VOLUME 10, ISSUE 19 | JUNE 17, 2014

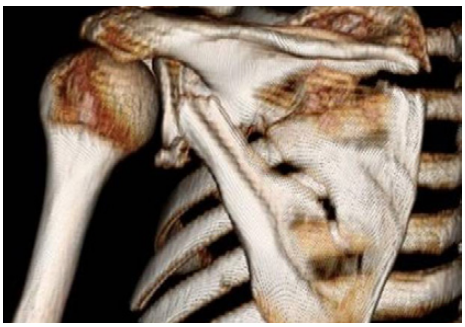
# Orthopedics This Week

## WEEK IN REVIEW

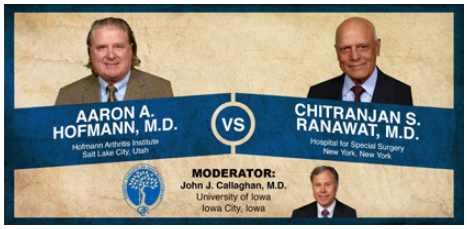
**4 AWOL Stryker Reps Defect to DePuy >>** Five Stryker sales reps in Northern California went AWOL on April 4, 2014. Before Stryker knew what happened, the five reps had resigned, gone over to DePuy Orthopaedics and brought their business with them. Stryker's business was decimated in the area so they sued the reps and DePuy for damages.

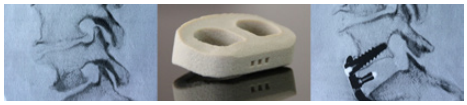
**8 Who Will Buy Smith & Nephew? And Why? >>** For a company that is not officially for sale, Smith & Nephew is attracting a lot of buying interest. While Medtronic will not likely buy the firm, Stryker may. Has scale economics trumped innovation economics? Read on to see what it all means.

**13 Minnesota's Peter Cole, M.D. – King of Scapula Repair >>** When Peter Cole started his quest no medical text chapter had yet been written about the scapula fracture repair. Today, with more than 30 peer reviewed articles to his credit, Cole is the King of Scapula Repair. This is a story every orthopedist should read.



**16 Hofmann, Ranawat Debate Post in Posterior Knee >>** "I think that the ultracongruent insert provides excellent posterior stability, it's bone sparing and technically easy, there are fewer complications, and it's certainly time saving," says Aaron Hofmann. "Wait," says Chit Ranawat. "RP-PS has better survivorship and improved ROM compared to fixed bearing posterior stabilized."



## BREAKING NEWS

**20** The **Politicization of Orthopedists**

Insurance Execs **Win Obamacare Jackpot**

**First 3-D** Printed **Spine Cage** Implanted

**$35 Billion** New Healthcare Spending Imminent

**Five Class III** Device Categories Proposed

**Medtronic Board Clears Itself** of Infuse Off-Label Violations

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

# Orthopedic Power Rankings

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

**THIS WEEK:** Go big or go home. That's the operative strategy in today's amazing med device consolidation wave. Every major medical device company seems to be in play. This week's is a $45 billion mash up of Medtronic and Covidien. Expect plenty of change as these mega-firms figure out how to integrate each other. What's the Chinese symbol for "opportunity" again?

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 1 | Zimmer | 27.31% | 4.61% | There is something about the purity of ZMH + Biomet deal. Builds on the strengths of the two firms. |
| 2 | 2 | Stryker | 15.71 | 4.16 | Integrating MAKO is proving to be a migraine-style headache. But at these prices SYK is THE cheapest equity in ortho. Still #2. |
| 3 | 3 | Exactech | 10.15 | 12.96 | When the dust settles from all of these mega-mergers, Exactech will still be there offering personalized service. |
| 4 | 7 | Integra LifeSciences | 11.77 | 6.00 | Could or would IART join the party? For a few years, not lately, acquisitions were a big part of IART's growth. |
| 5 | 5 | Symmetry Medical | 6.55 | 6.41 | Who else is big in large joints? Why, Symmetry Medical—the largest private label manufacturer of orthopedics in the world. |
| 6 | 6 | Orthofix | 6.75 | 3.01 | Analyst expectations for this June quarter are very modest—virtually no sales growth and down earnings. |
| 7 | 4 | Smith & Nephew | 20.25 | 17.96 | Having been bid up by speculators, SNN's valuation is no longer in the bargain category. Profit taking likely. |
| 8 | 8 | Medtronic | 28.84 | 0.08 | Merging with Covidien. Moving to Ireland. $45 billion deal. Second largest medical device company after JNJ. |
| 9 | NR | MicroPort Scientific | 35.16 | 5.07 | Fascinating company. They take Memphis USA made hips and knees, add innovation and aim for #1 share in China. Is that cool or what? |
| 10 | 10 | Johnson & Johnson | 26.58 | 1.65 | If DePuy were opportunistic and nimble, they'd jump all over today's musical chairs in large joints. But...JNJ has a hard time with nimble. |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | Smith & Nephew | SNN | $91.41 | $16,325 | 17.96% |
| 2 | Bacterin Intl Holdings | BONE | $0.77 | $42 | 14.78% |
| 3 | Exactech | EXAC | $24.75 | $338 | 12.96% |
| 4 | MiMedx Group | MDXG | $6.04 | $638 | 11.85% |
| 5 | Tornier N.V. | TRNX | $22.54 | $1,095 | 10.76% |
| 6 | Symmetry Medical | SMA | $8.63 | $324 | 6.41% |
| 7 | Integra LifeSciences | IART | $47.01 | $1,531 | 6.00% |
| 8 | Zimmer Holdings | ZMH | $105.58 | $17,718 | 4.61% |
| 9 | Stryker | SYK | $83.44 | $31,632 | 4.16% |
| 10 | RTI Biologics Inc | RTIX | $4.53 | $257 | 3.66% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | Aurora Spine | ASG | $2.65 | $42 | -16.14% |
| 2 | Baxano Surgical Inc | BAXS | $0.62 | $30 | -14.01% |
| 3 | ConMed | CNMD | $44.04 | $1,199 | -10.43% |
| 4 | Globus Medical | GMED | $23.23 | $2,171 | -2.72% |
| 5 | TiGenix | TIG.BR | $0.67 | $107 | -2.21% |
| 6 | K2M Group Holdings | KTWO | $14.90 | $567 | -1.32% |
| 7 | LDR Holding Corp | LDRH | $24.74 | $645 | 0.00% |
| 8 | Medtronic | MDT | $60.70 | $60,749 | 0.08% |
| 9 | NuVasive | NUVA | $33.69 | $1,570 | 0.39% |
| 10 | CryoLife | CRY | $8.71 | $245 | 0.46% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Medtronic | MDT | $60.70 | $60,749 | 16.10 |
| 2 | Zimmer Holdings | ZMH | $105.58 | $17,718 | 17.85 |
| 3 | Johnson & Johnson | JNJ | $102.53 | $290,068 | 18.18 |
| 4 | Stryker | SYK | $83.44 | $31,632 | 20.01 |
| 5 | Exactech | EXAC | $24.75 | $338 | 20.37 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $33.84 | $624 | 282.31 |
| 2 | NuVasive | NUVA | $33.69 | $1,570 | 108.69 |
| 3 | Symmetry Medical | SMA | $8.63 | $324 | 77.74 |
| 4 | Smith & Nephew | SNN | $91.41 | $16,325 | 29.00 |
| 5 | Integra LifeSciences | IART | $47.01 | $1,531 | 26.65 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Exactech | EXAC | $24.75 | $338 | 1.13 |
| 2 | Globus Medical | GMED | $23.23 | $2,171 | 1.48 |
| 3 | ConMed | CNMD | $44.04 | $1,199 | 1.92 |
| 4 | Zimmer Holdings | ZMH | $105.58 | $17,718 | 2.12 |
| 5 | Stryker | SYK | $83.44 | $31,632 | 2.20 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $33.84 | $624 | 15.34 |
| 2 | NuVasive | NUVA | $33.69 | $1,570 | 9.72 |
| 3 | CryoLife | CRY | $8.71 | $245 | 6.57 |
| 4 | Symmetry Medical | SMA | $8.63 | $324 | 6.48 |
| 5 | Smith & Nephew | SNN | $91.41 | $16,325 | 2.93 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Alphatec Holdings | ATEC | $1.36 | $133 | 0.65 |
| 2 | Symmetry Medical | SMA | $8.63 | $324 | 0.80 |
| 3 | RTI Biologics Inc | RTIX | $4.53 | $257 | 1.17 |
| 4 | Bacterin Intl Holdings | BONE | $0.77 | $42 | 1.27 |
| 5 | Exactech | EXAC | $24.75 | $338 | 1.40 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.67 | $107 | 18.68 |
| 2 | MiMedx Group | MDXG | $6.04 | $638 | 9.50 |
| 3 | Wright Medical | WMGI | $30.24 | $1,509 | 5.87 |
| 4 | LDR Holding Corp | LDRH | $24.74 | $645 | 5.78 |
| 5 | Globus Medical | GMED | $23.23 | $2,171 | 5.00 |

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

# AWOL Stryker Reps Defect to DePuy

**BY WALTER EISNER**

On the morning of Friday, April 4, 2014, the managers at Stryker Corporation's headquarters in Kalamazoo, Michigan, knew something was wrong. Something out of the ordinary was happening in Northern California.

Five Northern California sales representatives from Bakersfield and Fresno had gone AWOL and couldn't be reached.

Over the course of that day, Stryker Sales Manager Burr Cota, and several other Stryker employees attempted to reach their sales reps by phone, email and text messaging multiple times. None of the five—Brett Sarkisian, Keegan Freeman, Michael Nordyke, Taylor Smith and Bryan Wyatt—returned any of the messages.

*RRY Publications LLC*

## Defected to DePuy

The next day, Saturday, April 5, without any advance notice, the reps all resigned, effectively immediately, via resignation letters sent by FedEx.

The following week, Stryker discovered that all had taken jobs with DePuy Orthopaedics, Inc. and orthopedic surgeons who were previously Stryker customers were scheduling surgeries with DePuy through the five, now DePuy, reps. Prior to that time, none of those surgeons had apparently used DePuy products.

## Stryker Sues

It immediately became "readily apparent" to Stryker managers that the missing five had breached their employment agreements and duty of loyalty to Stryker, and that DePuy had engaged in tortious conduct in connection with the "misdeeds" of the former employees. Those are the charges in a lawsuit filed by Stryker on May 30, 2014 against the five former reps and Warsaw, Indiana-based DePuy Orthopaedics.

Brett Sarkisian and Bryan Wyatt started at Stryker in February 2008 as Reconstructive Sales Representative. Michael Nordyke began in May 2011 as a Trauma Sales Representative. Taylor Smith and Keegan Smith were both hired as Reconstructive Sales Associates in December 2011 and June 2012, respectively. Both were promoted to Sales Representative in January 2014.

