

# Orthopedics This Week

## WEEK IN REVIEW

**4 Pay for Play Scandal Brewing at FDA >>** Allegations that a couple of medical professors and FDA advisors shook down drug companies for hundreds of thousands of dollars to “impact” FDA thinking, has a U.S. Senator calling for an investigation. Is the FDA about to be embroiled in a “Pay for Play” Scandal? See what we found.

**8 Dr. Robert Haar’s Declaration of Independence >>** “Let me just tell you something. Insurance companies aren’t watching your back, hospitals aren’t watching your back, the government is not watching your back. Guess what: we’re going to take this healthcare mess and we’re going to fix it.” Read more of what Dr. Haar is doing to fix healthcare on the upper east side of New York City. He’s not alone by any means.

**11 Pagnano, Thornhill Debate Kinematic Alignment of the Knee >>** “End the tyranny of the tibia!” exclaims Mark Pagnano. “The data show that for 80% of knee replacements mechanical axis alignment works very well, and it’s been a durable, reliable way to do knee replacement.” Counters Tom Thornhill, “We’re going to look back years from now and see that the stuff we’re putting in now is completely obsolete. I’m interested to see if the satisfaction improves if we improve the kinematics.”



**15 OIG POD Report: The Rest of the Story >>** John Steinmann, D.O., says everyone, including himself, has an agenda when it comes to PODs. The recently released OIG study on PODs continues a device industry and media narrative that “Doctors in Business is Bad.” He gets on the record to tell the rest of the OIG report and POD story.



**18 New Data on 3-Hour Out-patient Partial Knee Replacement // More Pain for Younger Hip Replacement Patients // ACL: Independent Drilling of the Femoral Tunnel Needed >>** A new study has found that after unicompartmental knee arthroplasty (UKA), day of surgery discharge for appropriate patients can be both safe, efficient and even increase patient satisfaction. Ryan Nunley, M.D. has found that 20% of hip replacement patients have severe post-operative thigh pain and lateral hip pain. UVA researchers are focusing on obtaining the correct location of graft placement and tunnel location in ACL reconstruction.

## BREAKING NEWS

- 21 Challenging Quarter for Medtronic Spine** .....
- It’s Official. DePuy Settles Hip Lawsuits for \$2.5 Billion** .....
- IPO for Amedica** .....
- Dr. Hosalkar’s Retractions** from Orthopedic Journals .....
- 1,500 Hospitals Hit With Medicare Payment Penalties** .....
- Sailing as Rehab for Spinal Cord Injury Patients** .....

**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** With the Dow over 16,000 and NASDAQ about to clear 4,000, Christmas has come early to Wall Street. Is a sell-off on the horizon? Don't think so. Flow of funds into stocks still strong. This is also the time of year investors adjust for next year's tax returns. Most won't sell now and incur profits. Our guess; the yellow flag starts waving after the new year. Maybe February.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	NuVasive	6.30%	32.59%	Valuation is rich, but investors are looking at several items including NUVA's international expansion. Like Japan.
2	2	Exactech	10.00	8.39	Management's making a habit of beating Wall Street's forecasts. Surrounded by behemoth companies, EXAC finds ways to outperform.
3	7	Integra LifeSciences	11.77	4.08	The recent public offering of stock attracted new institutional interest. Stock is still the 5th least expensive equity in ortho.
4	10	Orthofix	16.25	7.12	OFIX is beginning to remind us of ARTC and DJO in the sense that all three companies went through extended 10-Q "quiet" periods.
5	3	Globus Medical	28.53	5.02	Last quarter GMED beat EPS estimates by 15.80%, yet Wall Street's geniuses are still forecasting a mere 6% EPS growth for the year. Really?
6	6	Zimmer	27.31	0.59	\$1.5 billion in cash on the balance sheet. Time to join the consolidation party.
7	4	Stryker	15.22	1.02	Will MAKO be a boom or a bust? The key is what happens after the purchase is final. Our guess? MAKO found the right home at SYK.
8	5	Medtronic	28.84	1.53	Been a tough month for MDT. Downgraded by Argus. Weaker spine sales than expected. Clearly a company in transition.
9	9	Smith & Nephew	20.78	1.06	Got to say, SNN's new Healicoil is a nifty product. Not just for its material, but that coiled shape is innovative and practical.
10	8	Johnson & Johnson	26.73	3.13	Strong showing this week as one of the prime components of the DOW average. But, really, it's noise. Still waiting for Synthes to show a little synergy.

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	\$33.40	\$1,490	32.59%
2	CryoLife	CRY	\$10.43	\$288	32.03%
3	TiGenix	TIG.BR	\$0.51	\$87	30.77%
4	Wright Medical	WMGI	\$30.34	\$1,430	13.68%
5	MiMedx Group	MDXG	\$5.95	\$582	10.59%
6	Symmetry Medical	SMA	\$8.94	\$333	9.02%
7	Exactech	EXAC	\$23.77	\$322	8.39%
8	Orthofix	OFIX	\$21.97	\$427	7.12%
9	Conmed	CNMD	\$39.29	\$1,080	5.65%
10	Globus Medical	GMED	\$18.62	\$1,230	5.02%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	\$1.03	\$47	-18.90%
2	Tornier N.V.	TRNX	\$17.96	\$871	-15.44%
3	Bacterin Intl Holdings	BONE	\$0.50	\$26	-15.25%
4	RTI Biologics Inc	RTIX	\$2.99	\$169	-11.28%
5	ArthroCare	ARTC	\$35.71	\$1,010	-3.72%
6	Alphatec Holdings	ATEC	\$1.91	\$186	-1.55%
7	MAKO Surgical	MAKO	\$29.93	\$1,540	0.57%
8	Zimmer Holdings	ZMH	\$89.24	\$15,260	0.59%
9	Stryker	SYK	\$74.28	\$28,110	1.02%
10	Smith & Nephew	SNN	\$65.67	\$11,750	1.06%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	\$21.97	\$427	8.82
2	Medtronic	MDT	\$57.60	\$57,450	15.61
3	Zimmer Holdings	ZMH	\$89.24	\$15,260	15.96
4	Smith & Nephew	SNN	\$65.67	\$11,750	16.12
5	Globus Medical	GMED	\$18.62	\$1,230	16.61

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$33.40	\$1,490	87.89
2	Symmetry Medical	SMA	\$8.94	\$333	44.70
3	Integra LifeSciences	IART	\$45.95	\$1,480	29.27
4	CryoLife	CRY	\$10.43	\$288	26.74
5	ArthroCare	ARTC	\$35.71	\$1,010	22.89

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	\$18.62	\$1,230	1.11
2	Orthofix	OFIX	\$21.97	\$427	1.26
3	Conmed	CNMD	\$39.29	\$1,080	1.54
4	Exactech	EXAC	\$23.77	\$322	1.59
5	Zimmer Holdings	ZMH	\$89.24	\$15,260	1.68

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	\$33.40	\$1,490	7.15
2	CryoLife	CRY	\$10.43	\$288	6.69
3	Integra LifeSciences	IART	\$45.95	\$1,480	3.91
4	Symmetry Medical	SMA	\$8.94	\$333	3.73
5	Johnson & Johnson	JNJ	\$95.25	\$268,740	2.81

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$0.50	\$26	0.76
2	Symmetry Medical	SMA	\$8.94	\$333	0.81
3	Orthofix	OFIX	\$21.97	\$427	0.92
4	RTI Biologics Inc	RTIX	\$2.99	\$169	0.95
5	Alphatec Holdings	ATEC	\$1.91	\$186	0.95

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	\$5.95	\$582	21.52
2	TiGenix	TIG.BR	\$0.51	\$87	16.62
3	MAKO Surgical	MAKO	\$29.93	\$1,540	14.99
4	Johnson & Johnson	JNJ	\$95.25	\$268,740	4.00
5	Medtronic	MDT	\$57.60	\$57,450	3.46

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

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# Pay for Play Scandal Brewing at FDA

BY WALTER EISNER

**D**o you want to impact FDA thinking for a mere \$20,000?

That's what two professors and FDA advisors asked drug companies when they offered to hold closed door meetings to develop consensus statements on regulatory policy for pain medication. FDA officials, according to the *Washington Post*, who regulate painkillers, sat on the steering committee of the panel, which met in private, and co-wrote papers with employees of pharmaceutical companies.

## Pay for Play Allegations

This "pay to play" allegation was first uncovered in hundreds of emails discovered as a result of a Freedom of Information Act request by the watchdog group, Public Citizen. The discovery was followed by stories in early October in the *Washington Post* and *MedPage Today*.

Those stories got the attention of West Virginia U.S. Senator Joe Manchin who on October 9, 2013 demanded that the FDA turn over records of all meetings held with the drug companies.



West Virginia U.S. Senator Joe Manchin



Logo courtesy of FDA/Photo Creation by RRY Publications LLC

In a letter to FDA Commissioner Margaret Hamburg, M.D., Manchin called for a full investigation of FDA's actions and those of its personnel in light of the reports' findings.



Margaret Hamburg, M.D./AdvaMed

"I am gravely concerned by the allegations of 'pay to play' between the FDA and pain medicine companies and am calling for a full investigation to see how deep this goes," wrote Manchin. He also charged that the collaboration between industry and FDA could have resulted in the agency delaying a decision to reschedule hydrocodone "even

after their own expert advisory panel recommended it."

"It is a shame that some of these companies were able to influence the FDA's decision with a \$25,000 contribution, while West Virginian families are destroyed by the addiction these pills cause," he added.

## Information Demanded From FDA

Manchin also demanded that Hamburg release information regarding the details of all meetings, including all conference panels and conferences at which "payments over \$1,000 were made to the FDA or the organizing entity."

The information Manchin wants from the FDA includes all the meetings described in the *Washington Post* article, as well as all information related to the meetings organized by Professors



Dennis Turk, Ph.D./University of Washington



Robert Dworkin, Ph.D./University of Rochester Medical Center

Robert Dworkin and Dennis Turk that involved the FDA. He also wants a list of all the companies and amounts they paid to attend the meetings.

Furthermore, he wants all emails written by the professors and Deputy Commissioner Douglas Throckmorton regarding these meetings and a list of all former FDA employees who left the

agency to go to work for any of the companies that paid to attend the meetings.

Alexander Gaffney, news editor of *Regulatory Focus* wrote on October 10, 2013 that Manchin's request would presumably include nearly every major conference attended by FDA. For example, the September 2013 AdvaMed conference, which saw attendance of numer-

ous FDA staff, has standard registration rates for the full conference ranging from \$995/\$1,595 to as high as \$2,595.

Gaffney wrote that is uncertain if FDA maintains or even collects this information. Gaffney reached out to several people with experience scheduling meetings with FDA staff. None could recall having received requests from FDA for any information outside of copies of the registration form and the cost of the conference to attendees.

