VOLUME 9, ISSUE 28 | SEPTEMBER 10, 2013

# Orthopedics This Week

## WEEK IN REVIEW







## BREAKING NEWS



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

# Orthopedic Power Rankings

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

**THIS WEEK:** Macroeconomic factors driving ortho valuations—and we don't mean Obamacare. Institutional investors are erecting a wall of worry. Two issues: the Fed and Syria. Last Friday's jobs report was supposed to signal a direction for the Fed. But, while health care jobs grew, the report failed to meet expectations. Then Syria has become high drama with implications for U.S. global leadership. Result: weaker dollar, money on sidelines.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 2 | Integra LifeSciences | 11.77% | 7.28% | Investors like what they are seeing. Rising profit margins and a return to YOY earnings gains by Q4. |
| 2 | 1 | Globus Medical | 28.53 | (1.35) | GMED has the HIGHEST P/E to growth rate in Ortholand. That means investors are linking GMED's ROA to future growth. |
| 3 | 3 | Stryker | 18.71 | (2.63) | Big, diversified ortho not getting much love right now. But SYK's positioning is really interesting. Sort of mini-JNJ, but without the pharma...Yet. |
| 4 | 5 | Smith & Nephew | 20.78 | (0.36) | We kind of doubt that the interest in SNN is coming from the ortho side of the biz. More likely wound care. |
| 5 | 10 | NuVasive | 6.30 | 0.22 | Concerns over OIG have washed through. It was always overblown. Back to the basic story—growth. |
| 6 | 9 | Conmed | 10.57 | 1.63 | Pop! Here comes Conmed? Wall Street broker Needham likes what they see. Put a "BUY" on CNMD. |
| 7 | 4 | Zimmer | 29.28 | (3.28) | What good are high profit margins if they just build cash balances? ZMH now sitting on $1.2 billion—in a buyer's market for ortho assets. |
| 8 | 7 | Medtronic | 28.78 | (3.12) | JNJ's purchase of Synthes holds a lesson for MDT. Sitting on $10 billion in cash, MDT has the means to make a similar move. |
| 9 | 6 | Johnson & Johnson | 26.68 | (6.94) | So far this year, JNJ has had its best stock appreciation run in a decade. But now the profit taking has begun. |
| 10 | NR | Orthofix | 16.25 | 1.68 | It's been a rough few weeks but the worst is over. OFIX is way undervalued at these prices. |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | Integra LifeSciences | IART | $40.51 | $1,138 | 7.28% |
| 2 | MAKO Surgical | MAKO | $15.50 | $729 | 5.08% |
| 3 | Orthofix | OFIX | $23.01 | $448 | 1.68% |
| 4 | Conmed | CNMD | $33.10 | $910 | 1.63% |
| 5 | NuVasive | NUVA | $23.18 | $1,033 | 0.22% |
| 6 | Smith & Nephew | SNN | $60.34 | $10,840 | -0.36% |
| 7 | Globus Medical | GMED | $16.76 | $1,556 | -1.35% |
| 8 | Stryker | SYK | $68.93 | $26,065 | -2.63% |
| 9 | Tornier N.V. | TRNX | $18.89 | $903 | -2.98% |
| 10 | Medtronic | MDT | $53.46 | $53,325 | -3.12% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | MiMedx Group | MDXG | $4.20 | $405 | -27.34% |
| 2 | TiGenix | TIG.BR | $0.32 | $40 | -15.34% |
| 3 | CryoLife | CRY | $6.18 | $171 | -12.46% |
| 4 | RTI Biologics Inc | RTIX | $3.39 | $191 | -12.18% |
| 5 | Alphatec Holdings | ATEC | $1.95 | $189 | -11.36% |
| 6 | Wright Medical | WMGI | $24.37 | $1,147 | -10.70% |
| 7 | Exactech | EXAC | $18.86 | $254 | -10.02% |
| 8 | Symmetry Medical | SMA | $8.05 | $300 | -9.85% |
| 9 | ArthroCare | ARTC | $32.44 | $916 | -8.57% |
| 10 | Baxano Surgical Inc | BAXS | $1.74 | $79 | -7.45% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $23.01 | $448 | 8.95 |
| 2 | Zimmer Holdings | ZMH | $79.88 | $13,544 | 12.91 |
| 3 | Medtronic | MDT | $53.46 | $53,325 | 14.21 |
| 4 | Globus Medical | GMED | $16.76 | $1,556 | 14.86 |
| 5 | Smith & Nephew | SNN | $60.34 | $10,840 | 14.87 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $23.18 | $1,033 | 82.79 |
| 2 | Symmetry Medical | SMA | $8.05 | $300 | 32.20 |
| 3 | RTI Biologics Inc | RTIX | $3.39 | $191 | 25.26 |
| 4 | ArthroCare | ARTC | $32.44 | $916 | 21.99 |
| 5 | Integra LifeSciences | IART | $40.51 | $1,138 | 19.91 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Globus Medical | GMED | $16.76 | $1,556 | 0.99 |
| 2 | Exactech | EXAC | $18.86 | $254 | 1.21 |
| 3 | Orthofix | OFIX | $23.01 | $448 | 1.28 |
| 4 | Conmed | CNMD | $33.10 | $910 | 1.37 |
| 5 | Zimmer Holdings | ZMH | $79.88 | $13,544 | 1.41 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $23.18 | $1,033 | 8.71 |
| 2 | CryoLife | CRY | $6.18 | $171 | 4.41 |
| 3 | Symmetry Medical | SMA | $8.05 | $300 | 2.68 |
| 4 | Johnson & Johnson | JNJ | $87.16 | $245,623 | 2.65 |
| 5 | Medtronic | MDT | $53.46 | $53,325 | 2.20 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Symmetry Medical | SMA | $8.05 | $300 | 0.73 |
| 2 | Bacterin Intl Holdings | BONE | $0.59 | $30 | 0.89 |
| 3 | Alphatec Holdings | ATEC | $1.95 | $189 | 0.96 |
| 4 | Orthofix | OFIX | $23.01 | $448 | 0.97 |
| 5 | RTI Biologics Inc | RTIX | $3.39 | $191 | 1.07 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | MiMedx Group | MDXG | $4.20 | $405 | 14.96 |
| 2 | TiGenix | TIG.BR | $0.32 | $40 | 9.77 |
| 3 | MAKO Surgical | MAKO | $15.50 | $729 | 7.10 |
| 4 | Baxano Surgical Inc | BAXS | $1.74 | $79 | 5.40 |
| 5 | Globus Medical | GMED | $16.76 | $1,556 | 4.03 |

