

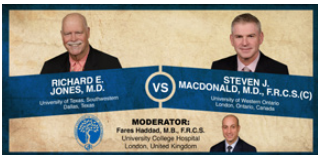
Orthopedics This Week

WEEK IN REVIEW

4 Obamacare May Not Survive a 2nd Supreme Challenge >> The Roberts Court wants a second look at Obamacare. Odds are it may not survive this vote. And in the process two legacies—the President’s and a U.S. Chief Justices’—may well be changed forever. And as that drama unfolds, the medical device tax repeal may well be able to slip through and get to Obama’s desk for signature. Read how.

8 Peer Review Scam Hits Close to Home >> How often is the managing editor of a major peer review journal also the lead author of a study appearing in that same journal? To put an even finer point on it, how often in such cases is the “peer review” process a scam? Thanks to *Retraction Watch*, the web site that tracks bad behavior on the part of peer-reviewed authors, we have an answer.

11 Jones v. MacDonald Over Tourniquetless TKA >> “OK, so you have a bloodless field using a tourniquet in TKA,” says Dickey Jones. “But there are many downsides, such as nerve damage and a delay in the recovery of muscle function.” Hold on says Steve MacDonald, “There is no clinical evidence of nerve damage or delays in muscle function recovery when employing a tourniquet.”



14 Stanford Researcher: Remove High Heels, Reduce OA Risk // American Joint Replacement Registry Adding 2,500 Procedures a Week! // Uncertain Surgeons Reduced to Guessing When Choosing Implants >> West Point graduate turned orthopedic surgeon says that women walking in high heels have a gait pattern that is strongly associated with OA. David Lewallen, M.D., Medical Director for the AJRR says that in 2015 the registry will exceed 250,000 procedures. And on implant choices, you would think that in 2014 you wouldn’t hear, ‘Geez, I don’t know. I should probably just use a nail.’



BREAKING NEWS

- 17 PearlDiver and Humana Form Landmark Data Mining Alliance**

- Brothers Create Radical Carpal Tunnel Treatment**

- Feds Recover Record \$\$\$ for False Claims**

- Japan’s New Device Regulations – Faster Than FDA**

- Zimmer Offers to Divest Some Knees and Elbows in Europe**

- Aurora Spine’s Zip 51 Gets FDA Clearance**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: You know you're in a bull market when the negatives are things like a strong dollar and lower oil prices because the U.S. is producing so much. Meantime, more patients have insurance, employment is up and surgeons are busier than ever. Overall the rate of medical inflation is slowing rapidly so the pressure on Medicare and the payers is also easing. It's a good time to be an orthopedics supplier.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	11.52%	7.50%	13% dividend increase and Jim Cramer says Buy, Buy, Buy.
2	2	Medtronic	28.84	9.23	Chinese government has approved Medtronic's acquisition of Covidien. Green light all the way.
3	4	Zimmer	29.12	3.58	Zimmer Biomet deal is getting all the regulatory approvals done overseas. Should be a good new year celebration.
4	3	NuVasive	8.01	10.42	The capital markets are lov'n that spine business. Only NUVA has a valuation (2.90 PSR) that is in line with other ortho companies.
5	5	Smith & Nephew	19.92	2.81	Will she or won't she? Most analysts expect Stryker to bid for SNN. But will SNN agree to dance?
6	7	ConMed	10.51	5.86	ConMed's new management now making the rounds of the analyst meetings. So far, investors are liking what they're hearing.
7	6	Globus Medical	29.68	10.08	On a valuation basis, the best thing to say about GMED is the earnings power, which keeps the P/E to Growth ratio at a very low 1.45.
8	9	Integra LifeSciences	12.57	4.15	This is the least expensive equity in ortho. Will a tighter focus and rising margins help? Yes, no doubt.
9	10	Johnson & Johnson	28.44	(0.28)	With the market shift to smaller cap growth stocks, the valuation for JNJ is back where it should be.
10	8	MicroPort	16.53	(5.18)	This is the Rodney Dangerfield of orthopedic stocks. Gets no respect. With its remarkable position in both the U.S. and China, should be valued higher.

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Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Holdings	KTWO	\$19.11	\$710	12.02%
2	NuVasive	NUVA	\$46.10	\$2,169	10.42%
3	Globus Medical	853	\$24.03	\$2,354	10.08%
4	Medtronic	MDT	\$75.04	\$73,863	9.23%
5	Stryker	SYK	\$94.62	\$35,797	7.50%
6	MiMedx Group	MDXG	\$10.82	\$1,157	5.97%
7	ConMed	CNMD	\$44.11	\$1,214	5.86%
8	RTI Biologics Inc	RTIX	\$5.25	\$299	5.00%
9	Tornier N.V.	TRNX	\$27.55	\$1,347	4.83%
10	Integra LifeSciences	IART	\$48.71	\$1,597	4.15%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	\$2.95	\$20	-28.86%
2	LDR Holding Corp.	LDRH	\$31.26	\$815	-7.57%
3	MicroPort Scientific	853	\$0.47	\$670	-5.18%
4	Wright Medical	WMGI	\$28.61	\$1,461	-5.17%
5	TiGenix	TIG.BR	\$0.63	\$101	-0.82%
6	Aurora Spine	ASG	\$1.28	\$20	-0.39%
7	Johnson & Johnson	JNJ	\$108.51	\$303,731	-0.28%
8	Alphatec Holdings	ATEC	\$1.41	\$138	0.00%
9	Orthofix	OFIX	\$29.62	\$546	1.44%
10	Exactech	EXAC	\$21.73	\$300	1.64%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	\$108.51	\$303,731	18.07
2	Exactech	EXAC	\$21.73	\$300	19.06
3	Medtronic	MDT	\$75.04	\$73,863	19.22
4	Globus Medical	GMED	\$24.03	\$2,354	19.76
5	Zimmer Holdings	ZMH	\$114.96	\$19,469	19.82

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	\$10.82	\$1,157	1078.87
2	RTI Biologics Inc	RTIX	\$5.25	\$299	439.59
3	Orthofix	OFIX	\$29.62	\$546	189.23
4	NuVasive	NUVA	\$46.10	\$2,169	118.99
5	CryoLife	CRY	\$10.41	\$291	35.65

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	\$10.41	\$291	1.19
2	Exactech	EXAC	\$21.73	\$300	1.27
3	Globus Medical	GMED	\$24.03	\$2,354	1.45
4	ConMed	CNMD	\$44.11	\$1,214	1.89
5	Integra LifeSciences	IART	\$48.71	\$1,597	1.90

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	\$10.82	\$1,157	71.92
2	RTI Biologics Inc	RTIX	\$5.25	\$299	29.31
3	NuVasive	NUVA	\$46.10	\$2,169	10.41
4	Orthofix	OFIX	\$29.62	\$546	10.28
5	Smith & Nephew	SNN	\$35.18	\$15,714	3.36

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$2.95	\$20	0.57
2	Alphatec Holdings	ATEC	\$1.41	\$138	0.67
3	RTI Biologics Inc	RTIX	\$5.25	\$299	1.18
4	Exactech	EXAC	\$21.73	\$300	1.22
5	Orthofix	OFIX	\$29.62	\$546	1.37

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.63	\$101	17.75
2	MiMedx Group	MDXG	\$10.82	\$1,157	11.97
3	LDR Holding Corp.	LDRH	\$31.26	\$815	7.30
4	Wright Medical	WMGI	\$28.61	\$1,461	5.17
5	Globus Medical	GMED	\$24.03	\$2,354	5.11

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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Obamacare May Not Survive a 2nd Supreme Challenge

BY WALTER EISNER



Photo creation by RRY Publications LLC / Sources: Pete Souza and U.S. Government

The underpinnings of Obamacare appear to be cracking.

U.S. Senator Chuck Schumer, the third ranking Democrat in the U.S. Senate and a chief proponent of Obamacare, dropped a bombshell at the National Press Club on November 25, 2014.

Schumer said the Democratic Party had made a political mistake by pushing for Obamacare. He said that after passing a stimulus package to jumpstart the economy during the economic downturn, Democrats “put all of our focus on the wrong problem” by turning to the healthcare reform effort.

“[I]t wasn’t the change we were hired to make,” Schumer said, noting that 85% of Americans receive healthcare coverage from their employer or the government.

Schumer was explaining why he thought voters punished Democrats

in the 2014 mid-term elections and returned control of the Senate back over to Republicans and increased the Republican majority in the U.S. House of Representatives.