Before resigning, Stryker claims the defendants solicited at least five Stryker customers to terminate their business with Stryker in favor of DePuy.

## Stryker "Decimated"

According to the suit, the above noted conversions of business, which happened over the course of a single weekend, could only occur if the defendants conspired with DePuy and with each other to transition those major customer accounts to DePuy while still employed by Stryker.

Stryker also said it discovered that all or some of the defendants solicited one another to leave Stryker en masse without prior notification to DePuy.

"It's clear the Defendants engaged in a calculated and systemic attempt to decimate Stryker's Recon and Trauma business in the territory," states the lawsuit.

As a result of the defendants' "wrongful conduct," Stryker anticipates losing 90% of its recon business, 60-70% of its trauma business and has been unable to staff reconstructive revision and shoulder surgeries.

Given the loss of all of its recon sales reps, Stryker claims it will take years for the company to regrow its market presence in the territory. "It will

*Stryker Headquarters/Stryker Corporation*

take Stryker approximately 12 to 18 months to train new Recon sales reps and it will take at least that long, if ever, to rebuild relationships with the doctors in this market."

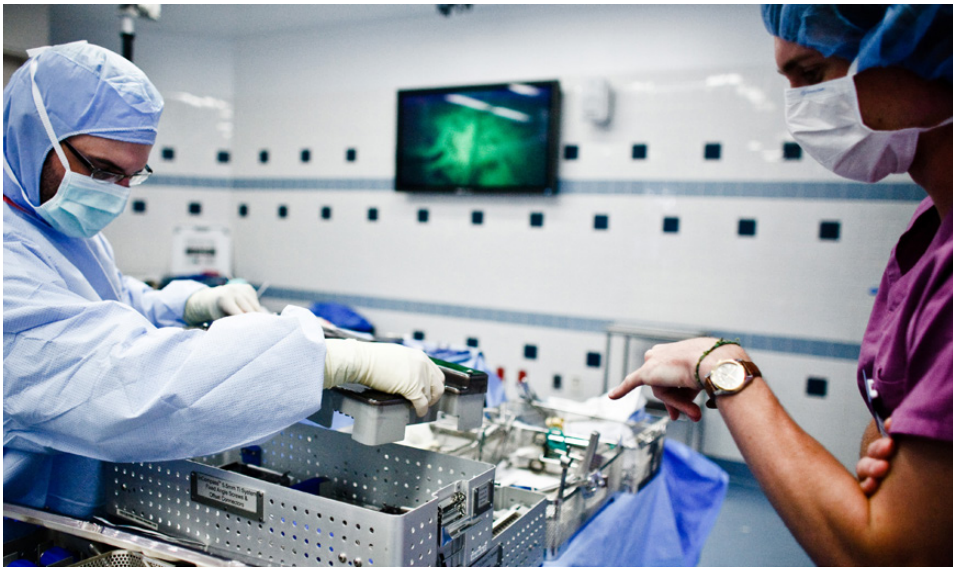
The company projects it will lose $3.4 million worth of business in 2014 and additional amounts in later years-due to the wrongful conduct.

## Premeditated Conspiracy Alleged

Stryker says it relies heavily on its sales representatives and the relationships they cultivate on Stryker's behalf with the surgeons and hospitals in their respective territories. The reps provide technical product information and specifications, coordinate training for surgeons utilizing its products, and are frequently present during surgical procedures. As a result, the reps become the face of Stryker to its customers.

Those customers typically establish long-standing relationships with Stryker and abrupt changes to different manufacturers are uncommon. Typically the company and the surgeon or hospital enter into a contract containing certain terms and conditions. The negotiations of those terms typically take weeks, if not months. Therefore, argues Stryker, the defendants and DePuy must have been cooking up this scheme long before the reps resigned.

Before using DePuy products, the surgeons would be required to learn about the technical specifications and requirements of the new products and negotiate a contract between the company and surgeon. Stryker's suit says none of these events could have occurred



*Andrew Huth*

over the April 5th weekend. The transition period would take weeks, if not months. The defendants would have had to do all this before leaving Stryker.

## Cover Up of Deception

In fact, claims Stryker, the reps purposely misled Stryker to cover up this "conspiracy."

Before quitting, the defendants allegedly loaded a number of fictional surgeries into Stryker's system. Following the resignations, Stryker learned those cases did not exist.

Stryker believes the defendants did this to hide their intent to leave Stryker en masse and their efforts to convert Stryker's business to DePuy prior to their resignations. "They began soliciting Stryker's customers to leave Stryker and move their business to DePuy before leaving Stryker," alleges the lawsuit.

On April 15, Wyatt covered five surgeries on behalf of DePuy with a surgeon who, prior to Wyatt's departure, was a Stryker customer. The other defendants did the same, says Stryker. These customers had previously generated millions in annuals sales for Stryker. Before the resignations, DePuy had no presence in the territory. Stryker says DePuy didn't even have a sales representative in the area.

## Employment Agreements Cited

Stryker says it invested a lot of time and money in training and development of defendants, who were given access to confidential and proprietary information. Therefore, Stryker required all the defendants to enter into post-employment, confidentiality and non-compete agreements.

All the defendants, according to Stryker, agreed that they would not solicit, attempt to solicit, induce or influence, or assist another to solicit, induce or influence any Stryker customer to terminate its relationship with Stryker, for 12 months after employment.

They all agreed to the same thing regarding any Stryker employee, agent, or independent contractor. Stryker's lawsuit exhibits all the former employees' contracts. As we've seen in previous lawsuits, those agreements can become a point of dispute between the parties.

## Stryker – Synthes Round One

This isn't the first time these two aristocrats of orthopedics have clashed over sales reps in Northern California.

In late summer and fall of 2011, as DePuy and Synthes were merging, three Synthes USA spine sales representatives in San Francisco—Michael Russell, Jonathan Sassani and Kristen Phillips-Cheng—resigned from the company and promptly went to work for Stryker Corporation.

Synthes accused Stryker of raiding their sales force in the San Francisco area to "obtain an improper competitive advantage through the use and disclosure of Synthes' confidential information and trade secrets by Synthes' former sales employees…."

Stryker could have cut the language from the Synthes suit and pasted it into their current suit as they allege the same damages and conduct. Synthes claimed the defendants breached their contractual duties to Synthes by using confidential information and trade secrets to solicit Synthes' customers in violation of the one year Non-Solicitation Agreements.

That lawsuit was eventually settled out of court in March 2012.

## Demands

Stryker is demanding a jury trial to consider the following counts:

- Breach of Contract and Duty of Loyalty against the five former reps.
- Aiding and Abetting Breach of Duty of Loyalty, Tortious Interference

With Contract and Prospective Economic Advantage with Stryker's Workforce and Customers and Corporate Raiding, against DePuy.
- Stryker is also charging Unfair Competition against all the defendants.

Stryker is asking the court to stop the defendants from soliciting Stryker's customers, prospective customers, and Stryker employees. The company is also seeking actual, incidental, compensatory, exemplary, punitive and consequential damages in an amount to be determined at trial.

## Lawsuits Galore

As the number of orthopedic manufacturers continues to decline through consolidation and demand driven by newly insured patients climbs, it's likely more reps and distributors will look around for their best deal.

Zimmer Holdings, Inc. recently accused Stryker of a "Trojan Horse" poaching scheme in Texas. Stryker sued Biomet, Inc. last fall accusing Biomet of poaching two sales reps from them in Louisiana and New York. Smith & Nephew sued a Biomet distributor in Austin, Texas in 2012.

In the meantime, if anyone has seen the five AWOL Stryker reps wandering around in Northern California, tell them to phone home. ♦

# Who Will Buy Smith & Nephew? And Why?

**BY ROBIN YOUNG**

For a company that is not officially for sale, Smith & Nephew, plc (SNN)is attracting a lot of buying interest.

Most recently Medtronic, Inc. was mentioned in the financial press as a prospective buyer—until they squashed that idea at an analyst meeting.

Before that, in late May, *The Financial Times* reported that Stryker Corporation (SYK) was preparing a takeover bid for Smith & Nephew. Big companies don't usually like their internal merger and acquisition musings splashed all over the raucous press.

Smith & Nephew, however, is a London based company and has to abide by the rules of the UK Takeover Panel. The Panel, which was established in 1968 to issue and administer the City Code on Takeovers and Mergers, regulates takeovers. They try to make sure shareholders are treated fairly. In their view competition and mergers are matters of public interest.

So when the Panel heard rumors that Stryker might be interested in Smith & Nephew they contacted Stryker and popped the question: are you planning to bid for Smith & Nephew in the next six months?

As it happened, the very day the news broke about the UK Takeover Panel's inquiry to Stryker, CEO Kevin Lobo was appearing on Fox Business News. So on May 28, Lobo was asked on national television about Stryker's heretofore private sizing up of Smith & Nephew.

He was ready and said, essentially, nothing. To quote: "We were in preliminary evaluations about considering a transaction. For the next six months we are not in a position to make an offer."

*Morguefile*

Notice the key words: "…preliminary… considering…evaluating." "…not in a position to make an offer."

Naturally every major Wall Street analyst heard Lobo and assumed that Stryker would buy Smith & Nephew.

To be fair, the analysts did cite one hard fact—Zimmer is buying Biomet.

## Analyst Speak

From Wells Fargo's research department to its institutional investors:

> "We think that an acquisition of SNN by SYK would make strategic sense, given the recently announced ZMH/Biomet transaction and the specula-

tion of further consolidation in the orthopedic industry. The combined SYK and SNN would have over 30% market share of the hip and knee markets, second only to the combined ZMH/Biomet, assuming the acquisition is completed. Given that SYK was only at an early stage of evaluating a takeover of SNN, we would not be surprised to see SYK eventually bid on SNN."

From Royal Bank of Canada's research department:

"**Scale is becoming more important in orthopedics, and SNN looks ripe for the picking.** JNJ management highlighted at its recent MD&D day its thoughts on the potential benefits of scale going forward in this "new" healthcare environment. The potential acquisition of SNN would vault SYK into the clear #1 or #2 market share position in several important key orthopedic markets such as recon, trauma, and sports medicine. For example, we estimate that SYK/SNN would have the following combined worldwide market shares: sports medicine ~37%, recon ~34%, and trauma ~25%."

## Spasm of Consolidation

The power structure of medicine is almost certainly shifting. It appears to be moving from the healthcare provider to payers and government.

Changing regulations, reimbursement policies, medical device taxes, healthcare reforms and rise of payer power are altering the structure of orthopedics and driving companies to consolidate.

Synthes Inc., a Swiss medical device company, was recently acquired by Johnson & Johnson for $21.3 billion. In their explanation of the deal to investors, Synthes cited more aggressive bargaining by increasingly budget controlled hospitals and the slow growth of key products as the proximate reason to drive economies of scale through consolidation.

