news release.

Dr. Stone told *OTW*, "The Meniscus Transplantation Center is the culmination of over 20 years of our research and development to optimize the replacement of this key shock absorber of the knee. Now that substantial data and patient experiences confirm the benefit of replacing the meniscus, even in arthritis, we feel confident that a core team focused on this tissue transplantation is fundamental to obtaining superior outcomes."

Asked about the development process, Dr. Stone commented to *OTW*, "The process of forming a dedicated center was somewhat torturous as we needed to collect enough patient data over a long enough period of time for a procedure that was not reimbursed by insurance or even accepted in the general orthopaedic community. The feeling was that a meniscus could not survive in the arthritic knee nor would it make enough of a difference to the patient outcomes. Determined patients who asked, 'Doc, isn't there a shock absorber you can put in my knee and buy me time,' drove the process. In the 2-12 year outcome study, only 18 patients in the first 119 severely arthritic knees required conversion to a joint arthroplasty. Many insurance companies now do reimburse for meniscus transplantation and the dedicated rehabilitation program required for success."

—EH (November 30, 2011)

The Stone Clinic

Is Age 90 the New 85?

Is age 90 the new 85? In 1980, there were 720,000 people aged 90 and older in the United States. Last year that number had increased to 1.9 million people who were age 90 and older. By 2050 that number is expected to reach eight million, according to a report—"90+ in the United States: 2006–2008"—from the U.S. Census Bureau, commissioned by the National Institute on Aging (NIA) at the National Institutes of Health.

The report states that a majority of the 90-plus population are widowed white women who live alone or in a nursing home. Most are high school graduates. Social Security provides almost half of their personal income, and almost all of them have health insurance coverage through Medicare and/or Medicaid.

Wikimedia Commons and Brandon Myrick

The report also states that a person who has lived to 90 years of age has a life expectancy today of 4.6 more years while those who pass the 100 year mark are projected to live another 2.3 years. The majority (84.7%) of those 90 years and older reported having one or more limitations in physical function. Some 66% had difficulty in mobility-related activities such as walking or climbing stairs.

An older person's likelihood of living in a nursing home increases sharply with age. The proportion of those aged 85-89 who live in nursing homes is 11.2 but the percentage jumps to 31% for those aged 95-99.

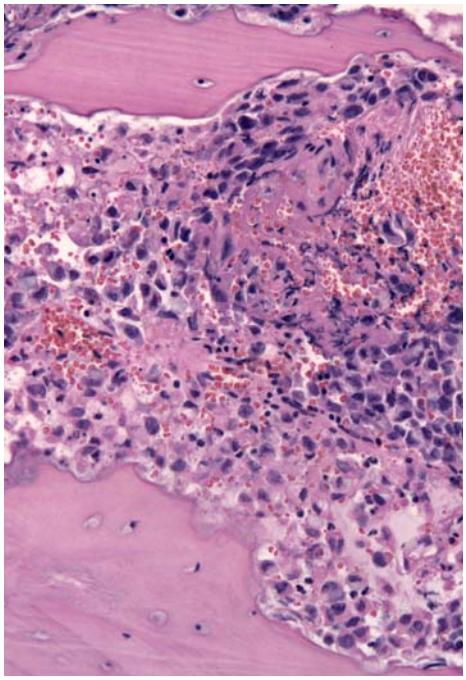
"With the aging boom it is critical to develop demographic data providing as detailed a picture as possible of our oldest population," said National Institute of Health Director Richard J. Hodes, M.D., according to the November 11 press release. "The information on a variety of factors—income, health status, disabilities and living arrangements—will be particularly useful to researchers, planners and policymakers."

Copies of the report are available at http://www.census.gov/prod/2011pubs/acs-17.pdf.

—BY (November 28, 2011)

Slowing Spread of Cancer to Bones

Putting the brakes on bone cancer… A study involving 30 countries has shown that denosumab can slow the spread of prostate cancer to bones in men at high risk of disease progression. The article—published online in the *Lancet*—is by Professor Matthew R. Smith, Massachusetts General Hospital, Cancer Center, Boston, Massachusetts, and colleagues.



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Preclinical studies suggest that osteoclast inhibition might prevent bone metastases, possibly via a molecular pathway involving the signaling molecule RANKL. Denosumab is a fully human monoclonal antibody that specifically targets, binds and inactivates RANKL. In this study, the authors analyzed the effects of denosumab on bone-metastasis free survival in men with castration-resistant prostate cancer, who had no evidence of bone metastases at baseline, and a high risk

of progression based on standard prostate-specific antigen (PSA) tests.