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

# New Study Says MIS Deformity Surgery EQUAL to Open Surgery! ♦ Stem Cell Breakthrough for Segmental Bone Defects ♦ Olympic M.D. Uncovers Keys to Bone Health ♦ AAOS' Remarkable Programs in Vietnam and China

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

**MIS EQUAL to Open for Deformity Correction** A new study, led by Neel Anand, M.D., clinical professor of surgery and director of spine trauma at Cedars-Sinai Spine Center in Los Angeles, is giving hope to those with scoliosis. The research team has found that minimally invasive surgery (MIS) is effective for the long-term correction of spinal deformities, including adult scoliosis. Dr. Anand, whose work was just published in *Spine,* tells *OTW,*

*Dr. Westin with Ashley Wagner/Courtesy of Dr. Westin*

> "This is the first study documenting the long-term results of MIS techniques for spinal deformity. We compared the efficacy of MIS techniques over two to five years; we found that a combination of three novel MIS techniques provided correction of adult spinal deformity comparable to traditional (open) surgery. The good news is that with MIS there were significantly improved functional outcomes, excellent clinical and radiological improvement, faster recovery times, less blood loss, and lower complication rates.
>
> My team and I started doing MIS correction of spinal deformities in 2003, utilizing a series of technologies and techniques. In 2008 we published our first paper on the technique and its feasibility and in 2010 the results at one to three years. It's terrific to now have concrete data on this most important topic. Deformity correction is one of the biggest operations we do, and has the greatest morbidity; complication rates of open spinal adult deformity are approximately 40-60%.
>
> The biggest advantage of this approach is that there is not much blood loss because it means that the patient is more likely to have an easier recovery and not wind up in ICU. With open surgery the blood loss is 2-3 liters; while with MIS it's about 200cc. In addition, because the patient is not losing much blood they don't have the associated complications such as DIC [disseminated intravascular coagulation], cardiac events, stroke and so on. The complication rate with MIS is almost half that of open surgery. There are limitations, however. This is not for all patients. If someone has had a previous spinal fusion and then develops a deformity and needs an osteotomy, then traditional open techniques may still be needed. But for those well selected patients who can undergo MIS correction techniques, effective long-term cor-

rection and results can be obtained with less complications than traditional open methods."

**Stem Cell Breakthrough for Segmental Defects** Researchers from Cedars-Sinai have received a $5.18 million grant from the California Institute for Regenerative Medicine (CIRM)to develop a novel approach to treat segmental bone defects—without grafting bone. The principal investigator, Dan Gazit, Ph.D., D.M.D., told *OTW*,

"This is truly a new idea, namely recruiting the stem cells from the injury site instead of using bone grafts or stem cells that have been cultured ex vivo, in the lab; you are using a reservoir of stem cells that already resides within the bone marrow. Our technology consists of two steps: first we recruit the stem cells to the bone fracture site…then we deliver a bone-forming gene into the recruited cells using a short ultrasound pulse that opens tiny pores in the cell membranes, thus allowing the DNA to enter.

We first worked with rodents, taking three years to figure out how to recruit a critical mass of resident stem cells. This was important because you can't successfully treat an injured organ unless you have significant numbers of these cells at the site of tissue loss. If you don't have enough stem cells, efficient regeneration cannot be achieved since the therapeutic gene you deliver using the ultrasound does not reach the right target. After recruitment we turn the stem cells into active cells that differentiate and start to regenerate bone.

I'm thrilled that for the last several years we have been receiving emails from all over the world asking about using stem cells in orthopedic situations that seem hopeless. Together with Dr. Hyun Bae, an orthopedic surgeon who is the co-Principal Investigator in this project, we hope to leverage the funding we received from CIRM and make this technology available for millions of patients worldwide. Our first goal, upon successful completion of the funded project, which will take three years, will be to embark on phase one clinical trials."

**Olympic M.D. Discovers Keys to Bone Health** When the Olympic skaters hit the ice in Sochi, Russia, this coming February they will have undergone a week of preparatory medical "bootcamp." That event, "Champs Camp," was just held at the Olympic Training Center in Colorado Springs, Colorado. Craig Westin, M.D. is one of the U.S. Figure Skating Team physicians, Medical Director of Chicago's Joffrey Ballet,

and orthopedic specialist with Illinois Bone & Joint Institute. Dr. Westin, who is one of two physicians designated by the U.S. Figure Skating Association for Sochi, tells *OTW*,

> "All of the top U.S. skaters undergo a comprehensive review that includes their medical status and needs, including physical therapy and dietary. Their skating programs are also reviewed by U.S. judges including those who will be at the Olympics.
>
> During the daytime the skaters perform their programs in a simulated competition environment. They also see sports psychologists, nutritionists, orthopedic surgeons, and primary care doctors. In the evenings the specialists from each field get together and discuss the data for each competitor, and how we can help optimize his or her health so they can perform their best.
>
> The most interesting things I learned this week were the effects of metabolic and dietary status on performance. The skaters get dexascans to measure not only bone density but body composition (lean mass versus fat). They also have blood tests including iron levels, Vitamin D and cortisol stress hormone). In a sport like figure skating, being light and small is perceived as an advantage, but in fact, body weight is not the right thing to focus on. The important thing is to maximize muscle mass and minimize body fat. This is done by matching the caloric demands of the sport with caloric intake and the timing of that intake. If a skater burns 4,000 calories a day, but is only taking in 3,500 calories, then they are not meeting their caloric needs and the body perceives that as starvation. In relative starvation the body stores the calories as more fat and less muscle mass.
>
> These skaters should have the strongest bones ever because of the physical loading of their bodies, but some are not optimizing their calcium and vitamin D metabolism. Skating is an indoor sport so these athletes are not exposed to a lot of sun. Many of them have adequate calcium intake, but in the absence sunshine, vitamin D does not become active. With-

out active D the calcium doesn't get into the bones well. These kids are super athletes and if they have health problems it isn't obvious by looking at them. Champs Camp is a superb opportunity to go over any and every issue that might get in the way of our Olympic athletes being at their best in Sochi."