Harvard business professor Michael Porter, Ph.D. (the Thomas Kinkaid of management science) developed a simple framework for looking at competition in any industry. Using the Porter model, here's how the shifting balance of power in orthopedics looks.

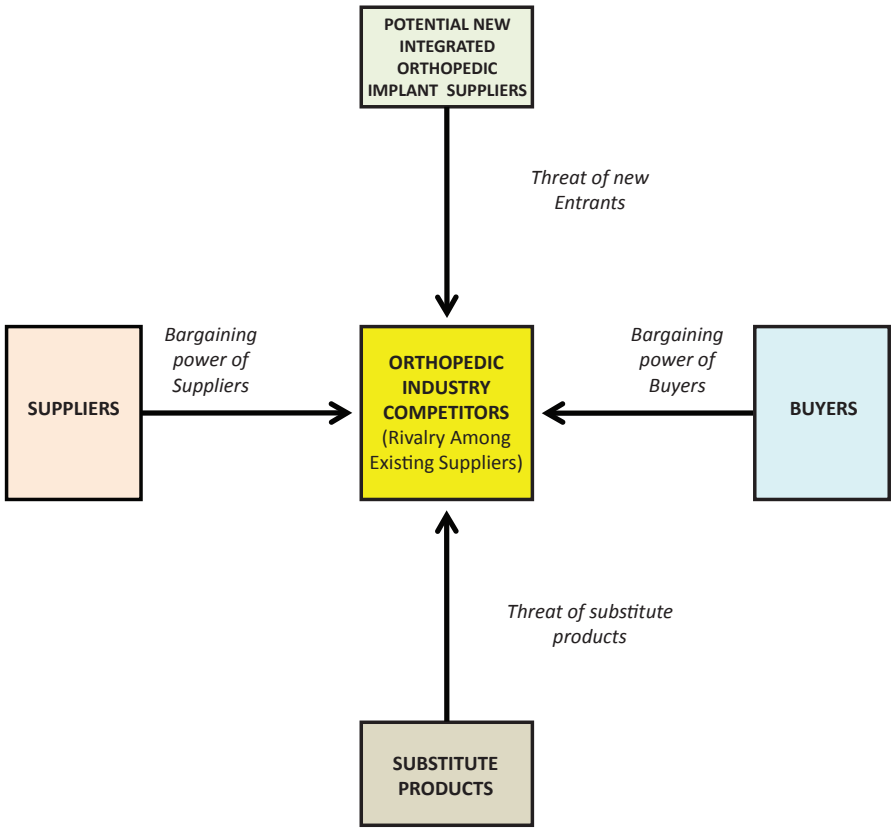
Five companies (Zimmer, Biomet, Stryker, DePuy, Medtronic Spine and Smith & Nephew) sell more than 90% of all orthopedic implants. Their products are a close substitute for each other. In practice, they compete fiercely and drive points of differentiation which, to an outsider, may seem minor but to the Stryker or Zimmer or Smith & Nephew or DePuy rep, are EVERTHING.

Excepting for a minute MicroPort Scientific Corporation's purchase of Wright Medical Group, Inc.'s large joint business, the threat of a new, diversified orthopedic implant entrant coming into the market is almost nil. Likewise the power of suppliers of titanium, stainless steel or polymer—the raw materials for most implants—is also negligible.

In terms of substitute products, that threat is also low, but the rise of biologic and cellular treatments for arthritis and degenerative disc disease are dark horse threats to traditional implants.

## Rise of the Buyer

The bargaining power of the buyer of orthopedic implants, however, is changing fast. The principal source of competitive pressure in orthopedics today is coming from the buying side of the business.




*Michael Porter, Ph.D., Harvard Business School*

Buyers of orthopedic implants and instruments are growing in strength and negotiating power. So much so, in fact, that orthopedic implant companies like Stryker or DePuy or Zimmer are arguably at a competitive ***disadvantage*** to the buyers.

Who are these ever more powerful buyers? They are the large integrated hospital chains, they are the massive payers like Medicare, Aetna, United, Cigna and so forth and they are the regionally powerful bundlers of healthcare services.

The annual spending budgets of these actors are many multiples larger than the combined revenues of the top five integrated orthopedic companies.

In this industry, the buyer's ability to apply competitive pressure to orthopedic implant suppliers has become painfully apparent to all industry participants.

Size negotiates with size. Larger buyers force sellers to get larger too. No one wants to negotiate from a position of weakness.

## Scale, Not Innovation

Orthopedics is morphing into an industry driven by scale economics, not innovation economics.

The most important rivalries in the coming decade will not so much be between individual suppliers (i.e., DePuy, Stryker, Zimmer) as they will be between suppliers and buyers (payers and bundlers).

When asked by analysts about the causes of industry consolidation, Zimmer's management pointed to consolidation among hospitals and private practices, and the presumption that such action will continue in the wake of economic and regulatory pressures as the primary drivers of industry consolidation. "They're [buyers of orthopedic implants] going to be looking for savings…by partnering with fewer vendors that can offer a fuller portfolio of solutions," said David Dvorak, Zimmer's CEO.

Michael Orsinger, chairman of Johnson & Johnson's DePuy Synthes orthopedics unit, said on May 22 that customers are

demanding a "one stop shop" approach toward implants. He predicted that it will drive continued consolidation in the industry. Volume is the name of the game, said Orsinger. And the shifting landscape may lead JNJ to accept "a slightly lower margin, but compensated by larger volume," and ultimately, he hopes, higher profits.

What is happening in the orthopedic industry today, in other words, is a structural change.

## Smith & Nephew

Wells Fargo senior analyst for medical supplies and devices, Larry Biegelsen, expects that a merger of Stryker and Smith & Nephew would be highly accretive to Stryker shareholders and would change Stryker's sector market shares as follows:

**Orthopedic Market Share Worldwide by Sector**

| | Stryker | Smith & Nephew | Combined | Rank |
|---|---|---|---|---|
| **Hips** | **22%** | **12%** | **34%** | **#2** |
| **Knees** | 19% | 12% | 31% | #2 |
| **Recon** | 21% | 12% | 32% | #2 |
| **Spine** | 8% | 0% | 8% | #3 |
| **Trauma** | 15% | 9% | 24% | #2 |

*Source: Wells Fargo Research Report*

The new attractive gal at the orthopedic dance has been around for quite a while. Smith & Nephew, in fact, predates the American Civil war.

The company was founded in London in 1856 by Thomas James Smith of Kingston upon Hull who went into business as a dispensing chemist. A few months before his death in 1896, Smith was joined by his nephew, Horatio Nelson Smith, and the business became known as *T.J. Smith and Nephew*.

In 1928 the company developed the wound management product Elastoplast. By 1977 the company acquired the pump manufacturer Watson-Marlow Pumps, before selling it to Spirax-Sarco Engineering in 1990. In 1986 it went on to acquire one of the pioneers of orthopedic implants Richards Medical Company for £201 million.

In 2002 the company acquired Oratec Interventions, a surgical devices business, for $310 million. It went on to buy Midland Medical Technologies, a hip resurfacing business, for £67 million in 2004.

The company acquired Plus Orthopedics, a Swiss orthopedics business, for U.S. $889 million in April 2007 and BlueSky, a U.S. wound care business, for $110 million in May 2007.

In September 2007 Biomet, Inc., DePuy Orthopaedics Inc. (part of Johnson & Johnson), Smith & Nephew, plc and Zimmer Holdings Inc. entered into settlement agreements, under which they agree to pay $300 million in total, adopt industry overhauls and undertake corporate monitoring to avoid criminal charges of conspiracy.

The company acquired Healthpoint Biotherapeutics, a specialist in the bioactives area of advanced wound management, for $782 million in December 2012.

In February 2014, Smith & Nephew announced the purchase of ArthroCare Corporation for $1.7 billion in cash. This was seen as a move to broaden the company's sports medicine range for minimally invasive surgery moves the company into the ear, nose & throat market.

Last year Smith & Nephew posted up sales of $4.4 billion and operating profit of $810 million. The company earns about 18 cents on every sales dollar. Interestingly, Smith & Nephew pays out nearly 42% of its earnings to its shareholders. Which is the same as Stryker. Zimmer, by contrast, pays out only 18%.

## What Now?

Once the dust has settled, will this be the new orthopedics industry? *(See chart on page 12)*

Eight years ago, April 3, 2006 to be exact, Biomet stunned the orthopedic world by announcing that it had hired Morgan Stanley to conduct an auction to sell the business. The announcement came amidst a backdrop of board room intrigue which resulted in the shocking resignation of Biomet co-founder and industry legend, Dane Miller.

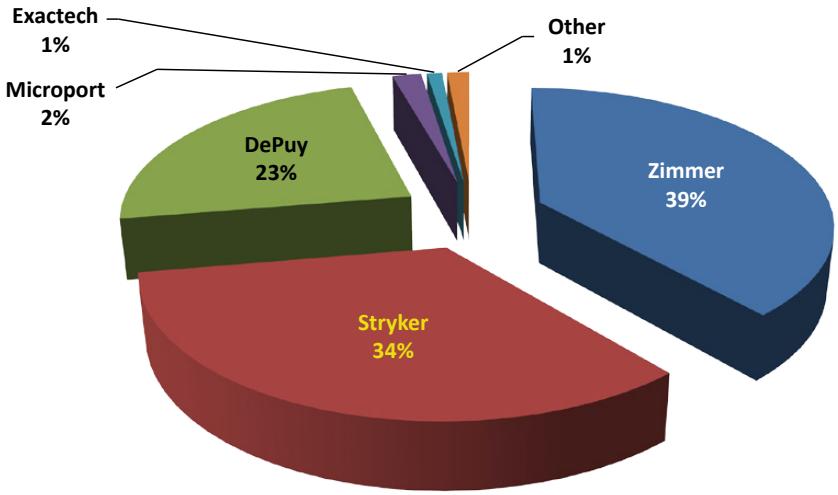
Two weeks later analysts on a conference call with then Zimmer CEO Ray Elliott and his CFO Sam Leno asked about the apparent Biomet sale. To

be sure, the ***idea*** of a large integrated orthopedic company putting itself up for sale was slightly astonishing. Elliott answered analysts by saying that Zimmer's M&A strategy was more geared to product or division "bolt-ons."

Morgan Stanley's auction of Biomet was a success. A consortium of private equity firms paid a 27% premium to buy Biomet for $10.9 billion later that same year.