The study enrolled 1,432 patients across 30 countries, with 716 assigned to denosumab and 716 to placebo. Denosumab significantly increased bone-metastasis-free survival by a median of over four months compared with placebo. Denosumab also significantly delayed time to first bone metastasis. However overall survival was similar in both groups. Rates of adverse events and serious adverse events were similar in both groups, except for osteonecrosis (weakening and destruction of the jaw bone) and hypocalcaemia. A total of 33 (5%) patients on denosumab developed osteonecrosis of the jaw versus none on placebo, and hypocalcaemia occurred in 12 (2%) of patients on denosumab and two (<1%) on placebo.

The authors said in the November 16, 2011 news release: "Extensive contemporary preclinical research suggests a vicious cycle of complex bidirectional interactions between prostate cancer cells and the bone microenvironment, and tumour–bone interactions have been advanced as the foremost mechanism for the bone-dominant pattern of metastases in prostate cancer."

They conclude: "Improvement in bone-metastasis-free survival and time to first bone metastasis with denosumab treatment in our study shows that a bone-targeted agent can delay time to bone metastasis in men with prostate cancer. Our findings also provide the first direct clinical evidence for the important role of the bone microenvironment and RANKL signaling in the development of bone metastases in men with prostate cancer."

—EH (November 21, 2011)

extremities

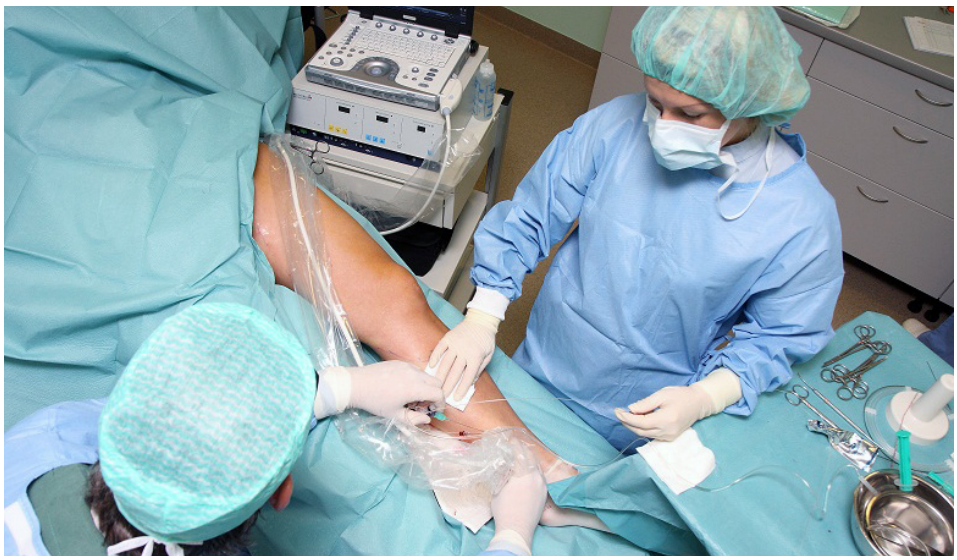
Patient Positioning Problems? New Technology!

Sometimes…the larger the patient, the larger the problem of positioning. Royal Philips Electronics—using the input from surgeons worldwide—has introduced something that should help. The Veradius Neo mobile C-arm sports a flat detector to allow surgeons to more easily and precisely handle challenging patients and procedures. It also features a completely new C-arc geometry, which is designed to accommodate even obese patients with increased maneuverability. Veradius Neo also offers flexible dose management settings and advanced flat detector imaging technology to support surgeons in performing the latest image-guided surgical interventions to help improve patient care.

"Veradius Neo is truly the product of a collaborative process that included the input of many surgeons and technologists from around the world," said Bert van Meurs, senior vice president and general manager, Interventional X-ray, for Philips Healthcare, in the November 23, 2011 press release. "With customers' input, particularly their hands-on evaluation of early designs, we've developed a mobile C-arm that is easy to position, even for very large patients."

To simplify communication between surgical team members and make it easy to quickly move to a requested position, the Veradius Neo now has a color-coded geometry. Once in the desired position, the system's advanced flat detector technology provides high-quality images without the distortion that is inherent in images produced by previous generation image intensifier technology. Surgeons can use these undistorted images to help place screws and other devices with precision.