### A Clear Conflict of Interest

In his letter to Commissioner Hamburg, Manchin wrote that the allegations of improper relationships between the FDA and the pharmaceutical industry, "clearly demonstrate a conflict of interest by allowing pharmaceutical companies to have undue influence over the FDA's decision making process."

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According to reports, continued Manchin, the two medical professors organized a panel in consultation with the FDA on how to test the safety and effectiveness of painkillers.

“According to e-mails between these two professors, pharmaceutical companies paid as much as \$25,000 each to have a seat at the table with FDA officials. When challenged by the companies on the cost, one of the professors responded that ‘20k is small change, and they can justify it easily if they want to be at the table.’ The professors continued to justify the high cost of admission to these closed-door meetings by pointing out that the pharmaceutical companies are “impact[ing] FDA thinking...for very little money.”

According to the *Washington Post* story, the agency told the newspaper that FDA officials did not benefit financially from their participation in the meetings. But two FDA officials later went on to work as pharmaceutical consultants and the e-mails portray an agency that, by allowing itself to get caught up in a panel that seemed to promise influence for money, had blurred the line between the regulators and the regulated.

In a statement, the FDA said “we take these concerns very seriously.” But, it said, “we are unaware of any improprieties” associated with the group.

Deputy Director Throckmorton said in an interview that strict rules of transparency and funding apply to the public-private partnerships that the agency

engages in and that these efforts are important for the government and the industry.

But the group in this case was not initiated by the FDA, he said, and so was a private partnership to which those rules did not apply.

“There are rules in place for us to have these discussions,” Throckmorton said. This group “was set up as a private group.”

The group was organized by the two medical professors, Dworkin of the University of Rochester and Turk of the University of Washington, and the e-mails for the most part describe their efforts at financing and organizing the group’s meetings.

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### Senator Scoffs at Agency “Who Me?” Defense

The Senator scoffed at Throckmorton’s assertion that because the panel was not initiated by the FDA, the rules prohibiting “pay to play” did not apply.

“I find that claim questionable and truly hope that the FDA will rethink their extremely misguided policy on this matter.”

He added that if the FDA is seriously alleging that its conduct is proper and that payments by the pharmaceutical industry to participate in closed-door advisory panels are not impacting its decisions, then the FDA should have no problem disclosing the requested information to his office in a prompt manner.

### Promoting Public Health and Painkillers

Manchin reminded the Commissioner that her job is to promote public health and that task requires the agency to evaluate scientific data and put the public first. “These recent reports raise serious doubts about the FDA’s ability to make objective and scientifically based decisions regarding the proper treatment of prescription painkillers. Even worse, when challenged by another federal agency, the National Institutes of Health, on the stigma of this ‘pay to play process,’ the FDA balked and continued with the arrangement.”

The painkiller industry is a booming business, wrote Manchin, with profits growing to \$9 billion in the U.S.

As the painkiller market grows, continued Manchin, so does the epidemic of addiction and abuse. “Recent data from the Centers for Disease Control (CDC) demonstrates the role that opioid pain

relievers play in overdose deaths. The CDC study showed that drug overdose deaths increased for eleven straight years since 1999. Sixty percent of the drug overdose deaths (22,134) involved pharmaceutical drug products, and prescription drug products containing oxycodone, hydrocodone, methadone and others represented three-quarters of those deaths (16,651). This is a problem that the FDA must address.”

### Manchin’s Crusade

Manchin has been urging the FDA to reschedule hydrocodone combination drugs from Schedule III to Schedule II. “In spite of these conversations, I continue to be frustrated with the amount of time the FDA has taken to properly schedule these drugs. It has been 4 years since the second petition requesting that the FDA and the Drug Enforcement Administration (DEA) evaluate the proper scheduling of hydrocodone combination drugs. Even more con-

cerning, it has been over 8 months since I testified at the Drug Safety and Risk Management Advisory Committee (DSaRM) where the FDA’s own advisory panel, consisting of leading scientists and researchers in the field, overwhelmingly voted to recommend rescheduling hydrocodone combination drugs.”

The FDA, according to the *Washington Post* has been criticized for failing to take precautions that might have averted the epidemic of addiction to prescription drugs including Oxycontin and other opioids.

“These e-mails help explain the disastrous decisions the FDA’s analgesic division has made over the last 10 years,” said Craig Mayton, the Columbus, Ohio, attorney who made the public records request to the University of Washington. “Instead of protecting the public health, the FDA has been allowing the drug companies to pay for a seat at a small table where all the rules were written.”

Even as the meetings were taking place, the idea of FDA officials meeting with firms that had paid big money for an invitation raised eyebrows for some. In an email to organizers, an official from the National Institutes of Health worried whether the arrangements made it look as if the private meetings were a “pay to play process.”

In perhaps an unrelated reaction, Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research reported said that agency will re-classify hydrocodone-based painkillers, such as Vicodin and Lortab, as a Schedule II substance. Currently hydrocodone combinations are classified as Schedule III.

Well played Senator. But we still want to see the evidence from the meetings. ♦

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# Dr. Robert Haar's Declaration of Independence

BY ROBIN YOUNG

“Let me just tell you something. Insurance companies aren't watching your back, the hospitals aren't watching your back, and the government is certainly not watching your back. Guess what: us docs are not sheep in the headlamp. We're not powerless to do anything or to change anything. We're going to take this healthcare mess into our own hands and we're going to fix it.” – Dr. Robert Haar, Orthopedist to the Upper East Side of New York.

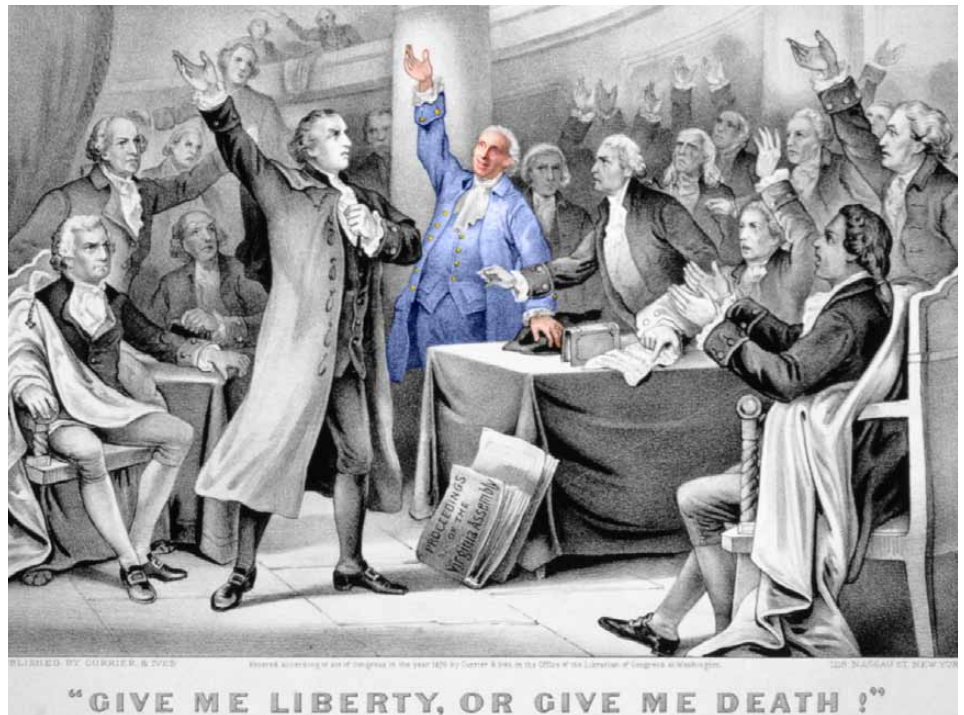


Why is this man smiling? Dr. Robert Haar, M.D.

After about three decades of fencing with insurers, reading *The New York Times* accuse physicians of putting personal gains ahead of patient welfare and working more as an administrator than as a physician, Dr. Robert Haar has had enough.

He's chucking insurance over the side.

Effective this year, Dr. Haar's Regency Healthcare Clinic is going all cash, all transparent, and all patient-focused.



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No more army of administrative assistants filling out forms and fighting with insurance companies to get paid.

Enough is enough.

## In the Patient's Best Interest

Dr. Haar's decision to go the all cash route is fairly recent, but the stimulus behind it was a long time in coming. We caught Dr. Haar after a long day in the clinic and he was very candid about this move. In his view, going all cash, all transparent was really in the best interests of his patients.

As Dr. Haar sees it, “When a patient looks online or tries to call a hospital purchase center and ask ‘what's the charge’ they'll find that a lot of these

hospital staff don't know. They don't know what they'd charge for cash, they don't know what the surgeon's going to charge and they don't even know what the anesthesiologist would charge. When a patient calls the average surgery center or hospital, they find that the staff is clueless. The patient hears ‘we'll get back to you’. And when they get back to the patient, it's always stick-er shock.”

Indeed. We're reminded of the recent *New York Times* article which told the story of a patient in Washington State who'd been told that a knee replacement operation would cost about \$65,000, not including the \$13,000 implant.

We at OTW knew that the *New York Times* article was way off base because

not two weeks earlier we'd published our ranking of the top hospitals in the U.S. for total knee operations (TKA). These were not only the hospitals with the lowest complication rates in the country but also had the highest volumes in the country (those attributes are often found working hand in hand). Not a single one of the hospitals in our survey charged anywhere near \$65,000 for a TKA. In fact, the range of charges was closer to \$17,000 – \$30,000.

### Wal-Mart and Lowe's

And, it seems, the larger companies are also looking at more direct payments to providers like Dr. Haar.

Wal-Mart and Lowe's have decided to offer free hip and knee replacement surgeries to their employees. They launched a program called the Employers Centers of Excellence Network (ECEN) and are starting to offer no-cost (to the patient) knee and hip replacement surgeries for their employees.

The two companies negotiated directly with four orthopedic centers:

- Johns Hopkins Bayview Medical Center in Baltimore, Maryland
- Kaiser Permanente Orange County Irvine Medical Center in Irvine, California
- Mercy Hospital in Springfield, Missouri
- Virginia Mason Medical Center in Seattle, Washington.

In exchange for a flat cash fee for both surgeries (no hidden costs, no extra charges for the anesthesiologist or rehabilitation and no co-pay) Wal-Mart and Lowe's are offering to pay 100% of a hip or knee replacement where everything is covered including travel, lodging and living expenses for the patient and a caregiver. This program covers 1.5 million employees!

Could Dr. Haar be onto something?

"As we all know" said Dr. Haar, "there are millions of people who are uninsured or work for self-funded companies. There is a growing need for providers and facilities that provide transparent pricing where patients know what exactly a price for a procedure is. And that is a global or bundle payment. There are no hidden fees. No surprises at the end of the episode of care. They know exactly what they are paying for up front. Without the administrative

hassle, overhead and layers of bureaucracy that are usually commensurate with insurance based care."

