VOLUME 10, ISSUE 23 | JULY 22, 2014

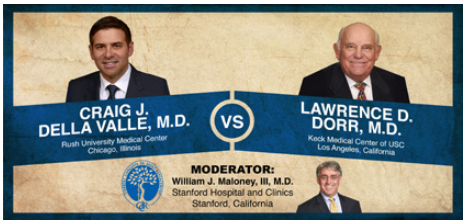
# Orthopedics This Week

## WEEK IN REVIEW

**4 Surprise! Omega 3 May Trump Fat in OA Patients // Diagnose Scoliosis With Light! // Massive, 40,000 Patient Trauma Study Announced >>** Duke Researchers find that weight loss correlates directly with OA pain reduction. Is light based surface tomography superior to X-rays for scoliosis diagnosis? And orthopedic research whiz Mo Bhandari announces early results from his massive, 40,000 patient global trauma study. Incredible early data!

**7 More Cases Emerge From FBI's California "Spinal Cap" Investigation >>** More cases are emerging from the FBI's "Spinal Cap" investigation. Now the allegations are around unapproved spine devices, bribed docs and elected officials, and tragically, a dead baby. It all started with the flawed California workers' comp law and the ways in which administrators, surgeons and companies tried to game the system.

**11 Della Valle, Dorr Debate Constrained Liners in Revision THA >>** "Larger femoral heads have decreased the need for constrained liners," argues Craig Della Valle." "And constrained liners don't always work." "Hold on," says Larry Dorr. "I've used constrained liners for 20 years and I haven't had the failure rates that have been reported."




## BREAKING NEWS

**14 Biomet** Turns **Profit Corner**

**Paraplegics Could Walk Again**: FDA Approves ReWalk

New Study: Prolotherapy for Treating **Tennis Elbow**?

Over 40,000 **Zimmer NexGen Knee** Tibial Components **Recalled**

**"Jimmy" Andrews, M.D.** Gets His Own **Baseball Card!**

**Hospital Ships** Take Center Stage **at RIMPAC**

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

# Orthopedic Power Rankings

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

**THIS WEEK:** We're in the thick of earnings season and the financial results so far (with Biomet, Stryker and DePuy reporting) indicate that pricing pressures are continuing to affect results. Interestingly, sales are holding up well which indicates that demand is quite healthy, but pricing pressures are affecting profit margins. Overall, investors are letting values drift south. If they are buying at all, they seem to be moving to lower valuation orthopedic equities.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 1 | Symmetry Medical | 6.55% | 0.23% | In contrast to the overall orthopedic theme of margin pressure, SMA is about margin expansion due to Clamonta sale and other factors. |
| 2 | 2 | Medtronic | 28.84 | (2.21) | MDT and Covidien is evolving into an extended meditation on tax inversion and what, if anything, Congress can do to change it. |
| 3 | 7 | Integra LifeSciences | 11.77 | (0.84) | The consensus of Wall Street's analysts is the IART will report 11-12% sales growth for Q2. The real question is: will IART expand or contract margins? |
| 4 | 3 | Orthofix | 6.75 | (0.98) | Can OFIX beat $100 million sales this quarter? It's very close. Last quarter, management beat consensus by 32%. This quarter should be interesting. |
| 5 | 9 | Zimmer | 28.42 | (3.39) | Biomet's return to profitability on the eve of a merger with ZMH doesn't hurt. Still waiting for definitive FTC "ok." But if they have to divest of anything, they can do that. |
| 6 | 6 | Stryker | 15.71 | (2.69) | MAKO, Small Bone Innovations, Patient Safety Technologies, Pivot Medical and Berchtold. Lots of acquisitions. Lots of integration. |
| 7 | 5 | Exactech | 10.15 | (4.31) | Checking consensus estimates for Q2 reveals an interesting anomaly; 11% earnings growth on 5% sales growth. Margin expansion. |
| 8 | 4 | NuVasive | 6.05 | (1.32) | On a comparative valuation basis, NUVA not exactly the blue light special anymore. Most analysts expect down earnings (YOY) for Q3. |
| 9 | 10 | Conmed | 35.16 | 0.57 | Now buyers are coming back into CNMD. Perhaps selling pressure has ended or perhaps Q2 will bring investors a pleasant surprise. |
| 10 | 8 | Johnson & Johnson | 26.58 | (0.98) | Trauma sales rose 7% in Q2 which tells us that Synthes integration issues are history. Large joint recon also up nicely. |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | MiMedx Group | MDXG | $6.61 | $698 | 5.76% |
| 2 | Wright Medical | WMGI | $31.82 | $1,588 | 2.15% |
| 3 | ConMed | CNMD | $44.01 | $1,198 | 0.57% |
| 4 | CryoLife | CRY | $9.01 | $253 | 0.56% |
| 5 | Symmetry Medical | SMA | $8.87 | $333 | 0.23% |
| 6 | Integra LifeSciences | IART | $47.32 | $1,541 | -0.84% |
| 7 | Smith & Nephew | SNN | $89.53 | $16,011 | -0.86% |
| 8 | Johnson & Johnson | JNJ | $101.80 | $288,002 | -0.98% |
| 9 | Orthofix | OFIX | $34.19 | $630 | -0.98% |
| 10 | NuVasive | NUVA | $33.61 | $1,566 | -1.32% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | Aurora Spine | ASG | $2.16 | $34 | -21.71% |
| 2 | TiGenix | TIG.BR | $0.76 | $121 | -17.74% |
| 3 | Baxano Surgical Inc | BAXS | $0.51 | $25 | -16.44% |
| 4 | LDR Holding Corp. | LDRH | $22.35 | $583 | -13.44% |
| 5 | Bacterin Intl Holdings | BONE | $0.66 | $36 | -9.59% |
| 6 | RTI Biologics Inc | RTIX | $4.24 | $240 | -7.63% |
| 7 | MicroPort Scientific | 853 | $0.62 | $879 | -6.81% |
| 8 | Tornier N.V. | TRNX | $21.95 | $1,066 | -6.64% |
| 9 | Exactech | EXAC | $23.76 | $325 | -4.31% |
| 10 | Zimmer Holdings | ZMH | $102.44 | $17,191 | -3.39% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Medtronic | MDT | $62.36 | $62,123 | 16.45 |
| 2 | Johnson & Johnson | JNJ | $101.80 | $288,002 | 17.49 |
| 3 | Zimmer Holdings | ZMH | $102.44 | $17,191 | 18.39 |
| 4 | Stryker | SYK | $82.16 | $31,146 | 19.48 |
| 5 | Exactech | EXAC | $23.76 | $325 | 19.55 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $34.19 | $630 | 285.23 |
| 2 | NuVasive | NUVA | $33.61 | $1,566 | 108.43 |
| 3 | Symmetry Medical | SMA | $8.87 | $333 | 79.90 |
| 4 | MicroPort Scientific | 853 | $0.62 | $879 | 34.52 |
| 5 | Smith & Nephew | SNN | $89.53 | $16,011 | 28.44 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Exactech | EXAC | $23.76 | $325 | 1.09 |
| 2 | Globus Medical | GMED | $23.08 | $2,157 | 1.47 |
| 3 | ConMed | CNMD | $44.01 | $1,198 | 1.92 |
| 4 | Stryker | SYK | $82.16 | $31,146 | 2.16 |
| 5 | Zimmer Holdings | ZMH | $102.44 | $17,191 | 2.20 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $34.19 | $630 | 15.50 |
| 2 | NuVasive | NUVA | $33.61 | $1,566 | 9.70 |
| 3 | CryoLife | CRY | $9.01 | $253 | 6.80 |
| 4 | Symmetry Medical | SMA | $8.87 | $333 | 6.66 |
| 5 | Smith & Nephew | SNN | $89.53 | $16,011 | 2.87 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Alphatec Holdings | ATEC | $1.33 | $130 | 0.64 |
| 2 | Symmetry Medical | SMA | $8.87 | $333 | 0.83 |
| 3 | Bacterin Intl Holdings | BONE | $0.66 | $36 | 1.09 |
| 4 | RTI Biologics Inc | RTIX | $4.24 | $240 | 1.10 |
| 5 | Baxano Surgical Inc | BAXS | $0.51 | $25 | 1.24 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.76 | $121 | 21.27 |
| 2 | MiMedx Group | MDXG | $6.61 | $698 | 10.39 |
| 3 | Wright Medical | WMGI | $31.82 | $1,588 | 6.18 |
| 4 | MicroPort Scientific | 853 | $0.62 | $879 | 5.75 |
| 5 | LDR Holding Corp. | LDRH | $22.35 | $583 | 5.22 |

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

# Surprise! Omega 3 May Trump Fat in OA Patients // Diagnose Scoliosis With Light! // Massive, 40,000 Patient Trauma Study Announced

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

*Salmon, pumpkin seeds and spinach/OSU Special Collections & Archives: Flickr Commons, Dinkum, Daniel Schwen and Wikimedia Commons*

**Surprise! Omega 3 May Trump Fat in OA Patients** Are you obese and dealing with osteoarthritis (OA)? Watch the quality of what you eat, says new research from Duke University. Specifically, says Farshid Guilak, Ph.D., director of Orthopaedic Research, get your omega 3s. Dr. Guilak, the vice-chair of Orthopaedic Surgery, tells *OTW*, "Obesity is the number one preventable risk factor for OA, but the connection hasn't been sufficiently researched as most people believe the disease comes from joint loading that wears out the cartilage. The data say otherwise, however. Obese people have more OA in their hands, but obesity would not be expected to increase loading in the hands…and if someone loses a mere 5-10 pounds they will experience a decrease in OA pain."