As indicated by the company, the flat detector on the Veradius Neo has a greater dynamic range than older image intensifier technology, meeting these high requirements by provid-



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ing high contrast digital subtraction angiography (DSA) runs and roadmap guidance. Regarding X-ray dose, the Veradius Neo incorporates a full range of dose management features that allow low X-ray dose for lengthy minimally invasive procedures. Philips beam filters enhance the quality of X-ray while the monoblock design results in sharp pulses to support excellent dose efficiency. The easily removable grid on the flat detector makes it possible to visualize small anatomy and extremities with exceptional image quality.

—EH (November 28, 2011)

Magic Wand for Preop Planning

A magic wand for orthopedists? Maybe…it's the Sectra Visualization Table. Sectra, a company born out of Linköping University in Sweden, is using algorithms to identify a bone or a bone fragment, according to the user's touch interaction, and remove it from the image. Accordingly, orthopedic surgeons can gain an overview of the joints, thereby facilitating pre-operative planning specifically in orthopedic surgery. As with the rest of the functionality, the new segmentation tool is operated using the fingertips.

"I had the opportunity to test the new segmentation tool and it feels like this table knows what I am thinking, it is like magic," says Göran Sjödén, associate professor, consultant orthopedic surgery at Sundsvall Hospital in Sweden, in the November 22, 2011 news release. "This will improve the quality of my operations as I see things I am never able to see on a regular X-ray image. And the table's user interface is really intuitive."

Sectra

With Sectra Visualization Table, a large medical multi-touch display, multiple users can interact collaboratively with the real-size 3D images generated by CT and MRI scanners to gain deeper understanding and insight into the structure, functions and processes inside the body. They can, for example, visualize different kinds of tissues and cut through sections with a virtual knife.

Per Elmhester, Ph.D. MScME, RadIT Product Manager Clinical Solutions, told *OTW*, "The image data is acquired by a CT scanner and sent to the Sectra Visualization Table where the 3D volume is rendered automatically. The user then simply points at the bone to be removed and selects 'cut', and instantly the bone or bone fragment is removed. The most challenging task in developing the bone segmentation tool was definitely to keep the intuitive user interface. The feedback we've received from users so far indicates that we succeeded!"

—EH (November 25, 2011)

trauma

Injured Athletes: Who is Responsible?

Ethics and the injured athlete… Experts from NYU Langone Medical Center and NYU School of Continuing and Professional Studies' Preston Robert Tisch Center for Hospitality, Tourism and Sports Management held a panel discussion recently on the ethics of who is responsible for ensuring appropriate medical treatment of an athlete that is injured—particularly if the player may have a concussion. The panel was hosted by the Department of Orthopaedic Surgery at NYU.

Key takeaways from the evening include: Understand the issues—a great deal has been learned about concussions in the last 10 years, but they are complex and can be difficult to diagnose, especially on the field. While medical, sports and equipment experts are working to evolve technology, guidelines and rules to keep contact sports safe—equipment alone does not protect the brain from being jarred during contact.

Participants also concluded that awareness is vital: The more players, trainers, coaches, parents and sports organizers understand about the real—and often hidden—dangers of head injuries, the more likely the right decisions will be made on the practice field, sideline or locker room. Professional leagues, retired players and other advocacy groups also help the medical community develop best practices and support better awareness in youth and recreational programs. The media and Internet play a key role in providing information on the potential long term dangers of head injuries.

All panelists agreed that everyone is responsible—no matter what the age or level of play—when a potential injury to the brain is involved there is no gray area: athletes must be removed from play and receive appropriate medical attention despite any desire of the athlete, and even a parent, to continue playing.

The members of the panel included orthopedic surgeons, professional team physicians, ethicists, former professional athletes, coaches and members of the sports media.

Claudette Lajam, M.D., assistant professor in the Department of Orthopaedic Surgery, NYU Langone Medical Center and a team physician for USA Cycling, told *OTW*, "What the orthopedist might not know about concussion is that symptoms of a serious injury may not appear until hours or days after an injury. It is imperative to take into account the mechanism of injury and the energy involved when making the determination of keeping an athlete in play after a significant head impact."