### Dr. Haar's Practice

Dr. Haar received his medical degree from Tufts University School of Medicine and completed his residency at Montefiore/Albert Einstein. He's been treating patients for nearly 30 years.

In line with his new emphasis on cash and transparency, Dr. Haar renamed

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MCL Repair	\$8,900	Arthroscopic Rotator Cuff Repair	\$9,500	Thoracic Percutaneous Discectomy	\$12,500
Arthroscopic PCL Repair	\$9,900	Third Degree Acromioclavicular Dislocation Repair	\$12,500	Lumbar Endoscopic Rhizotomy	\$12,400
Arthroscopic Knee Synovectomy	\$4,950			Sacroiliac Joint Injection	\$1,850

Source: [www.regencyhealthnyc.com](http://www.regencyhealthnyc.com)

his clinic Regency Healthcare ([www.regencyhealthnyc.com](http://www.regencyhealthnyc.com)) and revamped his website. Physically, he is located at roughly 90th Street and York just off the FDR Drive across from a beautiful park. Regency offers a full range of orthopedic procedures including knee, shoulder, foot and ankle, spine, hand and arm.

In fact, here's a selection from his price list which he posts on his website: (See table above)

"The bread and butter of my practice are knee and shoulders. The most commonly performed procedure is knee arthroscopy. Certainly we expect that to be our most common procedure and that is priced the lowest given the rest of the procedures that we offer our patients. I think that is very fair and very attractive approach."

In terms of pricing, Dr. Haar is competitive with his nearby hospitals (which includes Hospital for Special Surgery). In fact, says Dr. Haar, "We're more competitive than the average ambulatory surgery center because our costs are lower! We don't have the administrative load that these other providers do. We don't have all these administrators in \$4,000 suits in burlwood offices.

I never saw a CEO from Aetna or Cigna or UnitedHealth[care] who wasn't running around in custom tailored, thousand dollar suits."

On Dr. Haar's website is the following statement: "We make every effort to decrease the cost of your medical care. Therefore, we request payment arrangements for all office services at the time they are rendered unless prior arrangements have been made. We accept cash, checks, MasterCard, and American Express for your convenience."

### Regulatory Issues

We asked Dr. Haar about any regulatory issues and he said: "From a regulatory, from a compliance or from any other vantage point, this is clean, this is transparent, this is free market, this is an alternative to having to deal with insurance companies.

"Patients generally know what they need, what they want and if they're not sure then they would see their local physician, they might have imaging studies, they may have conservative care. This is an a la carte surgical procedure menu for patients who know they need certain surgical procedures and can select those procedures that

they may need and know exactly what they're paying for.

The all cash, all transparent approach "really doesn't change the type of patients I'm seeing although a sizeable number are un-insured for whatever reason. Either their employers don't offer insurance or they are self-employed or they are small businesses or they can't or don't want to buy insurance. Often they think they're healthy but all of a sudden they have an injury or a condition develops where they need a procedure. So there are very few alternative for these sorts of individuals."

### After 30 Years...

"When you've been in the trenches as long as I have, you get sick and tired of having to hire an army of people to collect your money."

And from the perspective of the patient and companies who are taking a more active role in funding their employee's healthcare needs, Dr. Haar's leap into a cash-based practice may well be the trend of the future. Notably, it is being driven by the physician.

As Dr. Haar told us: "This is just the tip of the iceberg." ♦

# Pagnano, Thornhill Debate Kinematic Alignment of the Knee

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

“**E**nd the tyranny of the tibia!” exclaims Mark Pagnano. “The data show that for 80% of knee replacements mechanical axis alignment works very well, and it’s been a durable, reliable way to do knee replacement.” Counters Tom Thornhill, “We’re going to look back years from now and see that the stuff we’re putting in now is completely obsolete. I’m interested to see if the satisfaction improves if we improve the kinematics.”

This week’s Orthopaedic Crossfire® debate is “Kinematic Alignment of the Knee.” For the proposition is Mark Pagnano, M.D. of Mayo Clinic in Rochester, Minnesota; against the proposition is Thomas Thornhill, M.D. from Harvard Medical School in Boston. Moderating is William Maloney III, M.D. from Stanford University in California.

**Dr. Pagnano:** “Is it time to end the tyranny of the tibia? Historically in total knee replacement [TKR/A] we have focused on durability, which has been appropriate because most surgery has been for marked deformity in older patients. But today we tend to deal with smaller deformities, thus as we move forward more of the attention is going to be focused on function.”

“I propose that the 3D position of the femoral component will be proven to be the prime driver of total knee function...and that we surgeons systematically get this wrong in most TKA. By ‘systematically’ I mean that our surgical technique and our instrumentation do this.”



Current Concepts in Joint Replacement/RRY Photo Creation

“For three decades TKA has been dictated by two rules surrounding the tibia: ‘Cut me at 90 degrees and minimize the thickness of bone you cut.’ There are unintended consequences that impair function. First, why zero degrees varus/valgus? In the early 80s some total knee designs had greater failures when the tibia was in more than three degrees of varus. And why a minimal thickness cut? Because 1980s biomechanics work suggested increased risk of loosening with greater levels of resection.”

“What’s wrong with those rules? First, the total knee designs that highlighted these problems are not currently used on a routine basis. And many designs with coronal plane deformity have done reasonably well in mild degrees of varus. Second, early total knees had few sizes; today there are multiple sizes.”

“And the unintended consequences? If we cut at zero it changes the joint surface in most, but not all, knees; it tends to over-resect the lateral side in

both extension and flexion. That then dictates specific changes to the femoral side. A minimal tibial cut causes relatively tight flexion and extension gaps. Then the surgeon cuts more distal femur, cuts more posterior femur, and these biases are built into the instruments that we use.”

“In a typical varus knee we do all these things to compensate for a minimal thickness tibia cut at 90 degrees: over-resect the femur medially in extension and flexion, change the joint line position in extension and flexion, underestimate the anteroposterior AP size of the femur, change the posterior offset (both medially and laterally), and externally rotate the femur to artificially fill a loose lateral side. Is it any surprise that some TKAs don’t function well?”

“There’s evidence that many modern knees seem to tolerate small degrees of tibial varus, and the depth of resection has no effect on durability. We can explore a new paradigm in which the

femur assumes the preeminent position. And within some—for instance, no tibia more than 3 degrees of varus—make the tibia accommodate the femur.”

“Our new femoral component designs have multiple sizes and we can carefully match the tibial inserts to the femur and maximize the kinematics of current knee designs. So what would this look like? Cut the distal femur to match the anatomy. Make the thickness of the cut match the thickness of the implant, recognizing that cartilage loss tends to make you over-resect. You should match the AP size to the native femur, recognizing that posterior wear tends to make us undersize by one half or one size in modern designs. Remember that modern designs have three millimeter sizing increments. And in femoral rotation with the typical varus knee any additional rotation is abnormal. Your posterior sizing and rotation guide already positions the guide in some degree of external rotation. When you account for cartilage loss, the proper rotation relative to native anatomy is close to zero.”

“Then you balance the knee, but that’s done on the tibial side. If the native is zero, cut at zero; if it’s 2 degrees of varus, cut at 2 degrees of varus. If it’s more than 3 degrees, then just go to 3 degrees. You should resect enough tibia to make an extension gap. Then re-cut as needed.”

“So in 2013 modern knee replacement is durable enough to let us explore ways to get better function. One approach is to consider the femur as the prime driver of function.”

**Dr. Thornhill:** “I agree with virtually everything Mark said, but you’ve got to limit it to 3 degrees of varus. So is kinematic alignment in TKR a new concept? Not really.”



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“Kinematic alignment aligns the best fitting component along the transverse axis of the femur (more valgus) and then aligns the tibial component perpendicular to the femoral axis, risking varus. You remove the osteophytes to restore ligament length and balance, and then the knee rotates around the femoral condylar axis... and you don’t have to do as much soft tissue balancing.”

“Some of the drivers of this are custom instruments, custom prostheses, and some of the newer technology knees. Many of the companies have attempted to recreate normal kinematics to improve patient satisfaction, assuming that those two things are linked.”

“When I say that it’s not completely new, I mean that in terms of the coronal alignment if you go back to the PCA Universal Instruments you see that it put the femur in 7, 9, or 11 degrees of

valgus and the tibia in 3 degree of varus. One of the reasons for failure was that if you aim for 3 degrees you may get 5 degrees or even more.”

“Regarding coronal alignment and early failure due to tibia vara, Stephen Howell’s 2013 study involved 214 knees and a mean follow up of only 38 months... but there were no differences in the kinematic versus the mechanically aligned knees. But if you examine the scattergram, over 75% of the tibial components were in varus and the function was good regardless of the alignment category. In a 2010 study from Mayo Clinic they defined the mechanically aligned knee as being in the central portion; in their study, almost 25% were malaligned by their criteria. These are some of the best knee surgeons in the world and I think there are rotational errors. This axis is also influenced by the hip, the hindfoot, and the fore-

foot...and by dynamic forces including the abduction moment.”

“Total knees are not real knees! And varus is poorly tolerated. In a 2012 *JBJS* study from Germany the authors found that a deviation of 1 degree in an instrumented knee with strain gauges increased the medial load by 5%. In a 2004 study from Merrill Ritter and his group there were over 3,000 knees. They found that varus tibial alignment of more than 3 degrees was associated with a higher incidence of failure. The femoral J curve...whether you should subscribe to the big ball/little ball or a single radius of curvature with less contact area or a gradual reduction in radius, I think remains to be seen.”

“Do we really want to reproduce ‘normal’ kinematics with our current materials, especially because the soft tissues are bad? As for the constitutional varus issue, we can refer to Johan Belleman’s study with 250 asymptomatic healthy volunteers. Of these, 32% of males and 17.2% of females were in constitutional varus. When you’re doing a total knee on someone like this I don’t think you want to put them back into the classic mechanical alignment because you’re going to overstress and have to balance more.”

“So I end with George Santayana: ‘Those who cannot remember the past are doomed to repeat it.’”

**Moderator Maloney:** “Mark, a rebuttal?”

**Dr. Pagnano:** “The data show for 80% of knee replacements that mechanical axis alignment works very well, and it’s been a durable, reliable way to do knee replacement. If we’ll primarily be dealing with patients with marked bone deformities or bone loss that remains

the right way to do knee replacement. But for a subset of patients where function is the prime driver it’s not going to be changes in implant design, but changes in surgical technique that get us to better function for patients who are not quite satisfied with their knee.”