It’s Called Balance of Power

The odds of either repealing Obamacare or the medical device tax, say knowledgeable Washington insiders, are small. Democrats can still filibuster and the President will certainly veto anything that threatens to upset his legacy legislative accomplishment.

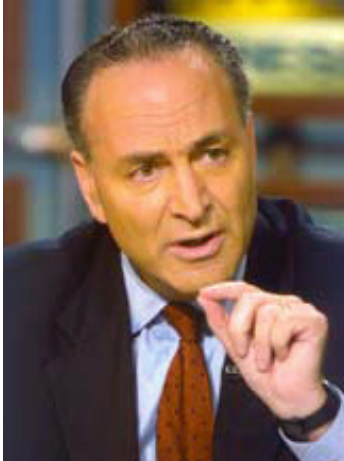
While Schumer’s backtracking will certainly be red meat for those pushing to repeal and replace the healthcare law and dump the medical device excise tax, the real threat to Obamacare isn’t going to come from the legislative branch. It’s likely going to come from across the street from the Capitol building, the less public and more deliberate judicial branch, the U.S. Supreme Court.

The Court has agreed to hear *King vs. Burwell* and Chief Justice John Roberts will have a chance for a “do-over” after he enraged conservatives by siding with liberal justices in 2012 and writing the opinion that Obamacare was constitutional.

Obama’s Legacy Meets Robert’s

The healthcare law may well define the legacies of the President and the Chief Justice.

Obama’s historic legacy is already set if for no other reason than being the first African-American elected to the White House. But he will also be remembered as the President who successfully steered the country’s fiscal policy through the worst economic crises since the Great Depression. But as far as healthcare is concerned, Obama’s policy legacy is still up for grabs. Roberts, now in his tenth year as Chief Justice, is still searching for his place in history. To date, his



U.S. Senator Chuck Schumer
Wikimedia Commons



Chief Justice John Roberts
Supreme Court of the United States

decidedly tortured logic regarding the Affordable Care Act is his signature accomplishment.

Before we dig into *King vs. Burwell* and Roberts' second bite of the apple, let's get back to the politics of repeal and the device tax.

Device Tax Repeal

With dissension among Democrats, Congressional Republican efforts to repeal the medical device tax have a chance to succeed. The new Senate Majority Leader Mitch McConnell immediately targeted the tax in his victory speech, calling it a "big, big mistake."

The 2.3% excise tax on medical devices will raise \$29 billion over the next decade. Last year, the Senate voted 79 to 20 to repeal the tax, with 34 Democrats joining the majority on a nonbinding sense-of-the-Senate measure. Hardcore liberal senators like Elizabeth Warren of Massachusetts and Al Franken of Minnesota, who have device manufacturers in their states, voted against the tax.

"Red Herring" Issue

Industry leaders continue to complain that the tax is costing jobs and stifling

innovation. Wall Street analysts have said the cost of the tax and the extra business from newly insured patients is almost a wash.

The Congressional Research Service estimated in a November report that the tax will have "fairly minor effects" on the industry's output and jobs (reducing them by no more than 0.2%) and a "negligible" effect on the price of health care.

"With relatively small effects on the U.S. medical device industry, it is unlikely that there will be significant consequences for innovation and for small and mid-size firms," the report said. "To the extent that the tax does fall on profits, economic theory indicates that there would be no effect on output or jobs. Stockholders, however, would lose money, but that loss would be reduced because of device exemptions and income tax offsets."

Allan Lichtman, distinguished professor of history at American University in Washington, D.C., told *U.S. News & World Report* that the device tax is a "red herring issue."

So why is device tax repeal getting so much attention?

"Not one American in 100 can tell you what a medical device tax is and why it matters," said Lichtman. But given Democratic internal dissension and support from liberal senators with large device makers in their states, Lichtman says it's the best shot Republicans have of taking a bite out of Obamacare and demonstrating bipartisan support for dismantling the law.

Device Tax and Obamacare Delinked

As leaders of AdvaMed had told us, the device tax and Obamacare are not directly linked because the device tax goes into the government's general coffers. Repealing the tax only lowers tax collection and increases the federal debt. Politicians don't have to vote to repeal Obamacare to repeal the tax.

If the device tax can be skillfully maneuvered through the legislative process and placed on the President's desk, it has a chance. If however, it gets muddled into something the President can veto (like a repeal of Obamacare or tax reform), chances of repeal are slim.

King vs. Burwell

The future of Obamacare in its present form may rest on the definition of one word—"State."

King vs. Burwell is likely to be heard by the Supreme Court in March and decided in June. The justices will dissect the meaning of one word on page 95 of the 906-page Patient Protection and Affordable Care Act—one word that could render health insurance premiums unaffordable for millions of Americans.

Meaning of "State"

The law says that tax credits will be available through exchanges "estab-

lished by the State.” When the law was drafted, it was assumed that all 50 states would create their own exchanges. After it passed in March 2010, 36 states, many controlled by Republicans, decided to opt out and let the federal government operate the exchanges, as the law allows.

In 2012, the Internal Revenue Service made the subsidies available in all states. The challengers of the law claim those subsidies cannot be offered in exchanges operated by the federal government. Without subsidies, insurance costs would likely skyrocket.

The meaning is clear, say the challengers. Subsidies can be offered only in state exchanges because that’s what Congress intended.

The administration’s lawyers say the word, “State,” must be read in the con-

text of a law clearly intended to make health insurance available to everybody.

To make their case that this wasn’t just a drafting error and that Congress meant what it said, the law’s opponents say lawmakers purposely made tax credits available only in state-run exchanges as an incentive for governors and legislatures to create their own exchanges. Otherwise, the argument goes, their residents would get cheated out of a major benefit.

In other words, if you’re a citizen in a state that doesn’t set up an exchange, you still pay the tax but don’t get the tax credit.

What if...

Richard Wolf, writing for *USA Today* on November 22, 2014, says legal

and public policy experts speculate on what might happen to the law if Roberts shoots for his own legacy and rules against Obamacare this time.

There could be a chain reaction, beginning with the impact on premiums. More than seven million people could lose subsidies in 2016, according to the non-partisan Urban Institute. On average, the subsidies pay more than 75% of premium costs, or about \$4,700 per year.

Without subsidies, wrote Wolf, more than eight million people would be exempt from the requirement that individuals purchase insurance, because it no longer would be affordable. Hundreds of thousands of employers would be exempt from penalties for not covering employees, because their workers would not be subsidized in states with federally operated exchanges.

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But even that would not necessarily kill the law, wrote Wolf.

First of all, individuals in the 14 states operating their own exchanges would still be eligible for tax credits. Additional states, such as those with Democratic governors or with Republican governors who have accepted increased Medicaid funding—another of the law’s carrots—might set up exchanges.

Other sections of the law would remain intact. Those include a guarantee that insurance companies cover everyone, the Medicaid expansion, Medicare cost containment measures and allowing young people under 26 to remain on their parents’ policies.

Roberts In the Middle

Roberts could be in the middle again, as the law has four likely votes on the court—Justices Ruth Bader Ginsburg, Stephen Breyer, Sonia Sotomayor and Elena Kagan. Where the other four justices who dissented in Robert’s 2012 opinion—Antonin Scalia, Anthony Kennedy, Clarence Thomas and Samuel Alito—stand is unclear. But, writes Wolf, it takes four votes in private conference to hear the case, and they are the most likely antagonists.

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Courts are historically known by its chief justice. Roberts knows the “Roberts Court” will be remembered at least in part for its battles with Obama over his most cherished domestic policy achievement.

What is Roberts likely to do this time?

Wolf concludes that Roberts’ vote in a recent voting rights case suggests he might not step in to save the health law this time.

Roberts voted to strike down a key provision of the Voting Rights Act. The provision the high court declared unconstitutional defined which states had to get federal approval (or pre-clearance) before making changes to their voting laws. Roberts’ opinion for the majority ordered the provision struck because it was based on old data. Congress, he reasoned, could simply update the formula to respond to “current conditions” if it wished to.

If, in June, Roberts redeems himself with conservatives and says Congress should clarify the definition of “State” and sends Obamacare back to Congress, it’s going to be a long hot summer in Washington, D.C. ♦



Supreme Court of the United States/Wikimedia Commons

Peer Review Scam Hits Close to Home

BY ROBIN YOUNG

How often is the managing editor of a major peer review journal also the lead author of a study appearing that that same journal?