"My team and I took note of the growing literature showing that obese patients show signs of low grade, chronic inflammation, and hypothesized that OA in obese patients may be related to systemic and metabolic factors. The cytokines involved in obesity were the same ones that people have been investigating in OA for years; however, to date, no one had thought that the problem was emanating from the fat and not just mechanical load."

"In this study, we used lard in order to study what saturated fats do to mice with OA caused by a knee injury. We gave the first group a diet of 60% saturated fats (either lard or an omega 6 rich diet); these mice got much worse than those on a normal diet. The second group had a diet of 60% saturated fat, but also received a small supplement of omega 3. We found that just adding this small supplement completely eliminated the deleterious effect of having all these other fats in the diet. Our goal is to find the mechanism by which this occurs. We have thus far shown that it's probably not the increased weight, but the inflammation caused by a unhealthy diet."

"Now, we are working on a study to determine what effects weight loss will have on inflammation, knee pain, and OA severity. We have a number of overweight patients who are on a weight loss program; we will follow them closely and see how these changes affect their metabolic disease and OA pain. We will also assess how they walk and the biomechanics of their knees. Upon completion of this study we hope to conduct a study where we have one group that receives a diet rich in omega 3s and one group on a 'normal' diet."

**Diagnose Scoliosis With Light…and Other Innovations in Scoliosis Treatment** Spine surgeons now have a diagnostic tool that is healthier and more nuanced than traditional X-rays. Baron S. Lonner, M.D. is the chief of the Division of Spine Surgery at Mount

Sinai Beth Israel Hospital in New York. Dr. Lonner, the chair of the Advocacy Committee for the Scoliosis Research Society tells *OTW*, "There are currently about eight medical facilities in the U.S. that have this wonderful new capability of doing non X-ray diagnostic evaluations of patients through surface topography that uses harmless light rays. This technology allows us to follow pediatric patients and adults over time and detect subtle changes in spine curvature and body shape. The surgeon typically takes an X-ray at the first visit and combines it with the surface topography; approximately six months later—how long depends on skeletal maturity and curvature size—the patient will return for a repeat surface topography. If there has been no change in his or her condition then we will continue to follow this person using only surface topography."

"This is a novel technology and although it is widely used in Europe, as of yet it has not gained traction in the U.S. I believe that will change as we complete prospective, multicenter studies, however. We are currently involved in such a study, and to date we have found a reliable correlation between the magnitude of the curve and the 3-D spinal deformity of the patient as measured on X-ray. Also, even if the X-ray and the surface topography don't give an equivalent number, we are using multiple parameters on the surface topography such as waistline alignment, shoulder symmetry, prominences on the back, etc. That way we can determine over time whether there are significant changes in those parameters. If that is the case then we would obtain an X-ray. We combine all of this information with a physical exam, thus there are multiple levels of checks and balances involved."

"Another addition to the non-operative armamentarium of the scoliosis specialist, is Schroth Method. This set of exercises and physical modalities for scoliosis patients emanated from Europe and has received a lot of lay press in the United States. This method may help decrease back pain associated with scoliosis…and it may be of some benefit in combination with bracing for prevention of curve progression, but more studies are needed. Some advocate using this method in skeletally immature (growing) patients with curves that are small in order to prevent curve progression. A prospective-randomized study on those who have undergone Schroth versus those who have not is needed."

"My team and I are beginning to study the psychosocial aspects of scoliosis. I am the principal investigator on a study looking at body image disturbance in those with scoliosis. We just published a validation of the body image disturbance questionnaire in the *Journal of Bone and Joint Surgery* that gets to the root of what these patients may be experiencing emotionally. With this questionnaire, which we have validated in adolescent idiopathic scoliosis, we initially looked at surgical patients. Not surprisingly, we found that the larger the curve, the more body image disturbance. Interestingly, there were some people with significant curvatures who have no body image disturbance and may be more resilient than other patients with large curvatures. If you spend enough time with our adult patients they will tell you about their emotional pain from having a spinal deformity…how it embarrasses them and makes them feel so different. We intend to study these issues further in the adult scoliosis patient in a prospective study that we hope to embark upon in the coming months. We have also recently validated a new questionnaire that my research team and I have validated, called the TAASQ, Truncal Anterior Asymmetry Scoliosis Questionnaire that is designed to assess the impact of scoliosis on the patient's frontal appearance—that is what the patient sees in the mirror. We are studying how well surgery and bracing correct the anterior or frontal appearance of the patient's torso."

**Massive, 40,000 Patient Global Trauma Study Launched** The need for such a massive study could not be greater. While orthopedic surgeons in the West are mulling over whether to install a fluoroscopy-based navigation system or a computed tomography–based navigation system, orthopedic surgeons in India or Morocco may be telling a patient with an open fracture to wait two to four days for treatment. These and other such glaring access discrepancies didn't sit well with one famed researcher and his colleagues, who decided to organize a massive international study involving 40,000 patients. Mohit Bhandari, M.D., professor and research chair in Orthopaedic Surgery at McMaster University in Canada, tells *OTW*, "In 2011 the United Nations kicked off a program on Road Safety with the goal of cutting traffic deaths by 50% over 10 years. The sad truth, however, is that the needle hasn't moved at all in the first three years of this program—there has been NO reduction in global traffic deaths."

"Fortunately, the Canadian Institutes of Health Research provided us with a $500,000 grant for our study, known as INORMUS (International Orthopaedic Multi-centre Study in Fracture Care), so that we might begin to assess the burden of trauma in developing nations. To date we have recruited 6,000 patients in India and hope to reach 40,000 patients worldwide within the next two years; we are looking specifically at fractures and dislocations. Our goal

of this observational study is to assess what patient and institutional factors are predictive of complications within 30 days of a major traffic accident. In developing nations data collection isn't a top priority, and when looked at how they get their records we saw that there was a disconnect with how the government gets its data. Many hospitals don't have what we would call records. When there is a traffic accident, a police officer writes up a report and *that* goes into the files and essentially becomes the medical record. You might say that the cops are diagnosing fractures, etc."

"From the data on our initial 6,000 patients we found that some people wait up to four days to have an open fracture treated. In rural India 70% of people traveling to a hospital for care arrive in something other than an emergency vehicle—even rickshaws. Within 30 days, 18% of these patients have major complications. And amazingly, 59% of patients experienced a delay in irrigation and debridement (between 7-48 hours). Mortality is 2% in 30 days, but we are not capturing those who already died on the street. And while 2% may not sound shocking, imagine that many people coming into a U.S. hospital with a only a fracture and being dead within 30 days."

"The fact that the U.N. program has shown no reduction in mortality in the first three years is a good indication that this issue is more complex than it may appear (there are issues corruption, for example). The prevention idea isn't working so well…lots of people will get hit no matter what we do. So our focus is now, 'What can we do at the point of the broken bone?' Once the patient arrives at the hospital there is a better opportunity to optimize care."

"So what we have learned from these first patients is that we can do research like this—fast with good quality data. We have also confirmed that the burden of severe injuries in these countries is high. This initial work will provide important insight towards the development of clinical trials to test simple, life and limb saving interventions that will come to the aid of countless people worldwide." ♦

# More Cases Emerge From FBI's California "Spinal Cap" Investigation

**BY WALTER EISNER**

The 2002 California law that required workers' compensation carriers to pay 100% of a hospital's documented cost of spinal hardware set in motion a number of schemes to try to maximize the amount of money being collected for spine surgery. As a result, the U.S. Attorney's office announced a new round of cases complete with lurid allegations of bribes, inflated billing practices, unapproved devices and lethal pain cream compounds to alleviate back pain—all under an FBI investigation called "Spinal Cap."


*Photo manipulation by RRY Publications LLC/Wikimedia Commons*

## Spinal Cap

"Spinal Cap" netted its first big fish when Michael Drobot, the former owner and operator of Pacific Hospital of Long Beach and various distribution and pharmaceutical companies, admitted to compensating physicians to refer patients to his hospital and bribing a state senator to keep the workers' comp law on the books.

*Michael Drobot/nbclosangeles.com*

The investigation uncovered one of the largest workers' comp fraud cases in California's history, involving more than 150 insurance companies. The investigation also resulted in the law being wiped off the books.

When Drobot pled guilty to criminal fraud charges in February 2014, Eric Weirich, deputy commissioner of the enforcement branch of the California Department of Insurance, said in a joint press conference with the U.S. Attorney's Office, "I assure you, this is the first in many cases to come."

Those cases are now landing in the laps of numerous grand juries, triggering civil lawsuits, more criminal prosecutions and petitions and complaints to the California Medical Board.

## Unapproved Devices

Citing the Drobot case, Arthur Golia filed suit on June 13, 2014, in the Superior Court of California County of Los Angeles, accusing, Jack Akmakjian, M.D., a spine surgeon, a distributor and a mom-and-pop machine shop of putting seven non-FDA approved devices into his spine.

*Jack Akmakjian, M.D./Tri-City Regional Medical Center*

Golia is suing Akmakjian, the Parkview Community Hospital Medical Center in Riverside, California, and Spinal Solutions, LLC et al. for engaging in a

"systematic pattern of fraud and deceit, fueled by the payment of illegal kickbacks, designed to illegally profit from grossly inflating the charges for implantable medical hardware used in connection with spinal fusion surgeries."