**Moderator Maloney:** “Tom?”

**Dr. Thornhill:** “We’re going to look back years from now and see that the stuff we’re putting in now is completely obsolete. I’m interested to see if the satisfaction improves if we improve the kinematics. And if we improve the kinematics and have the component drive it to normal kinematics and you get a conflict with the soft tissues then you’re going to make it harder to put in...and maybe have a higher failure rate.”

**Moderator Maloney:** “How do we know if we are improving the kinematics?”

**Dr. Thornhill:** “There are some good simulators. I can’t really tell you that those simulators are in fact reproducing, but I think it’s going to be radiostereometrics (RSA) and doing studies where you’re confirming in vitro the kind of things you see on simulators.”

**Moderator Maloney:** “I agree that improving kinematics is important, but I think we’re a long way from being able to accurately measure that during activities of daily living. Mark, I’m more confused than ever on alignment. Is it the same for every patient?”

**Dr. Pagnano:** “One of the fundamental problems is trying to come up with one rule for all patients, when realistically there’s probably an ideal alignment for every individual patient...and there is some penalty to pay as soon as you deviate from that.”



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\* Walsh WR, Oliver RA, Gage G, et al. Application of resorbable poly (lactide-co-glycolide) with entangled hyaluronic acid as an autograft extender for posterolateral intertransverse lumbar fusion in rabbits. *Tissue Eng Part A*. 2011;17:213-220.

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**Moderator Maloney:** “Tom, what’s your goal for femoral component positioning? Is it the same for every patient?”

**Dr. Thornhill:** “I’d never put a valgus knee in more than 5 degrees of femoral valgus by my cut. A varus knee I’d put that in 5, 6, or 7 degrees.”

**Moderator Maloney:** “How about the rotational alignment?”

**Dr. Whiteside:** “I’ve changed. I’ve used predominantly the transtrochlear axis.”

**Moderator Maloney:** “Using the transepicondylar axis is hard to do with small incision surgery, so are you making a more standard incision to do that?”

**Dr. Thornhill:** “I make an incision so that I can see everything I need to do.”

**Moderator Maloney:** “Mark?”

**Dr. Pagnano:** “We’ve seen that the size of the incision makes little difference when you consider all the other things we do in contemporary knee replacement with regard to pain management, rapid rehabilitation, and patient expectations. Surgical technique as far as the size of incision or approach really makes no difference.”

**Moderator Maloney:** “So for the valgus knee do you not want to go more than 5 degrees?”

**Dr. Pagnano:** “I don’t accept an arbitrary number, so the caveat would be that if a patient has a post-traumatic deformity that’s a totally different situation. But by and large I’m looking at the native anatomy and as long as that doesn’t result in some bizarre alignment

like 15 degrees of varus or valgus I’m letting that be my starting point.”

**Moderator Maloney:** “You talked about tibial varus and looking at the preop X-ray. How do you estimate that when a patient’s got fairly bad wear on the medial side?”

**Dr. Pagnano:** “That can be difficult. Many of those patients with marked wear actually have posteromedial wear so you can sometimes define a point anteriorly to get that slope. Other times you can look at the opposite knee and get some idea.”

**Moderator Maloney:** “Thank you both.” ♦

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## OIG POD Report: The Rest of the Story

BY JOHN STEINMANN, D.O.

On October 24, 2013, the U.S. Department of Health and Human Services, Office of Inspector General (HHS/OIG) released a study into the prevalence and use of spinal devices supplied by physician owned distributors (PODs).

This study was conducted in 2012 and consisted of 971 random spinal fusion cases billed to Medicare from 589 hospitals. Hospitals responded to questionnaires and provided hard copies of invoices. HHS/OIG then electronically analyzed this data.

### OIG Findings

This study identified that:

1. Approximately one in five spinal fusions are supported by a physician owned distributorship
2. Surgeons using devices supplied by a POD implanted 13.4% fewer devices per surgery than surgeons obtaining products through traditional distribution
3. There were no identifiable costs savings on devices supplied by the PODs
4. Spinal fusion surgery grew at a rate of 21% in those hospitals that used PODs vs. a rate of 9% at all hospitals
5. Spinal re-fusions at hospitals using PODs decreased from 6% prior to obtaining implants from PODs to 5% after contracting with PODs.

HHS/OIG tackled this complex issue and attempted to provide meaningful data about this newer distribution model. While there are significant



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limitations in this study and we do not know if any of the results carry statistical significance, some observations seem warranted.

### What the OIG Didn't Find

First, the claim that PODs save money could not be established. A study published on the web site of the American Association of Surgeon Distributors (AASD), however, demonstrates that in the select group of AASD member distributorships, the cost savings were very substantial.

This discrepancy is not hard to reconcile as the OIG largely studied a model without structure or standards while the findings reported on the AASD web site refer to ethically and legally structured PODs

Second, the frequently cited criticism that PODs incentivize increased use of spinal devices and an increase in refusal rates was also not supported by this study.

In a spinal fusion procedure, the surgeon determines the number of implants to place and where to place them within the spine. There is no scientific consensus as to the optimal implant density for spinal fusion procedures. The OIG report found that when a POD provides the implants, the implant density is 13.4% less than with the traditional distribution model.

This finding of lower implant density in POD cases, suggests that surgeon owners, as a whole, do not make surgical implant decisions based on their financial interests.

Lastly, the finding that spinal fusion surgery grew at hospitals that utilize PODs is certainly of concern.

But by HHS/OIG's own admission, there is not sufficient information to indicate the reason—was it due to a financial incentive or due to the surgeon's desire to reduce his or her inventory requirements by consolidating to fewer hospitals or growing partnerships between hospitals and surgeons to create centers of excellence.

In the end, this study resulted in a draw; implant usage and re-fusions went down with PODs, while costs were the same and fusion rates went up—in a completely unregulated model that has no standards by which participants must act.

#### **AASD Guidelines, Transparency and Disclosure**

Consider what a different picture this study would paint if there were guidelines that required disclosure, utilization tracking and cost savings.

The American Association of Surgeon Distributors has set such standards and for the 11 ePODs (ethical PODs) that have gained membership, the story is quite different. Two separate studies have demonstrated 36% cost savings with no increase in use of spinal devices among members of the AASD.

This study is available on the AASD web site at [aasdonline.org](http://aasdonline.org). The AASD standards ensure transparency, disclosure, legal compliance, utilization tracking and cost savings, all addressing valid concerns of the HHS/OIG's office. These AASD standards are becoming an increasingly recognized framework for the legal and ethical application of this valuable model.



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### The Narrative: “Docs in Business Is Bad”

There is a clear interest on behalf of the existing medical device industry to eliminate the competition brought on by this model and a clear interest by the media to report only what is “interesting or sensational.”

Each has its pre-established narrative and looks only to accept those facts that support that narrative. The narrative, for both, appears to be that, “Doctors in business is bad.”

Of the five conclusions of the study cited above, you will not find the media or industry discussing that there was a decrease in implant usage per surgery in those cases using devices from a POD nor will you hear the media or industry reporting that the rate of re-fusion surgery went down, instead you will only hear that there were no cost savings and an increase in spinal fusion rates. Everyone has an agenda.

### Providers Must Ensure Quality and Cost

It is time to let common sense speak. There exists a clear market failure when we, in the U.S., pay twice what Europe does for U.S. manufactured devices. This is not an insignificant market failure either, representing a \$10-\$15 billion dollar overpayment annually by the American public.

Corporate business interests simply cannot be expected to shepherd the necessary transition to greater value in healthcare. Instead, the providers of health care must step up and ensure the American public obtains the highest quality healthcare for the lowest cost. This must be done in a structured



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environment that ensures transparency and value.

Endorsement of the standards of the American Association of Surgeon Distributors will immediately result in billions of dollars of saving to the healthcare system and signal the American public's demand for change.

#### Where Do We Go?

As the HHS/OIG concludes this study and indicates that they are offering no recommendations, where do we go from here?

The “bad doctor” stories are getting old. While such stories may increase viewer-

ship or readership, they will never lead to a solution that will improve the value of healthcare in America. The price of orthopedic and spinal devices in America is excessive and there has never been a credible study or opinion that would suggest otherwise.

The properly structured physician owned distribution model (ePOD) effectively restores market forces and results in considerable societal benefit. While it is understood that left without structure, abuse potential exists, there is proof that endorsing a set of standards such as those published by the AASD will result in patient protections, necessary transparency and very meaningful healthcare savings. ♦

# New Data on 3-Hour Outpatient Partial Knee Replacement // More Pain for Younger Hip Replacement Patients // ACL: Independent Drilling of the Femoral Tunnel Needed

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

**O**utpatient Uni Knee Arthroplasty...Home in 3 Hours! Don't fear the outpatient experience, says the largest study ever on outpatient partial knee replacement. Robert S. Gorab, M.D. is the chief medical officer at the Hoag Orthopedic Institute (HOI) in Irvine, California. He tells *OTW*,

“Our study, just published in *The Journal of Arthroplasty*, found that after unicompartmental knee arthroplasty (UKA), day of surgery discharge for appropriate patients can be both safe, efficient and even increase patient satisfaction. We took 160 consecutive patients with appropriate risk profiles and performed all the procedures on an outpatient basis. We found that there were no readmissions, no re-evaluations for nausea, no falls, and no acute post-surgical complications. We had a broad age range—people in their 40s all the way up to 83 years of age. And the average length of stay was less than three hours!

The success of these procedures can largely be attributed to the strong educational process that we have at our facility. There are both nurse practitioners and physician assistants that work through the educational process with the patient; they review safety issues and provide education for the family. In all, they spend approximately an hour and a half with each patient the week before surgery in order to optimize the entire process. Some patients also receive pre-



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surgical physical therapy, such as gait training with ambulatory aids.

I believe that in order to successfully perform these partial knee replacement surgeries on an outpatient basis you need a facility with solid orthopedic infrastructure that performs a reasonable volume to handle these larger procedures. The administrative team, in cooperation with the physician leaders, must spend time standardizing surgical protocols and recovery pathways to optimize results. We also have a physical therapy department in our office that sees the patients after surgery and before they go home to ensure they are safely discharged.”

## 20% Have Severe Thigh, Hip Pain After Hip Replacement

Despite improvements in hips implants, thigh and groin pain remain challenges for many young, active patients. Ryan Nunley, M.D., assistant professor of orthopedics at Washington University in St. Louis, tells *OTW*,

“We have just presented our work indicating that the incidence of thigh and groin pain in young, active hip replacement patients is underreported. However, we found that when you ask about these issues in a blinded way (using a mailed survey) they're more honest about the pain. A large percentage of these patients

have thigh pain after hip replacement and 10-20% have severe thigh pain and lateral hip pain; they just learn to live with it over time.