**AAOS' Remarkable Projects in Vietnam and China** "Sign your site" has made its way to Vietnam…the American Academy of Orthopaedic Surgeons (AAOS) comprehensive review course is coming to Argentina. Lynne Dowling, director of the International Department at AAOS, gives *OTW* an update on its projects around the globe.

"One of the most exciting things is that in the past six months the AAOS board of directors has renewed its interest in international work and has 'greenlighted' several new educational program concepts. Over the years the AAOS leadership has seen how the demand for participation in our annual meeting has escalated; they have also witnessed a significant increase in demand from the global orthopedic community for AAOS to come into countries and provide educational courses.

Our Vietnam efforts are going well; we have three programs in three cities where topics such as pediatric spine, adult reconstruction, and arthroscopy are taught. In this program, which is run in cooperation with the Vietnamese Orthopaedic Association, each program is rotated to a new location every three years. There are lectures, outpatient clinic visits, and live surgery with preselected patients; the U.S. faculty serve as mentors and consultants. Not only have we seen an improvement in surgical skills and care, but we are focusing on several patient safety measures including sign your site, preoperative time out, and the appropriate pre-op delivery of antibiotics. The Vietnamese medical personnel are making huge changes in these areas.

Next year, we will be starting a similar program, 'Founding Principles in Orthopedics' in three cities and provinces in China. We worked with the Chinese Orthopaedic Association (COA) to identify a broad variety of hospitals based on need, capacity, and size of the orthopedic department. Along with the COA president, Professor Yan Wang, we collaborated with each hospital and surveyed them using a tool developed by AAOS. This past May I traveled with a traumatologist to five sites; we did inspections, met with the leaders and staff, and then we reported back to the AAOS international committee. During the first quarter of 2014 our six U.S. faculty will spend a week working with the staff in China; then we will all meet back in the U.S. and design a customized program for each particular institution. U.S. faculty will not directly engage in live surgery until year three of the program. With China's enormous patient population it is important to create especially tight guidelines about what they will and won't treat. One reason we are taking our time is to give the Chinese personnel enough time to study English in depth, something they are very willing to do.

Lastly, we are partnering with the Argentine Orthopedic Association to create a new educational program. The program, which will launch in Buenos Aires in December 2014, will be available to all doctors in Latin America. This is a colleague-to-colleague initiative where we take the AAOS comprehensive board review course, work with and train 18 pre-selected Argentine faculty how to teach the 3.5 day program, and, with support from two U.S. faculty on-site in Argentina, conduct the comprehensive orthopedic review course, in Spanish, to Latin American orthopedic surgeons. A translated edition of the AAOS Comprehensive Orthopaedic Review books and question and answer book will be made available to all course participants. The course will be held annually in December for at least three years." ♦

# It's Official! LDR Files Papers to Go Public

**BY ROBIN YOUNG**


*Image created by RRY Publications, LLC / Sources: LDR logo, Wikimedia Commons and Thomas J. O'Halloran*

Could LDR Spine be ringing the NASDAQ bell soon?

Austin, Texas-based LDR Holding Corporation, that reported $90 million in product sales for the year ending December, 2012, filed documents with the Securities and Exchange Commission (SEC) on August 26, 2013 to sell shares of its company to the general public.

The new stock issue is being underwritten by three regional brokerage firms; Piper, Jaffray & Hopwood; William Blair; and Bryan, Garnier & Co.

If successful, the underwriting would make LDR the 5th pure play spine company trading in the public markets after NuVasive, Inc., Baxano Surgical, Inc., Globus Medical, Inc. and Alphatec Holdings, Inc..

## Spine Company Performance

Overall, LDR is the 11th largest spine company with approximately a 1% share of the worldwide market for spinal implants and instruments. The following table lists all public spinal implant suppliers and their respective sales levels. *(See table on page 9)*

While spinal implant and instrumentation sales industry-wide have been stuck in neutral since 2011, LDR has doubled in size between 2010 and 2012. To be sure, LDR's sales growth came off a comparatively low base. In 2012, for instance, the company added $13 million of incremental sales (from $78 million in 2011 to $91 million in 2012). By comparison, Globus Medical and NuVasive, the two fastest growing spinal implant suppliers, added $54 million and $44 million respectively in the same 12-month period.

The key to Globus' and NuVasive's strong performances has been robust new product introductions as well as a steady investment in marketing and distribution.

LDR is off to good start in this regard with last month's (August 2013) FDA premarket approval of the company's Mobi-C cervical artificial disc, the first for two-level indications.