*Parkview Community Medical Center*

Golia claims he is only one of thousands of patients in Southern California who received such, non-FDA approved hardware.

## Dr. Akmakjian, Spinal Solutions et al.

Akmakjian performed lumbar fusion surgery on Golia in January 2010 at the Parkview Medical Center. Golia claims that Akmakjian knew that Spinal Solutions and other defendants, including Roger Williams, Jeff Fields and Mary Sisler Williams, were producing "knock-off" implants, consisting of screws, rods and cages. Akmakjian also allegedly knew the hardware was being distributed by Michael McGrath through Comprehensive Intra-Operative Services, Inc. McGrath allegedly entered into agreements with hospitals, like Parkview to sell the devices produced by Spinal Solutions and William Crowder, the owner and operator of Crowder Machine & Tool Shop in Temecula, California.

Crowder served as a contractor for Spinal Solution. An attorney for the machine shop's owner reportedly denied the allegations, saying it is impossible that the elderly machinist mass-produced the hardware.

Golia further claims that Akmakjian was paid by Spinal Solutions in the form of cash, plane travel and other perks to use the unapproved implants. He accuses Akmakjian of participating in a wider fraud scheme involving kickbacks paid by hospitals and vendors and overbilling payers including insurance companies.

According to a report by the *Center for Investigative Reporting* on July 3, 2014, a woman identifying herself as Akmakjian's office manager said there would be no comment. Parkview Community Hospital did not respond to questions.

## Workers' Comp Free-For-All

The lawsuit outlines how the now changed California law, which reimbursed 100% of the documented costs of implantable hardware, had rewarded hospitals for entering into contracts with third-party "marketers" who would, in turn, refer or steer spinal fusion candidates to their facility. The marketers, including McGrath, were allegedly paid "referral fees" by the hospitals. The hospitals also allegedly paid "referral fees" to chiropractors and physicians.

After the passage of the law in 2002, hardware distributors allegedly began to dramatically increase the cost of spinal hardware, knowing that workers' compensation carriers were required to pay 100% of the hospital's documented cost, plus $250. By 2009, claims Golia, a pedicle screw that could be purchased for between $300 and $500 wholesale would end up on a hospital bill at approximately $12,500. Profits soared.

The defendants in this case, allegedly, started to produce the implants in 2007. Parkview, claims Golia, paid Akmakjian rebates, refunds, commissions, or other compensation to perform surgeries at Parkview. He said Parkview knew that Akmakjian was prescribing unapproved hardware, but turned a blind-eye as part of the consideration paid to the surgeon.

In a similar lawsuit filed in January 2014, David Solomon, a Los Angeles man who had implants from the Crowder machine shop put in his back in 2011, claims one of the screws broke, requiring him to undergo a second surgery in 2013. He has ongoing pain and loss of movement, his lawsuit says.

In January 2012, the FDA sent Spinal Solutions a Warning Letter citing a variety of quality control violations. On April 22, 2013, the agency announced that the company was recalling spinal implants because problems with the products "could cause patient harm due to implant breakage, movement, or inadequate sterilization."

An FDA spokeswoman told the *Center for Investigative Reporting* that the agency could not comment on ongoing litigation or confirm the agency is investigating.

## Akmakjian's Medical Board Pain

In addition to his patient, Arthur Golia, Akmakjian has other problem.

On April 14, 2014, the Attorney General for the State of California, on behalf of the executive director of the Medical Board of California, filed a motion accusing Akmakjian of gross negligence, prescribing dangerous drugs without an appropriate prior examination or medical indication; excessive prescribing and failure to maintain adequate and accurate records. The

state wants Akmakjian's license revoked or suspended.

## Tragedy Strikes

The Golia lawsuit against Akmakjian isn't the only link to the Spinal Cap investigation.

On June 14, 2014, *AP* reported that 15 doctors, pharmacists and other medical professionals in Southern California were charged in a $25 million workers' compensation scheme that prosecutors said was linked to the death of a baby.

One of the pharma professionals charged was, you guessed it, Michael Drobot, the managing partner of Industrial Pharmacy Management.

Drobot, Andrew Jarminski, M.D., Healthcare Pharmacy, Allied Medical Group and Industry are also all being sued by Priscilla Lujan, the mother of a five-month-old child who died after coming in contact with a transdermal cream prescribed by Jarminski for Lujan's back and knee pain.

## Dangerous Compound

According to the lawsuit, Lujan went to Jarminski's Long Beach office in February 2012 for treatment of injuries she suffered while working at Goodwill Industries. Medical records reportedly showed Jarminski prescribed Lujan a compound transdermal cream comprised of the antidepressant amitriptyline, the pain reliever tramadol and the cough suppressant dextromethorphan.

Lujan went home and applied the cream to her knee and back. After using the medication, she took care of her baby, including preparing a bottle for him and bouncing him on her knee and holding him over her shoulders, according to her attorney.

She put the baby to sleep in her bed and awoke in the morning to find him unresponsive. He died an hour later "as a result of multiple drug intoxication," according to the autopsy report. The report also stated that the baby had high levels of three drugs in his system—the same drugs in the compound cream prescribed by Jarminksi. Tramadol and dextromethorphan were present at lethal levels, the coroner found.

## Involuntary Manslaughter

The death was ruled a homicide by the coroner, who said medication residue was found on one of the baby's bottles. Lujan was arrested for her son's death,

but the Los Angeles District Attorney declined to file charges because of insufficient evidence, according to spokeswoman Jane Robison.

Jarminski is being charged with involuntary manslaughter by the Orange County grand jury.

The cream Jarminski prescribed for Lujan was costly. Workers' compensation records show Jarminski's office billed $1,700 for the initial 25-day supply of the cream.

According to Lujan's attorney, when she was informed the cream was linked to her son's death, she said she didn't want any more of the cream. But, according to the lawyer, Jarminski continued to send her more cream by mail and bill workers' comp for it.

"Compounds and the prices charged for them by compounding pharmacies are a growing problem for the health care system," said Riddhi Trivedi-St. Clair, a senior manager with Express Scripts Inc., which manages prescription benefits for thousands of employers, including Los Angeles County.

According to data provided by Express Scripts, the number of injured California workers filing a prescription for at least one compounded medicine increased by 157% last year, compared with 2012.

Jarminski is reportedly associated with Allied Medical Group, as is Daniel Capen, M.D., who was also indicted by the grand jury on fraud charges.



## More to Come

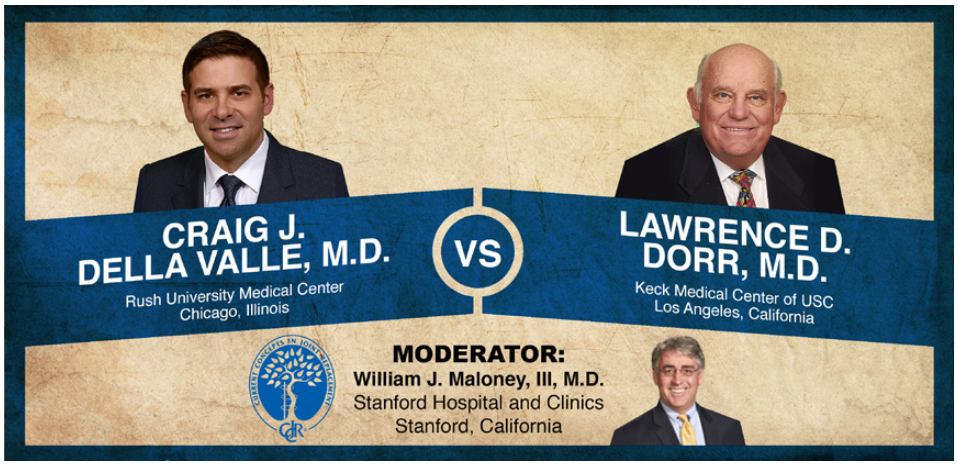
We have likely not seen the last of the California Spinal Cap investigations. The State Compensation Insurance Fund, which oversees workers' comp claims for the state, wants to recoup some of the $160 million it paid over the past dozen years. Other public and private payers are no doubt examining potential false claims. Then there are the possible kickback violations if any physicians are found guilty of taking money to refer patients to hospitals. ♦

# Della Valle, Dorr Debate Constrained Liners in Revision THA

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

"Larger femoral heads have decreased the need for constrained liners," argues Craig Della Valle." "And constrained liners don't always work." "Hold on," says Larry Dorr. "I've used constrained liners for 20 years and I haven't had the failure rates that have been reported."

This week's Orthopaedic Crossfire® debate is "The Use of Constrained Liners in Revision THA: More Problems Than They Solve." For the proposition is Craig J. Della Valle, M.D. of Rush University Medical Center. He; against the proposition is Lawrence D. Dorr, M.D. of Keck Medical Center of USC. Moderating is William J. Maloney III, M.D. from Stanford Hospital and Clinics.




*Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Della Valle:** "Dislocation is the number one reason for total hip arthroplasty (THA). It's also probably the most common complication after THA. Large femoral heads have changed the usage of constrained liners, and this has been facilitated by highly cross-linked polyethylene (HCLP). Because HCLP has facilitated the use of larger heads there doesn't seem to be a meaningful increase in wear when you use a larger head. Such heads have been shown in two Level I studies to decrease the risk of dislocation in both primary and revision THA."

"Michael Ries looked at his dislocation rate after his revision THA procedures. He found that large heads—if the abductors were intact—really decreased the risk of dislocation. When the abductors were deficient even large heads didn't prevent that complication. These liners can be engaged into a compatible shell and they can be cemented into a well fixed shell. About 10 years ago John Callaghan showed that when cementing these into a shell he had over a 90% success rate."