To put an even finer point on it, how often in such cases is the “peer review” process a scam?

Thanks to *Retraction Watch*, the web site that tracks bad behavior on the part of peer-reviewed authors, we have an answer. (<http://retractionwatch.com/2014/11/26/the-peer-review-scam-how-authors-are-reviewing-their-own-papers/>).

In a post titled “The Peer Review Scam: How authors are reviewing their own papers”, *Retraction Watch* reported on BioMed Central’s discovery that there were about 50 papers in their editorial system whose authors had recommended fake peer reviewers.

Said the writers for *Retraction Watch*:

“In the past 2 years, journals have been forced to retract more than 110 papers in at least 6 instances of peer-review rigging. What all these cases had in common was that researchers exploited vulnerabilities in the publishers’ computerized systems to dupe editors into accepting manuscripts, often by doing their own reviews. The cases involved publishing behemoths Elsevier, Springer, Taylor & Francis, SAGE and Wiley, as well as Informa, and they exploited security flaws that—in at least one of the systems—could make researchers vulnerable to even more serious identity theft. **While this is a story about a technological vulnerabil-**

Retraction Watch

Courtesy Retraction Watch.com

ity, the fact that many journals ask authors to recommend reviewers plays a big role (*emphasis added*).”

The Spine Journal

Has anything like this ever happened to otherwise well regarded orthopedic journals?

Yes, it has.

In June 2011, *The Spine Journal (TSJ)* devoted its entire issue to a critique of BMP-2. The lead author of the critique was also *The Spine Journal*’s editor in chief—Eugene J. Carragee, M.D.

Retraction Watch noted in their examination of cases where peer-review publishing houses like Elsevier (publisher of *The Spine Journal*) allowed papers to be published where peer-review rigging had occurred the issue is that journals ask authors to recommend reviewers.

What do you do when a journal’s editor is also the author of a study? And not

just any study, but a study that tackles such a controversial issue as BMP-2?

Did Editor Carragee ask Author Carragee to recommend an editor and a slate of peer-reviewers? And what did Author Carragee say to Editor Carragee? We doubt there was much discussion or debate.

Festering Bias

These concerns would not still be surfacing if the original June 2011 study by Carragee didn’t have so many flaws—both methodological and data analytic flaws—or if either NASS (North American Spine Society) or Elsevier had listened to the call from many corners of the spine community for a review of the Carragee paper to determine if, in fact, he had omitted data or mis-characterized payments to researchers.

Given the importance of these issues and the magnitude of concern over Carragee’s handling of these conflict of interest issues, NASS’ and Elsevier’s radio silence is confounding.

Shouldn't these concerns have been put to bed by now?

As *Retraction Watch* and the BioMed Central study are clearly showing, this issue will not get better over time. In orthopedics, this single example of an editor also being the author of a highly controversial and flawed study brings the *Retraction Watch* concerns close to home.

Carragee's June 2011 Study

Carragee's June 2011 study claimed that 13 original rhBMP-2 studies were seriously flawed because of payments to the authors of those studies from the study's sponsor, Medtronic, Inc. Carragee and his fellow authors then embarked on an aggressive PR campaign to convince regulators, CMS, and the general public that both patients and physicians who used rhBMP-2 had been "living dangerously" over the decades since those studies were published.

When we reviewed Carragee's study in 2011 we discovered a number of deeply troubling mistakes, omissions, and what appeared to us to have been a systematic pattern of bias.

There were three specific areas which caused us concern:

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

OTW's Call for Carragee's Resignation

When no independent investigation occurred to check these allegations

and Carragee repeated the flawed data from the podium at NASS and in press releases, this publication called for his resignation in June 2013. Here is what we said:

"There are the duties and responsibilities all physicians have to uphold the canons of their profession. There are then the obligations of those to whom we rely on for impartial interpretation and analysis of clinical and scientific evidence.

"It has become increasingly clear that The Spine Journal Editor in Chief Dr. Eugene Carragee has abandoned even the pretense of impartiality.

"Dr. Eugene Carragee needs to step aside. If he doesn't, the publisher (Elsevier) and the board of trustees for the North American Spine Society need to meet and review Dr. Carragee's research and public comments regarding BMP-2, Infuse, Medtronic and all of the clinical researchers who've been attacked by him in both press release form and in the pages of The Spine Journal.

"As for The Spine Journal, the peer review publication of the North American Spine Society which has been the standard for excellence in clinical and scientific spine research since 2001, it must act immediately. Dr. Carragee's failure to maintain impartiality and good judgment have clearly damaged this outstanding journal.

"This is not about BMP-2 or Infuse or Medtronic. This is about scientific impartiality, avoidance of hyperbole in pursuit of clinical accuracy and navigating the often conflicting opinions of passionate clinicians. In short, it is about mature scientific leadership. Our peer review journal editors must

be paradigms of clinical and scientific judgment."

"He (Dr. Carragee) has spoken eloquently in the past about eliminating bias from clinical research. Unfortunately, he has failed that test personally and professionally at a time when the broader spine surgeon community and patient population needed a cool, reasoned scientific voice most.

"Some people will argue that Dr. Carragee should be allowed to finish out his multi-year contract as The Spine Journal's editor. Given what we know now, we don't agree.

"If Elsevier or NASS will, as we recommend, review Dr. Carragee's statements and invite those former BMP-2 researchers whom he has accused of being bought and paid for by Medtronic to present their side of the story, we are confident that the arguments on behalf of Carragee as Editor in Chief of The Spine Journal will collapse in their entirety."

The Problem of Author Self-Referring Reviewers

This is a link to BioMed's discussion—[blog examining the case this morning](#)

Finally, as *Retraction Watch* readers like OTW have noted, fake reviews—often involving self-peer review—have been the basis for a growing number of retractions.

Here is what the journal *Nature* said on the larger phenomenon "[The Peer Review Scam.](#)"

As *Retraction Watch* reminds us, orthopedics is not immune from self-peer-review temptation. Vigilance is the price of honesty. ♦



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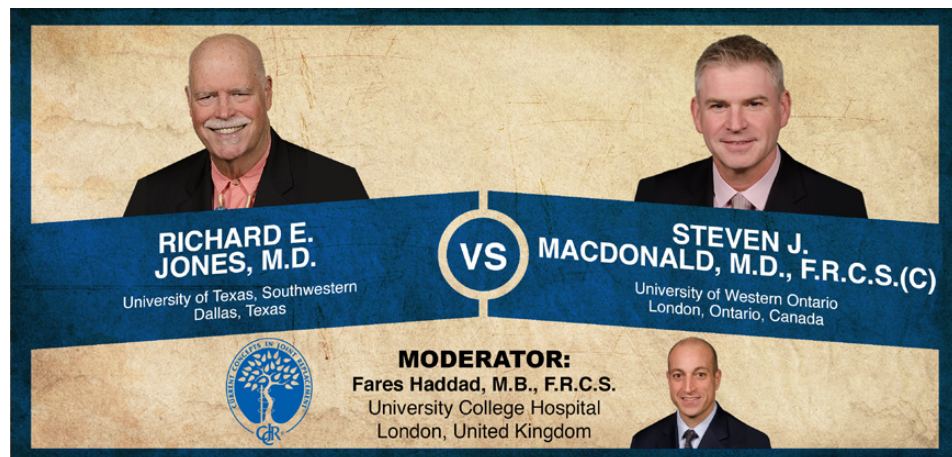
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Jones v. MacDonald Over Tourniquetless TKA

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



Current Concepts in Joint Replacement/RRY Photo Creation

“OK, so you have a bloodless field using a tourniquet in TKA,” says Dickey Jones. “But there are many downsides, such as nerve damage and a delay in the recovery of muscle function.” Steve MacDonald counters, “There is no clinical evidence of nerve damage or delays in muscle function recovery. And several studies show decreased overall blood loss.”

This week’s Orthopaedic Crossfire® debate was part of a landmark event, the first Brazilian CCJR meeting. The event, which took place in September 2014, was held in Iguassu Falls. This week’s Orthopaedic Crossfire® debate is “Tourniquetless TKA: Let It Bleed.” For the proposition was Richard E. Jones, M.D. of the University of Texas, Southwestern. Against the proposition was Steven J. MacDonald, M.D., F.R.C.S.(C) from the University of Western Ontario. Moderating is Fares Haddad, M.B., F.R.C.S. of the University College Hospital in London, United Kingdom.