## Stock Market's Take

Investors, generally, seem reasonably well disposed to spinal implant manufacturers. Despite negative press and ever more restrictive payers, investors like this industry's strong gross profit margins and the, still, strong underly-

| Worldwide Spine Market Revenue Model 2010-2016E ($ in millions) | | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013est | 2014est | 2015est |
| Medtronic, Inc.* | $3,420 | $3,322 | $3,139 | $3,088 | $3,150 | $3,250 |
| DePuy Synthes Companies | 1,933 | 1,961 | 1,920 | 1,850 | 1,870 | 1,890 |
| Stryker Corporation | 648 | 688 | 728 | 740 | 760 | 775 |
| NuVasive, Inc. | 476 | 531 | 581 | 625 | 665 | 700 |
| Globus Medical, Inc. | 288 | 332 | 386 | 440 | 500 | 530 |
| Alphatec Spine | 175 | 198 | 196 | 210 | 215 | 220 |
| Zimmer Holdings, Inc. | 234 | 225 | 209 | 205 | 200 | 205 |
| Biomet, Inc. | 165 | 153 | 162 | 170 | 180 | 200 |
| Integra LifeSciences Holding Corp. | 0 | 134 | 145 | 150 | 155 | 160 |
| Orthofix International, NV | 138 | 144 | 147 | 150 | 150 | 155 |
| **LDR Holding Corporation** | **59** | **78** | **91** | **no est** | **no est** | **no est** |
| Baxano Surgical, Inc. | 32 | 19 | 15 | 20 | 34 | 50 |
| Other | 975 | 956 | 943 | 842 | 701 | 630 |
| **Total Revenue** | **$8,543** | **$8,741** | **$8,662** | **$8,600** | **$8,700** | **$8,900** |
| *includes Infuse | | +2.3% | (0)% | (0)% | 1% | 2% |

*Source: Robin Young Consulting*

ing demographic pull. Globus Medical, in particular, is showing investors what might possible in terms of return on equity.

In the last three months, Globus Medical has been the best performing, pure play spinal implant stock in the stock market followed by NuVasive, then Alphatec and then by Baxano (see chart below). Globus' shareholders are up about 18% since mid-June. NuVasive's shareholders are up about 8% and Alphatec's owners are bouncing around breakeven. And for reasons that are unique to Baxano, those shareholders are underwater by about 10%. *(See graph to the right.)*


*Yahoo Finance*

Since June, Globus and NuVasive delivered the best sales and earnings performance of the public spine companies and the market appears to be valuing both companies accordingly.

If the chart above has any lessons for LDR it is that the market will price their equity based on sales and earnings performance—not because they sell spinal implants. There was a time when spinal implant companies benefitted from a kind of investor halo effect. No longer. When it comes to spine, investors are asking for basic sales and earnings growth.

## Compared to Other Pure Play Spine Companies

Compared to other pure play public spine companies, LDR has the highest gross profit margin. There can be many reasons for this (pricing, lower cost of production, etc.) but the end result is

| $000s | LDR | NuVasive | Globus Medical | Alphatec | Baxano |
|---|---|---|---|---|---|
| 2012 Sales | $90,918 | $620,255 | $385,994 | $196,278 | $14,570 |
| Gross Profit % | 83.8% | 75.3% | 80.5% | 63.1% | 70.4% |
| Selling & Marketing % | 57.0% | 60.0%* | 43.7% | 59.2% | 237.1% |
| Operating Profit % | (1.4%) | 6.0% | 29.7% | (0.5%) | (204.1%) |
| PSR | NA | 1.65 | 4.05 | 0.94 | 5.69 |
| PEG | NA | 2.45 | 1.43 | NA | NA |
| P/E | NA | 20.63 | 25.54 | NA | NA |

*Source: Robin Young Consulting*
* Includes admin expenses

that LDR has more money available for R&D, selling and marketing and administrative expenses. *(See table above)*

LDR spends about 57% of its sales dollars on selling and marketing. While this may seem high, it actually reflects the state of the spine business these days. As Baxano's numbers illustrate, in today's hyper competitive spine market, the ante in amount for playing with the big boys is north of $30 million per year. So, for LDR, that spent $52 million in 2012 on sales and marketing, the percentages going forward will likely stay high.



## LDR's Key Product Platforms

LDR has two primary product platforms:

- **VerteBRIDGE**, which allows surgeons to fuse the spine without screws or external plates. It can be, therefore, a zero-profile construct. It also is designed to be implanted with a minimally invasive surgical technique. The VerteBRIDGE products are poly-ether-ether-ketone, or PEEK, polymers and fit for one- or two-level cervical and lumbar fusion with or without supplemental fixation. The VerteBRIDGE products are brand named ROI-C, ROI-A, ROI-A Oblique and Avenue L.
- **Mobi non-fusion.** The highlight of the platform is LDR's recently approved Mobi-C cervical disc replacement. Mobi-C endplates have short, lateral, inclined teeth for stability and fixation. The endplates are titanium plasma sprayed and coated with hydroxyapatite. Mobi-C's mobile bearing core moves within the prosthesis as the neck bends and twists and can minimize stresses in the implant-to-bone interface. One of Mobi-C's key features is its ability to be adjusted, removed or repositioned intra-operatively. LDR will be selling Mobi-C for treatment of symptomatic cervical disc disease with radiculopathy or myelopathy at one or two contiguous levels.

## Use of Proceeds

The LDR team plans to use any dollars raised as follows:

- $4-6 million to launch Mobi-C in the U.S. market
- $10-15 million to expand U.S. and international sales and marketing
- $10 million to repay outstanding debt

Management also disclosed in its SEC filings that it would like to use up to $17.5 million to pay holders of Series C preferred stock in exchange for agreeing to vote in favor of the conversion of their preferred stock to common stock. But, management said, it may try to pay the Series C holders from debt—not equity—proceeds.

LDR's main lender is Escalate Capital Partners and they have about $10 million outstanding currently at a 13.2% rate of interest.

Finally, management reserved the right to use proceeds to acquire and invest in complimentary products although they have no particular transactions in mind.

## The French Connection

With this IPO (initial public offering), LDR joins two other spinal implant companies with foreign born CEOs. Maybe its mere coincidence, but three-fifths of the CEOs of pure play public spine companies were born outside the U.S. Les Cross, CEO of Alphatec is Australian. David Paul, founder and CEO of Globus Medical is from India. And LDR's Founder, CEO and President Christophe Lavigne is French.