"But not all constrained liners are created equal. Furthermore, many of these studies that have examined the use of constrained liners are now 10 years old. A lot of the situations in the past where we used constrained liners I think we would now use a large head—such as abductor deficiency. Maybe the results aren't quite as good in contemporary practice."

"I did a complex allograft revision—a structural revision—that I was proud of until the patient came in six weeks postop and was abductor deficient. I had read the article and knew that I needed to use a constrained liner, but unfortunately it pulled the cup out of the pelvis."

"There are additional negatives of constrained liners. Almost all of them decrease range of motion [ROM], which leads to impingement and then higher stresses on the polyethylene. Oftentimes they require thin polyethylene and depending on the design, sometimes it's not cross-linked. There's also an increased risk of late loosening. Also, if a constrained liner fails, in the vast majority of cases another operation will be necessary. The number one rule with constrained liners is that these liners will not compensate for component malposition."

"Is there an alternative? There is a lot of European literature showing that dual mobility articulations both decrease the risk of instability and can be used for recurrent instability. Although these bearing couples also have their own problems, including intraprosthetic dislocation, wear, and higher torques."

"They do, however, solve some pretty difficult problems. If you do use these they can be on their own or cemented into a well fixed shell. I did have some

problems, however. I took a dual mobility liner and scratched up the back as I would with a polyethylene liner; I cemented it into place and it quickly flipped out of the acetabulum. So now I use a dual mobility cup that's meant for cementing into the acetabulum…now we don't have any problems."

"In a recent study we compared dual mobility articulations to constrained liners for pretty similar indications; the dual mobility articulations performed better. The risk of recurrent dislocation was lower. More importantly, the risk of repeat revision was lower in the dual mobility group. So at this point dual mobility is our go-to in lieu of a constrained liner."

**Dr. Dorr:** "I've used constrained liners for 20 years and I haven't had the failure rates that you've heard reported. I think the major cause of failure with these liners is poor surgical judgment…trying to use the constrained liner to make up for a bad situation. If you want success it's really simple: you must ensure that you press fit the liner against the metal edge of the cup. You don't want a liner that falls into the cup and you don't want a liner proud [when the outer lip of the liner is not flush with the rim of the shell] of the cup. Also, you have to scratch both the polyethylene and metal liner. And you must ensure that the cup is in a good position."

"I prefer a liner without a hood because it can increase the risk of impingement; and with impingement you have some risk for dislocation with a constrained liner. Also, the cement should never be more than 2mm."

"I have a few technical tips. Use a power drill to scratch the implants. Use the cement more liquid than the normal doughy cement used with an acetabular component because then it's too stiff and you can't get the liner down against the metal shell. If you have rotational pegs on the shell you need to remove them; the liner has to be flush against the shell. And you must pressurize the liner until the cement is hard. I want a tight fit in there. John Callaghan and I showed (both in the lab and in a clinical study) that this technique is very reproducible and successful."

"Here's a tip about getting the head to seat fully into the polyethylene: dry the polyethylene and the femoral head. If you don't you can't get a lock in there. I think some failures occur because the head isn't totally locked in. With the one I use today you can't get the ring in unless it's locked."

"The dual mobility cups are like a boxer who's flexible and makes you want to be like him. A fancy dual mobility boxer shows his moves and the old guy with the constrained liner is just standing around in the background…and it just takes one punch."

**Moderator Maloney:** "Craig, one minute."

**Dr. Della Valle:** "The decision making is always difficult, and because dislocation is such a common complication in hip replacement, I think surgical judgment is really important. In some of the cases Dr. Dorr mentioned I may have just used a large head. And while large heads also have their negatives, in general they seem to do a good job in terms of decreasing instability where in the past we may have used a constrained liner."

**Dr. Dorr:** "It's difficult to use a large head in a cup that's 49mm."

**Dr. Della Valle:** "Agreed."

**Dr. Dorr:** "If you have a poor abductor and you can't use a big head then you have to choose between dual mobility and a constrained liner to bail yourself out."

**Moderator Maloney:** "Larry, if a socket is retroverted 10 degrees are you going to put a constrained liner in?"

**Dr. Dorr:** "No. You just have to have the same criteria for cup position using a constrained liner that you would have for a cup position being correct for a regular liner. You're using a constrained liner in a limited situation and in a bad situation where there is failure of biological constraint for the hip. There's only two ways we can get constraint in a hip. In a hip you get biological constraint by the muscles in the capsule… and if you don't have it you must have mechanical constraint. That's when we use some of these mechanically constrained liners. So the decision for using it is based on the absence of biological constraint or the ability to get biological constraint. You still must have component position."

**Moderator Maloney:** "I've seen people assess lateral opening but not anteversion, and I think it's critical to make sure you have reasonable anteversion when you put a constrained liner in… or else it's going to pull out."

**Dr. Dorr:** "That's one of the big problems we have with regular cups too because we see a lot of these talks on how they use imaging intraoperatively, but a lot of it only gives them inclination, not anteversion."

**Moderator Maloney:** "Craig, any situations today where you would use a constrained liner?"

**Dr. Della Valle:** "In a small female …a 48mm cup where you're abductor deficient and to get in a dual mobility articulation is going to be difficult."

**Moderator Maloney:** "Larry, one of the most common situations we see is a big revision with poor bone quality, etc., and you'd really like to put a constrained liner in, but you're worried about the liner pulling the whole acetabular reconstruction out."

**Dr. Dorr:** "That's when you've got poor biological constraint and you need mechanical constraint, but you've got poor bone and you can't get good component fixation. I'd put a cast on for at least two months. Sometimes we have to use fracture principles. If the bone is no good you can't just hope that it's going to act like a primary hip replacement."

**Moderator Maloney:** "Craig, it seems like you're transitioning to this dual mobility concept. Where are you using it?"

**Dr. Della Valle:** "The biggest ones are abductor deficiencies and complex revisions where you're concerned about fixation of your acetabular revision. And while I think the dual mobility does impart more torque than a large head, it's less than a constrained liner. In these situations where I would have cemented in a constrained liner we've gone to cementing in a dual mobility liner. It's also helpful with the older systems where all you can get is a 28 or 32mm head…and for a dual mobility bearing you need a 28."

**Moderator Maloney:** "Is there any primary situation where you'd use a dual mobility socket and/or a constrained liner today?"

**Dr. Della Valle:** "I do some dual mobility for primaries, but in general those are acute femoral neck fractures for a THR. Also, alcoholic or drug dependent patients, patients with cerebral palsy or Parkinsons's disease."

**Moderator Maloney:** "Larry, your thoughts on dual mobility?"

**Dr. Dorr:** "I haven't used it, but I know that there are people having success in a revision situation…so it's probably a good device. ♦

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

COMPANY

# DePuy Synthes Hip-Checks Consensus

DePuy Synthes reported sales of $2.469 billion during the second quarter of 2014, beating consensus of $2.45 billion. Excluding currency, sales were up 3.3% over the previous year's quarter.

### Strong Hips, Weak Knees

Hips were strong, rising 5%, while knees were weak, climbing only 1%. During a conference call with analysts on July 15, 2014, company management said they could not account for the knee weakness other than to say that a new seasonality may push knee procedures to be much more back-end loaded to the end of the year as patients hit their deductible. Management told analysts that demand for its Attune Primary Total Knee System was helping to offset pricing pressure. Pricing for knees in the U.S. was down approximately 2.6%, offset by positive 1.5% mix, for a negative 1.1% pressure.

The rise in hips including a 4% rise in the U.S. and up 6% outside the U.S. was primarily driven by the company's primary stem portfolio, along with the second quarter U.S. launch of the new Corail Revision Hip System launch.

| DePuySynthes 2Q2014 | Sales ($ in millions) | % Change* |
|---|---|---|
| **Total Reported Sales** | **2,469** | **3.3%** |
| Knees | | 1.0% |
| Hips | | 5% |
| Spine | | 1% |
| Trauma | | 7% |

*Source: Johnson & Johnson*
** Constant Currency*

*Logo courtesy of DePuy Synthes*

### Spine Stabilizing

Spine sales improved slightly in the second quarter, rising by 1%. Joanne Wuensch, BMO Capital analyst, noted that the spine sales were the first positive growth rate since the third quarter of 2011. She added that the spine business continues to demonstrate increasing stability in the post-Synthes integration phase. Spine sales in the U.S. dropped -2%, but sales outside of the U.S. pulled the business into positive ground. Mike Matson of Needham & Company said in spite of the slow U.S. sales, this marked the third consecutive quarter of improved growth, which may indicate that the disruption caused by the Synthes integration is abating.

### Trauma Growing Strong

Wuensch said that for a second consecutive quarter, trauma sales were strong, up 7%, excluding currency, with U.S. sales up 4% and sales outside the U.S. up 11%. "While [the first quarter of 2014] was aided by a recovery from last year's Nail recall, the [second quarter] was primarily aided by a successful tender offer in the Middle East, reflecting the benefits of a broader product bundle," added Wuensch.

### Hospital Utilization Depressed

Management noted that it continued to see slight declines in surgical and lab procedures at rates that were consistent with the past 12 months. In addition to the continued depressed hospital utilization, management also noted that a strengthening economy should help drive utilization higher.

With regard to orthopedics, management noted that increasing pricing pressure and market softness weighed on growth.