—EH (November 23, 2011)

Wikimedia Commons and Philadelphia Eagles

AAOS Programs Wins CLIO Award

Driving itself used to be exciting enough…now many feel the need for speed and speed dialing, texting, etc. The American Academy of Orthopaedic Surgeons (AAOS) and the Auto Alliance are trying to do something about that. Its national "Decide to Drive" Public Service campaign, designed to spread awareness of the importance of driver focus behind the wheel, received the Silver Award at the CLIO Healthcare Awards—one of the world's most-recognized awards competitions for advertising, design and communications.

"Distracted driving can cause lifelong injuries that orthopaedic surgeons would rather prevent than treat. "Decide to Drive" was organized to function as a national conversation—between children and their parents, among drivers in various online forums, and between surgeons and their patients—and the conversation has certainly started," said AAOS CEO Karen Hackett, FACHE, CAE, in the November 11, 2011 news release. "On behalf of the Academy's 36,000 members, our staff and the Academy's creative and sponsoring partners, we are grateful to have won this award. Hopefully this win will reiterate our message."

The "Decide to Drive" partnership began with printed PSAs—sponsored by the Orthopaedic Trauma Association—in the form of counter cards placed in thousands of AAOS surgeon-members' office waiting rooms. The public relations effort eventually reached airports, shopping malls, buses and bus shelters, as well as broadcast across the country. Since then, the campaign has included a national survey on behaviors and perceptions of distracted driving, a website allowing users to report incident of distracted driving (www.decidetodrive.org), Facebook and Twitter campaigns, a partnership with the Driving School Association of America, and more.

Just this fall, the program created a distracted driving classroom curriculum to distribute to more than 10,000 schools nationwide to help teach fifth and sixth graders to urge their parents, and others, to keep their eyes on the road. The campaign also is sponsoring a poster contest for children and teens in grades 5 through 12, inviting them to develop a public service ad to warn drivers of the dangers of distraction behind the wheel.

Sandra Gordon, director of public relations for AAOS, told *OTW*, "Creating the Decide to Drive Campaign has been one of the most meaningful pieces of work in my career. I had the honor of meeting and working with Smokin' Joe Frazer, who was our campaign spokesperson. In filming our television public service ad, I will never forget the sound that the two cars crashing made. I remember that sound every time I get behind the wheel and might even be tempted to multitask. But, most important, I know the campaign is making a difference in the lives of so many people…including orthopaedic surgeons. The stories posted on www.decidetodrive.org are amazing and it is hard to imagine what drivers do behind the wheel."

—EH (November 21, 2011)

Sandra Gordon, Director of Public Relations/AAOS

spine

Osteoporotic Bone Screw Scores Well in Sheep Test

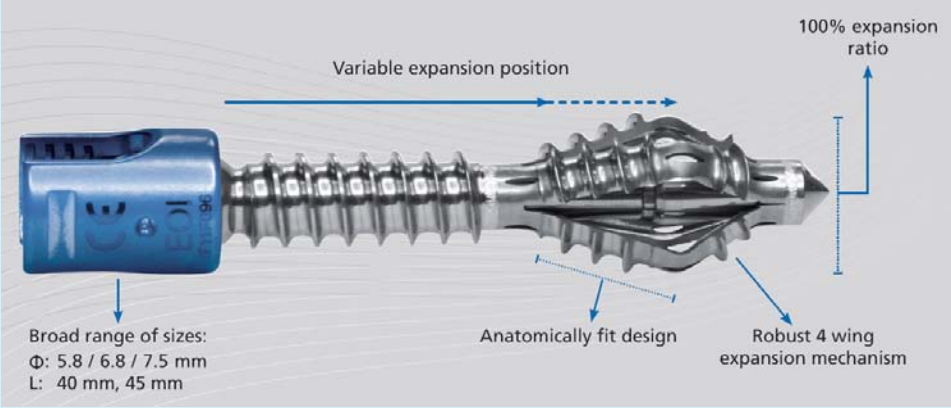
A six-month long study in sheep of the XPED expandable screw resulted in a favorable outcome, according to Dr. Ory Keynan, the principal investigator. Dr. Keynan is head of Service for Degenerative and Age-related Spinal Disorders at the Sourasky Medical Center, Tel-Aviv. He explained that "solid fixation of pedicle screws is the cornerstone of a successful spinal fusion. It's particularly important in compromised bone quality such as in the elderly population, in various bone pathologies, and in revision surgery."

The XPED Pedicle Screw System is manufactured by Expanding Orthopedics, Inc. a privately owned Israeli company which launched the product at the EuroSpine Congress in Milan in October 2011.