In LDR's case, the fact that Lavigne is French has a bearing on LDR's product development culture. In fact, Lavigne has tapped into France's long, long history of medical product engineering and innovation to give LDR a clear area of differentiation…and strength.

French scientists have contributed significantly to medical technology, generally, and to spine therapies specifically. Most motion preservation implants, PEEK polymer implants and the early dynamic stabilization implants originated in France

Christophe Lavigne, who graduated from IUT Dijon, France, ESARC Paris and the European Business School Federation in Zurich, comes from this tradition.

But France's contributions go way beyond that.

Here's a partial list: *(See below)*

## A Public LDR

It's kind of cool that this French transplant (to Austin, Texas!) has chosen to go public. With the FDA approval of Mobi-C and a clearly innovative line of implants, Christophe and his underwriters should be able to get this issue sold successfully (barring, of course, unforeseen market gyrations).

One final item. We have it on excellent authority that Founder and CEO Christophe Lavigne played a hot lead guitar professionally in France. He is, in fact, a French rock 'n roller. We are hoping that Lavigne, instead of ringing in the NASDAQ bell, would play a lick or two on his well worn guitar.

Saisissez le jour! ♦

| | | | |
|---|---|---|---|
| First ligature of arteries. Ambroise Pare. 1565 | First modern blood transfusion. Jean-Baptiste Denys. 1667 | First modern dentistry. Pierre Fauchard. | First cataract surgery. Jacques Daviel. 1748 |
| Discovery of osmosis. Used in all hospitals today. Jean-Antoine Nollet. 1748 | First surgical removal of breast tumor. Henri Le Dran. 1757 | First stethoscope. Rene Laennec. 1816 | First medical quinine. Joseph Bienaime Caventou. 1820 |
| First codeine. Pierre Robiquet. 1832 | First aspirin. Charles Frederic Gerhardt. 1853 | First hypodermic needle. Charles Pravaz. 1853 | Concept of the "Blinded Experiment" where bias is removed from the test. Claude Bernard. |
| Discovery of plasmodium and its role in malaria. Charles Louis Alphonse Laveran. 1880 | First neonatal incubator. Etienne Stephane Tarnier. 1881 | First rabies vaccine. Louis Pasteur and Vuillemin. | Radium. Pierre and Marie Curie. 1898 |
| Mantoux test. Charles Mantoux. | First antipsychotics. Henri Laborit. 1952 | Cause of Down Syndrome. Jerome Lejeune. 1958 | First bone marrow transplant. George Mathe. |
| First insulin pump. Jacques Mirouze. 1981 | First tuberculosis vaccine. Albert Calmette. Camille Guerin. 1921 | Discovery of HIV. Francoise Barre-Sinoussi and Luc Montagnier. 1983 | First abortion pill (Mifeprisone). Etienne-Emile Baulieu. 1988 |
| First hand transplant. Jean-Michel Dubernard. 1998 | First telesurgery. Jacques Marescaux. 2001 across the Atlantic Ocean. | First face transplant. Bernard Devaunchelle. 2005. | |

*Source: Robin Young Consulting*

**Still**
the first to market.

**Still**
available today.

**Still**
a safe and truly biologic solution.




## OP-1® Products from Olympus Biotech.

If you're using BMP to heal bone, you still have a choice in products, and the choice is easy. OP-1, the first true osteoinductive* biologic commercialized in the United States, is still available today and still formulated for ease of use and predictable delivery. For healing the most challenging cases, the first way is still the better way.

*Data is available on file.

# IMPORTANT SAFETY INFORMATION

**HUMANITARIAN DEVICE**

OP-1 IMPLANT is authorized by Federal law for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. The effectiveness of this device for this use has not been demonstrated.

OP-1 PUTTY is authorized by Federal law for the repair of symptomatic, posterolateral (intertransverse) lumbar spine pseudoarthrosis in patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion and who have at least one of the following compromising factors: osteoporosis, diabetes or nicotine use. The effectiveness of OP-1 PUTTY for this use has not been demonstrated.

Brief summary of contraindications and warnings:

- OP-1 IMPLANT/OP-1 PUTTY is contraindicated in patients who (1) are pregnant (2) have or have had a malignancy (3) are skeletally immature (4) are pregnant or want to become pregnant within 2 years of treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.
- The use of OP-1 IMPLANT/ OP-1 PUTTY may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.
- There are no adequate well controlled studies of OP-1 IMPLANT/OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

Please see the package insert for the complete indication, contraindications, warnings, precautions, adverse events and other important medical information.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

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# Doc Privacy Rights Thrown Out

**BY WALTER EISNER**

*Photo Creation by RRY Publications LLC*

On May 31, 2013, a Florida federal district court lifted a Carter-era injunction that prevented the Centers for Medicare and Medicaid Services (CMS) from disclosing the physician payments section of the a database known as the Carrier Standard Analytic File—which includes details of Medicare payments made to individual physicians.

Federal investigators use the database to uncover fraudulent claims, but CMS drew the line at public dissemination. Until this court action, CMS kept information on specific providers private, confidential and hidden from the public.

With the lifting of that injunction, CMS is now considering if and how the agency will disclose specific payments made to physicians. Physicians appear divided on the issue.

## Injunction of Privacy

In 1978, as it had done in 1977, CMS planned to release a list of all physicians and providers who received Medicare reimbursements including the amount paid to each physician. Before the second list could be released, the Florida Medical Association and six physicians, joined by the American Medical Association (AMA), filed a lawsuit to enjoin the Carter Administration from releasing this data.

In 1979, a federal court in Florida issued the injunction against public disclosure saying the information was protected by the Privacy Act and that physicians' right to privacy trumped the public's right to know about specific payments.

Dow Jones & Co. challenged the injunction in 2011.

## Injunction Lifted

In her ruling lifting the injunction, U.S. District Judge Marcia Morales Howard said that new case law had narrowed the scope of the Privacy Act over the ensuing three decades and no longer supported such a broad injunction.