Dr. Jones: “What’s the benefit of doing a total knee arthroplasty (TKA) with

a tourniquet? You have a bloodless field...and there is potentially a better bone cement implant interface for fixation. The downsides—and it’s a long list—are direct (secondary to pressure); indirect (secondary to hypoxia). And there is a delay in recovery of muscle function...vascular problems, altered hemodynamics. When you exsanguinate a limb, you get a 20% increase in circulatory volume. Some patients’ hearts may not be ready for that. And there is reactive hyperaemia when you release the tourniquet as well as a 10% increase in limb size that increases soft tissue tension and secondary pain.”

“There is a higher risk of vascular injury, particularly in arteriosclerotic or calcified arteries. There is increased risk of DVT with trauma to the vessel walls; also, increased levels of thrombin/anti-thrombin complexes, which leads to 5.3x more risk for large venous emboli propagation (per a transesophageal echo). There is also a high percentage of wound leakage.”

“In our early experience, we had high risk patients who had previous DVT or

pulmonary embolism, multiple scarring and compromised cardiovascular structure. But for the last 20 years we have used no tourniquet on any primary or revision total knee.”

“A 2009 survey by the American Association of Hip and Knee Surgeons (AAHKS) found that 37% always use a tourniquet, 58% always use a tourniquet except if there is a vascular concern; only 5% of the entire AAHKS population use a tourniquet and then put it up during cementation.”

“Our operative protocol: regional anesthesia because it helps control blood pressure and reduce bleeding. The incision and approach is made with the knee in 90 degrees of flexion. We do meticulous hemostasis on the way in, and all vessels are readily seen and coagulated (we use an argon beam coagulator). We use ropivacaine with epinephrine periarticularly, coagulating the posterior tissues during flexion/tension balancing; we also do saline jet lavage. Then we deliver filtered carbon dioxide through a CarboJet system to dry and prepare the bone beds. We then use three grams of tranexamic acid and 100cc’s of saline topically administered. We do routine closure and a bulky, compressive Robert Jones-type knee dressing. Increased cement penetration counters bone resorption over time. And since bone into which cement is interdigitated initially resorbs steadily with time and service, maximal interdigitation is important.”

“We found no differences in blood loss or transfusion rate and less postop pain. They had faster straight leg raise and better knee flexion gains. There were

fewer wound healing disturbances and the cement penetration was equivalent.”

“We always go along the medial border of the patella use an argon beam coagulator, which we use as a regular bovie. Same thing with the coag part of this argon beam coagulator...we use a midvastus approach. And we use only rotating platforms.”

Dr. MacDonald: “I am opposed to the premise that I’m going to perform a TKA without a tourniquet. I have done TKA without a tourniquet in a select few patients, i.e., the vasculopath with no distal pulses and non complaining patients in the cadaver lab. There are few randomized clinical trials to guide us, and there is no registry data, and there are many opinion pieces. So why use a tourniquet? Blood loss.”

“In a meta-analysis of 15 papers with 1,000 total knees there was significantly greater intraoperative blood loss without a tourniquet. What’s curious is that overall blood loss—*intraoperative and postop*—was not different whether or not you use a tourniquet.”

“Several studies show decreased blood loss overall. In a randomized clinical trial (RCT) with 72 patients the tourniquet group had lower overall blood loss, but had slightly more postoperative pain. We all appreciate that some patients do get thigh pain after a tourniquet is used.”

“Another RCT looks at using a tourniquet just for cementing or using it for the entire procedure. They were going to do over 200 cases, but they stopped at 65 because of the higher risk of transfusion if you’re only using it for part of the procedure. There were no differences in any other outcome measure. You

want a dry bone surface for cementing; if you don’t have that the theoretical risk is late loosening. But note that the majority of TKAs performed historically worldwide have been done with a tourniquet, so I don’t think we can simply say that you can’t get loosening if you don’t use a tourniquet.”

“There are alternatives. I use pulsatile lavage with a tourniquet, but there are different ways to get a dry bone surface. But they all come with a cost in terms of dollars and time. In a series of 3,500 total knees they found a direct correlation between OR time and infection. So if you’re going to use an alternative make sure that you’re not all of a sudden adding five or ten minutes to the procedure time.”

“The stated downsides to a tourniquet are either basic science theories, rare, or short term. Vessel wall damage leading to increased DVT. There’s not a single clinical paper out there that supports this. In one tourniquet versus no tourniquet study all patients underwent ultrasounds pre- and post-op to determine if there was any increase in thrombosis—there was not. There is no clinical evidence for an increase in wound healing disturbances or delay in muscle function; nerve damage is rare.”

“Don’t use a tourniquet if you’re concerned about the theoretical risks and you have alternates to achieving a dry field and your alternate ways don’t increase OR time. If you’re highly intelligent then you should use a tourniquet.”

Moderator Haddad: “Do you ever think while doing a TKA, ‘I wish I could inflate the tourniquet now.’”

Dr. Jones: “I say that we always put the tourniquet on, but we never put it up.

The reason there ended up being more initial blood loss in those patients who just had the tourniquet up briefly was because of the reactive hyperemia from letting the tourniquet down. That was a flawed study.”

Moderator Haddad: “Steve, some people argue that even putting a tourniquet on adds time before the operation that’s not intraoperative time. Then, people are deflating it to get hemostasis at the end. Is that your practice?”

Dr. MacDonald: “I keep the tourniquet on until the dressing goes on. If you’re going to use it you should do so for the entire procedure.”

Dr. Jones: “I agree. Use it all the way and don’t let it down. And get a good compressive and obdurating dressing on there.”

Moderator Haddad: “What kind of pressure should we be putting it on?”

Dr. MacDonald: “I put it up to 300 for every patient; for a morbidly obese leg I put it to 350. There is some evidence that you could do it 100 points above their mean systolic pressure. Do you use a tourniquet for your knees?”

Moderator Haddad: “We use it just for cementing and it’s based on blood pressure.”

Dr. MacDonald: “We don’t know which is right, but there are two theoretical ways to go. Same number or modified depending on the patient’s blood pressure.”

Dr. Jones: “Let’s say you do it at 350, Steve. Do you ever have an occasion where you have to raise it another 100 because you’re getting a lot of leak? The fatter the patient is the more difficult

it is to get the tourniquet up without leaking.”

Dr. MacDonald: “When the tourniquet leaks like that I say to my residents and fellows, ‘This is why you use a tourniquet.’ But you can’t keep putting it higher and higher. If you are getting it leaking through then I will deflate the tourniquet and just cope with the regular bleeding.”

Moderator Haddad: “Many of your patients have a pretty high body mass index and it can be tough to get a decent tourniquet on. What about access? In your revisions, do you sometimes feel that the tourniquet is restricting you from getting as high as you need to?”

Dr. MacDonald: “If you’re doing a tumor type prosthesis I would use a

sterile tourniquet so that it goes on in the operative field so you can pop it off it you have to go higher to get access to the distal femur.”

Moderator Haddad: “Dickey, Steve said that it takes you a long time to do the CarboJet lavage.”

Dr. Jones: “With my team I was out of the OR about 30 minutes faster than all of my partners when they were using a tourniquet. That’s terrible data.”

Dr. MacDonald: “Your partners must be slow. What are they doing?”

Moderator Haddad: “Steve, what do you think is the minimum clinically significant time difference between a standard operation and an operation that increases your infection risk?”

Dr. MacDonald: “We don’t know. I think it’s a continuous variable and it’s multifactorial...and probably somewhat patient specific. Is five minutes a difference? Probably not.”

Dr. Jones: “When that two hours turns into two hours and five minutes, then two hours and fifteen minutes, then you’re starting to worry a bit. The standard for leaving a tourniquet up in North America is two hours.”

Moderator Haddad: “Thank you, gentlemen.” ♦

Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 – 13 in Orlando, Florida.



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Stanford Researcher: Remove High Heels, Reduce OA Risk // American Joint Replacement Registry Adding 2,500 Procedures a Week! // Uncertain Surgeons Reduced to Guessing When Choosing Implants

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



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Stanford Surgeon, Army Commander, High Heels, and OA... **Put THAT Together** She has commanded an Army image intelligence unit and is now professor and vice chair of research in the department of Orthopaedic Surgery at Stanford University. Now, Constance Chu, M.D., is investigating osteoarthritis and high heels. Dr. Chu told OTW, “My overarching—no pun intended—goal is to investigate the mechanical, structural, and biological aspects of osteoarthritis (OA) all together. We often approach OA from only one of these and end up falling short. In collaboration with Tom Andriacchi, Ph.D., professor of mechani-

cal engineering, we are finding that women walking in high heels show gait patterns similar to people with osteoarthritis. The good news? You remove the heels and the gait changes completely reverse themselves.”