Fast forward to 2014. Today the answer to the question of "Would Zimmer buy Biomet" has changed to "yes." And with that answer, the strategic calculus at every other major firm shifts yet again. We're in a brand new world in orthopedics. ♦

**Global Hip and Knee Implant Sales**




*Robin Young Consulting Group, Inc.*

# Minnesota's Peter Cole, M.D. – King of Scapula Repair

**BY BILOINE YOUNG**

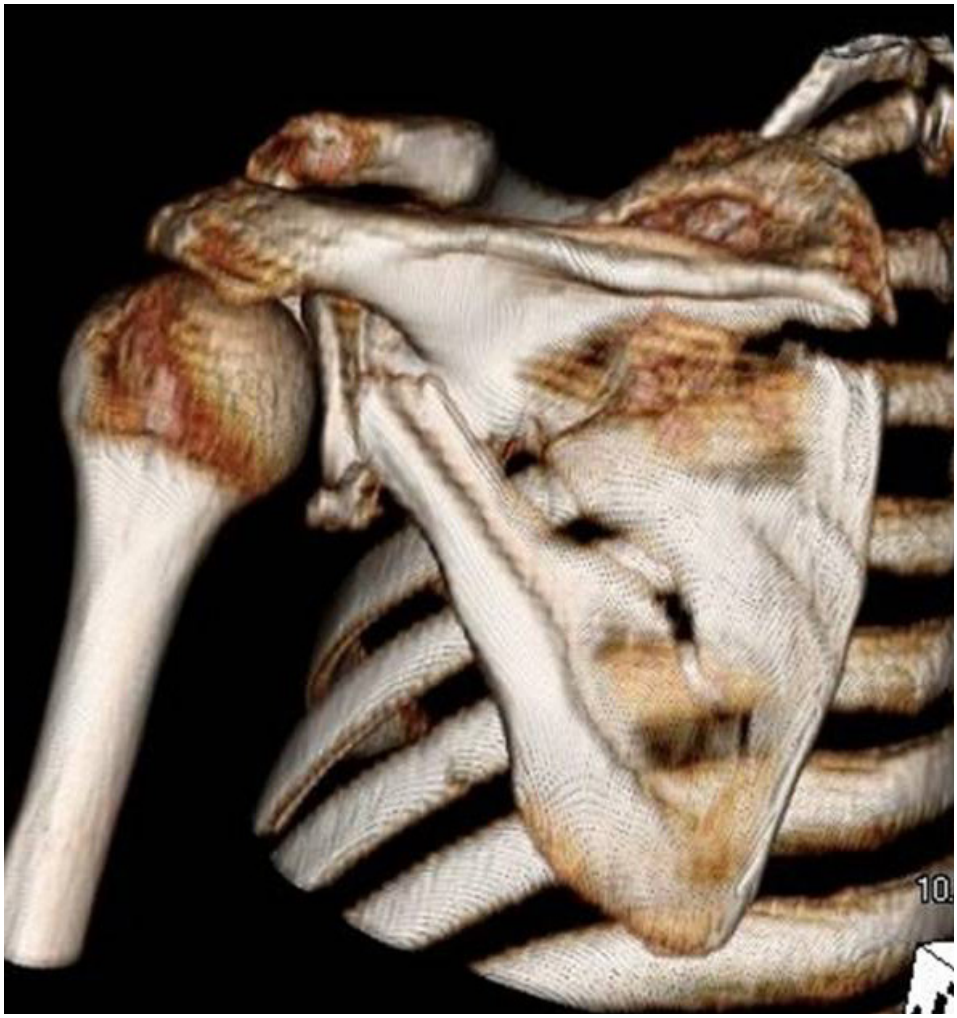
It is not easy to break a shoulder blade. Breaking a shoulder blade—or scapula—takes a great deal of force. In 80% of the time a patient who has broken a scapula will also have major chest wall injuries. Half of the time there will be broken bones in the upper body, 15% of the time the victim will have severe cervical and cranial injuries.

Ronald Engleman, Jr., an engineer from New York City, understands broken scapulas. He broke his when the galloping horse he was riding took a sudden turn to its right and Ronald's body continued straight ahead, over the head of the horse to a hard landing on his shoulder. Engleman had been focused on getting his foot out of the stirrup and landing somewhere besides on his face.

His friends got him to the nearest hospital in Wheeling, West Virginia, where doctors found that Engleman had broken his scapula and some ribs but that his lungs remained unpunctured and he had no bleeding in his chest. Doctors told him that the broken ribs and scapula would heal on their own and sent him home. They advised him to consult an orthopedic surgeon but no one mentioned to him that the bones of his scapula were not only broken but also displaced.

A week later Engleman, still sore and swollen, saw the chairman of the orthopedic department at a hospital in Brooklyn. The doctor told him "it looks like a pretty bad break. You may need an operation, I can't tell without a CAT scan of the shoulder."

For a week Engleman called daily, trying to schedule a CAT scan. When his insurance company told him it needed more information from his doctor before the scan could be scheduled, he decided to try a third hospital, the one at New York University in Manhattan. Here a surgeon who specialized in shoulders arranged for the scan. After the doctor saw it he told Engleman he would have to accept not being able to raise his arm and the pain. He advised him to just live with the disability. "If I were operating on you," he told Engleman, "I would risk more nerve damage."



*Courtesy of Peter Cole, M.D.; Regions Hospital Scapula Institute*

## Doug Helfet, HSS to the Rescue

It had now been three weeks since the accident. Engleman was a young father and he could not accept not being able to lift and play with his children. He looked to his friends for advice and one of them suggested Dr. David Helfet, the chief of Orthopaedic Trauma at the Hospital for Special Surgery (HSS) in New York City.

Engleman, X-rays and NYU CAT scan in hand, got an appointment with Helf-

*Peter Cole, M.D. Chief of Orthopaedics Regions Hospital, Saint Paul, Minnesota*

et the Friday before Hurricane Sandy was due to hit New York. Helfet confirmed that Engleman needed surgery but added that he, Helfet, was flying to India that evening and so could not schedule the operation. He told Engleman that, with the kind of displaced scapular fracture that he had, he should contact Dr. Peter Cole at Regions Hospital in Saint Paul, Minnesota.

Engleman did. He found Cole to be a fit young surgeon with curly reddish hair. A New Englander who had graduated from the University of Miami School of Medicine, Cole had done his internship and residency at Brown University Hospital in Rhode Island and a trauma fellowship at Harborview Medical Center in Seattle, Washington.

When he finished his training, Cole began looking for areas in orthopedics to specialize in what had been neglected or that had not been discovered or developed. He admits to having felt a bit of pioneer spirit when he found that the scapula or shoulder blade was the most neglected bone in the body.

No chapter had yet been written in a medical text about the scapula. No one had described the techniques for surgical repair and few had written papers on the problems associated with failure to treat the displaced parts of the scapula. As was the case with cracked ribs, doctors said to their patients, "Well, it will heal on its own and there is not much we can do about it." There was a perception that "they will do fine."

Cole believes doctors got away with that attitude because the shoulder has so much compensatory motion. It has more motion than any other joint in the body. Because of all the motion, people who had damaged their scapula were able to accommodate the deformity enough to get by. Observing this, doctors thought they were doing all right by their patients by not treating broken scapulas with surgery. The fact was that few knew how to approach the fracture anyway.

## Cole's Aha! Moment

Cole dedicated his career to changing that. It bothered him that surgeons were treating the scapula differently from how they treated every other bone in the body. As an orthopedic surgeon Cole had been trained to treat every bone in a manner to restore its alignment, length, rotation and stability. Yet he had been told by his mentors that the shoulder blade was different.

Cole did not believe that. There was no way that the shoulder blade could be different from every other bone in the body, he thought. His axiom was "function follows form." "I decided I would establish indications for surgery on the scapula and if a patient met those standards on the displacement of the fracture or the angle of deformity, I would operate," he said.

That was a bold position for a young surgeon to take. He was doing surgery that was new and innovative. Because medicine in the United States is an evidence-based discipline he knew he would get criticism. Though he was busy gathering evidence, when he was starting out he had little of it. When asked to justify his treatment he would reply that he wanted to treat patients the way he, himself, wanted to be treated, "I do not want my shoulder blade to be deformed and not be able to raise my arm," he said. "I am doing for the scapula what I would do for any other bone. You need to prove to me why you are not doing surgery."

Believing that it was irresponsible to do something innovative and not study it, Cole established a registry of his patients. He recorded everything: strength, motion, healing, X-rays, functional outcomes.

When he had data on about 70 scapular patients Cole presented his finding at a national conference. At the end of his presentation well known surgeons rushed the podium to severely criticize him for operating on bones that had not been operated on before—and for performing surgeries when there was no proof that he was making a positive difference.

## Cole Answers Critics With 30 Peer Reviewed Papers

Cole, though certainly taken aback, says that he has a great deal of respect for the colleagues who took him to task in those early years and challenged him to prove the benefit of what he was


*Regions Hospital Scapula Institute*
*Photograph by Billie Young*

doing. He calls that the "sharpening iron within our profession."

Cole now finds himself invigorated in a different way. Now it is easier sailing. "The spinnaker is out," he says, "the wind is behind our backs." Now he is defining new techniques, new ways to fix the bone, new approaches to the incision on the body, new diagnostic strategies. He says that his vision is to put himself out of business because "my colleagues will all know how to fix broken scapulas instead of me being the only guy who knows how to do it."

Twelve years since he started, Cole and his associates have published more than 30 papers in peer reviewed journals, have 15 book chapters to their credit and Cole has conducted a master's class in Switzerland on his surgery. Patients have come to their Regions Hospital Scapula Institute from all over the U.S. and other countries for surgery on broken scapulas.

## Return to 80-90% Functionality

Ron Engleman had his surgery with Cole on November 6, 2012, a month following his accident. He was hospitalized at Regions for three days and then began out-patient physical therapy. Cole had him return to St. Paul for check-ups after six weeks and again after three months. At that point Engleman had achieved 80% of his former mobility in his shoulder but Cole was not satisfied. He wanted it to be over 90%. He told Engleman that his therapist was going too easy on him, that he had to have more intensive, aggressive therapy. Otherwise, he warned, scar tissue would become fibrous and he would lose mobility. Engleman took pain medication before his sessions with his therapist and complied with Cole's recommendation.

Engleman is now pain free. "When the first couple of doctors said that there was nothing that they could do, I felt awful. I was just starting out with kids. I had to be a daddy who could do things and I could not lift my 35 pound son. I wanted to be able to teach my children to swim," he said.