The native hip socket is not a perfect hemisphere, so we put in a metal hemisphere that may overhang and rub against the tendon if we don't get the fitting just right. On the femoral side most surgeons are currently using uncemented tapered stems with conventional length implants which might account for the rate of thigh pain.

Several companies are coming out with shorter stems, the thought being that perhaps if the stem didn't go down as far into the bone then there may be less thigh pain. We are currently studying this at our institution, comparing shorter stems to longer devices to see if the former improve functional outcomes.

As in so many surgical situations, it is about managing expectations. When patients are told that they could have thigh pain or lateral hip pain then they expect it and report higher satisfaction rates. Our current implants for hip replacement are much improved, but thigh and groin pain are a real challenge for some patients. It's especially important to develop better implants because young, active patients are the fastest growing segment of the hip arena."

**Disc Herniation and Pain: New Understandings of a Very Complex Disease Process**

Irving M. Shapiro B.D.S., Ph.D. is the director of the Division of Orthopaedic Research at Thomas Jefferson University in Philadelphia. He tells OTW, "My colleague Dr. Risbud and I have just published a review article in *Nature Reviews Rheumatology*

and a series of articles in the *Journal of Biological Chemistry* and *The American Journal of Pathology* on the events that trigger degenerative disc disease and the molecular changes that are linked to the generation of radicular pain. Both of these processes are initiated by an increase in levels of inflammatory cytokines especially TNF, IL-1  $\alpha$ , IL-1 $\beta$ , IL-6. These agents provoke the synthesis of matrix digesting enzymes especially MMPs and ADAMTSs which degrade matrix macromolecules within the nucleus pulposus. With loss of matrix constituents, there is often tearing or herniation of the annulus fibrosus, leading to vascularization and chemokine-dependent migration of immune cells into the disc. These cells further amplify the inflammatory state of the disc, and elicit a rise in levels of neurogenic molecules including neurotransmitters and neuromodulators. These molecules influence the activities

of nociceptive neurite sprouts from the dorsal root ganglion and cause radicular pain."

Dr. Risbud added, "While the immediate approach to preventing disc pain is to prevent the release of inflammatory molecules, a more subtle approach might be to limit immune cell invasion into the herniated disc."

**Michael Bronson, M.D. Named Honoree by Arthritis Foundation**

Dr. Michael Bronson, vice chairman of the Department of Orthopaedic Surgery and chief of the Joint Replacement Center at the Icahn School of Medicine at Mount Sinai, has been named as the Medical Honoree by the Arthritis Foundation at their annual Jingle Bell Run/Walk on Saturday, December 7, 2013.

Dr. Bronson is being honored by the Arthritis Foundation for his contin-

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ued efforts to assist those who live with arthritis. He will serve as the key medical spokesperson for the disease itself, treatment and quest for a cure. Dr. Bronson will be raising awareness about the disease and money through with the goal of helping New York City event organizers reach the fundraising goal.

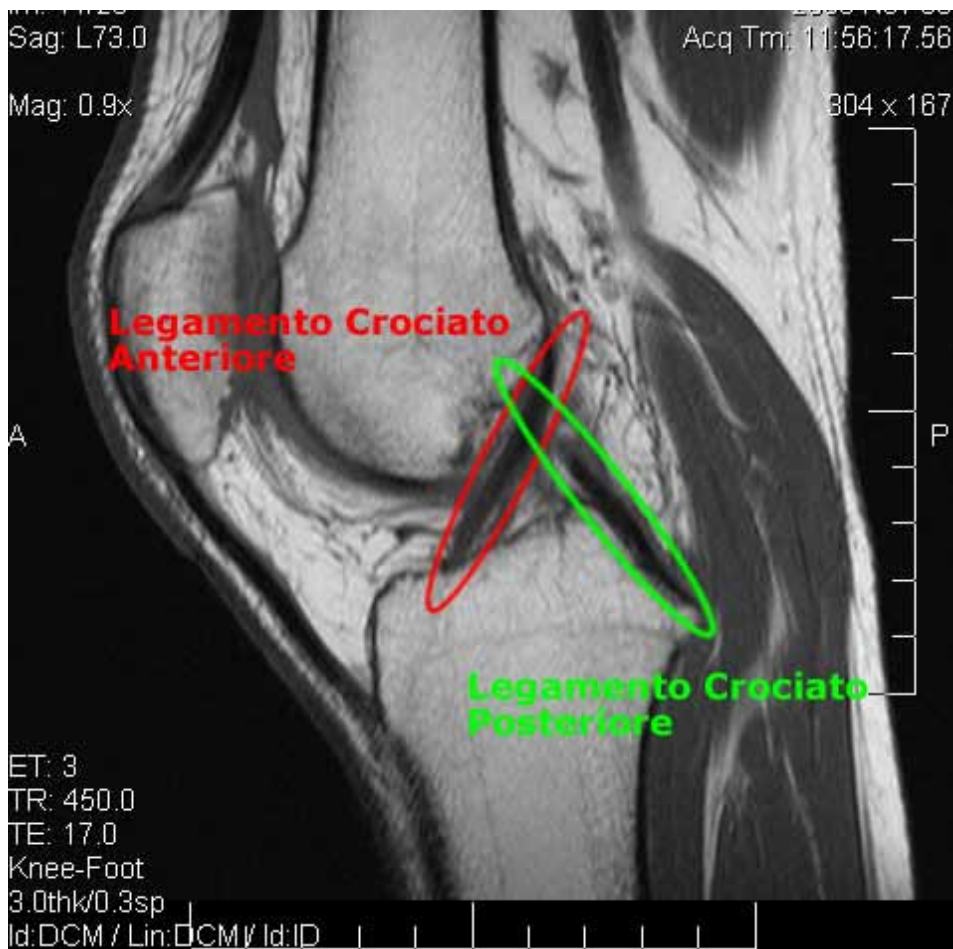
Dr. Bronson is the founding surgeon of the Joint Replacement Center and LeFrak Center for Patient Education at the Icahn School of Medicine at Mount Sinai, one of the leading centers of its kind in the country and the only one of its kind in New York City. Dr. Bronson is one of the nation's leading orthopedic surgeons specializing in the field of joint replacement. He has been published extensively and lectured around the world and has appeared on national and local television and radio. He has been interviewed extensively in *The New York Times*, *USA Today*, *U.S. News and World Report*, *the Associated Press*, *Bloomberg* and other publications.

**ACL Reconstruction: Independent Femoral Drilling Needed** “Focus on what’s important,” says Mark D. Miller, M.D. of the University of Virginia (UVA). Dr. Miller, the S. Ward Casscells Professor of Orthopaedic Surgery at that institution, tells OTW,

“All of the recent sensationalism in the lay press regarding ‘new ligaments,’ PRP, and other ‘advances’ need to wait for the science to catch up with the hype. The field needs to focus on more important things, like getting ACL [anterior cruciate ligament] reconstruction right. At UVA we are studying techniques to ensure the correct location of tunnels for ACL grafts. We are conducting lab and clinical research to evaluate ideal tunnel locations. We have

just completed a series of three high tech CT cadaver studies which demonstrated the need for independent drilling of the femoral tunnel instead of the traditional drilling through the tibial tunnel (trans-tibial). Trans-tibial drilling does not consistently put the femoral tunnel in the footprint of the ACL, and that is what is required for an anatomic ACL reconstruction. Independent femoral drilling does bring new challenges, however, and we have developed ways to protect the medial femoral condyle and to ensure that the femoral tunnel is long enough. We are also researching the ideal tibial tunnel location in ACL reconstructions; several recent studies (including our own) have suggested that we need to move our tibial tunnels more anteriorly.

The biggest obstacle to new techniques being popularized is that it requires people to learn new techniques. Sadly, a lot of surgeons are unwilling to change the way that they have done things in the past. We are in the process of planning more research to prove that anatomic ACL reconstruction yields the best long term results. As pay for performance, bundled payments, preferred providers, and other new insurance issues arrive, we all see that the future of remuneration depends upon results, and adopting new techniques is an important part of that concept. Those surgeons who don’t keep up to date with advances may take some time to be convinced of the value of it. We should all embrace the concept of ‘lifelong learning.’” ♦



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## It's Official. DePuy Settles Hip Lawsuits for \$2.5 Billion

It's official. DePuy Orthopaedics, Inc. announced on November 19, 2013, that the company and a court-appointed committee of lawyers representing ASR hip plaintiffs have reached a \$2.5 billion deal to compensate patients with failed hip revision surgeries.

According to *Bloomberg*, Susan Sharko, one of the company's lawyers, told U.S. District Judge David Katz in Toledo, Ohio, that the company would pay an average of about \$250,000 for each surgery and cover related medical costs for an estimated 8,000 patients. It's not the \$4 billion previously reported by *Bloomberg*, but the amount could go higher because the settlement doesn't bar patients whose hips fail in the future from seeking compensation. That may add billions of dollars to the ultimate value of the settlement.

Andrew Ekdahl, head of DePuySynthes Joint Reconstruction, said the settlement program provides compensation for eligible patients without the delay and uncertainty of protracted litigation. "We are committed to the well-being of ASR patients, as demonstrated by the voluntary recall and the program providing support for recall-related care."

The company issued a statement saying the settlement agreement will help bring to a close significant ASR litigation activity in the U.S. However, some lawsuits in the U.S. will remain." DePuy will continue to defend against remaining claims and believes its actions related to the ASR Hip System have been



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appropriate and responsible," said the statement.

In August 2010, the company said it issued a voluntary recall of the ASR hip system after receiving new information from the UK National Joint Registry as part of the company's ongoing surveillance of post-market data concerning the ASR, which showed a revision rate that was not in line with data previously reported in that registry. "The product continues to perform well in some patients. Since the recall decision was made, DePuy has worked to provide patients and surgeons with the information and support they need, including the global program providing support for recall-related care, which has thus far resulted in thousands of payments to patients," said the company.

Under the terms of the accord, only plaintiffs who had an ASR hip implanted in the U.S. and had it removed by August 31, 2013, are eligible for this settlement, Sharko told *Bloomberg*. The patients must have had the implant

for at least 180 days before having it removed, she said.

### Payment Structure

The program is structured in two parts, she said. Under one part, patients will receive a base award of \$250,000, subject to reductions. Under the other part, the award will go higher for patients who can demonstrate "extraordinary injuries" related to their hip implant or removal, Sharko said.

The company was facing about 12,000 suits filed in federal courts and state courts in California, Illinois and New Jersey. The settlement covers the more than 7,500 patients who had surgery to have DePuy hips removed. The remaining claims were filed by patients who haven't yet had revision surgeries. According to the company, funds had already been set aside to cover the settlement and are not expected to affect future earnings.

—WE (November 24, 2013)

## Challenging Quarter for Medtronic Spine

It was, in the words of Medtronic, Inc. CEO, Omar Ishrak, a challenging quarter for Medtronic Spine.