“High heels keep most people from fully straightening the knee when walking. This can put more stress on the kneecap and other parts of the knee. Interestingly, when someone tears the ACL or is elderly, we see similar gait changes. And, these are high risk groups for knee OA. While it can be hard to know whether the gait changes cause osteoarthritis, or are a result of the dis-

ease, being able to readily change this variable through shoes will enable us to better study these questions. Going forward, we are planning to evaluate high heel warriors (lifelong devotees of high heels) to see how they may have adapted to the shoes.”

“My ultimate goal is to provide personalized OA risk evaluation, something that is not being done anywhere as of yet. I want disease modification, so I’m most excited by the fact that a simple action of changing one’s shoe can reduce or eliminate what I believe to be a high risk movement pattern. Going forward we are planning a systematic evaluation

of how different shoes can be used to reduce knee loading for people with knee pain and risk for osteoarthritis.”

American Joint Replacement Registry Taking Off! Growing, transparent, and led by professionals who have “been there”...sounds like a superb way to shape a registry. David Lewallen, M.D., an orthopedic surgeon with Mayo Clinic in Rochester, Minnesota, is the medical director of this initiative—the American Joint Replacement Registry (AJRR). Dr. Lewallen, past president of both The Hip Society and the American Association of Hip and Knee Surgeons, commented to OTW, “At this point we have collected over 150,000 hip and knee arthroplasty procedures in the AJRR registry since its inception in 2008 and we are adding roughly 2,500 new procedures per week. There are over 380 hospitals that have signed on and we have just released our first formal annual report

(which covers the period through January 1, 2014).”

“The real plus for hospitals and surgeons is that it’s a way of collecting their information in an organized fashion that gives them a chance to be benchmarked against national metrics. The ability to segment the data to hospitals of similar size is extremely valuable. This means that academic centers can assess the quality of their services and compare them to other large academic centers as opposed to, say, a small suburban hospital outside of Chicago. One reason such apples-to-apples comparisons are important is that the case mix in hospitals varies greatly...and it’s important to be able to risk adjust the information. Being able to do this gives value, meaning, and context to the data we are providing.”

“We are unique among registries in that we are an independent 501c3 with a

multi stake holder board and governance. We have representatives on our board from the American Academy of Orthopaedic Surgeons, The Hip Society, the American Association of Hip and Knee Surgeons, the Knee Society, the CEO of a Chicago area hospital representing the American Hospital Association, two members from health insurance companies, representation by Orthopedic Industry from the Advanced Medical Technology Association, and most importantly a board seat for the chair of our separate AJRR Public Advisory Board. Such participation helps ensure a wide range of viewpoints, and goes a long way to ensuring transparency.”

“An additional way that the AJRR can benefit surgeons is that it can serve as a venue for surgeons to meet their documentation requirements to the Centers for Medicare and Medicaid (CMS) for the Physician Quality Reporting System



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(PQRS). After 2015 physicians who are not providing the appropriate quality reporting documentation to CMS will be hit with penalties. Doctors participating in our registry can use the AJRR as a means of supporting these reporting requirements.”

“A year from now we will likely we’ll be surpassing 250,000 procedures in the registry; as we obtain longitudinal follow-up we will start looking at survivorship of implants. If you look at other national registries most of them start putting out interesting information about survivorship at five or six years into it. We are already able to give descriptions of the practice of arthroplasty care in the U.S. Note that CMS data only provides the Medicare piece—nearly 50% of arthroplasty procedures are done in non-Medicare patients, where national practice patterns and results have been a bigger question mark for a long time.”

“Thus far, we can say that the mean age of patients in the registry is around 67 years for both hips and knees. We also have information on the most common causes for early revisions: for both knees and hips, it is infection. However, in hips periprosthetic fracture is a close second at 30.7% of revisions in the first three months postop.”

“I’m also pleased that we have the ability to track new technologies as they become available. For example, to our surprise we’ve found that in a subset of total knees performed in 2013, 75% of them were done by surgeons using highly crosslinked polyethylene (XLPE). This is novel information about current practice trends, and is especially important given that this is a relatively new technology. This is just one example of the detail and clarity that our registry can increasingly provide as time goes by. For surgeons interested in participating in the AJRR, helping to get their

hospital on board, or in simply getting more information on our registry, they can contact me directly or any of our AJRR staff at: www.ajrr.net”

Implant Choices: From Hemming and Hawing to Statistical Reasoning

Eric Swart, M.D., a resident at Columbia University, often witnesses the rather unscientific decision making process that his peers undertake when deciding whether to use an expensive or a “budget” hip implant. He and his colleagues decided to embark on a cost effectiveness analysis in order to attain statistics-based clarity. Dr. Swart told OTW, “I’ve witnessed a number of my colleagues taking the conservative route (the expensive implant) with implant choices because if there was a problem someone would say, ‘Why did you use the cheap implant?’ My colleagues and I decided to do a study on the parameters that can be used in order to make cost-effective implant choices; our focus was on intertrochanteric hip fractures.”

“We have historically used the rather inexpensive extra medullary sliding hip screw when it comes to stable fracture; with unstable fractures, however, we have most often used the more expensive intramedullary nail. We used an expected-value decision-analysis model in an attempt to estimate the total costs and health utility based on the choice of one of these two treatments. One of the things that made this especially difficult is that our treatment is evolving with time. It’s hard to look at the data from 15 years ago and say that it applies today. Techniques have changed, as has recognition of what is necessary for surgeons to be successful. The good thing is that these modeling techniques can help get over some amount of uncertainty and still give you [an] answer.”

“Our research team found that fixation failure rate and implant cost were

the most important determinants of implant choice. We found that hip screw fixation is more cost-effective in cases where there is stable fracture or in cases where the stability is in question; using a nail was found to be more cost-effective for reverse obliquity fractures.”

“Some patterns are simple and are clearly stable and surgeons all agree that the less expensive implant is the way to go. Some agree that with a sub trochanteric fracture you need an intramedullary nail. But with a comminuted fracture most people think, ‘Geez, I don’t know. I should probably just use a nail.’ Our analysis reveals that this decision doesn’t ‘buy’ you very good results. If I could control the next 10 years of research I would focus on getting better primary data and looking at a more reliable classification of fracture patterns. There is an extraordinary lack of agreement on this issue.” ♦

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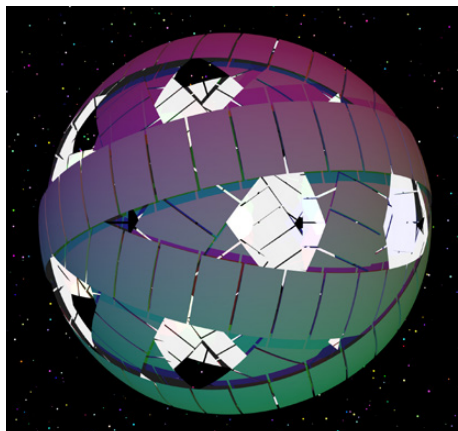
PearlDiver and Humana Form Landmark Data Mining Alliance

Creating what will be the mothership of all outcomes research, PearlDiver Technologies, a division of Liventa Biosciences, is teaming up with Humana Inc. to provide healthcare professionals with an unprecedented amount of data. With PearlDiver's proprietary portal, healthcare researchers, investigators and other professionals will be able to conduct lightning fast, customized research in a longitudinal fashion. Comprehensive Health Insights, Inc. (CHI), the healthcare outcome research group of Humana, will work with PearlDiver to integrate Humana's proprietary data into PearlDiver's research system.

In the November 25, 2014 news release, PearlDiver President and Chief Technology Officer Benjamin Young noted, "This offering provides a fast and economic way to perform an immense amount of research. Studies that were once performed over months and years now can be done over an entire population in minutes. Such capabilities emphasize our focus on the evolution of the way research is performed."

"This strategic alliance will provide a unique capability for clients to leverage integrated claims and other public data in one central repository," said Steve Chick, Market Vice President of Humana. "This functionality provides the ability to answer real world research questions in real-time, and identify potential treatment patterns and other outcomes research that supports Humana's vision on improving population health."

"Users will be able to conduct outcomes research within private payer and Medi-



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care populations. They will be able to refine research hypotheses as research progresses, create custom cohorts of patients based upon diagnoses and/or procedures, and track custom patient groups longitudinally."