### Ortho Market Growth Steady

Matson said that combining the DePuy Synthes and Biomet, Inc. results, he estimates that the second quarter's recon growth was 3% on a constant currency basis, which is in line with his 3% estimate and 3% growth in the first quarter. — *WE*

## HSS Awarded #1 Stop in the Nation for Orthopedics…Again!

Play it again, Louis Shapiro…Hospital for Special Surgery (HSS) has once again been ranked the No. 1 hospital in the country for orthopedics by *U.S. News & World Report* in its 2014 "Best Hospitals" survey.

"We are honored to be recognized nationally as the best in our specialized field for the fifth consecutive year," said Louis A. Shapiro, HSS president and CEO, in the July 15, 2014 news release. "The entire HSS family consistently meets and exceeds the high standards that we set for ourselves; providing compassionate care with unsurpassed excellence. Patients from 105 countries have travelled to Hospital for Special Surgery for their treatment because of our unmatched commitment to quality care, safety, and results."

According to the news release, in 2013 more than 29,000 surgeries were performed at HSS. Areas of expertise include joint replacement, spine surgery, sports medicine, orthopedic trauma, hand surgery, foot and ankle surgery, limb lengthening and osteoporosis and metabolic bone disease. Additionally, the hospital has established a number of specialty centers including innovative centers for Women's Sports Medicine, Hip Pain and Preservation, Osteoporosis Prevention, and Computer Assisted Surgery, as well as the newly opened Lerner Children's Pavilion. Other special services include the Mary Kirkland Center for Lupus Research, the Barbara Volcker Center for Women and Rheumatic Disease, the Gosden-Robinson Inflammatory Arthritis Center, and the Center for Skeletal Dysplasias.

Louis Shapiro told *OTW*, "Like every hospital, we work very hard to attract the best talent and deploy the most advanced science, but what makes HSS exceptional is a factor that distinguishes the best organizations in any field, and that is culture. HSS culture is what unites a diverse combination of world-class talents with the shared purpose of helping each and every patient get back to doing what they love most."

Todd J Albert, M.D., HSS surgeon-in-chief, told *OTW*, "What I think is unique and differentiating that I have noticed about HSS is the pervasive pride for the institution that all who work here feel. This guarantees the unwavering dedication of all staff and physicians to accept nothing less than the best for every patient. This feeling is palpable inside the institution." — *EH*

*Hospital for Special Surgery*

## Biomet Turns Profit Corner

Biomet, Inc.'s revenue grew by 7.7% in the past quarter. The company also reported net income of $67 million, a turnaround from a loss of $221 million a year earlier. The company turned a profit just in time to be acquired by Zimmer Holdings. Inc., scheduled for early 2015.


*Image created by RRY Publications, LLC / Source: Biomet, Inc.*

Biomet's knee sales rose 5.1%, hips increased by 3.5%, sports, extremities and trauma (S.E.T) climbed 5.9% and spine was up a whopping 21.7%.

### Good for Ortho

As the first major orthopedic maker to report quarterly results, it's tempting to extrapolate Biomet's results to the overall orthopedic market. However, BMO Capital Market analyst Joanne Wuensch says due to inconsistent reporting calendars, the results can be difficult to read through for other device makers. But, says Wuensch, the first look is "quite good for the group."

Management noted several products that contributed to the growth, particularly the Vanguard Knee portfolio, including its Vanguard XP Bicruciate Knee, which was introduced at the

last meeting of the American Academy of Orthopaedic Surgeons. In hips, the demand for the company's new G7 Acetabular System was cited, including several thousand G7 procedures completed globally, and in the month of May, 29% of the surgeons using the G7 were reported as new Biomet hip customers. The company also received approval to market the G7 Bispherical Acetabular Cup in Europe during the quarter.

For spine, management highlighted that the 2003 Lanx acquisition was going well and that sales trends were positive as a result, quantifying that 200-250 basis points of the overall growth rate was from the acquisition.

S.E.T. highlights noted by Wuensch included the Signature Patient-Specific glenoid instruments (almost 50% of U.S. shoulder patients that used these products in the last month were new customers) and a new total foot system (launched in the quarter, with a comprehensive set of plates). Sales of the JuggerKnot brand products also contributed to the growth. In the trauma business, the company launched the DVR Volar Rim Plate ePAK, an upper extremity trauma device during the quarter. The company said that extremities grew double digits for the 26th straight quarter.

Bank of America analyst Bob Hopkins observed that U.S. recon sales were slightly below his expectations. He attributed that, at least in part, to a degree of potential distraction related to the pending acquisition by Zimmer. Zimmer and Biomet sales reps are still competing in the field. Hopkins also believes Biomet's results support his view that the ortho market remains healthy, and will likely grow faster in 2014 than it did in 2013. — *WE*

**BIOLOGICS**

## New Hydrogels Hold, Support Stem Cells

In a first for bone tissue repair, researchers at the University of Rochester, New York, have encased regenerative stem cells in a hydrophilic polymer. This prevented the stem cells from leaving a repair site in the body early and speeded up the healing process, according to Vaun Saxena, writing for Fierce *Drug Delivery*.

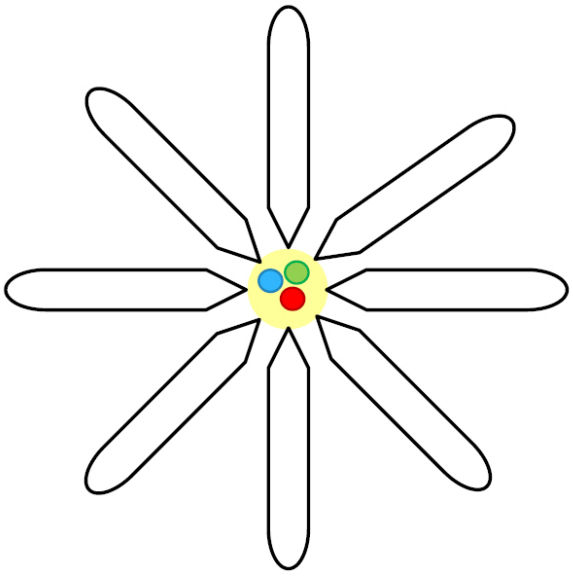
Hydrogels are hydrophilic polymer chains that easily absorb water and are being researched by biotechnologists for their potential drug delivery applications because they exhibit properties similar to human tissue."Our success opens the door for many—and more complicated—types of bone repair," assistant professor of biomedical engineering Danielle Benoit, Ph.D. said in the university's news release. "For example, we should now be able to pinpoint repairs within the periosteum—or outer membrane of bone material," he said.

Currently, according to Benoit, stem cells are injected directly into bone tissue without any protective substance to shield them from the body's immune system, which sees them as foreign agents. By modifying the hydrogels, the researchers successfully controlled the amount of time it took for the polymers to dissolve, allowing for the customization of stem cell behavior based on specific needs and circumstances.

In a related development researchers at Tohoku University in Japan have come up with a stretchable and durable electrode-hydrogel. This hydrogel withstood repeated stretching and sterilization procedures while maintaining electrical conductivity, *Asian Scientist* magazine reported. The device kept its shape after being repeatedly bent, stretched to twice its length, immersed in water for 6 months and autoclaved for 20 minutes at a time.

In addition to withstanding that abuse, the Tohoku team said that cultures of neural and muscle cells on the hydrogel were able to "adhere, proliferate and differentiate," which are key to developing bio-integrated wearable devices featuring integrated electronics.

"Our study paves the way for the development of complex electronically responsive and spatially controlled nerve muscle cell co-cultures, opening a new avenue of 'intelligent biorobotics'," the Tohoku team, led by Matsuhiko Nishizawa, wrote in *Advanced Healthcare Materials*. — *BY*



*Wikimedia Commons and Aweckel*

LARGE JOINTS

# Over 40,000 Zimmer NexGen Knee Tibial Components Recalled

Zimmer Holdings, Inc. is recalling 41,180 stemmed tibial components of the NexGen Complete Knee Solution system.

According to an FDA Enforcement Report for the week of July 9, 2014, the company is initiating a voluntary recall of specific identified lots "due to the potential that the threads may be out of specification." The recall is of various sizes and part of the "NexGen systems of semi-constraint, non-linked condylar knee prosthesis."

The lots can be found here: http://www.accessdata.fda.gov/scripts/enforcement/enforce_rpt-Event-Detail.cfm?action=detail&id=68457&w=07092014&lang=eng

### Recall Initiated May 19

The recall was initiated May 19, 2014 with a letter to relevant parties. The recall is considered a Class 2 recall, indicating the damaged device might cause temporary or serious medical complications. Zimmer sent out an urgent medical device recall letter to medical professionals on June 10. The components are manufactured by Zimmer Manufacturing B.V. in Puerto Rico.

In its letter to medical professionals, Zimmer reportedly said some of the tibial baseplates were made with defective threads in a hole where surgeons screw in a drop-down stem extension or stem plug. If not threaded correctly, the device could loosen and fail.

### Complications

Zimmer said the problematic device could lead to one or more post-surgery complications:

- Infection: The patient runs the risk of serious infection if the surgery is delayed or if a secondary implant is not immediately available and the surgeon must close the patient and return later.
- Bone Loss: The patient may have additional bone loss if the tibial device is cemented in place and the surgeon must remove and replace it.
- Early Revision Surgery: If the device loosens or infection occurs, this could lead to revision surgery.
- Dislocation: If the stem is not properly placed, the devices may not adequately lock. This could lead to a dislocation.