Revenue of \$746 million declined 3% on a constant currency basis or 5% as reported. Core Spine revenue of \$636 million was down 1% while BMP revenue of \$110 million declined 17%.

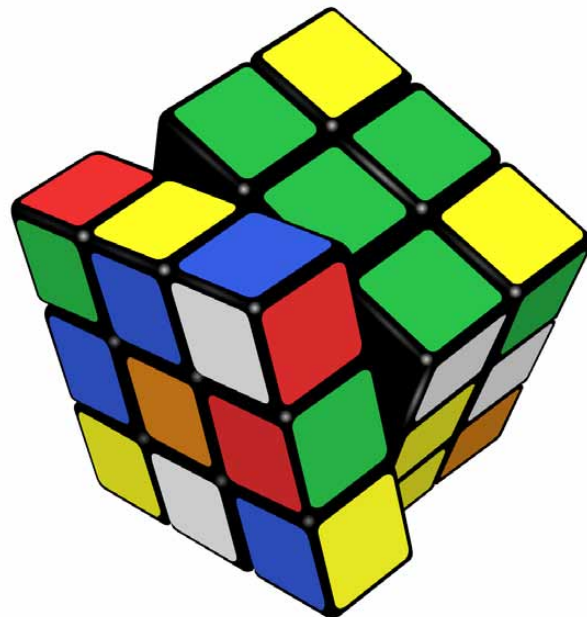
There was some good news. The thoracolumbar, cervical, and other biologic product lines all grew this quarter, both globally and in the U.S., driven, says the company, by procedural innovation and new technologies. There were declines in balloon kyphoplasty and interbody devices.

“We are performing at or better than the market in almost every one of our business lines,” said Ishrak. “This quarter also represented another quarter where our overall organization delivered consistent, dependable growth, with strong performances in some areas offsetting challenges in other parts of our business.”

In spine, we continue to work with the FDA to bring our next generation cervical disc to the U.S. market. And we expect to follow that launch with a series of cervical plate launches in 2015.

### Challenges

Analysts asked Ishrak why the company’s spine business wasn’t performing better. Ishrak noted that last quarter’s spine results were good and he has every confidence that “the cadence of product launches we have in spine actually will deliver over the next few quarters.”



Rubiks Cube / Source: Wikimedia Commons

Medtronic Spine 2Q14	Sales (\$ in millions)	% Change*
Total Sales	\$746.0	down 3%
Core Spinal	\$636.0	down 1%
Biologics	\$110.0	down 17%

Source: Medtronic  
\* constant currency

Chris O’Connell, president of Medtronic’s Restorative Therapies Group said there were a couple of holes in the product line, particularly in the interbody space, and a couple of small categories like peek rods that remain under pressure. “But overall I think our perspective is it’s a relatively stable situation and we expect that the core spine business to be stable into the back half of the year. As pointed out, the BMP and the BKP businesses are both hurting us right now, although the kyphoplasty business does seem to be showing signs of stabilization in the U.S. and we watch the BMP part closely.

Jefferies Analyst Raj Denhoy said the weak performance reflected “continued end-market weakness and InFuse sales

that continue to plummet, with management now expecting a mid-teens sales decline for the year.”

### Stable Spine Market, Innovators Taking Share

After Medtronic’s report, Piper Jaffray analyst Matt Miksic says he continues to view the overall spine market as stable and modestly improving low single digit market growth, with smaller innovative players like LDR, Globus, and NuVasive taking share from larger legacy players like DePuySynthes and Medtronic. He expects those companies to continue to gain share and outperform the market going forward

“Based on our analysis of Q3 results across the spine market we estimate the market grew ~3% again in Q3, which is slightly higher than Medtronic’s ‘flat-ish’ commentary but roughly in line with ~3% growth reported in Q2.”

—WE (November 24, 2013)

## IPO for Amedica

Silicon nitride orthopedic and spine device maker Amedica Corporation is hoping to raise \$35 million in an initial public offering (IPO).

The Salt Lake City, Utah-based company filed papers with the U.S. Securities and Exchange Commission (SEC) on November 8, 2013 to raise the funds. The company had initially filed the SEC documents confidentially in September. It's not the first attempt at an IPO, as the company previously filed for an IPO in May 2007, before withdrawing the offering three months later based on market conditions.

Founded in 1996, the company had sales of \$23 million for the 12 months ended June 30, 2013.

The plans are to list on the NASDAQ exchange under the symbol AMDA.

Amedica uses its silicon nitride technology platform to develop, manufacture and sell a broad range of spine medical devices and is developing products for use in total hip and knee joint replacements. The company operates an ISO 13485 certified manufacturing facility,

and, its spine products are FDA cleared, CE marked, and are currently marketed in the U.S. and select markets in Europe and South America.

The company claims its devices offer doctors and patients an alternative to PEEK and titanium that is osteopromotive, anti-infective and may result in faster fusion. It is the only company in the world that has FDA clearance to manufacture and distribute silicon nitride implants.

Earlier this year, Amedica released the Valeo II AL interbody fusion device in the U.S.; and signed a distribution agreement with K2M to get its silicon nitride-based implants into the European market.

In February 2006, the company received FDA 510(k) clearance for the first load-bearing ceramic spinal device, and in 2007, for its Valeo Interbody Fusion Devices, Cervical Plating System and Pedicle Screw System. In its product development pipeline, the company points to a ceramic cervical disc, and hip and knee implants that make full use of silicon nitride technology's material properties.

—WE (November 24, 2013)

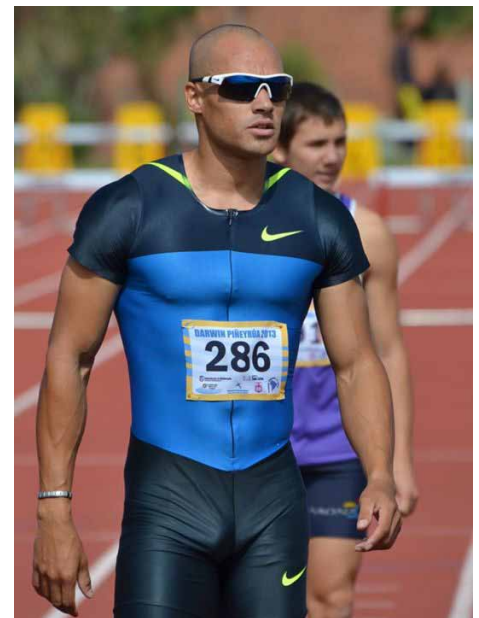


Amedica Corporation/Headquarters

## LARGE JOINTS

### Elite Athletes Protected Against Diabetes

A study of almost 400 former elite male athletes shows that former status as an elite athlete reduces the risk of developing type 2 diabetes in later



Andres Silva / Source: Wikimedia Commons and N.varcasia

life by 28%. The research appears in *Diabetologia*, the journal of the European Association for the Study of Diabetes (EASD), and is by Dr. Merja Laine, University of Helsinki, Helsinki, Finland, and colleagues.

The study of Finnish male athletes follows-up on work that began in 1985, when a questionnaire was sent to 1,518 former athletes and 1,010 controls, and further questionnaires were sent out in 1995 and 2001. In 2008, an invitation to participate in a clinical study was sent to all former athletes who were still alive (747, of whom 392 participated) and controls (436, of whom 207 participated) and had answered at least

one of the previous questionnaires. The clinical study included a physical examination, laboratory tests and questionnaires.

The former athletes were divided into three groups based on their active career sport: endurance, mixed and power sports. Participants without a history of diabetes underwent an oral glucose tolerance test (75g of glucose delivered over 2 hours). Current volume of leisure-time physical activity (LTPA) was determined by self-reported questionnaires and expressed in metabolic equivalent hours. Data on reimbursable diabetes medication from participants and non-participants were obtained from a central Finnish register.

The researchers found that being a former elite athlete reduced the risk of developing type 2 diabetes by a statistically significant 28%. However, this reduction varied among the different sports categories: the risk reduction was 61% for those who had had careers in endurance sports (a statistically significant finding) while for mixed sports the reduction was 21% and power sports was 23% (both not statistically significant).

The risk of type 2 diabetes decreased with increased LTPA volume, by 2% per 1 MET-h per week. The former elite athletes also had a 42% lower risk of impaired glucose tolerance (IGT), a precursor state to full blown diabetes. The authors said in the news release, “With ageing, the former athletes maintained their physically active lifestyle better than the controls.” They conclude: “A former career as an elite athlete protected from both type 2 diabetes and IGT in later life. In addition, the volume of current leisure-time physical activity was inversely associated with the prevalence of type 2 diabetes.”

Dr. Laine told OTW, “The former athletes were divided into three groups. The division was made according to the type training needed to achieve optimal results. Endurance sports (long and middle distance running, cross country skiing), mixed sports (soccer, ice hockey, basketball, track and field: jumpers, sprinters, hurdlers, decathletes) and power sports (boxing, wrestling, weight lifting, track and field throwers).”

—EH (November 22, 2013)

## Hip Fracture? Get to the OR ASAP

The speed of surgery after a hip fracture may have a significant impact on outcomes for older patients, and faster may be better, say researchers at McMaster University. Their study, which involved 60 people aged 45 or older, was just published in the *Canadian Medical Association Journal (CMAJ)*.

Of the participants, who hailed from Canada and India, half received accel-

erated surgery within six hours and half had standard care of surgery 24 hours after diagnosis with a hip fracture. Among patients receiving standard care, 47% suffered a major complication of death, heart attack, stroke, pneumonia, blood clot or major bleeding event. However, only 30% of the patients in the accelerated surgery group suffered one of these complications.

“We believe that the shortest time possible to treatment may provide the greatest potential for benefit, as is the case in acute heart attack and stroke,” said Dr. P.J. Devereaux in the November 18, 2013 news release. Dr. Devereaux is an associate professor of medicine and epidemiology at the Michael G. DeGroot School of Medicine at McMaster and co-principal investigator of the pilot trial.

Dr. Mohit Bhandari, a professor of surgery at the McMaster medical school and co-principal investigator, added: “This pilot provides encouraging evidence that accelerated surgery may substantially improve outcomes in these patients.”



Wikimedia Commons and Booyabazooka

Dr. Bhandari told *OTW*, “It has long been perceived that patients with hip fractures should have surgery delayed until they can be ‘medically optimized’ for an operative procedure. These wait times can sometimes result in several day delays while cardiovascular indices are optimized for surgery. Using these approaches, however, have not decreased perioperative mortality from hip fractures over the past 30 years—suggesting that other issues may be at play.”