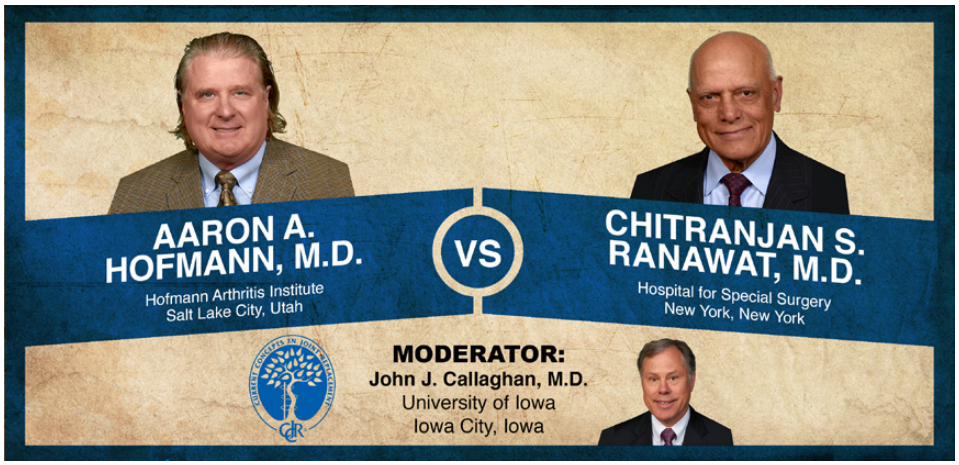
Cole notes that the majority of scapula fractures—perhaps as many as 85%—do not require surgery. He is occupied finding out where that threshold is, developing new diagnostic and minimally invasive approaches and inventing new instrumentation to make the surgeries on a broken shoulder blade even more successful. ♦

# Hofmann, Ranawat Debate Post in Posterior Knee

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

"I think that the ultracongruent insert provides excellent posterior stability. It's bone sparing and technically easy, there are fewer complications, and it's certainly time saving," says Aaron Hofmann. "Wait," says Chit Ranawat. "RP-PS has better survivorship and improved ROM [range of motion] compared to fixed bearing posterior stabilized."

This week's Orthopaedic Crossfire® debate is "The Posterior Stabilized Knee: No Post Required." For the proposition is Aaron A. Hofmann, M.D. from the Hofmann Arthritis Institute in Salt Lake City; against the proposition is Chitranjan S. Ranawat, M.D. from Hospital for Special Surgery. Moderating is John J. Callaghan, M.D. from the University of Iowa.




*Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Hofmann:** "I don't think you need a post if you have a deficient knee. If you want to save the posterior cruciate ligament (PCL) you must protect it from the saw, so I put a 1/4 inch osteotome in front of it. The problem is really the quality of the tissue you're saving. In 1987 John Insall told us that the exact tensioning of the PCL is difficult and may depend on luck. I think I've begun to believe him over the years, and now I sacrifice the PCL every time."

"When I went back and looked at my own PCL sparing (I thought) knees about eight years ago, I found that 3% of them had some posterior sag…and that they actually didn't have a PCL. And the solution that Dr. Ranawat's going to defend today is the posted version that came about in 1978. The named attributes of this version were improved operative exposure, ease of balancing collaterals, reduction of poly wear, greater contact area, and lower normal forces."

"But it wasn't all positive. We know that there are always a small number of patients with stress fractures. And there are some with dislocation (especially with the earlier designs), sometimes requiring reduction with an anesthetic."

"Then there is the patella clunk syndrome. The fibrous tissue nodule that goes into the intercondylar notch gets stuck and clunks and catches. It's a small incidence now, but I do occasionally see people with this issue."

"Each week I have patients complaining about the rattle in their knees. It's usually a little flexion laxity. I turn to the ultracongruent insert, which was conceived in 1991. It's an extension of the total condylar, has a 12.5 mm anterior buildup, it has more congruent articulation, a higher contact area, but there is no box cut for the femur. This has been copied by at least six manufacturers and the ultracongruent insert is my favorite implant. I use this 100% of the time as opposed to the standard insert for PCL salvage."

"Nearly 20 years ago in Seth's lab they looked at the type of stability the PCL provided, and the ultracongruent was always above the 350lb force that the PCL provides. So I think that the ultracongruent insert provides excellent posterior stability, it's bone sparing and technically easy, there are fewer complications, and it's certainly time saving. We get great motion with this implant; make sure when using it that the PCL isn't functioning because it would create a kinematic conflict. So I use flat insert trials just to be sure."

"There is no rollback just simply a congruent surface against the femur and provides great stability."

**Dr. Ranawat:** "Why use an ultracongruent insert? It is helpful in preventing posterior subluxation of the tibia. That occurs when there is an incompetent PCL, excessive tibial slope, and/or reduced posterior femoral offset. There are two recent publications supporting ultracongruent inserts. One from

Peters in 2013 and one from Hofmann in 2010. However, two gait analysis studies from 2012 (Daniiliadis and Massin) show variable knee kinematics in flexion."

"There is data indicating that the CR (cruciate retaining), the PS (posterior-stabilized) and RP-PS (rotating-platform posterior-stabilized) total knees will give you similar results—a failure rate of 3-4% at 10 years. But if you look at the meta analysis from Bercik (*Journal of Arthroplasty* 2013) it says that the CR and PS results are similar. However, range of motion (ROM) is superior with the PS knee. And there are a number of Level I and II studies showing that the RP-PS has a slight edge over the fixed bearing."

"All good things in life ultimately prevail. If ultracongruent was the best then you would all be using it. So the total knee—no matter what kind—must have several things in order to be successful. It must be properly aligned, the soft tissue must be balanced (both in flexion and extension), the joint line must be maintained, you must size the femoral component correctly to restore offset, and you must have proper cement fixation."

"In 2012 I published a study in the *Journal of Bone and Joint Surgery* on the results of the RP-PS total knee. My hypothesis was that at 10 years RP-PS should have better survivorship and improved ROM compared to fixed bearing posterior stabilized (FB-PS) total knee replacement. In 2000 I gathered 138 consecutive RP-PS knees and followed them prospectively. All of the patellae were resurfaced and all components were fixed with cement."

"A total of eight patients were lost to follow-up and 20 had died. We examined the Knee Society Pain Score and Functional Score, ROM, the Western Ontario and McMaster Universities Arthritis Index (WOMAC), and a patient administered questionnaire. It asked if they had any knee pain in the last three months, if they had any noise in the knee, if they were satisfied with the knee, and asked about sports activities."

"All the results on the different parameters were very good; ROM improved after surgery. Postop, 40% were still participating in sporting activities. As for the question, 'Do you have any pain in your knee?' 14% said 'yes.' The other questions: anterior knee pain (7.5%), noise and crepitation (9.4%), painful crepitation requiring scar excision (2.8%). According to the patient sur-

vey, 95% were satisfied; five patients were dissatisfied due to pain in the operative knee and in other joints. There was no spinout; three were revised (one for infection and two for fracture due to falls)."

"Radiographically, there were no radiolucent lines or loosening. Survivorship for mechanical reasons was 100%, and it was 95% for all reasons. So our results support the basic science data that the RP-PS is superior to PS. So what is the place of the ultracongruent insert with the CR knee? How many inserts are being used among all of you? If you are using an increasing amount of them then it's a good insert. If your numbers aren't growing, then consider RP-PS."

**Moderator Callaghan:** "Aaron, a minute to tell Chit where he's wrong."

**Dr. Hofmann:** "Debating Dr. Ranawat is like debating your father…you're just not going to win. One point, though. The ultracongruent is a kinematic mismatch if you're saving the cruciate ligament. If you get rollback with the ultracongruent then that lip is going to go outward. You don't save the posterior cruciate if you're using the ultracongruent. That lip will be a kinematic conflict with the extensor mechanism. This is a sacrificing concept. And we don't want to confuse the issue of the rotation with the rotating PS. The ultracongruent that's rotating would be the LCS [low contact stress] knee, which is a very deep dish, conforming implant that doesn't have a post and works exceptionally well."

**Moderator Callaghan:** "Chit?"

**Dr. Ranawat:** "The RP-PS was designed to address spinout of the low contact stress (LCS) knee. When you have an ultracongruent, but no post, in about 1-3% there is spinout…and when that happens you need a revision. This occurs if the balance of the soft tissue sleeve in flexion is uneven. My point is that when you use a PS knee, technically it makes the operation relatively simpler. The main disadvantages of PS knees were anterior knee pain and crepitation. I believe that this has nothing to do with PS; it has to do with the location and anterior margin of the box. If you can modify the design—in the trochlear groove—then I think the incidence of this would decrease. Note that we cannot eliminate anterior knee pain after TKR [total knee replacement]. My theory is that the knee is made preferentially with innervation and blood supply—they go together intramedially. So any time you disturb that—even in a uni total knee—there are a certain percentage of patients who have anterior knee pain. This pain is due to the disturbance of the C fibers due to surgical intervention.

"That may also be the reason why a varus knee hurts more than a valgus knee."

**Moderator Callaghan:** "When did you get this revelation that you weren't going to be a PCL retainer anymore?"

**Dr. Hofmann:** "When we did our first seven-year review we found out that 3% of our patients had lost their PCL (and there's no way to predict who they are). Also, I was training fellows and they had the choice between saving the PCL or using an ultracongruent… and they all left and started using the ultracongruent because it was an easier operation. If I had a healthy PCL I would save it; it's gotten to the point where we sacrifice it because training a lot of people makes it easier to take it."

**Moderator Callaghan:** "Do you not buy that rollback is important for range of motion?"

**Dr. Hofmann:** "The lowest point in the ultracongruent is not dead center, so it starts posterior—6 mm posterior. So there's already some rollback; you keep a low lip on the posterior side. These patients have fantastic ROM. My average ROM is 125 degrees."

**Moderator Callaghan:** "Chit, can you go over the cause of noise and how you have come to prevent that?"

**Dr. Ranawat:** "The noise is caused by scar tissue, predominantly in the superior area. So you want to remove all of the synovial lining and the soft tissue around it and cauterize it. That reduces the risk of forming scar tissue. It's a design issue…the post has to be in the right location. In the data you heard the post was too far posterior—you get better ROM with this, but you create more patellofemoral symptoms. Engagement should be around 65-70 degrees of flexion. Surgical technique is also important. In addition the anterior margin of the box is critical. In the PFC System we had to keep it there because we were converting a primary to a revision system and you need a robust box to put a bolt there."

**Moderator Callaghan:** "Aaron, it can be tricky to get that insert in. Any tricks?"

**Dr. Hofmann:** "You must have exposure. You hyper flex the knee and dislocate the tibia anteriorly so you have a straight shot to the tibia. My technique for inserting the poly is the same no matter what style I'm using."

**Moderator Callaghan:** "Thank you gentlemen." ♦

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

COMPANY

# Paradigm Spine: Two Articles Address Fusion, coflex Effectivenss

Paradigm Spine, LLC has announced the recent publication of two focal clinical research articles addressing both the costs and morbidity associated with fusion procedures performed in the treatment of spinal stenosis, and separately its comparative effectiveness relative to the company's coflex Interlaminar Stabilization device and procedure.

In the recently released publication titled "*Comparative Cost Effectiveness of coflex Interlaminar Stabilization Versus Instrumented Posterolateral Fusion for the Treatment of Lumbar Stenosis*" published in the March 2014 edition of the *Journal of Clincoeconomics and Outcomes Research*, researchers suggest that the coflex Interlaminar Stabilization device and procedure is better utilized from a comparative effectiveness perspective for the treatment of lumbar spinal stenosis, when compared to instrumented spinal fusion, with savings measured over a five-year time table estimated to be approximately $11,700 per surgical case.