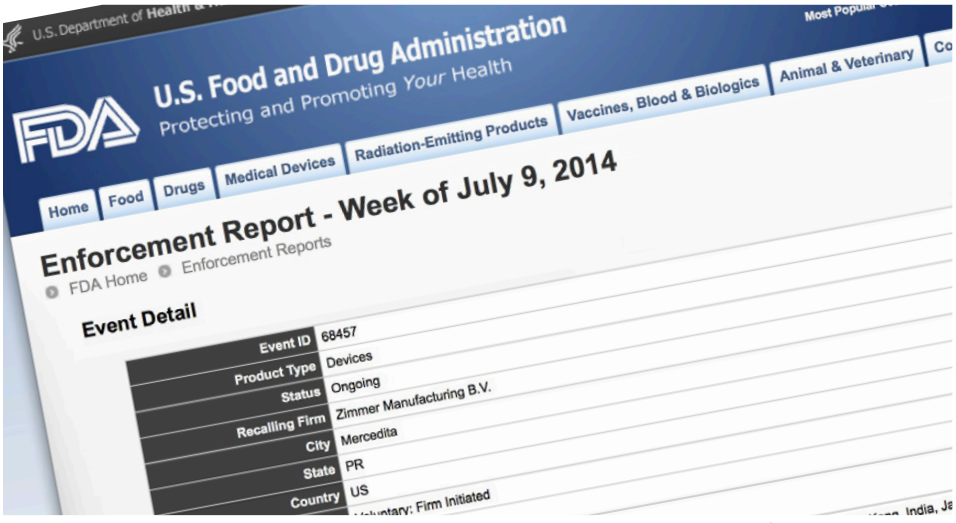
According to *drugwatch.com*, the device is commonly used with other Zimmer knee replacement systems like the LPS-Flex and CR-Flex minimally invasive knee replacement devices. Surgeons install the tibial component during minimally invasive knee surgery, which has shorter recovery times, less blood loss and a greater range of motion because of tissue-sparing techniques. They assemble the component once the new knee is put in place. That tends to make the faulty pieces more problematic.

### Complaints and Lawsuits

Within months of the company's urgent device correction letter, *drugwatch* reports that the FDA received 114 complaints of early loosening and found that the company provided improper instructions and warnings about the device to surgeons. The FDA issued a Class 2 recall, affecting 68,383 devices that had already been implanted.

Shortly after the FDA issued its recall, injured patients started filing lawsuits. A multidistrict litigation (MDL) was opened in the U.S. District Court of Illinois under the oversight of Judge Rebecca Pallmeyer.

Today, there are more than 1,000 lawsuits. In an order issued in March 2014, Judge Pallmeyer identified six Zimmer NexGen bellwether trials (each side selected three cases) and scheduled the first bellwether cases for trial in February 2015. — *WE*




*Enforcement Report/FDA*

# New Study: Autografts Last Longer for ACL Reconstruction

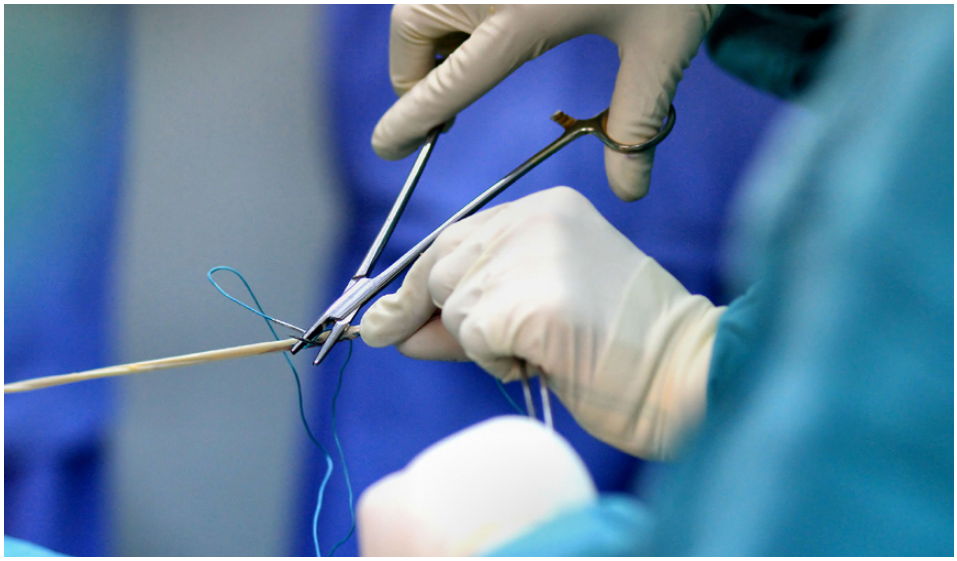
Anterior cruciate ligament (ACL) injuries occur about 200,000 times each year and about 100,000 of those patients undergo reconstructive surgery.

Seventy percent of ACL injuries occur when patients participate in agility sports, mainly basketball, soccer, skiing, and football. ACL injuries are more prevalent in patients 15-45 years old since people in this age group are more likely to maintain an active lifestyle. Women are more likely to suffer an ACL injury although greater numbers of men become injured since men are more likely to participate in sports.

On July 11, 2014, researchers presented the results of a new study regarding the use of autografts for reconstructing ligaments. The data was presented at the American Orthopedic Society of Sports Medicine's Annual Meeting (AOSSM). Lead author, Dr. Craig R. Bottoni, from Tripler Army Medical Center in Honolulu, revealed that when reconstructing ligaments, allografts fail more frequently than autografts.

Bottoni followed 99 patients who'd had an ACL reconstructed either from an allograft, tissue from a donor, or an autograft, tissue taken from the same individual. Bottoni and his team followed these patients for 10 years and found that 80% of grafts remained intact and stabile.

Although the majority of grafts remained in good condition, patients with an allograft experienced a failure rate that was more than three times higher than those reconstructed with an autograft.



*Caption: Anterior cruciate ligament reconstruction surgery/Wikimedia Commons and Phalinn Ooi*

All allografts were from the same tissue bank and processed in the same fashion, the grafts were fixed identically in all knees, and all patients followed the same postoperative recovery procedure.

Since the study only examined a tibialis posterior allograft, the authors cautioned that it would be premature to draw conclusions about other types of allografts. Out of 99 individuals studied, 95 were in active military duty and 87 were male. There were 13 allograft failures and 4 autograft failures in the group that required revision reconstruction. Between the remaining allograft and autograft patients, there was no difference in mean Tegner, SANE, or IKDC scores. — *SB*

EXTREMITIES

## Paraplegics Could Walk Again: FDA Approves ReWalk

Thanks to an electronic device, those with severe injuries—even paraplegics—could be walking again soon. Initially tested at MossRehab in Philadelphia, this device has now been approved by the FDA and can be used outside of the hospital environment. Described by MossRehab as a "motorized exoskeleton suit," the ReWalk uses motion sensors and measures a patient's upper body movements and shifts in gravity.

Alberto Esquenazi, M.D., chief medical officer at MossRehab, said in the July 2, 2014 news release, "This is an incredible step forward in allowing patients who normally would be unable to walk, who are dependent on wheelchairs, to now be able to use a device that will permit them walking mobility around their house and the community.

Asked about the product development, Dr. Esquenazi told *OTW*, "We helped improve the device design and the algorithm that makes the system walk. We also demonstrated the functional outcome of achieving seat-to-stand and ambulation for patients who otherwise are completely paralyzed."

As for what might be especially challenging for patients regarding training, he commented to *OTW*, "Learning where their balance is during standing and walking in view of lack of sensation in their legs as a result of the spinal cord injury."

*Einstein Healthcare Network*

*Einstein Healthcare Network*

MossRehab is part of Einstein Healthcare Network. — *EH*

## New Study: Prolotherapy for Treating Tennis Elbow?

Chronic lateral epicondylosis (CLE) accounts for 4-7 out of every 1,000 primary care office visits annually. More commonly known as tennis elbow, CLE is often a misnomer because the disease is not necessarily more common in tennis players. In fact the prevalence of CLE in industrial workers is 30% of all cases with symptoms lasting from six months to two years, regardless of therapy.

*Wikimedia Commons and the National Photo Company*

Tennis elbow is a noninflammatory condition. Characteristically, it entails collagen degeneration, mucoid degeneration, fibroblast proliferation, and neovascularization. Traditional treatment is rest, physical therapy, nonsteroidal anti-inflammatory drugs, and, in the most severe cases, surgery. Corticosteroid injections can be effective in the short-term, but many physicians suggest a "wait and see" approach is more reasonable since tennis elbow is understood to be a self-limited condition.

Doctors from the University of Wisconsin and Griffith University studied the use of prolotherapy (PrT), which is an injection-based therapy to treat chronic musculoskeletal pain and tendinopathy including patients suffering from CLE.

Investigators in the study were: Dr. David Rabago, Dr. Aleksandra Zgierska, Jessica Grettie, Dr. John Wilson, Daniel Miller, Dr. Ken S. Lee, Dr. Rick Kijowski, Dr. Mary E. Sesto from the University of Wisconsin School of Medicine and Public Health; Dr. Amrish O. Chourasia from the University of Wisconsin's Department of Biomedical Engineering; and Dr. Michael Ryan from Griffith Health Institute in Australia. The study's title is: "Hypertonic Dextrose and Morrhuate Sodium Injections (Prolotherapy) for Lateral Epicondylosis (Tennis Elbow)" and it was published in the July 2013 issue of the *American Journal of Physical Medicine & Rehabilitation*.