“Our previous meta-analysis (CMAJ, Simunovic et al.) suggested a trend towards improved post-surgical survival with earlier surgery. This led us to design a trial focused on robustly testing the impact of accelerated surgery on major cardiovascular outcomes. Heart attacks and strokes are both serious events that have been dramatically impacted by early interventions. There is no reason to believe that hip fractures are no less important, and equally impacted by rapid intervention. Our pilot RCT seems to suggest we are right. We are launching the pivotal trial to include centers around the world.”

—EH (November 19, 2013)

## Mitek Launches RIGIDFIX, RIGIDLOOP

Mitek Sports Medicine, part of the DePuy Synthes Companies of Johnson & Johnson, has announced the addition of the RIGIDFIX Curve Cross Pin System, the first of its kind, designed specifically for use with the anteromedial (AM) portal approach to enable a more anatomic ACL (anterior cruciate ligament) reconstruction. The company also announced the launch of the RIGIDLOOP Cortical Fixation System, which when used with the INTRA-

FIX ACL Tibial Fastener System, provides surgeons with a total procedural solution for anatomic soft tissue ACL reconstructions.

In addition, the company announced that two new sizes of MILAGRO ADVANCE Interference Screws (30mm and 35mm) were added to Mitek Sports Medicine’s portfolio for soft tissue and bone-patellar tendon-bone reconstruction.

The RIGIDFIX Curve System uses the AM portal approach, and enables precise placement of two cross pins in the femoral tunnel. The cross pins provide strong fixation and the close to aperture fixation minimizes intratunnel graft micromotion, small movements of the graft inside the femoral tunnel, that may cause tunnel widening. The two cross pins create a compression fit that further enhances 360-degree graft to bone contact. The design of RIGIDFIX Curve is based on the original RIGIDFIX Cross Pin System, which has been used for ACL reconstruction through a transtibial approach for more than ten years.

“An anteromedial approach may provide a more anatomic placement of the graft and greater rotational stability of the knee, compared to transtibial drilling,” said Marc R. Labbé, M.D., Clinical Assistant Professor, Department of Orthopedic Surgery, Baylor College of Medicine, in the November 7, 2013 news release. “The RIGIDFIX Curve Sys-

tem provides a strong, rigid fixation and has features that enhance precision and ease-of-use.”

The RIGIDLOOP System consists of a titanium button that comes pre-loaded with a braided suture loop and offers excellent pull out strength. The new device is available in sizes 15mm-60mm in 5mm increments, as well as an Extra-Large (XL) button for femoral tunnels greater than 6mm in diameter. The system includes an innovative variable depth gauge that calculates total transosseous length, amount of graft in tunnel, socket reaming depth and implant size.

Ian Lawson, worldwide president of Mitek Sports Medicine, told *OTW*, “We look forward to continuing to bolster our knee portfolio in the future so that we can provide customers with advanced procedural solutions.”

—EH (November 18, 2013)



Mitek Sports Medicine

REIMBURSEMENT

## 1,500 Hospitals Hit With Medicare Payment Penalties

The second year of Medicare's Hospital Value-Based Purchasing Program (HVBP) will not be kind to nearly 1,500 hospitals that will be hit with negative reimbursement adjustments. Not surprisingly, physician-owned hospitals again fared the best.

Hospitals are judged on a variety of criteria, including comparative scoring, patient surveys, and a series of quality measures judging the frequency of basic care protocols. Patient outcomes are also part of the equation, with inpatient and 30-day mortality rates making up a quarter of the hospital's score. Some hospital representatives complain that the calculation is skewed towards hospitals with the resources to provide better patient accommodations or those who care for populations that are generally healthier or more compliant.

Patrick Conway, M.D., CMS' chief medical officer and Director of the Centers for Clinical Standards and Quality wrote in his blog that Medicare is no longer a program that "just pays the bills. Acute-care hospitals across the country not only are paid more for higher quality care, they also have skin in the game."

### More Losers Than Winners

According to government records, more hospitals are receiving penalties than bonuses this year, and the average penalty is steeper than it was last year.

*Kaiser Health News* reports that Medicare raised payment rates to 1,231 hospitals, while 1,451 hospitals are being



*Menzies Law/Financial Penalties*

paid less for each Medicare patient they treat.

### Top and Bottom

For half the hospitals, *Kaiser* reports the financial changes that started last month are negligible: they are gaining or losing less than a fifth of one percent what Medicare otherwise would have paid. Others are experiencing greater swings. Gallup Indian Medical Center in New Mexico, a federal government hospital on the border of the Navajo Reservation, will be paid 1.14% less for each patient. Arkansas Heart Hospital in Little Rock, a physician-owned hospital that only handles cardiovascular cases, will get the largest bonus, 0.88%.

Physician-owned hospitals that focus on just a few specialties have tended to do particularly well in the program, as evidenced by the Arkansas Heart Hospital's record bonus.

Hospitals in Maine, Massachusetts, Nebraska, New Hampshire, North Carolina, Utah and Wisconsin are faring the best, with 60% or more of hospitals getting higher payments, according to a *Kaiser* analysis. Medicare is reducing

reimbursement rates for at least two-thirds of hospitals in 17 states, including California, Connecticut, Nevada, New Mexico, New York, North Dakota, Washington and Wyoming, as well as the District of Columbia.

### Penalty and Bonus Breakdown

The average penalty grew to 0.26 percent, up from 0.21 percent in the first year of the program. North Georgia Medical Center in Ellijay is the only hospital besides Gallup to lose more than 1 percent of its reimbursements: it will lose 1.04 percent. Denver Health Medical Center, a highly respected safety-net hospital, is losing 0.71 percent of its reimbursements. The hospital that was penalized the most last year, Auburn Community Hospital in upstate New York, reduced its 0.90 penalty, but will still lose 0.55 percent.

The average bonus was 0.24 percent, almost the same as last year's 0.23 percent. Large bonuses are going to some major teaching hospitals, such as Thomas Jefferson University Hospital in Philadelphia and Duke University Hospital in Durham, N.C. Most are being distributed among smaller institutions,

such as Pikeville Medical Center in Kentucky.

Most winners from last year, according to the Kaiser survey, stayed winners and losers stayed losers. But there were some switches. Oaklawn Hospital in Marshall, Michigan, improved its score the most from last year. In place of a 0.26% penalty, Oaklawn will receive a 0.65% bonus. A number of prominent academic medical centers also turned around their scores. Vanderbilt University Medical Center in Nashville, Massachusetts General Hospital in Boston, New York-Presbyterian Hospital in Manhattan, Cedars-Sinai Medical Center and Ronald Reagan UCLA Medical Center, both in Los Angeles, and Yale-New Haven Hospital were among the 300 places that went from a penalty to a bonus.

A total of 416 hospitals that won bonuses last year will be penalized this year. Centura Health-St. Thomas More Hospital in Canon City, Colorado, dropped from a 0.08% bonus to a 0.72% penalty, the largest decrease.

### HVBP Program

Under the HVBP program, Medicare reduced payment rates to all hospitals by 1.25%. It set the money aside in a \$1.1 billion pot for incentives. While every hospital is getting something back, more than half are not recouping the 1.25 payment they initially forfeited, making them net losers. The payment adjustments are applied to each Medicare patient stay over the federal fiscal year that started October 1 and runs through September 2014. The potential bonuses and penalties were higher than they were last year, when the maximum at stake was 1%.

—WE (November 24, 2013)

## SPINE

### Sailing as Rehab for Spinal Cord Injury Patients

Researchers from the Kennedy Krieger Institute have announced the results of a pilot study demonstrating that use of a virtual therapeutic sailing simulator is an important part of rehabilitation following a spinal cord injury (SCI). While this study involved only people with SCI, the authors indicate the possibility that this approach may be used with people with a wide range of injuries including loss of limbs and brain injury.

The study, supported by Kennedy Krieger Institute's International Center for Spinal Cord Injury, the Johns Hopkins University and the University of Melbourne, Australia. This work, published in the *American Journal of Physical Medicine & Rehabilitation*, found that using a hands-on sailing simulator over a 12-week period helped participants safely learn sailing skills in a controlled environment, ultimately improving their quality of life by gaining the ability to participate in a recreational sport.

According to the authors, this study is one of the first to scientifically quantify the positive impact of therapeutic sailing following a spinal cord injury, including a significant increase in overall self-confidence and sense of accomplishment among participants.

"Sports and recreation are a very important component of the rehabilitation process, not only for general physical well-being, but for improving overall quality of life for patients who have sustained spinal cord injuries," says Dr. Albert Recio, study author and physician in the International Center for Spinal Cord Injury at Kennedy Krieger Institute, in the November 20, 2013 news release. "We are very pleased with the results of this unique training program and hope that this type of recreational tool can also help in the rehabilitation of patients with other disabilities."

Study participants had chronic spinal cord injuries that occurred more than six months prior to beginning use of the Virtual Sailing VSail-Trainer, the first sailing simulator available for people with paralysis. The stationary, motorized sailboat cockpit features specialized software that enables patients to navigate the boat around a virtual course in the same way as an actual sailboat in the water. Electronic sensors



Image created by RRY Publications, LLC / Sources: Wikimedia Commons and Craig Vetter/Morguefile and Charmomile

give the participant real-time feedback that matches their movements and allows them to control wind strength and water conditions.

During each session, a therapist assessed several physical and neurological indicators and compared the results to measurements taken prior to beginning the training program. All participants completed a questionnaire at the beginning and end of the study designed to evaluate their quality of life and self-esteem.

The results showed that all patients showed a significant positive increase in overall quality of life, including increased self-confidence and sense of accomplishment. Following completion of the training program, all subjects were able to successfully sail and perform specific maneuvers on the water at a sailing center in Baltimore, Maryland. And importantly, the subjects were able to participate in a sports activity with their respective family members and experienced a sense of optimism about the future.

—EH (November 21, 2013)

PEOPLE

**Dr. Hosalkar's Retractions from Orthopedic Journals**

Our friends at Retraction Watch (RW) reported on November 11, 2013, that a third orthopedic medical journal has retracted a paper submitted by San Diego-based orthopedic surgeon, Harish Hosalkar, M.D.

**Orthopedic Reviews Retraction**

The journal, *Orthopedic Reviews* issued the following notice:

*"The authors have retracted their paper "Open reduction and internal fixation of displaced clavicle fractures in adolescents." Specifically, upon further review, the authors have noted some errata in the data collection. The authors' clinical experience does not lead them to change the main conclusions of the paper, but due to the observed mistakes, they decided to retract the previously published article."*

RW calls this a "nifty construction. Our data don't support our beliefs. But our beliefs are right, so we can ignore the date. Where have we heard that before?"

**Journal of Children's Orthopaedics Retraction**

Back in July, RW reported that Dr. Hosalkar became embroiled in a messy affair after problems surfaced in data he had published while at Rady Children's Hospital — a facility he left under a cloud of recriminations. One of the retracted papers, titled "Clinical effectiveness of continuous passive motion (CPM) following femoroacetabular impingement surgery in adolescents," appeared last year in the *Journal of Children's Orthopaedics* (the official journal of the European Paediatric Orthopaedic Society).