CMS says since the 1979 injunction, a number of changes have occurred related to physicians' privacy interests in maintaining the confidentiality of their Medicare payments and the public

interest in disclosure of such amounts. For example:

- Public interest in the information has increased given the substantial growth in size of Medicare since 1979, both in terms of total cost per year and as a portion of the federal budget
- Changes in the Medicare reimbursement system that have resulted in greater standardization of payment amounts for physician services
- The creation of the Qualified Entity program (known as Medicare data sharing for performance reporting), authorized by Section 10332 of the Affordable Care Act, which allows CMS to disclose Medicare claims data to qualified entities for the production of public performance reports
- The greater consequences of Medicare fraud, waste, and abuse, which disclosure of payment information could help expose

In addition, the agency says during the past several years, CMS' management role as a processor of Medicare claims for services has evolved toward becoming "a more effective steward and partner of transformation in the health care system with the goal of incentivizing high quality care and better health at lower costs."

## CMS Seeks Support for Disclosure

With this transformation, the agency says it now receives multiple requests from various stakeholders for physician payment and reimbursement data. These requestors argue that this data is an important part of the ongoing research, assessment, and evaluation of programs and services necessary to make improvements in the delivery, quality, and cost of care.

Before acting on its own, the agency wants to confirm that the release of such information would serve the public good and asked for public feedback.

Specifically, CMS wants to know:

- How to properly weigh the balance between any potential privacy interest a provider has and the public interest in disclosure
- What specific policies CMS should consider with respect to disclosure of individual physician payment data, especially in order to prevent the release of any health information on any Medicare beneficiary
- What form any potential data release might take (e.g., line item claim details, aggregated data at the individual physician level)

## Health Data Initiative

CMS has been in disclosure mood since 2010, when its parent agency, HHS (U.S. Department of Health and Human Services), launched the Health Data Initiative to promote transparent, innovative, and safe data use. CMS is also engaged with a wide range of public, non-profit, and private sector stakeholders to foster the availability and use of health care data to drive innovations that improve health and health care.

Since the initiative, CMS says it has released an unprecedented amount of aggregated data in machine-readable form. These data range from previously unpublished statistics on Medicare spending, utilization, and quality at the state, hospital referral region, and county level, to detailed information on the quality performance of hospitals, nursing homes, and other providers. In May 2013, CMS released information on the average charges for the 100 most common inpatient services at more than 3,000 hospitals nationwide, followed in June with the release of average charges for 30 selected outpatient procedures.

## Physician Fears and Debate

As argued by the lawyers who brought the original AMA lawsuit, physicians are worried that specific information about their Medicare income might be disclosed. The data could, for example, make it possible to uncover specific patient case performance, which in turn could be used to determine whether specific physicians are performing the appropriate procedures. Also, if line items are disclosed, the data could be used to identify physicians with the highest number of procedures performed during a given period of time. That could be used to gauge a physician's patient volume or experience per period compared to competitors.

However, physicians are not united in their opinion about whether such data should be made public.

## ACPE Poll: Physician Leaders Divided

According to a new poll conducted by the American College of Physician Executives (ACPE), 46% of responding ACPE members said the data should not be made public and 42% said the data should be made public—12% were unsure. ACPE bills itself as the nation's largest health care organization for physicians in leadership positions.

acpe.org
American College of Physician Executives
The home for physician leaders

*Logo courtesy of ACPE.org*

ACPE emailed its 11,000 members and 588 responded. Participants were also asked to share their comments. According to the ACPE here is some of what their members had to say.

## In Favor of Privacy

Those who favored keeping the information private said the data is too easily misinterpreted by the public and could be used to portray physicians in a negative and unfair light.

"What purpose does this action serve?" wrote Kenneth Maxwell, M.D., from Winston Salem, North Carolina. "Publishing the amount of Medicare reimbursement without some form of normative information provides no useful information for consumers."

Several physicians said that reimbursement is complicated by a number of factors, including geographical location, the type of procedure performed and the cost of medication. They say the time and effort it would take to translate the data might be better spent on other resources.

"This is not a form of transparency that will benefit budgeting, planning or patient care," said James C. Salwitz, M.D., from New Brunswick, New Jersey.

## In Favor of Disclosure

Those who favor disclosure argued the public has a right to know how their taxpayer dollars are being spent. As consumers continue to demand increased access to health care data, the move to greater transparency will only grow stronger. It doesn't make sense to fight it, they say.

"We live in an information age," wrote Daniel McDevitt, M.D., FACS, from Atlanta, Georgia. "We should be able to look up online where our money is going at all times."

Others said fighting to keep the information private will make physicians appear overly secretive. "It gives an appearance of having something to hide, and thus reduces public trust in our profession," said Paul Buehrens, M.D., from Seattle, Washington. "I just can't understand that attitude."

Jon Burroughs, M.D., MBA, FACHE, FACPE, said, physicians and healthcare organizations that are not prepared for complete transparency of performance data are not going to excel in an era of accountability where internal and external customers will expect reliable quality, safety, service, and cost data to make informed healthcare decisions.

"Third party payers and educated consumers will demand this data prior to making healthcare decisions and large employers/payers will preferentially divert beneficiaries and employees to high quality/low cost venues (as Wal-Mart and large insurers currently do now). This is our future and those who embrace it will excel and those who resist it will not."

## Accuracy and Fairness

Peter Angood, M.D., ACPE's CEO, said the nearly even split in opinion suggests CMS was wise to ask the physician community for feedback, and should spend some time deliberating over the responses before making any decisions.

*Source: Peter Angood, M.D./ACPE*

"No matter what your opinion on this subject may be, there's no doubt the move toward greater transparency in medicine and increased public reporting is here to stay—and we believe it is necessary," said Angood. "Part of our job as physician leaders is to help ensure that when health care data is presented to the public, it is accurate, fair, meaningful and useful."