In a separate publication titled "*Perioperative Outcomes, Complications, and Costs Associated with Lumbar Lumbar Spinal Fusion in Older Patients with Spinal Stenosis and Spondylolisthesis*" published in the June 2014 edition of the *Journal of Neurosurgery Spine* (*JNS*), researchers highlight the incidence of patients undergoing lumbar decompression and spinal fusion for the treatment of spinal stenosis and spondylolisthesis, with an emphasis on the rate of complications, cost, and readmission rates for patients receiving these treatments.

Paradigm Spine Chairman and CEO Marc R. Viscogliosi told *OTW*, "We believe there is an opportunity to develop additional comparative effectiveness evidence on the entire spinal stenosis disease pathology and the various treatment options that exist, and correlating those treatment options to a more well-defined algorithm of care. While we know from the compendium of literature that surgical treatment of spinal stenosis results in better QALY [quality-adjusted life year] and ICER [incremental cost-effectiveness ratio] values compared to medical management, there remains differences in opinion of which specific types of stabilization treatment options to provide in the presence of back pain, facet pathology, low grade degenerative spondylolisthesis, and even simply neurogenic claudication. We are in process of developing compelling long-term Level 1 evidence which we believe may help inform physicians, payors, policy makers and patients."

Hallett Mathews, M.D., MBA, chief medical officer of Paradigm Spine, notes the importance of the data to assist surgeons with difficult decisions regarding patient treatment selection and the avoidance of costly mistakes. Dr. Mathews stated in the June 10, 2014 news release, "Fusion has been the mainstay of stabilization for decades now, and these studies, along with the landmark studies published by Davis, et al. in *Spine*, August 2013 and Davis, et al. in *JNS*, May 2013, prove to us that a less morbid, minimally invasive form of stabilization can occur after a decompression for the treatment of moderate to severe lumbar spinal stenosis without the need for rigid segmental stabilization with a fusion. Maintaining motion and not having to wait for arthrodesis has to be better for this patient group.' Dr. Mathews also mentioned that "coflex and its improved outcomes and operating efficiencies combined with reduced overall costs and multiple sites of care, including the ambulatory surgery setting, truly improve value for all stakeholders." — *EH*


*Image source: Paradigm Spine, LLC*

# First 3-D Printed Spine Cage Implanted

The world's first spinal fusion surgery using customized spine cages created with a 3-D printer was performed on May 28, 2014 by Vincent Fiere, M.D. at the Hospital Jean Mermoz in Lyon, France.

The operation, according to a news release from French-based MEDICREA group, used the company's UNiD ALIF intersomatic anatomical inter-body device.

**Design, Record and Print**

The device was developed from a 3-D digital file created from the extraction and treatment of pre-operatory scanner images of the patient, a process developed internally by the company's R&D teams. "The company's design, recording and production methods open the door to the future development of implantable devices that can identically reproduce the elements of the spine that need to be reinforced or replaced by artificial components printed in 3-D on implantable polymers or titanium," said the company statement.

Dr. Fiere said the cage, specifically 'printed' by MEDICREA for his patient, "positioned itself automatically in the natural space between the vertebrae and molded ideally with the spine by joining intimately with the end plates, despite their relative asymmetry and irregularity. I could also very precisely perform the restoration of the disc height and simultaneously correct the degree of lumbar lordosis using plans I had made several days before the operation with the help of MEDICREA's Surgimap software tool."

The device extends the company's UNiD platform, following the launch of the UNiD pre-curved osteosynthesis rod service in Europe earlier this year.

"Continuing our trajectory since the launch of our PASS LP UNiD rods which are made to measure for each patient, MEDICREA confirms its position as the pioneer of intelligent spinal implants, perfectly adapted to the morphology of each patient's spinal column and developed in a rational and planned manner to restore the fundamental mechanical equilibrium of the human body," said company President and CEO Denys Sournac. "By providing pre-planned customization, our goal is to improve patient outcomes and allow our surgeons customers to complete their plans in advance and solely focus on executing their strategy in the OR."

MEDICREA has 120 employees with headquarters near Lyon, France. The company also has a manufacturing facility for surgical instruments and implants located in La Rochelle as well as three distribution subsidiaries in the U.S., the UK and France.

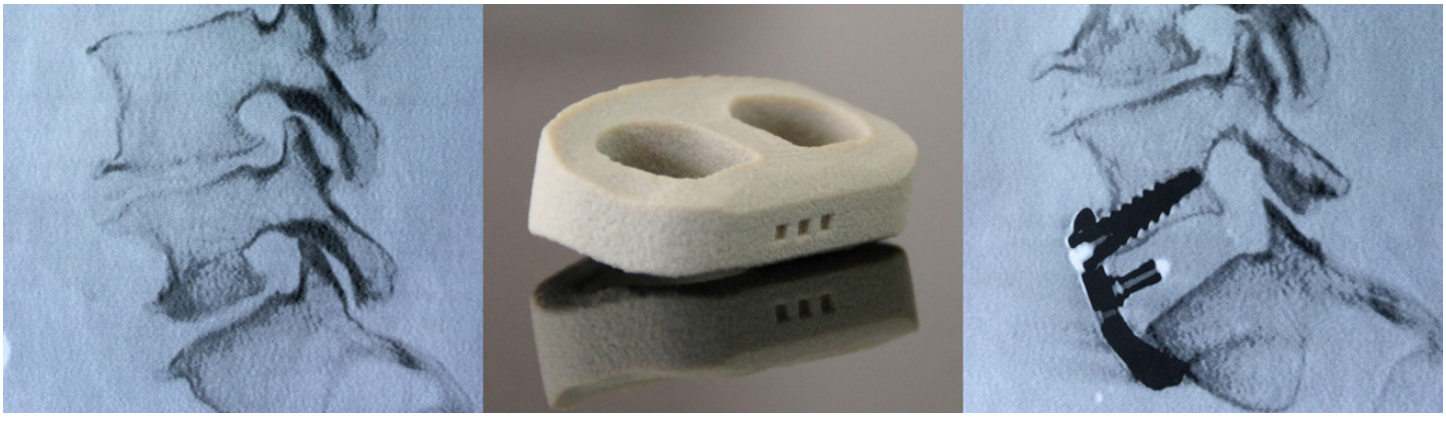
**FDA Oversight**

The regulatory pathway for printed devices is still in its infancy. The FDA says 3-D printed devices are treated like any other medical device. The agency has two laboratories that are looking into ways 3-D printing could affect the way medical devices are manufactured in the future.

The FDA's Functional Performance and Device Use Laboratory uses computer-modeling methods to determine how tweaks to a medical product's design could affect its safety and performance in various patient populations. The agency says understanding the effect of these tweaks helps the FDA evaluate devices that are customized to an individual patient or group.

The FDA's Laboratory for Solid Mechanics focuses on how different printing methods affect the strength and durability of the materials used to make the devices. The lab's findings "will help us to develop standards and set parameters for scale, materials, and other critical aspects that contribute to product safety and innovation," FDA scientists wrote in a recent blog post.

"Scan me up, Scotty." — *WE*



*MEDICREA group*

# Insurance Execs Win Obamacare Jackpot

Life is good at the top of the health-care food chain.

The chief executives of the 11 largest for-profit insurers earned more than $125 million in total compensation in 2013.

### Aetna's Bertolini Wins

Of the 11 insurers—Aetna, Centene, Cigna, Health Net, Humana, Molina, Triple-S Management Corporation, UnitedHealth, Universal American, WellCare and WellPoint—Aetna CEO Mark Bertolini earned the most, taking home $30.7 million in 2013—an increase of 131% from the year before, according to a recent *FierceHealthPayer* report.

In contrast, the administrator of Centers for Medicare and Medicaid Services (CMS), the biggest insurer was paid $165,300.

That's the biggest Obamacare jackpot for any health insurance executive since passage of the Affordable Care Act and exceeded the compensation of the next two highest paid health insurer CEOs combined. Centene CEO Michael Neidorff took home $14.5 million last year, up 71% from the previous year, according to Healthcare-Now, a non-profit group that advocates for a single-payer system.

Almost all of the 11 insurers saw their revenue and profits rise last year and several are predicting that they'll likely bring in higher-than-expected profits this year. Those predictions come as medical claims are rising as more consumers bought coverage from the health insurance exchanges.

*Aetna CEO Mark Bertolini/Creative Commons.*

### Average Comp Up 19%

The average pay for Fortune 500 health insurance CEOs grew from $11.6 million in 2012 to $13.9 million in 2013. And for the top nine insurers, CEOs saw their average compensation packages increase by more than 19% last year, while other insurers more than doubled their CEO pay.

### Top CMS Administrator

"In contrast, the top administrator of Medicare —our public, universal health plan for all seniors, which is more efficient, provides better financial protection, and receives higher marks from patients than private health insurers—is paid less than $200,000 per year. The culture of excess at these for-profit corporations is incompatible with the goals of an efficient, ethical health care system, where every dollar diverted from patient care represents a loss of access for real families," said Benjamin Day, director of organizing at Healthcare-NOW.

Day continued: "We face the highest healthcare costs and have among the worst health outcomes of any country in the developed world because we allow private health insurers and dozens of other intermediaries to act as for-profit middlemen in the health care system. Although many backers of the Affordable Care Act said it would rein in insurance company excesses, the law clearly hasn't curtailed top executive pay."

Hey, it's tough to manage all that risk while finding new ways to deny coverage and buy up hospitals. — *WE*

## Top Paid Insurance CEOs

| Company | 2012 CEO Compensation | 2013 CEO Compensation |
|---|---|---|
| Aetna | **$13,285,935** | **$30,725,409** |
| WellPoint* | $27,064,211 | $16,979,927 |
| Centene | $8,474,744 | $14,512,938 |
| Cigna | $12,881,495 | $13,524,079 |
| UnitedHealth | $13,887,455 | $12,073,284 |
| Molina | $4,951,315 | $11,903,124 |
| Health Net | $10,160,381 | $8,134,538 |
| Humana | $8,433,985 | $8,848,066 |
| WellCare* | $5,505,173 | $7,097,778 |
| CMS Admin. | $179, 700 | $165,300 |
| Average CEO | **$11,627,188** | **$13,866,571** |
| Average Worker | **$34,645** | **$35,239** |
| | * WellPoint 2012 and WellCare 2013 includes compensation for incoming and outgoing CEOs. | |

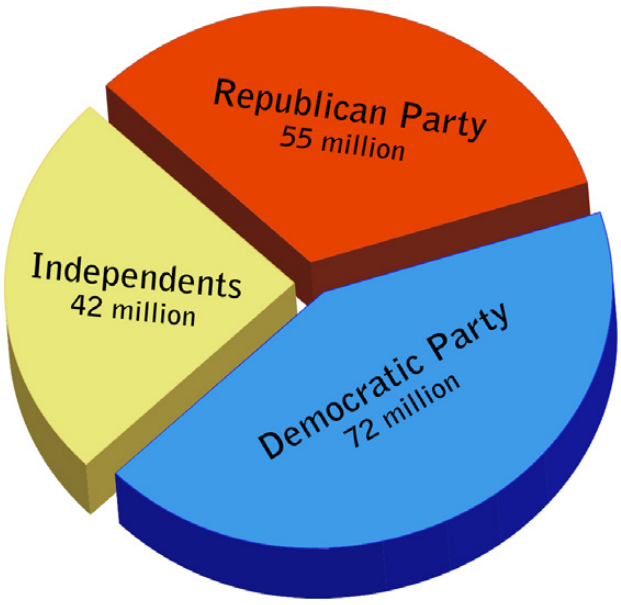
*Courtesy of Healthcare-NOW*

# The Politicization of Orthopedists

To which political party do doctors give their money—Democrats or Republicans? And is the existing pattern of donations changing? A study by the American Medical Association says that physicians are indeed becoming more political. Paul Demko, writing for *Modern HealthCare* and quoting the study, points out that physicians are much more likely to make political contributions now than they were two decades ago.