The study was a three-arm randomized control trial. Group 1 received ultrasound-guided PrT with dextrose solution (PrT-D). Group 2 received ultrasound-guided PrT with dextrose-morrhuate sodium solution (PrT-DM). Group 3 was the "wait and see" group.

*Nevit Dilmen and Wikimedia Commons*

All 26 patients (32 elbows) were diagnosed with self-reported lateral elbow pain for three months or longer and had failed one of the three most common treatments for CLE, nonsteroidal anti-inflammatory drugs, physician-initiated physical therapy, or corticosteroid injections before enrolling in the trial.

PrT-D and PrT-DM injections were given at 1, 4, and 8 weeks. With imaging from an ultrasound, up to 2.5 mL of the prepared PrT solution was "peppered" on the bone along the tendon and annular ligament in the sensitive areas. After 16 weeks, the "wait and see" group was offered PrT injection and exited from the study. The other two PrT groups were kept and evaluated again at 32 weeks after entry.

The outcomes test was Patient-Rated Tennis Elbow Evaluation (PRTEE).

Primary endpoint was change in the composite PRTEE score. Secondary endpoint was pain-free grip strength and magnetic resonance imaging severity.

How did PrT do? Patients receiving the PrT-D or PrT-DM showed significantly higher PRTEE scores versus baseline. The amount of PRTEE improvement in both PrT groups was statistically significant 16 weeks, while the "wait and see" group's scores were not.

Furthermore, PrT-D patients had the greatest grip-strength versus PrT-DM and "wait and see" patients. There was no difference in magnetic resonance imaging severity score. A tertiary outcome was treatment satisfaction rating and most patients reported being "very satisfied" or "satisfied." — *SB*

**TRAUMA**

## Hospital Ships Take Center Stage at RIMPAC

The naval might of 22 nations lies moored around the Hawaiian Islands. More than 40 naval vessels and 200 aircraft manned by over 25,000 personnel are gathered for RIMPAC, the biannual Rim of the Pacific maritime exercise. The vast armada of ships, submarines, and aircraft, participating in the largest international maritime exercise ever, will continue until August 1.

*Wikimedia Commons and U.S. Navy photo by Mass Communication Specialist 2nd Class Kenan O'Connor*

The 2014 RIMPAC marks the first participation of hospital ships in the history of the exercise. On July 1-2, Commander, U.S. Third Fleet (CF3) hosted the inaugural RIMPAC Military Medicine Symposium aboard the USS Peleliu (LHA-5). Moored at Joint Base Pearl Harbor-Hickam, the symposium attracted more than 120 international medical officials on the first day. Representing 12 nations including Australia, Brunei, Canada, China, Columbia, Indonesia, Japan, Mexico, New Zealand, Norway, Singapore, and South Korea, medical officials and service members were able to network with

other partner nations in the military medical community.

Canadian Army Lt. Col. Nicholas Withers, Combined Force Maritime Component Commander (CFMCC) surgeon and organizer of the symposium shared that the goal of the RIMPAC Military Medical Symposium is for countries to become familiar with other nations' method of operations. Should a major event happen, medical officers will know how others countries operate so they can engage with those nations and provide assistance. Another goal is for nations to share their newest medical practices.

On July 3, a hospital ship in Chinese People's Liberation Army Navy (PLA(N)) hosted a medical exchange conference as part of the symposium. Aboard the hospital ship, Peace Ark (T-AH 886), PLA(N) and U.S. Navy medical officers gave presentations about topics ranging from damage-control surgery to telecritical care. The Military Sealift Command hospital ship USNS Mercy (T-AH 19) will also host international guests. While at Pearl Harbor, both ships will hold expert exchanges and will later take part in simulated disaster relief operations at sea. — *SB*

## State-of-the-Art Rehabilitation Center Set to Open for Injured British Soldiers

Stanford Hall dates from the early 18th century. In the 1930's, Sir Julian Cahn remodeled the house by adding a nine-hole golf course, a trout lake, and a decorated outdoor swimming pool. The fortunate new tenants of this luxurious estate will be the British Army's seriously injured soldiers, as Stanford Hall undergoes renovations to become a rehabilitation center.

The current Defense Medical Rehabilitation Center is located at Headley Court in Surrey, but is set to be moved to Stanford Hall in Leicestershire by 2018. The Duke of Westminster bought Stanford Hall in 2011 with the intention of converting the estate into a £300 million treatment center. The Duke, one of Britain's wealthiest men, has now raised the money necessary to fund the new center entirely from private donations. In addition to the state-of-the-art rehabilitation center, Stanford Hall's 360 acres will contain a large swimming pool, hydrotherapy pools, and a 400-meter running track. A gait-analysis center is also scheduled to open in addition to a sunken garden, where patients can learn to navigate stones and cobbled paths.

Headley Court was bought after WWII by the Royal Air Force and has since been expanded to accommodate the now 20,000 patients who are treated there. The Ministry of Defense does not own Headley Court, but has spent about £30 million on improvements. The charity Help for Heroes has donated more than £8 million to Headley Court and the charity's funded facilities will be transferred to Stanford Hall. In addition to more extensive grounds, Stanford Hall is located closer to the Queen Elizabeth Hospital Birmingham, the main receiving hospital for military casualties.

Currently, Headley Court is designated a Defense Medical Rehabilitation Center. Stanford Hall will become a Defense and National Rehabilitation Center, where the wider public will be treated in the same facilities as the injured service members. Philip Hammond, the Defense Secretary, and Air Marshal Paul Evans, the Surgeon General, disclosed plans for the new Stanford Hall treatment center on Thursday, July 10, 2014. These plans will be detailed in a ministerial statement in Parliament. The development of Stanford Hall into a rehabilitation center for injured personnel will help honor the Military Covenant, approved in 2011, that commits Britain to the care of injured service members. — *SB*

*Stanford Hall in Leicestershire/Source: Wikimedia Commons and Asterion*

REIMBURSEMENT

# Millennials Pose Political Challenge for Ortho Leaders

Fifty-one percent of Millennials have a favorable view of the Affordable Care Act (ACA), also known as Obamacare; while 46% have a negative opinion. Accounting for partisanship and race, Democratic, independent, and non-white Millennials' unfavorable views of the President correspond with unfavorable views of the ACA, and vice versa.

According to a new Reason-Rupe survey released on July 10, 2014, the generation of 18-29 year olds known as Millennials, is a demographic sleeping giant with power to revolutionize the political landscape in the U.S. Their views on healthcare are worth knowing for leaders of surgical societies working to influence public opinion and public policy.

There's good and bad news for notoriously Republican (GOP) leaning orthopedic surgeons. Millennials are fiscal conservatives but due to Republican conservative social positions, tune out the party.

The survey found that two-thirds of Millennials currently have health insurance and a third do not. Of Millennials who have insurance, a third obtained it through their employer, 19% have individually purchased plans, 39% are on their parents' plan, and 5% have health insurance policies through their university or college.

Among the third that do not have health insurance, 54% said they would obtain it by the deadline this year, and 44% planned to pay the federal fine instead.

While Millennials are more supportive of the ACA than opposed, they do not support all of its components. Millennials are unwilling to pay more for health insurance in order to help provide coverage to the uninsured, 55% to 43%. Willingness to pay more to provide for the uninsured is dependent on whether the Millennial is currently paying for his own health insurance.

Millennials who pay for their health insurance oppose paying more to provide coverage to the uninsured, but Millennials who don't pay for their insurance and instead are on their parents' plan say they favor paying more.

In other words, according to the survey, Millennials' support for redistributive health insurance reforms depends on whether they personally will be held responsible for the cost to provide for others. While they support the idea of providing for the uninsured, they are not willing to shoulder the cost.

Both those who purchase their insurance individually or through their employer and those who are on their parents' plan support paying higher premiums if the benefit was universal rather than redistributive. Fifty-three percent favor paying more if it "resulted in expanded benefits for everyone, such as maternity care and mental health care," while 44% oppose paying more.

The survey concluded that the clearest political trends among Millennials are their staunch social liberalism and relatively ambivalent fiscal views.

> "As a group, Millennials vote Democratic en masse, but not necessarily out of support for the party as much as out of even greater dissatisfaction with a GOP platform seen increasingly as out of touch with their priorities. Though Millennials currently tend to support the general concept of government guaranteeing 'positive' rights such as education, health care, and income, many of their underlying attitudes indicate they may become a generation that is both socially liberal and more fiscally conservative over the coming decade."

When it comes to healthcare, Millennials seem to be saying they favor universal coverage, but want individuals to pay for it. If Millennials begin influ-

*2013 Woodstock/Wikimedia Commons and Ralf Lotys*

encing elections and elect leaders with those views, leaders at such specialty societies like the American Academy of Orthopaedic Surgeons and the North American Spine Society might have to reconsider their political contributions and lobbying strategies that have favored and targeted Republicans.

To read the entire 100+ plus survey, click here: http://reason.com/assets/db/2014-millennials-report.pdf. — *WE*

**SPINE**

## Titan Spine: FDA Clearance for Endoskeleton TL

It's a slam dunk for Titan Spine, LLC, which has just received clearance from the FDA to commercially release its Endoskeleton TL system, a spinal fusion system that utilizes a lateral approach. As noted by the company, the Endoskeleton TL represents the first lateral fusion device to feature surface technology that is designed to participate in the fusion process by creating an osteogenic response to the implant's topography.