Regarding the integration of PearlDiver and Humana data, Benjamin Young told OTW, "Humana has provided us with their raw data. We are converting this data into a format that our proprietary software can use to perform complex, longitudinal (multiple-year) healthcare outcomes, cost and other medical research projects. Under this alliance, Humana's massive database will be researchable directly through PearlDiver software. Our two firms will be pairing the Humana data with our Buckets Language data mining tool. That will, we believe, create the most complete, up-to-date, medical dataset that can be used by researchers to answer complex, longitudinal questions in record time. The Buckets Language data mining tool is, by far, the fastest data mining toolset on the market."

PearlDiver Senior Analyst Scott Ellison stated, "We are very excited about this alliance. Once we have completed integration of Humana's data into the PearlDiver database, and testing and de-bugging is completed, we hope to be setting up access to the data for our customers during the month of January."

Young noted, "The Humana dataset will be our largest dataset to date with over three billion de-identified patient charging records. These records will include all of their physician, outpatient, inpatient, prescription drug, and lab records. This will be the first time we will be able to longitudinally track a patient through their physician visits to their outpatient procedures to their inpatient stays along with their prescriptions drugs and their lab records. The initial dataset will span the years 2007 through the first quarter of 2014. We will be getting quarterly updates to the data which will make this dataset the most up-to-date data we've ever had. This dataset will probably run 3-6 months behind real time. The Buckets Language data mining tool was specially developed to work with really huge datasets (like the Humana dataset) and to be able to deliver accurate answers to researchers in seconds, minutes, and hours that used to take days, weeks, months, and even years to answer."

Asked if there is anything in particular that surgeon-inventors should know, Ellison commented to OTW, "PearlDiver has been piloting a program that gives research universities and research hospitals an inexpensive subscription to our Buckets Language data mining tool. This program has been a huge success for PearlDiver and all of our early participants have renewed their subscription and are eagerly looking forward to the new data. Our partnership with Humana/CHI will expand this program into the business world and we will be jointly selling subscriptions to the Buckets Language along with the Humana dataset. We believe that the customizability, the tracking capabilities, and the speed of the research software make this an ideal tool for both scholarly and commercial research." — EH

LDR Rings Nasdaq Opening Bell!

There were some extra special holiday bells ringing on December 2 for LDR Holding Corporation when the company—and specifically President and Chief Executive Officer Christophe Lavigne—had the honor of ringing the Nasdaq Stock Market Opening Bell. LDR is a medical device company focused on designing and commercializing novel and proprietary spinal surgical technologies.

The LDR team hit the Nasdaq MarketSite in Times Square, where Lavigne took the “stage” at 9:15 a.m. He told the world, “Good morning, thank you and merci! I am very happy for LDR to be part of the Nasdaq Exchange and to be here today. I, along with my two partners, founded LDR in France in 2000 with the goal to develop spine implant devices that would benefit patients suf-



LDR Holding Corporation

fering from debilitating spine conditions.”

“LDR technologies are designed to enable products that are less invasive, provide greater intra-operative flexibility, offer simplified surgical techniques and promote improved clinical outcomes for patients as compared to existing alternatives. We are very proud that one of our leading products, the Mobi-C Cervical Disc,

is the only disc replacement device FDA approved for both one and two-level cervical disc replacement. I would like to personally thank my two partners, the LDR Executive Team who is with me here today, our employees around the world, our Management Board and also our Investors, who together have made today possible.”

Ring a ding... — EH

LEGAL

Zimmer Offers to Divest Some Knees and Elbows in Europe

Zimmer Holdings, Inc. is offering to divest itself of some knee and elbow brands to get European regulators off the dime and approve their acquisition of Biomet, Inc.

“Remedy Package”

On December 4, 2014, the company said it has offered the European Commission (EC) a “remedy package” to help get the deal done. According to a company statement, the package addresses “discrete concerns” identified by the European regulators in their

preliminary assessment of the proposed acquisition of Biomet.

Divestitures

The package includes “the divestiture of one unicompartmental knee brand and one elbow brand in the European Economic Area (EEA) and one total knee brand in two EEA countries. The EC will market-test the proposed remedy package in the coming days. In parallel, the EC has ‘stopped the clock’ on its review of the proposed merger.”

The company says it continues to be

“encouraged by the substantial” progress of the regulatory process and still expects to close the deal in the first quarter of 2015. The deal is still waiting for the expiration of the Hart-Scott-Rodino Act waiting period in the U.S. and approval from Japan’s Fair Trade Commission.



European Union/Pixabay

On November 18, 2014, Zimmer announced it had agreed to extend the European deadline by a “limited number of days,” and provide the European regulators with additional information.

In October when the Europeans announced they wanted to investigate the proposed deal further, Wells Fargo analyst Larry Biegelsen said that, according to his consultant, the review was likely to be resolved through divestitures. The likely areas of divestiture, according to Biegelsen, were unicompartmental knees and shoulders, given the high combined market share.

EU – U.S. Coordination

BofA Merrill Lynch analyst Bob Hopkins said back in October that the possibility remains that the FTC could comment soon, but “conversations with FTC experts suggest FTC and EU regulators will likely coordinate the investigation to the extent permissible in order to reach agreement on any potential conditions placed on the deal. Coordination between the U.S. and EU could potentially push out the FTC ruling into early next year.” — *WE*

Japan’s New Device Regulations – Faster Than FDA

Japan is beginning to implement a new device regulatory scheme that it hopes beats the FDA in review times and makes it easier for device makers to commercialize their products in the country.

Separates Devices From Drugs

AdvaMed President and CEO Stephen Ubl applauded the new law which regulates medical devices separately from drugs for the first time. “Approved by

the Japanese government one year ago, the Pharmaceutical and Medical Device Law (PMDL) creates a framework for regulation of medical devices and diagnostics that takes into account their unique characteristics and will help improve patient access to safe and effective medical innovations in Japan—the world’s second largest market for medical technology products.”

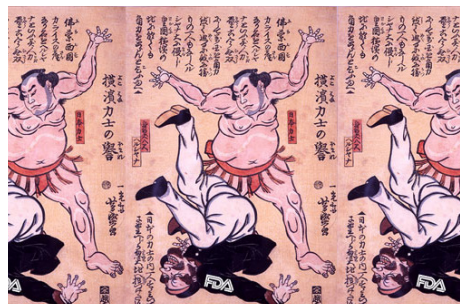
Before the new law was implemented manufacturers had to go through a highly complex and lengthy registration process.

“This very significant development will have a major, positive impact on medical technology manufacturers by streamlining regulatory requirements. For example, the new law expands the scope of products eligible for third-party certification, allows quality inspections to be conducted for product groupings as opposed to individual products, and simplifies the manufacturer accreditation process,” said Ubl.

Accelerated Approval Process

According to the Emergo Group, there is also an accelerated approval process for medical devices, especially for those the government thinks are important for public health.

Over the next four years, according to Emergo, “the PMDA (Pharmaceuticals and Medical Devices Agency) will pursue quality improvements of PMDA



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application reviews via enhanced training of regulatory staff, more effective consultation with applicants and more standardized evaluations of applications.”

Regulators also want to speed up the time it takes to evaluate devices. By 2018, they intend to set standard evaluation periods for all types of PMDA applications, including:

- New Devices - 12 months for normal and 9 months for priority review
- Improved - 7 months with clinical data and 9 months without
- Generic Medical Devices - 5 months for new approvals and 4 months for partial changes

Third-Party Certification

To reach these review goals, the PMDA intends to move toward third-party rather than governmental certification for some Class III devices. They plan to hold public-private meetings to evaluate whether they are meeting those goals and see if additional steps should be adopted.

Ubl: Faster Than FDA

Ubl added that the new device-specific regulatory framework will “dovetail with Japan’s regulatory agency performance plan to facilitate timely product approvals in the country. Implemented in April, the updated performance plan has the ambitious goal of making Japan faster than the U.S. FDA in approving the most advanced category of medical devices. Together, these improvements will allow Japan to build on the tremendous progress it has made over the past six years in reducing review times and allowing speedier patient access to innovative, life-saving and life-enhancing treatments and cures.” — *WE*

Feds Recover Record \$\$\$ for False Claims

Fighting health care fraud paid off to the tune of \$2.3 billion for the feds over the last year.