CMS has not provided a timeline for making a decision about releasing the data other than a September 6, 2013 deadline for receiving public comments. The AMA, which continues to oppose the release of the data, may decide to appeal the ruling. "Medicine has stood its ground during the last 34 years to defend an injunction that favored individual rights and protected innocent physicians from becoming targets of suspicion. The AMA is considering its options on how best to continue to defend the personal privacy interests of all physicians," reportedly said AMA President-elect Ardis Dee Hoven, M.D.

Under current CMS rules, news organizations and third parties will have to file Freedom of Information Act requests to gain access to the data and the agency could still decide to deny requests on a case-by-case basis.

In a recent *Wall Street Journal* article, Laura Handman, an attorney who represented Dow Jones in the case said, "Given President Obama's emphasis on data transparency, I feel his government will give this very thoughtful consideration."

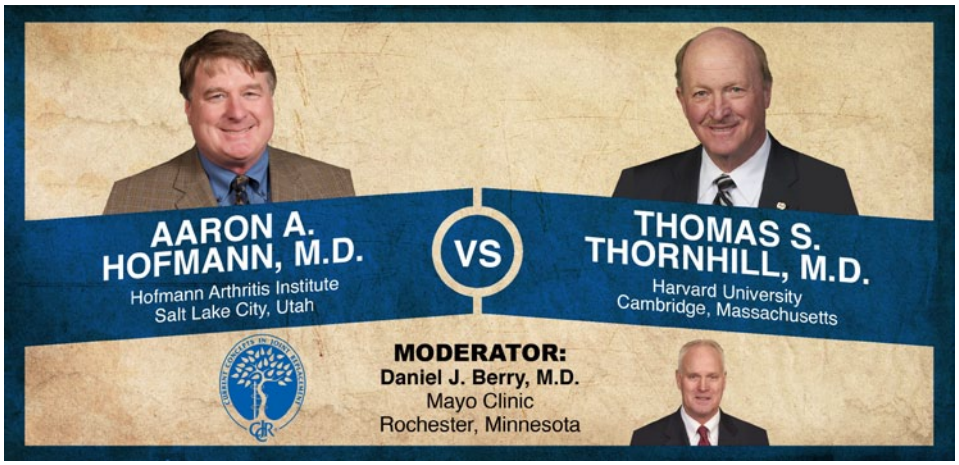
Judge Howard's ruling may be appealable but the overall trend to more disclosure seems unstoppable. While physicians seem to be divided over this issue, the trend is unambiguous. ♦

# Hofmann v. Thornhill Over Cementless Fixation

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

"You can get excellent clinical results with a cementless device…and cementless is equal to cemented." Or so argues Aaron Hofmann. "Hold on," counters Thomas Thornhill. "There are advantages of cementless total knees, however, we will be doing cemented knees consistently at some point in the future."

This week's Orthopaedic Crossfire® debate is "Cementless Fixation: It's Time for the Wine." For the proposition is Aaron A. Hofmann, M.D. of the Hofmann Arthritis Institute in Salt Lake City, Utah; against the proposition is Thomas S. Thornhill, M.D. from Harvard University. Moderating is Daniel J. Berry, M.D. from Mayo Clinic in Minnesota.




*Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Hofmann:** "I want to thank Seth for letting me debate my father. Twenty-six years ago I thought everything should be cementless. After listening to Dr. Thornhill and others I've done fewer cementless procedures each year, basically due to cost."

"The basic premise is that cementless must be at least equal to or better than cement. We were taken astray a bit because we did some animal studies and found that after six weeks there was solid ingrowth…but it didn't work on humans. So 20 years later we've seen a lot of changes, and now we have lots of surface technologies available."

"Some of our early data showed that titanium has an advantage over cobalt chrome; you get deeper and more penetration than if you use the latter material. There's really never been a problem on the femoral side…it's always the tibial side. The proximal tibia is only 24% bone, 76% marrow; that's the problem with trying to get attachment, so we use cement in every case. It's biologic cement if we're doing a non-cemented fixation. We grind up a slurry of bone from the underside of the tibial wafer, put it across the proximal tibia, and that becomes our biologic cement. The particles are there at the interface; it keeps the gaps away and drives particles into the porous coating to jump start that."

"Over the years we were accused of this being dead bone at the interface. But if you do tetracycline labeling of this bone and see that it lights up and shows that there's about 45% better immediate integration of that slurry of bone to the porous coating. And there's about 65% better ingrowth with the biologic cement."

"Regarding the tibia, you have to match the patient's slope to avoid subsidence. It's more critical if you're doing a cementless device. You also must be careful not to cook the bone while you're preparing it, so thermal necrosis occurs at 55 degrees and you have to irrigate that saw blade or make sure you're using new saw blades on the tibia and on the femur."

"Over the years we've learned that it doesn't matter how old the patient is… you can get good ingrowth into the porous coating. We also found that we had a 98% survival at 6-10 years, first of all on the patella. We don't use metal backed patellas because they have fallen out of favor, but they do work. When we examine our longer term follow-up of our first group of knees (360 patients with 89% cementless) the metal parts—the tibia and femur—survived 98% of the time.

These were all cruciate-sparing types of implants. We did have bad poly at the time so we were down to 94% poly survivorship and 95% of the patellas at 10-14 years. It wasn't the metal backing that failed. It was the poly that was

1.9mm on the edge that was a problem."

"The proof in the pudding is always in implant retrieval. We've been doing this for 25 years and you get great ingrowth into these implants—an average of 6-12%. This is good because there's only 26% bone in the proximal portion of the tibia. You can't get more into the porous coating than you have outside of the porous coating."

"So you can get excellent clinical results with a cementless device, and I think cementless is equal to cemented. You have a minimal amount of aseptic loosening and wear and excellent ingrowth upon retrieval. The cost of porous implant is the biggest question in my mind; it must be addressed."

**Dr. Thornhill:** "Aaron, my son…I have not taught you well. The best way to disarm your opponent in a debate is to go second, tell him the day before that you're going to be very benign and not say anything. But Aaron, I'm from Harvard, and you don't believe anybody at Harvard. I plan on beating you like a rented mule."