Scripps Health San Diego  
Harish Hosalkar, M.D.

Dr. Hosalkar wrote the article with James Bomar, a researcher who had done an internship at Rady Children's

**Clinical Orthopaedics and**

**Related Research Retraction**

The second paper, "Does Incisional Wound VAC after Major Hip Surgery in

Obese Pediatric Patients Reduce Wound Infection and Scar Formation? A Pilot Study," appeared in *Clinical Orthopaedics and Related Research*, also in 2012. The retraction notice read that *Clinical Orthopaedics and Related Research* "has been made aware of concerns about the integrity of the dataset" in the paper.

RW also found this erratum, in the *Journal of the American Academy of Orthopaedic Surgeons*, referring to the *Orthopedic Reviews* article:

*"On page 503, the second full paragraph in the second column, which cites reference 36 (Hosalkar HS, Parikh G, Bomar JD, Bittersohl B: Open reduction and internal fixation of displaced clavicle fractures in adolescents. Orthop Rev [Pavia] 2012;4[1]:e1), should be disregarded. There may have been inaccuracies in the collection of data published in the paper cited as reference 36."*

*"The Journal regrets the error."*

RW reported that, according to Bomar who had been looking for help finding a research project, Dr. Hosalkar sent him data that the physician had collected from an earlier study of adolescents who had undergone lower limb surgery. Dr. Hosalkar, however, suggested that Bomar was to blame, and that his sins were of omission.

Dr. Hosalkar said he was clearly responsible for negligent supervision. "But at the end of the day I had to go down to the ultimate rule, that the PI (Principle Investigator) is responsible."

**Alleged Racism**

Dr. Hosalkar told RW that in the wake of the revelations about the bad data he was asked to leave his positions at Children's Specialists of San Diego and at Rady Children's. He attributed his ouster to racism.

“I was the only non-Caucasian physician in the group. ... They wanted to use this to get me out of the practice. They said, ‘You are contaminating the kind of research’ that the institutions wanted to publish,” alleges Dr. Hosalkar.

Bomar told *RW* that the hospital conducted a six-month investigation into the affair and flatly denied that he had made mistakes. “It is an important thing that has been investigated thoroughly ... It was not my data. It was Dr. Hosalkar’s data.”

### Lawsuits Settled

Bomar also told *RW* that two lawsuits were initiated in the matter, which the parties settled for no monetary damages. *RW* spoke with attorneys for both Dr. Hosalkar and his former colleagues, neither of whom had much to say about the matter.

Here is what the Scripps Health San Diego website says about Dr. Hosalkar:

“Throughout his career, Dr. Hosalkar has been featured in several peer reviewed publications and he has book chapters to his credit. He has also received multiple awards for his work.”

Scripps also provided a link to Dr. Hosalkar’s published papers on PubMed. <http://www.ncbi.nlm.nih.gov/pubmed/?term=hosalkar>

To read the full *Retraction Watch* article, click here:

<http://retractionwatch.com/2013/07/23/three-retractions-two-lawsuits-one-institutional-inquiry-for-san-diego-orthopedic-surgeon/>

—*WE* (November 24, 2013)

## Father of Sacramento Orthopedics Dies at Age 93

Frank J. Boutin Sr., a surgeon known by many as the “father of orthopedics” in Sacramento, passed away on November 9, 2013 at the age of 93. Dr. Boutin is survived by his wife of 69

Coast where he served as chief resident at Stanford University Hospital and San Francisco General Hospital. In 1953, the family moved to Woodland, California, so that Dr. Boutin could become the first orthopedic surgeon at the Woodland Clinic.

Robert Szabo, M.D. was a longtime colleague of Frank Boutin. He tells *OTW*,



Robert and Frank J. Boutin

years, Charlotte “Tink” Boutin; daughter, Sue Boutin Atkinson; five sons, Steve, Peter, Don, Frank Jr., and Robert; 15 grandchildren; and seven great-grandchildren. He also leaves a cadre of friends, colleagues and patients whose lives were touched by the “gentleman surgeon.”

Born on June 9, 1920 in Spokane, Washington, Dr. Boutin went on to earn his undergraduate degree from Stanford University in 1942. He then enlisted in the Army, attended Stanford Medical School, and then served at Walter Reed Army Medical Center in Washington, D.C.

After his Army service, Dr. Boutin and his family headed back to the West

“I think Frank would most like to be remembered for being a patient advocate. Two things mattered to him: family and patients...and he treated patients like family.”

“Frank Boutin was one of the first people doing orthopedics in Sacramento. He dispensed a lot of good advice about setting up practices; in fact, he was the ‘go-to’ guy in this respect. He was the quintessential gentleman in every way.”

David Coward, M.D. remembers his friend and colleague as “setting the standard for patient care in the community.” Dr. Coward tells *OTW*, “the man of integrity walks securely.’ Frank J. Boutin Sr., M.D. was such a man. Dr. Boutin loved the practice of medicine and

devoted his life to caring for his patients for over 40 years. He was extremely dedicated to always doing the right thing for the patient. He mentored all of the ‘new orthopedic surgeons’ with his sage advice when we began our orthopedic practices in Sacramento. He had a tremendous influence on the entire orthopedic community in Sacramento. He will be missed, but his spirit will live on. He set the bar at a high level for all of us. Dr. Frank J. Boutin, Sr. was a great man, a wonderful friend and an amazing orthopedic surgeon.”

“Here’s one story from the memorial service that captures his dedication and concern for patient care: ‘Frank would never drink alcohol for 72 hours before any planned surgical procedure. And to take it one step further, he would not drink for 72 hours if there was even a chance he might be performing surgery. Needless to say Frank Boutin Sr., M.D. was not a drinking man!’”

Frank Boutin, Sr., M.D. had influences over many careers, including his son, Frank Jr, who is an orthopedist. Another son, Robert Boutin, M.D. is a professor subspecializing in an orthopedic radiology. He tells OTW:

“The headline in the newspaper called my dad the “Father of Orthopedics in Sacramento”, earning this reputation because he was the consummate professional...always a complete gentleman and skilled surgeon. He was a trusted source to consult on difficult cases, brought his integrity to difficult decision making, and mentored generations of younger orthopedists that subsequently began practicing in the Sacramento area.”

“He was also a go-to guy for getting difficult things done across a broad range of orthopedic disciplines. Reflecting on his career that started

during World War II, I can see why that generation is referred to as The Greatest Generation. His career began by caring for World War II soldiers with orthopedic wounds and training under Sterling Bunnell, the Father of Hand Surgery. But his career also included a wide array of other orthopedic subspecialties, including pediatric orthopedics, spine, arthroplasty, and arthroscopy. Constantly training to learn new techniques/information as it came along was extremely important to him.”

“What would my dad want us to remember about him? His dedication to his patients. After all, what would a weekend be without making several house calls! He loved it.”

“There are so many lessons one could learn from my Father’s life, but one aspect that permeates all others was his sense of duty. Yes, when there was a duty—or work—to be done, he did it. And thrived on it! In fact, I never heard him complain once about work. And much more incredibly, my mother adamantly maintains that she never heard him complain about work. Over 69 years of marriage—without complaining to your spouse about work. *If that’s not proof that they just don’t make ‘em like they used to, I don’t know what is!* Why didn’t he complain? He LOVED his work.”

“As you may know, surgeons like to get up early, and it didn’t matter whether my Father was going to the operating room or to the ski slopes—he was still the most driven person I’ve ever met. My Father had been a child in The Great Depression, and that had made a profound impression on him. As a kid, Dad truly came to know the value of even a single penny...and he wanted us kids to know it, too. So, although we got up early, and we got

to slopes early—and it was cold—we were not cold for long. That’s because, until half-day ski-lift tickets went on sale, at mid-day, Dad would have us side step up the hill—climb the hill under our own power—and then ski down with him. He knew that there is a certain joy that comes with *appreciation* and there is pride that comes with *accomplishment*—even on the ski slopes.”

“Dad headed a bilingual household... not French or Spanish, but ‘medical-ese.’ Not a Thanksgiving goes by that I don’t think of him carving a big juicy turkey, with surgical precision, and then quizzing us on the bird’s anatomy.

“*What do you think this muscle does?*” ...he’d ask.

“*What’s its anatomic origin?*” ... as he meticulously sliced the turkey breast. “*How about its insertion site?*” ... as he put another helping on your plate.

“Those interactions echo every time I quiz one of my medical students, or residents, or fellows—asking them exactly the same anatomic questions, when we’re looking at MRIs...on humans.

“I haven’t done it yet on turkeys.”

*They definitely don’t make ‘em like they used to!*

Contributions have been made on Dr. Boutin’s behalf to establish a Grand Rounds Lectureship in orthopedic surgery at the University of California Davis. For further information, please contact Robert Boutin, M.D. at [rboutin@stanfordalumni.org](mailto:rboutin@stanfordalumni.org)

—EH (November 19, 2013)



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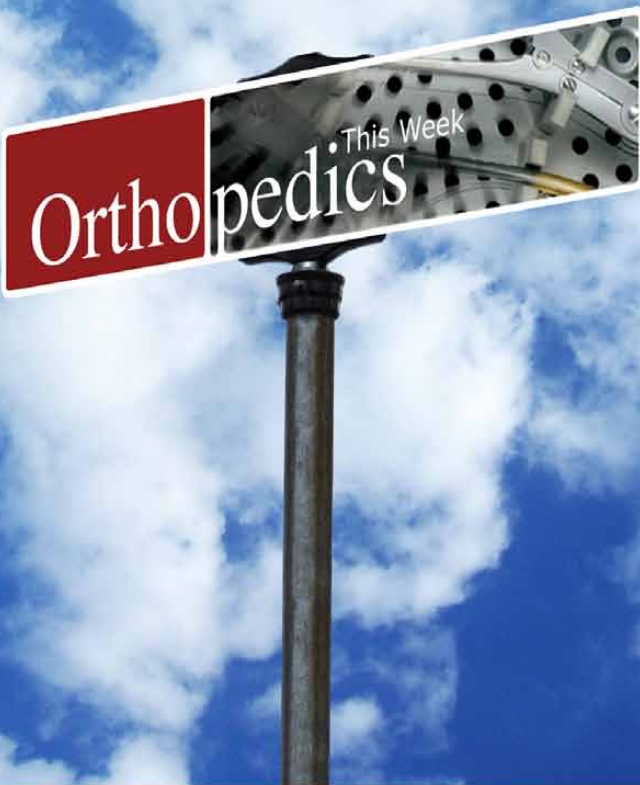
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