\$5.69 Billion Jackpot

The U.S. Department of Justice (DOJ) said on November 20, 2014 that for its previous fiscal year it recovered that amount in cases involving false claims against federal health care programs like Medicare, Medicaid and TRI-CARE. Accounting for all fraud cases, the department brought in a whopping \$5.69 billion.

Record Recoveries

Acting Associate Attorney General Stuart Delery said, "In the past three years, we have achieved the three largest annual recoveries ever recorded under the statute. This sustained success demonstrates that these figures result not only from large individual matters, but from a continuous commitment year

after year to pursue those who defraud taxpayers and to remain vigilant in identifying those who would unlawfully obtain money from the federal fisc."

While the \$2.3 billion for health care fraud was big and marks the fifth straight year of over \$2 billion in recoveries, health care crooks were pikers compared to the really big boys on Wall Street who got socked for \$3.1 billion for false claims for federally insured mortgages and loans.

The total amount reported by the feds only reflected federal losses and in many cases additional dollars went back to consumers and state treasuries.

J&J's Big Pocketbook

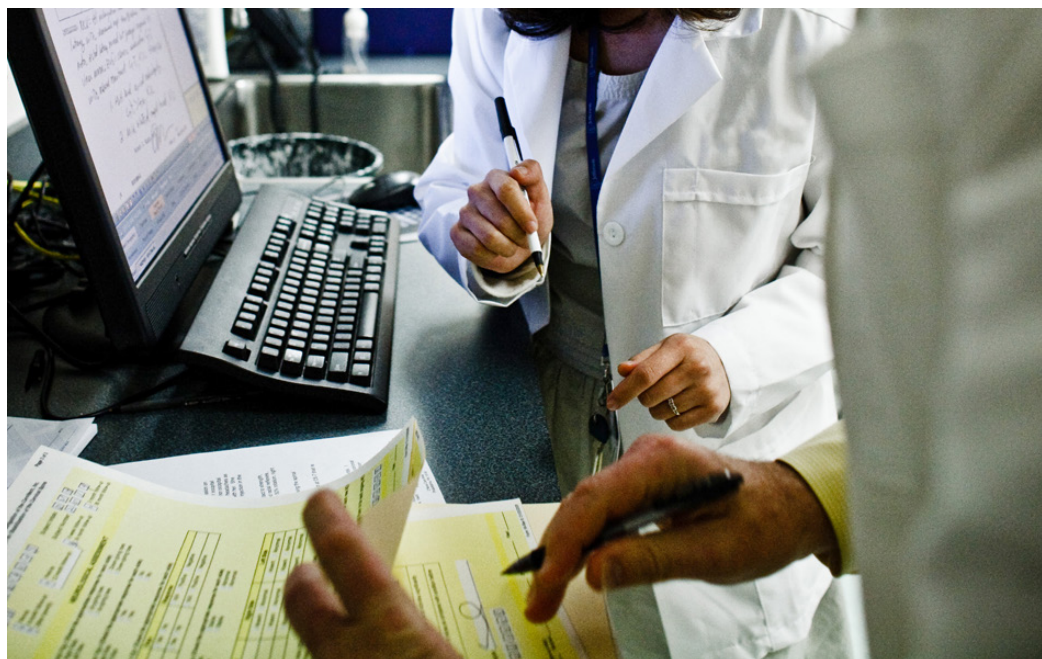
Orthopedic settlements didn't even merit mention, as Johnson & Johnson's (J&J) pharmaceutical business accounted for a substantial part of the \$2.3 billion in recoveries. J&J and its subsidiaries, Janssen Pharmaceuticals and Scios, paid \$1.1 billion to resolve False Claims Act claims relating to the

prescription drugs Risperdal, Invega and Natrecor. The government also accused J&J of paying kickbacks to physicians and to Omnicare Inc., the nation's largest provider of pharmaceuticals to nursing homes and long-term care facilities. In addition to the federal civil settlement, the DOJ says J&J paid more than \$600 million in civil claims for state Medicaid programs and \$485 million in criminal fines and forfeitures, making it one of the largest health care fraud settlements in U.S. history. The government also recovered \$116 million from Omnicare.

Hospital Misbehavior

Cases involving hospitals only got hit for \$333 million in settlements and judgments, with significant recoveries from two hospital chains. Community Health Systems Inc., the nation's largest operator of acute care hospitals, paid \$98.15 million to settle allegations that it billed Medicare, Medicaid and TRI-CARE for inpatient services that should have been provided in an outpatient or observation setting. Halifax Hospital Medical Center and Halifax Staffing Inc., hospital service providers in Florida, paid \$85 million to resolve allegations that it violated the Stark Law, which prohibits hospitals from billing Medicare for certain services when referred by physicians who have a financial relationship with the hospital.

Amedisys, Inc., a large home health services provider got nicked for \$150 million to resolve allegations that it billed Medicare for medically unnecessary services, for services to patients who were not homebound and for violations of the Anti-Kickback Statute.



Health Care Fraud/Federal Bureau of Investigation

Cardio

Cardio had three big cases where the government recovered \$85 million based on claims involving potentially life threatening conduct.

Boston Scientific Corp., which purchased Guidant LLC and Guidant Sales LLC, and Cardiac Pacemakers Inc. in 2006, paid \$30 million to settle claims that Guidant sold defective heart devices to hospitals that implanted them into Medicare patients. The Guidant devices allegedly short circuited, rendering them ineffective.

In the other two cases, Kentucky hospitals King's Daughters Medical Center and Saint Joseph Health System Inc. billed Medicare and Medicaid for coronary procedures the government alleged were unnecessary. King's Daughters paid \$39 million in federal claims and \$2 million in state Medicaid claims to settle allegations that it billed for medically unnecessary coronary stents and diagnostic catheterizations, and that it had prohibited financial relationships with physicians referring patients to the hospital. St. Joseph's paid \$16 million in federal claims and \$366,000 in state Medicaid claims to settle allegations that St. Joseph Hospital in London, Kentucky, billed Medicare and Medicaid for numerous invasive cardiac procedures that were performed on patients who did not need them, including procedures involving coronary stents, pacemakers, coronary artery bypass graft surgeries and diagnostic catheterizations.

It's interesting to note that all the mentioned cases were settled without anyone admitting guilt and getting the Medicare death penalty. — WE

LARGE JOINTS

Northwestern Memorial Named Hip, Knee Center of Excellence

Northwestern Memorial Hospital is being hailed by GE as one of the company's national centers of excellence for total hip and knee replacement. GE is offering coverage to program eligible members who have total hip or knee replacement surgery at Northwestern Memorial (this includes reduced out of pocket expenses and travel reimbursement).

"Northwestern Memorial is excited to provide high quality orthopaedic care to GE and its health plan members," said Terrance Peabody, M.D., chair of the department of orthopaedic surgery at Northwestern Memorial and the Edwin Warner Ryerson professor of orthopaedic surgery at Northwestern University Feinberg School of Medicine, in the November 21, 2014 news release. "Our joint replacement specialists are nationally recognized leaders for their work in risk stratification, pain management and rehabilitation, and complication prevention. Using innovative techniques and advanced technology, our surgeons are able to help patients with joint pain return to their normal, active lives."

The agreement opens the way for Northwestern Memorial to offer bundled services for hip and knee replacement at fixed prices for GE and its employees. GE members will

receive care from David Manning, M.D. and Matthew Beal, M.D. at the Center for Comprehensive Orthopaedic and Spine Care (CCOSC) in the 259 E. Erie Pavilion, the newest addition to Northwestern Memorial's downtown Chicago campus. The location offers one stop joint care, including pre-operative appointments, surgery, follow-ups and rehabilitation.

Hannah Alphas Jackson, M.D., M.H.S.A., Program Director of Value-Based Delivery at Northwestern Memorial Health-Care, told OTW, "The GE orthopedic Center of Excellence model steers employees and dependents to facilities, carefully selected by GE based on quality and efficiency of care, for their total joint replacement. It is a wonderful opportunity for partnership between our organizations to transform care delivery." — EH



Northwestern Memorial Hospital

Revision Surgeries Equal Six Percent

The first report is out from the American Joint Replacement Registry (AJRR) and it reveals that in 2013 6% of replacement operations were revision surgeries—most of them taking place within three months of the original surgery. Irvin Jackson, writing for *About Lawsuits.com*, notes that the data in the report covers only about 4.5% of joint replacement surgeries performed in the U.S. in 2013. He writes that “the number is expected to expand as more hospitals begin participating in the program.”