Keynan was the first surgeon worldwide to implant the XPED Pedicle Screw System. "So far, we have successfully implanted the XPED in over 20 patients, with the longest follow-up being one year. All patients are doing well and experience a decrease in pain and an improvement in functionality," he said.

As a result of the study he said, "We were able to demonstrate three very important features of the XPED expanding screws: ease of deployment, progressive bone in-growth in between the implant's expanded wings, and ease of removal—despite the bone in-growth. The increased osteointegration over time, as well as bone in-growth inside the expandable area, provided a progressively robust fixation of the screw within the vertebral body." He added that further studies are needed to determine long-term outcomes.

—BY (November 28, 2011)



Expanding Orthopedics Inc.

people

Tavenner Nominated to Head CMS

Marilyn Tavenner is taking over as Administrator of the Centers for Medicare and Medicaid Services (CMS) after 42 Republicans in the U.S. Senate blocked the permanent appointment of President Barack Obama's choice, Donald Berwick, M.D.

The Associated Press (AP) reported on November 29 that agency observers are expecting a change of style, but not of substance. Her appointment got unexpected support from Republican House Majority Leader Eric Cantor of Virginia. Cantor said Tavenner was "eminently qualified" according to the AP report. He doesn't get a vote because the Senate approves the appointment, but his support may help her with Republican senators.

Marilyn Tavenner/hampton.gov

The White House announced her nomination November 23 and she took over the agency on December 2.

Former HCA CEO

Tavenner, 60, served as Medicare's principal deputy administrator under Ber-

wick. The AP reported that she started her career as a nurse at two Hospital Corporation of America (HCA) facilities in Virginia. She eventually rose to chief nursing officer and then hospital chief executive in 1993. She then entered government service as Virginia's health care secretary. She came to Washington last year as Congress was debating the health care reform law.

The Association of American Physicians and Surgeons (AAPS), a group of private physicians, released a statement on November 30, declaring that the "new CMS pick [is] no better than Berwick." AAPS also pointed to Tavenner's 25-year career at HCA, which allegedly defrauded Medicare and Medicaid resulting in $840 million in fines in 2000 and another $640 million in 2003. The head of HCA at the time was Rick Scott, who is now the Republican governor of Florida.

The Washington Post reported that former colleagues describe her as a patient-centered manager, a hands-on medical professional equally comfortable in the board room and the emergency room. And in contrast to Berwick, Tavenner isn't associated with a grand vision for health reform or a particular policy agenda for Medicare and Medicaid.

—WE (December 2, 2011)

Francis Harrison Joins Alphatec

Per the November 16 press release, Francis Harrison, the former global vice president, regulatory affairs for Covidien of Boulder, Colorado, on October 17, accepted the position of vice-president for Regulatory, Clinical Affairs and Quality at Alphatec Spine, Inc.. At Covidien she was responsible for global registrations, regulatory compliance and product labeling for a business unit with more than $1 billion in annual sales.

Ms. Harrison brings more than two decades of regulatory, clinical affairs and quality experience to her new role at Alphatec Spine where she will be responsible for providing overall strategic direction and leadership.

Before her employment at Covidien, Ms. Harrison served as the global vice president, regulatory/clinical affairs and quality compliance at Lumenis, Ltd., a company that sold surgical, ophthalmic and aesthetic laser systems, as well as Class II disposable products. Prior to that position, she held a series of progressively senior regulatory affairs roles at C.R. Bard, a medical device company that sold products in the vascular, urology, oncology, and surgical specialty markets.

Francis Harrison

Ms. Harrison received a BS degree in biochemistry from San Diego State University and completed the Executive Development Program for senior regulatory professionals through the Kellogg School of Management. In her spare time she enjoys bike riding, looking after her dogs and country music.

"We are pleased to have Fran Harrison join Alphatec Spine," said Dirk Kuyper, the company's president and CEO. "Fran's expertise will provide the necessary leadership in a global regulatory environment in which the path to product approval is becoming less predictable, especially as we bring our innovative products to market, both in the U.S. and internationally. Fran's experience will provide us with the necessary leadership with respect to regulatory, clinical affairs and quality, which will help us achieve both our short-term and long-term goals."

Alphatec Spine, Inc. a wholly owned subsidiary of Alphatec Holdings, Inc., is a medical device company that designs, develops, manufactures and markets products for the surgical treatment of spine disorders, primarily focused on the aging spine.

—BY (November 28, 2011)

Rearview Mirror Forecast

+

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