According to the company, the Endoskeleton TL device utilizes Titan's proprietary roughened titanium surface technology which has been shown to upregulate the production of osteogenic and angiogenic factors that are critical for bone growth and fusion. In addition, the design of the TL device incorporates large windows and large internal volumes to allow for significant bone graft packing, clear CT and MRI imaging, desired bone graft loading, and the ability to pack additional bone graft material within the device following implantation.

Kade Huntsman, M.D., an orthopedic spine surgeon with the Salt Lake Orthopaedic Clinic in Salt Lake City, Utah, performed the first surgeries utilizing the Endoskeleton TL on July 9, 2014. In the July 14, 2014 news release he said, "I was extremely pleased with the performance of the system. For the first time, I was able to insert additional bone graft material in to a lateral device post-implantation, and the radiopaque nature of the TL made it extremely easy to place the device in the desired location. I am excited to offer the TL, and the benefits of its surface technology and design features, to my patients requiring lateral interbody fusion."

Andrew Shepherd, vice president of marketing for Titan, told *OTW*, "We are proud to be the first company to launch a lateral interbody device that features surface technology. The fact that we work closely with biomaterial academic thought leaders in the design of our surface technology highlights that our interbody devices, including the TL, are rooted in science. And while design features are extremely important, we know that our patients primarily benefit from the response that their cells have to the surface topography and associated surface energy of our implants. Encouraging and hastening the body's own natural healing process will always be our focus as we continue the development of next-generation surface technologies. I am proud and confident to proclaim that Titan Spine is the leader in surface technology for spinal implant applications." — *EH*

*Titan Spine, LLC*

PEOPLE

# Steven Arnoczky, D.V.M., Bruce Reider, M.D., Timothy Taft, M.D. Inducted AOSSM Hall of Fame

The American Orthopaedic Society for Sports Medicine (AOSSM) has welcomed three new members to its ranks: Steven P. Arnoczky, D.V.M., Bruce Reider, M.D., Timothy N. Taft, M.D. All three were inducted at the AOSSM Annual Meeting in Seattle, Washington, on Friday, July 11.

Dr. Arnoczky, a sports medicine researcher from Michigan State University (MSU), is currently the Director of the Laboratory for Comparative Orthopaedic Research at MSU and the Wade O. Brinker Endowed Professor of Veterinary Surgery in the College of Veterinary Medicine. He also holds appointments in the College of Human Medicine and the College of Osteopathic Medicine at MSU.

Dr. Arnoczky has received numerous awards, including the Neer Award from the American Shoulder and Elbow Society and the Kappa Delta Award for Outstanding Orthopaedic Research from the American Academy of Orthopaedic Surgeons.

Dr. Arnoczky told *OTW*, "Being selected to the AOSSM Hall of Fame is undoubtedly one of the greatest honors of my professional career. As a non-physician, I have always felt extremely fortunate to be associated with the AOSSM, its membership, and its research and education missions. To be among those individuals who have been deemed worthy for inclusion into the AOSSM Hall of Fame is, indeed, a humbling experience. I am very appreciative of this special honor."

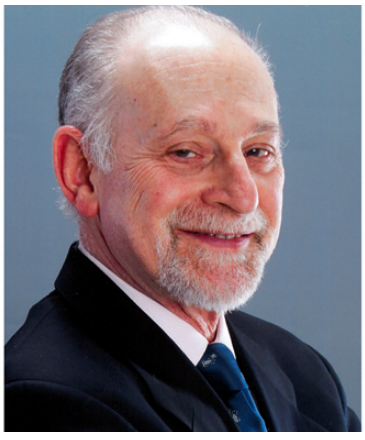
Bruce Reider, M.D. is a sports medicine orthopedic surgeon and University of Chicago (UC) team physician. He arrived at the University of Chicago in 1981, where he continues to serve as head team physician for the athletic programs. At UC, he founded the sports medicine fellowship program and was director of sports medicine for more than three decades. In 2013, in recognition of his long-time devoted care of the varsity athletes of the University of Chicago, he was awarded the Starkey Duncan Service Award. In addition to his duties at UC, he has served as team physician for several other colleges and high schools in the Chicago-land area and provided team coverage for wrestling and soccer at the national and professional levels.

Since 2002, Dr. Reider has been editor-in-chief of the *American Journal of Sports Medicine* and, since 2009, executive editor of the Medical Publishing Group for the AOSSM. He also serves as *Orthopaedic Journal of Sports Medicine* editor-in-chief.

Dr. Reider commented to *OTW*, "The individuals whose portraits hang in the AOSSM Hall of Fame have made exceptional contributions to Orthopaedic Sports Medicine and to the AOSSM. To be considered in the same context as these outstanding people is a wonderful honor."

Timothy N. Taft, M.D. is the Max Novich Distinguished Professor of Orthopaedics and director of sports medicine at the University of North Carolina in Chapel Hill (UNC). In addition to being the team physician and orthopedic surgeon for UNC, Dr. Taft has been the team, head physician or medical director for more than 40 U.S. teams at international competitions including the U.S. Swimming (1983-2004) Teams and the1980 USA Olympics Teams.

Dr. Taft told *OTW*, "I was honored to learn that I was being considered for the AOSSM Hall of Fame and humbled at being chosen by my peers as being someone who has made a distinctive contribution to Sports Medicine." — *EH*


*(Left to Right) Steven Arnoczky, D.V.M.; Bruce Reider, M.D.; Timothy Taft, M.D.*

## C. Lowry Barnes, M.D. New Chair at UAMS

C. Lowry Barnes, M.D. is being hailed as the new chief—chair—of the Department of Orthopaedic Surgery at the University of Arkansas for Medical Sciences (UAMS). Dr. Barnes, who will occupy this position as of August 1, 2014, will hold the Carl L. Nelson, M.D., Chair in Orthopaedic Surgery.

According to the news release, Dr. Barnes has been a UAMS professor of orthopedics for the past three years while he continued his private practice. He will see patients at UAMS and continue seeing patients in his practice at Arkansas Specialty Orthopaedics and St. Vincent Infirmary Medical Center.

G. Richard Smith, dean of the UAMS College of Medicine, said in the news release. "Our patients, students and trainees, and faculty staff will all benefit greatly from the broad experience, strong leadership and new vision that he brings to this post."

As noted in the news release, Dr. Barnes graduated with honors from the UAMS College of Medicine in 1986, then remained at UAMS for his internship and residency in orthopedic surgery. Dr. Barnes completed a fellowship in adult reconstructive surgery and arthritis surgery at Harvard Medical School and Brigham and Women's Hospital in Boston. In 1998, Dr. Barnes was founding managing partner of Arkansas Specialty Orthopaedics, where he was president for more than a decade. He has long been active at St. Vincent Infirmary Medical Center, serving on the board of directors from 1997-2010 and as president of the St. Vincent Infirmary Physician Hospital Organization.

*C. Lowry Barnes, M.D.*

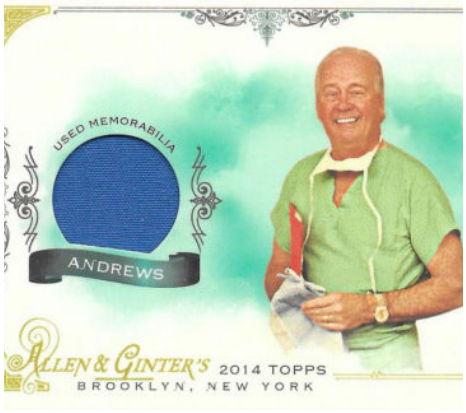
Dr. Barnes is a member of the Knee Society, the only Arkansas member since the death of Carl Nelson. He is a past president of numerous organizations, including the Arkansas Orthopaedic Society, the Southern Orthopaedic Association and the Society for Arthritic Joint Surgery. He serves as treasurer for The American Association of Hip and Knee Surgeons and has recently been named the Distinguished Southern Orthopaedist by the Southern Orthopaedic Association. Dr. Barnes has contributed to the Arkansas Arthritis Foundation for years, previously serving on the board of directors and earning the organization's Person of the Year honor in 2000.

Dr. Barnes told *OTW*, "Fortunately, our department is blessed with great faculty, staff, and residents. The Chancellor, Dean, and hospital CEO are very supportive of our department and are open to change. I hope to help develop a combined academic and private practice of orthopedics by working with my outstanding partners at Arkansas Specialty Orthopaedics and the forward thinking team at CHI St. Vincent, where I have practiced for more than 20 years. This will obviously not be a 'Barnes Project.' As another Arkansan said, 'It will take a village.'" — *EH*

## "Jimmy" Andrews, M.D. Gets His Own Baseball Card!

Maybe the legions of baseball stars helped by Dr. James "Jimmy" Andrews got together and voted. However it happened, Alabama sports medicine legend is a little blown away. He—and his scrubs—are now appearing on a Topps Allen & Ginter baseball card.

Dr. Andrews, who has operated on such luminaries as Emmitt Smith, and Drew Brees, is a founding member of Andrews Sports Medicine and Orthopaedic Center in Birmingham, Alabama. He is also founder of the American Sports Medicine Institute and a past president of the American Orthopaedic Society for Sports Medicine.




*Topps Allen & Ginter*

Additionally, Dr. Andrews is senior consultant for the Washington Redskins professional football team; medical director for the Tampa Bay Rays professional baseball team; and medical director of the Ladies Professional Golf Association.

Dr. Andrews tells *OTW*, "This is so unique I don't quite know how to comment! I am humbled that anyone would be interested." — *EH*

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