About 120 hospitals submitted data about 44,000 joint surgeries performed in 2013 along with information about 80,227 procedures that had been conducted since 2008. Jackson notes that the U.S. registry was launched after a similar but older registry established in the United Kingdom had detected that metal-on-metal implants were failing at rates up to 13%. Unfortunately, “the issues were not discovered until after hundreds of thousands of individuals had the defective implants placed in their body,” he wrote.

“We are pleased to be publishing our first comprehensive report,” said AJRR Board of Directors Chairman Dr. Wil-



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liam J. Maloney. “The data in this report covers the collection and analysis of data related to hip and knee replacement procedures that have taken place from when we began collecting data up until December 2013.” — BY

EXTREMITIES

Youthful Arm Injuries Cause Adult Surgeries

When Christopher Ahmad, M.D. Chief of sports medicine at Columbia University Medical Center, began seeing five to six patients a day who were complaining of sore arms, he became concerned. At the same time,

according to Shazia Khan, a reporter for *Warner Cable News*, Ahmad observed an increase in the number of major league baseball players who required surgery on their elbows.

Ahmad, who is head team physician for the New York Yankees, decided to look into it. As Khan reported, Ahmad had a theory that these mature professional athletes were experiencing injuries that dated back, in subtle ways, to injuries

to their arms that they had sustained when they were young players. He decided to find out.

the *American Journal of Sports Medicine*, were that three-quarters of the youth in the study reported having pain in their arms when throwing. Half of them reported being told to keep on playing despite experiencing pain—to throw through the pain.

Khan quoted Ahmad as saying, “If they are developing an injury and they are encouraged to push through it, they will get to a point where they will have irreversible damage in their shoulder and elbows that may affect them immediately, requiring surgery or may affect them later in life where they will have shoulder and elbow problems.”

Ahmad organized a study of 200 ball throwers between the ages of 8 to 18. Khan reports that the results of his investigation shocked him. Among his findings, published in



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Brothers Create Radical Carpal Tunnel Treatment

A doctor in Frederick, Maryland, Nathan Wei, M.D., is using a new procedure to treat carpal tunnel syndrome that has his patients grateful and excited about it. As described by Patti Borda Mullins, writing for the *Frederick News Post*, the procedure is done without general anesthesia, the patient has no pain from the procedure and the patient's symptoms are completely relieved.

As one patient told Mullins, "I've had (the procedure), but you can't tell it," she said, pointing to the pink dots on her wrist. "No one would know it but me. I'm just thrilled."

It began when Wei learned about the doctor brothers Danqing Guo and Danzhu Guo, of Green Bay, Wisconsin, who worked with a third brother Joe Guo, an expert in materials bio-science at Northwestern University. Together they developed the method that uses ultrasound to guide a thread

around delicate nerves and tendons in the wrist.

As Mullins described the procedure, it involves making small needle incisions through the wrist to allow for sewing using a special thread designed by Joe Guo.

The surgeon loops the thread around the transverse carpal ligament and saws through it to release the tension that causes symptoms. Wei told Mullins that the use of ultrasound and the special thread make the process unique. "Is that cool, or what?" Mullins wrote that he asked.

Daqing Guo went to Maryland to teach Wei the technique which they call "thread carpal tunnel release", or TCTR. Wei said that the first time he performed the procedure; it took him about 30 minutes. By the time he had done it a third time, he told Mullins that he completed it in 15 minutes. Patients recover in about 24 hours. Wei credits the use of ultrasound for the success of the treatment. "Most orthopedists do not know how to use diagnostic ultrasound," Wei said. "That is the secret sauce." — *BY*



Drs. Danqing Guo and Danzhu Guo, Courtesy of BayCare Clinic

High-Volume Hospital Best for TSA

Having a total shoulder arthroplasty (TSA)? Pick a hospital that performs many procedures. As outlined in *Arthritis Care and Research* and reported by Wayne Kuznar of MedPage Today, "hospitals with higher TSA volume had significantly lower rates of two key surgical complications—post-arthroplasty fracture and revision." This outcome held despite the fact that the higher volume hospitals dealt with more complex case loads.



Courtesy of Birmingham VA Medical Center and the Mayo clinic

A review of the Nationwide Inpatient Sample database provided the data. This is the largest all-payer inpatient care database in the U.S. It contains un-weighted data on about 8 million hospital stays each year. Researchers were Jasvinder A. Singh, MBBS, MPH, at the Birmingham, Alabama, VA Medical Center, and Rekha Ramachandran, MS, of the Mayo Clinic in Rochester, Minnesota.

According to Kuznar, the proportion of patients discharged to home was significantly higher in hospitals with a higher

annual TSA volume. Length of stay was shorter in the high volume hospitals but there was no difference in the rate of inpatient mortality between the low and high volume hospitals. However, the rate of complications was higher in hospitals with a lower volume of TSA patients.

The authors wrote that their study “indicates that TSA procedures at hospitals with high volume are associated with better outcomes compared to hospitals with lower volume, despite a higher patient complexity. As such, referral of more complicated cases to high-volume centers should be considered.” — *BY*

REIMBURSEMENT

CMS Wants to Sweeten ACO Pot

The Center for Medicare and Medicaid Services (CMS) wants to change the risk/reward equation for Accountable Care Organizations (ACOs) and is offering to sweeten the pot.

The agency is proposing to give ACOs an additional three years to get their act together before punishing them for not meeting financial goals.

There are now more than 330 ACOs serving about 5 million patients through the Medicare Shared Savings Program. ACOs earn bonuses if they meet Medicare benchmarks. The benchmarks are based on an ACO’s previous year’s performance. They pay a penalty if they miss the benchmark. Most ACOs currently have a three-year grace period from the penalties. Medicare wants to extend that grace period for three more years to entice more providers to participate in the program.

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According to *Kaiser Health News (KHN)*, in the first year of the program, 180 ACOs saved Medicare \$705 million. Half of those ACOs earned bonuses. Another 102 ACOs spent more than the Medicare benchmark, but didn’t have to repay Medicare because of the grace period.

The proposed change is one of dozens proposed by Medicare. *KHN* reported on December 1, 2014 that Sean Cavanaugh, Medicare’s director, said the

change was one of many prompted by concerns raised by ACOs. “The notion that 36 months later you’re going to be at downside financial risk is pretty intimidating.”



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If an ACO chooses to avoid the penalties after three years, they would be allowed to keep no more than 40% of the money saved by Medicare, rather than the 50% they can keep the first three years.

The agency is also proposing a “Track Three” model that allows ACOs to keep up to 75% of the money they save Medicare. But the risk for that extra reward is that if an ACO costs Medicare extra, then their pay-back responsibility rises from 10% to 15%.

Some providers have complained that it’s unfair for efficient ACOs to be held accountable for their previous years’ performance when less efficient providers get rewarded for beating their own inefficient performances. So CMS is also soliciting views on alternative ways of deciding whether an ACO has saved Medicare money.

KHN reports that under one option, ACO spending would be compared to the average spent by other doctors and hospitals in the region that are not part of an ACO.

The public has until February 6, 2015 to comment on the proposed rule. — WE

Aurora Spine developed the Zip 51 “as an alternative to pedicle screw fixation,” say company officials, “and designed it for stabilization and load sharing during T1-S1 thoracolumbar fusion procedures.” The device, they say, “it is also intended to be an adjunct to interbody fusion and the treatment of degenerative disc disease, spondylolisthesis, trauma and/or tumor.”

The Zip 51 represents Aurora Spine’s fifth FDA clearance in 11 months. “Aurora is changing spine surgery and we are thrilled to receive FDA clearance with the ZIP 51 another key product in the Aurora Spine MIS Fusion System,” said Aurora President and CEO Trent J. Northcutt. “This addition to our prod-

uct portfolio serves spine surgeons performing our screw-less minimally invasive procedure that prefer a slimmer profile and flared lower spikes. The success of our screw-less spine procedure is a testament to our laser focus on disruptive technology and our commitment to – Simplifying the Complex.”

According to the press release, Aurora’s Zip one-step locking mechanism eliminates the use of a set screw. Each Zip 51 implant features a large barrel designed for Zip Graft or other bone material. The device is designed in various sizes to accommodate variations in patient anatomy and is pre-packaged sterile. — BY



Courtesy of Aurora Spine Corporation

SPINE

Aurora Spine’s Zip 51 Gets FDA Clearance

Aurora Spine Corporation has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its slimmest minimally invasive interspinous fixation implant for spinal fusion—called the Zip 51.



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