During the 1992 election cycle, 11,801 doctors contributed the equivalent of $20 million to political campaigns. Two decades later, 67,852 physicians contributed a total of $143.2 million to candidates and causes.

Demko maintains that the change is being driven by the differences in perspective between male and female doctors. An analysis of the 11 election cycles covered by the study found that 57% of the contributions from male doctors went to Republicans. During the 2012 election cycle men gave 52.3% to Republicans and women doctors gave just 23.6%.




*Wikimedia Commons and Murray Buckley*

The study found that three quarters of the contributions made by male orthopedic surgeons to political campaigns supported Republican candidates. However, only a third of male psychiatrists supported Republicans. Among women, about half of the anesthesiologists who made contributions backed Republicans, but only a quarter of female family practitioners did.

A co-author of the study, David Rothman, said, "If surgery is in your name, you're on the Republican side. If pediatrics or psychiatry is in your name, you're on the Democratic side." Perhaps because 16 of the 20 physicians who serve in the U.S. House or Senate are Republicans, people assumed that doctors politically were on the right. That has changed.

Demko noted that in two of the last three election cycles, a majority of contributions made by doctors went to Democrats. If, as the study authors suspect, the gender difference is a driver of the shift, this situation will probably not change. Instead it will increase because women are making up an increasingly large share of the physician pool and are now about half of new medical school graduates. — *BY*

LEGAL

# Medtronic Board Clears Itself of Infuse Off-Label Violations

Physicians seek out information from device manufacturers about off-label uses for their patients. The FDA offers little guidance on exactly what constitutes promotion of medical devices.

With that, a Special Litigation Committee formed by the Medtronic, Inc. Board of Directors determined there was no evidence that the company promoted Infuse in an off-label manner.

**Shareholder Demands**

In 2012 and 2013, Medtronic, Inc. shareholders, led by Jennifer Howard and William Houston, demanded that the company sue certain current and former directors and officers for complicity in executing a scheme to evade the Federal Drug Administration's prohibition against off-label promotion of medical devices in order to increase sales of Infuse. The shareholders claimed the officers breached their fiduciary duties to the company by causing it to conspire with physicians to underreport adverse events in studies involving Infuse

In addition, several shareholder derivative actions were filed in Minnesota state court and U.S. District Court for the District of Minnesota.

**Special Litigation Committee**

In response, the company's Board of Directors established the Special Litigation Committee on August 23, 2012.

The findings of the committee may well set out legal defenses Medtronic will use in ongoing lawsuits, including the Humana, Inc. charges that the company conspired with surgeons to manipulate research and then market Infuse in an off-label fashion.

The committee was made up of George McGunnigle, a retired Minnesota state court judge and John Matheson, a corporate law professor at the University of Minnesota Law School. They were given the power and authority to investigate the shareholder claims and the derivative lawsuits to determine whether any rights and remedies should be pursued. In other words, should the company take legal action against those directors and officers?


*Colorado.gov, Medtronic, Inc. and RRY Publications*

**"No Merit" to Charges**

On May 30, 2014, after an 18-month investigation, the committee came back with their answers. The former judge and law school professor concluded that the claims against the officers and directors were without merit.

**Inadequate FDA Guidance**

In a June 10, Medtronic SEC regulatory filing, the committee noted, "Despite the Important Medical Information and the specific warning that the safety and effectiveness of such unapproved uses had not been established, many surgeons did begin to use INFUSE® in procedures other than the FDA-approved single-level ALIF."

Further in the report, the committee writes that physicians may seek information about a product's appropriateness for their patients, from the manufacturer.

"Therefore, physicians occasionally request information from a manufacturer about a contemplated off-label use. Although the FDA has long recognized this fact, it has not provided a precisely defined mechanism for a manufacturer to transmit information about off-label uses to a physician without the manufacturer running afoul of the FDA's ban on off-label promotion.

Therefore, manufacturers, including Medtronic, use FDA guidance documents, FDA letters to other companies, court cases, information about Depart-

ment of Justice prosecutions, and common sense to establish policies that balance a physician's need for scientific information about an off-label use with the FDA's prohibition of off-label promotion. Manufacturers, the FDA, and the medical community all recognize that a clinician, who determines that an off-label therapy would benefit his or her patient, should be able to access available information in order to maximize patient safety."

Furthermore, "there was little FDA guidance on exactly what did and did not constitute promotion of medical devices."

### Rejects Complaints

The committee determined that it is important to clearly state this finding: "it has not found support for and rejects the core proposition of the demand letters and derivative complaints—that Medtronic, with the knowledge and complicity of the defendants, designed and executed a scheme to evade the FDA's prohibition against off-label promotion in order to increase the sales of INFUSE®."

On June 4, 2014, the committee filed a motion for approval of its findings and for dismissal with prejudice of the consolidated shareholder derivative actions pending in the state court. The consolidated cases are captioned Daniel Himmel, derivatively on behalf of Medtronic, Inc. v. Gary L. Ellis, et al.

The committee also intends to file a similar motion on June 14, 2014 seeking the dismissal of a similar derivative action pending in the U.S. District Court for the District of Minnesota captioned Charlotte Kokocinski, derivatively on behalf of Medtronic, Inc. v. Arthur D. Collins, Jr., et al. — *WE*

## Five Class III Device Categories Proposed

The FDA wants to establish five categories of Class III devices.

After complaints from stakeholders that the original deadline of June 23, 2014 did not allow for enough time to analyze and respond to the proposal, the agency backed down and extended the deadline to comment on the proposed rule on classification and reclassification until September 22, 2014.

### Then There Were Five

The five categories of Class III devices would be defined by risks, benefits and available controls. According to the agency, moving to the new classifications could streamline classification of high-risk devices and promote consistent expectations about the process and provide for classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation.

Under the planned rule, Class III devices would fall into one of the following categories:

- Devices that present known risks that can't be controlled;
- Novel devices for which the risk-benefit profile is unknown or unfavorable;
- Devices for which general and special controls are insufficient, necessitating a full review of manufacturing information;
- Devices for which premarket review of any change affecting safety or effectiveness is required; and
- Combination products.

The FDA currently categorizes medical devices into one of three classes—Class I, II, or III—based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.

Recent changes to the FDA law allow for the reclassification of devices by administrative order instead of by regulation.

### Read It Here

Interested parties may submit electronic comments to http://www.regulations.gov or written comments to Docket No. FDA-2013-N-1529. Read Thursday's Federal Register notice here. The proposed rule is here: http://www.fdanews.com/ext/resources/files/03/03-31-14-Classification.pdf. — *WE*


*FDA*

BIOLOGICS

## Astonishing Sonic Tweezers Manipulate Cells Into Cartilage

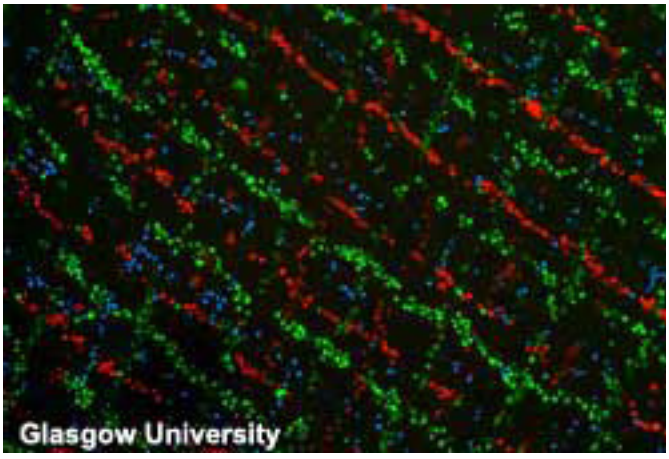
What are sonic tweezers? From *Nanowerk News*, an IT publication in the United Kingdom, comes a description that says that sonic/electronic tweezers are gravity-beating ultrasound beams that can grip and hold tiny clusters of cells. Cells in the grip of such devices can be levitated for weeks in a nutrient-rich fluid and be stimulated to grow and form better implant tissue than if the tissue were cultured in a glass petro dish.

By holding the cells in the required position the tweezers can mould growing cartilage tissue into exactly the shape researchers want so that an implant will be the right size and shape when it is inserted into the patient's knee.

Ultrasonic tweezers have been developed by a closely integrated team of researchers from four United Kingdom universities (Bristol, Dundee, Glasgow and Southampton) together with a select group of industrial partners. Their work has established the UK as a world leader in this technology.

Professor Bruce Drinkwater, of Bristol University who coordinated the program, said, "Ultrasonic tweezers have all kinds of possible uses in bioscience, nanotechnology and more widely across industry. They offer big advantages over optical tweezers that rely on light waves and also over electromagnetic methods of cell manipulation. For example, they have a complete absence of moving parts and can manipulate not just one or two cells (or other objects) at a time but clusters of several centimeters across—a scale that makes them very suitable for applications like tissue engineering."

Professor Martyn Hill from the University of Southampton, who led the cartilage tissue engineering work, said, "Ultrasonic tweezers can provide what is, in effect, a zero-gravity environment perfect for optimizing cell growth. As well as levitating cells, the tweezers can make sure that the cell agglomerates maintain a flat shape ideal for nutrient absorption. They can even gently massage the agglomerates in a way that encourages cartilage tissue formation."



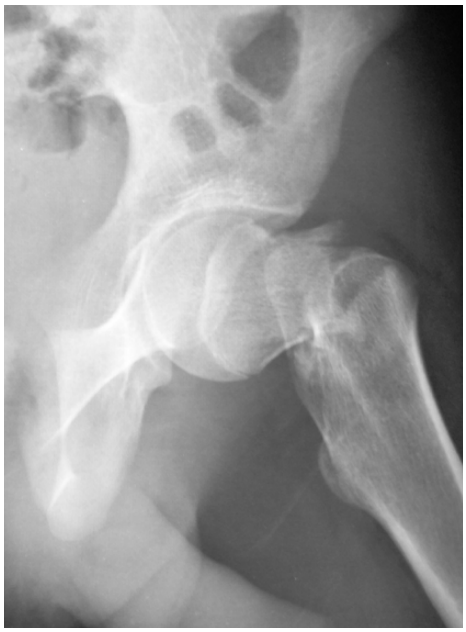

*Caption: Stained cells manipulated by sonic energy/Source: Courtesy of Glasgow University and Professor David Cumming*

The research program has also shown that ultrasonic tweezers can be used to build up cell tissue layer by layer. Members of the team anticipate that the tweezers could be used to help to reconstruct nerve tissue after severe trauma such as limb amputation. — *BY*

LARGE JOINTS

## Fractures Hotbed of Infection? Yes! New Study From Sweden

Surgical site infections (SSI) occur in 0.7% of knee replacement surgeries and in 1% of hip replacements. SSI's are the most common cause for rejection of the prostheses in hip replacement surgery, according to a number of studies presented in London at a conference of the European Center for Disease Prevention and Control (ECDC).



*Wikimedia Commons and booyabazooka*

A Swedish study, presented at the conference, found that fracture patients who get an artificial hip have a significantly higher risk of infection than do people who undergo similar surgery due to a degenerative hip disease. Investigators found that joint infections occurred most often in cases with secondary fracture prosthesis. This was about 2.8% of cases—including cases where internal fixation had failed. Younger patients

were at higher risk of infection than were older people.

The Swedish study revealed how difficult the treatment of postoperative infections can be. Only 40% of the cases could be cured. In 42% of the cases doctors brought the structural infection under control only after permanent resection arthroplasty. Almost all of these cases were fracture patients. Ten percent of the patients required a life-long antibiotic therapy and 8% died during their treatment.

"Adequate prophylactic measures are necessary, especially against staphylococcus aureus and coagulase negative staphylococci, the most decisive factors in infection among fracture patients," said the study's main author, Piotr Kasina, M.D., from the Karolinska Institute, Stockholm. His research group examined the records of 3,807 cases of hip replacement cases at the Stockholm South General Hospital between 1996 and 2005.

Researchers noted that the diagnosis of periprosthetic joint infections, and not just the treatment, presented challenges to orthopedic surgeons. An Austrian research team identified a new parameter for the detection of periprosthetic joint infections in revision arthroplasty. "We have compared the sensitivity and specificity of conventionally used biomarkers such as C- reactive protein [CRP] and leukocyte levels to that of PCT, IL-6 and interferon alpha. CRP has proven itself indeed as the best biomarker for diagnosing infections from periprosthetic revision surgery, but PCT and IL-6 were likewise shown to be helpful. They could be used as additional indicators when a diagnosis is not clearly conclusive," said Mathias Glehr, Ph.D., from the Graz University Hospital. — *BY*

## Symmetry Medical Launches Offset Acetabular Reamer Driver

Symmetry Medical Inc. has announced that it has launched the Dual Connection Offset Acetabular Reamer Driver through its OEM Solutions team. Symmetry indicates that its new Dual Connection Offset Acetabular Reamer Driver is used during total hip arthroplasty (THA) surgery to easily introduce acetabular reamers to the hip joint and to enhance visibility in minimally invasive procedures such as Direct Anterior Approach THA surgery. The driver features a patented drive shaft assembly designed and tested to meet the demands of THA surgery.

The product highlights include:

- Improved access to the acetabulum due to the low-profile reamer/driver connection
- Innovative design allowing easy disassembly to facilitate the cleaning and sterilization of the internal components
- An ergonomic silicone over-molded stabilization handle
- Compatibility with Symmetry's flagship 420SS Acetabular Reamers as well as the Low-Profile Parabolic Reamers

Thomas W. Barrett, senior vice president and chief commercial officer, Symmetry Medical OEM Solutions, said in the June 11, 2014 news release, "The launch of the Dual Connection Offset Acetabular Reamer Driver is a significant advancement in our proven line of acetabular preparation products and further enhances our comprehensive offering of instruments for the anterior surgical approach for hip arthroplasty. Our New Product Development team tested this device extensively to validate the mechanical longevity with a focus in optimizing the long term functional performance and the overall ease of use. By providing valuable proprietary product innovation that can be added to our customers' surgical instrument sets, we continue to support our OEM customers, orthopedic surgeons and the patients that they serve."

Barrett told *OTW*, "With the addition of the new dual connection offset acetabular reamer driver, we feel Symmetry Medical has the broad-

*Symmetry Medical Inc.*

est product portfolio to service our customer's needs for direct anterior approach hip arthroplasty. This procedure is growing in popularity due to the benefits it provides for patients and there has been an opportunity for improvement specifically in the area of instrumentation for preparing the acetabulum. The new Symmetry product was tested thoroughly by Symmetry Medical R&D and has documented performance longevity and a design with minimum components which results in optimum ease of use for cleaning and sterilization—both of which have been fully validated and are available to our customers. Our goal is to make it a simple process for our OEM customers to integrate this product into their existing hip instrument systems." — *EH*

## Three New Reconstructive Products From DePuy Synthes

DePuy Synthes Joint Reconstruction introduced three products for hip, knee and shoulders replacements on May 22, 2014.

**Shoulder**

According to the press release, the Global Unite Anatomic Shoulder Platform Shoulder System "enables surgeons to use the same humeral stem to repair shoulder fractures or perform a total (anatomic) shoulder replacement." For patients later needing a reverse total replacement, surgeons are able to covert the already-implanted humeral stem to a total reverse construct without the use of a stack-on adaptor. The use of a stack-on adaptor may overstuff the joint and limit the patient's range of motion."

**Hip**

"The Corail Revision Hip System is designed to treat patients in need of hip revisions who have mild to moderate femoral defects," according to the press release The company states that the Corail is the first and only tapered wedge revision stem in the U.S. Should patients need additional revision surgery in the future, the system has a bone-preserving design. The company says that an additional benefit is that the Corail stem requires the same number of instruments as the primary stem. Normally, more instruments are required for a revision surgery than the primary surgery.

**Knee**

The company also introduced the Trumatch Resection Guide for its recently released Attune Rotating Platform knee. A resection guide and pin guide are also available for the Attune fixed knee.

Per the press release, "Trumatch Personalized Solutions is a surgical instrumentation system that aids in knee implant positioning and procedural efficiency. The system utilizes as few as two traditional trays in the operating room (compared to an average of 6-9 trays) and eliminates up to nine surgical steps, which can increase procedural efficiency."

DePuy Synthes introduced the Attune knee system a year ago and implanting more than 31,000 of the devices during that time. Zimmer Holdings, Inc. also introduced a new knee, the Persona, a year ago.

The last two significant knee system launches before that were Biomet Inc.'s Vanguard and Stryker Corporation's Triathlon in 2004. — *WE*

*Caption: (Left to right) Trumatch Resection Guide, Global Unite Anatomic Shoulder Platform Shoulder System and Corail Revision Hip System/Image Credit: Reconstructive Products/DePuy Synthes*

REIMBURSEMENT

## $35 Billion New Healthcare Spending Imminent

Calling it "an emergency", bill co-sponsors Senator John McCain, Republican from Arizona, and Senator Bernie Sanders, Independent from Vermont, have rounded up virtually unanimous (519 in favor, 4 against) support for spending *an additional* $35 billion on private healthcare services over the next three years.

The bill, called the Unified Veterans Bill, is a response to the recent delay scandals that have plagued the Veterans Administration (VA). VA healthcare services, which have justifiably earned high marks over the years for coordination of care and leading in several technology areas including electronic medical records, has been overwhelmed with demand from returning Iraq and Afghanistan soldiers.

*Morguefile and Mensatic*

The VA's Office of Inspector General said in a report last month that 1,700 veterans seeking treatment at the Phoenix VA hospital were at risk of being "lost or forgotten." The VA has confirmed that at least 35 veterans died while awaiting treatment in Phoenix, although officials say they do not know whether the deaths were related to long waiting times for appointments.

The Veterans Affairs Department released an audit this week showing that more than 57,000 veterans have had to wait at least three months for initial appointments. An additional 64,000 veterans who asked for appointments over the past decade never got them.

The VA, which serves almost 9 million veterans, has faced mounting evidence that workers falsified reports on wait times for medical appointments in an effort to mask frequent, long delays.

One expert estimated that the VA would require approximately 700 additional physicians in order to adequately meet the current demand.

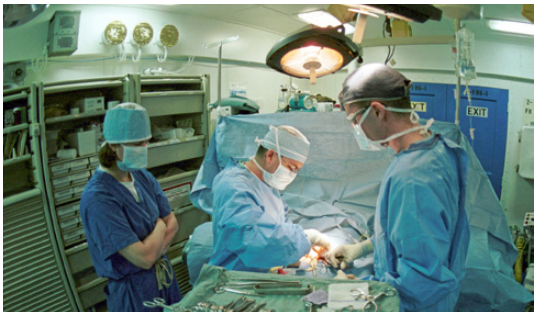
The bill, which is expected to reach President Obama's desk for signature in a matter of days, will pay private healthcare institutions to care for veterans.

Critics of the bill say that it is a "blank check" to spend billions of dollars with little or no way to rein it in. Said Senator Jeff Sessions, Republican from Alabama, the Senate bill created "an unlimited entitlement program" for veterans, and voted against it. — *RRY*

## Number of Hospital Employed Physicians up 34%

Hospitals are buying up medical practices. Richard Gunderson, writing in *The Atlantic*, reports that the number of physicians employed by hospitals grew by 34% between 2000 and 2010. In 2004 hospital human resources departments conducted only 11% of physician searches. Today that figure is 63%.

Hospital administrators argue that by employing their own physicians, their institutions can achieve greater integration of care. They can avoid variations in practice, such as the use of different medical devices for the same procedure—a common practice in joint replacements. They maintain that, when doctors are employees, hospital administrators can bring about better coordination of care among different medical specialties. Gunderson points out those hospitals can also charge more for certain tests and procedures.



*Wikimedia Commons and Photographer's Mate 3rd Class Jeff Stanislawski*

A major hazard of physician employment by hospitals is that doctors may feel that they have lost control over their practice, according to Gunderson. Morale may suffer if doctors are subjected to excessive institutional rules and regulations and feel pressure to practice according to prescribed patterns.

A recent study showed that the most important factor in promoting professional fulfillment among physicians is their ability to provide high-quality care to patients. Whether doctors work for a hospital or for their own practice group, the best tonic is ensuring that physicians can continue to care for patients as they see fit. — *BY*

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