"There are advantages of cementless total knees, however, we will be doing cemented knees consistently at some point in the future. The operative time is shorter; we're moving away from tourniquets, it's better for MIS (though I have concerns). If the systolic pressure is up in a knee I don't like to cement. Cement extrusion is something that I tell residents and fellows to look at very carefully because this is third body wear."

"When we looked at this in the first cohort of our patients, we could say some things about cemented femurs. We were not as good because our numbers were not as good in the patella and in the tibia. At that time our institution had a disproportionate number of rheumatoids, who have a slightly high risk for cementless. We had over 50% uncemented femurs with 100% survivorship of the cementless femoral component at 10 years. We didn't have enough uncemented patellae or uncemented tibias to make any conclusion at that time. But at Mayo Clinic—and granted these were earlier cemented designs—they had 92% 10 year survivorship for cemented implants compared to 61% for their cementless counterparts."

"We know the problems of access to debris and the affected joint space, as well as the problems with well-fixed screws and osteolysis that has been changed in many hands. There's a variable substrate, particularly in the tibia."

In a typical varus knee you might see sclerosis and cysts; the fact is that cement in this area creates a uniform

proximal tibial mantle. That, I think, makes it easier for loading the tibia in a cemented situation. It also allows for antibiotic delivery and potential for other drug delivery of biologic agents."

"Regarding the surgical cut precision that many people say is important, well, we are not always that good. 'A little putty and a little paint makes the carpenter what he ain't.' Cement does help a bit in that situation. I have a 58 year old patient with a cementless knee. There was no failure of fixation; it was a failure of soft tissue balance. There was over-resection on the femur; it was loose, globally unstable."

The problem is that when we removed the components we put a dental dam around the patella and got a bit too close to the bearing surface. We restored the joint line, restored the stability, and everything was good. But there ended up being a lot of debris after the surgery, and I'm concerned about third body problems."

"So what will be the tipping point to cementless TKA [total knee arthroplasty]? It's going to be new material technology. There are many companies now that have trabecular metals that are very good: better coefficient of friction, better surface roughness, better cutting potential, and very good porosity, ultrastructure, and biocompatibility for ingrowth. As for high flex designs there has been some femoral failure, both cemented and uncemented. But cost is going to be 'the thing.'"

"So Aaron, fine…take the wine out, put it in bottles, but at least for the present time, leave it in the cellar."

**Moderator Berry:** "Aaron, you said that you have seen the percent of uncemented implants in your own practice go down. What percentage of your standard primary knees now are uncemented?"

**Dr. Hofmann:** "I went from 89% cementless to about 10% cementless and that's purely based on cost. I'm in charge of keeping implant costs down, and if the implant costs an extra $1,000 because it has porous coating then that's hard to justify in a Medicare patient."

**Moderator Berry:** "So for the entire healthcare system, if the technology is more expensive, if the results are maybe as good (but not necessarily better), if it's technically tougher, then why do it even in that 10%?"

**Dr. Hofmann:** "Durability. I've written about total knees in patients less than 50 and those things are as durable as anything we've seen…more durable

than a cemented knee. So I think there's a logic to looking at that patient group. There's no logic in looking at an older patient group. If you can justify $1,000 total for a porous implant then that takes up the cost of the cement and the extra OR time."

**Moderator Berry:** "So if you're going to use it in 10% of your patients—and they're younger—what are your indications for doing an uncemented knee?"

**Dr. Hofmann:** "They must have good quality bone. The post traumatic patient, the smoker…they are not good candidates for cementless. I even cemented a 31 year old recently who had terrible bone with hardware still in place. That isn't good biologic material for ingrowth."

**Moderator Berry:** "Tom, do you do any uncemented knees anymore?"

**Dr. Thornhill:** "I resurface the patella every time and I don't have a good option, so once I've bought into it I've got the cement in hand. So if I'm doing a cruciate retaining rotating platform knee, it's actually easier to use a femoral trial. I don't do any uncemented tibias, but I will do uncemented femurs… particularly with some of these newer materials. That way I can get my trial femur out, let the tourniquet down, make sure I've got the debris before I put my final insert in. I think there may be something to this loading of the bone. I think it will be a thing of longevity. We published a paper this year looking at what price people are willing to pay for an implant to gain xyz. So in a 75 year old person there's probably no benefit, as opposed to a 45 year old. And we're tending to look at knees as commodities now, which is a real problem."

**Moderator Berry:** "Aaron, if you've decided to do an uncemented knee do you do anything to test the fixation of the implant as you pound it in (or afterwards)?"

**Dr. Hofmann:** "Not after the implant is in, but there's a crude test that we use routinely. When we put the broach in, if you can hit on the broach with your mallet hand (not with a metal mallet) then that bone in the central portion of the tibia will not support a cementless implant. I'm also still using screws on the tibial side, so I have to get good initial fixation."

**Moderator Berry:** "Tom, do you have any way of testing your femoral component once you pound it on or do you judge that it's sufficiently fixed as you pound it on?"

**Dr. Thornhill:** "It's like anything else… when you get a component you must know the nuances of the system. You can tell from your implant related to your trial fit and then it's literally the fixation. I want to be able to get it to start to scratch fit anteriorly and posteriorly. It's the AP fit…if I can pull it off or move it then I would bail."

**Moderator Berry:** "Thank you both." ♦

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COMPANY

## Top Rated (#1!) Knee Hospital Announces Major Expansion

An institution that performs more than 2,000 total hip and knee replacements annually, putting it—in terms of volume—among the top 20 hospitals nationwide, is opening a new Center for Advanced Joint Replacement. The Christiana Care Health System has created the Center, which features 30 private rooms and a new therapy gym, on the 7th floor of Wilmington Hospital.

Christiana Care is one of only 128 hospital health systems in the nation—and the only hospital health system in Delaware—to earn the highest rating for knee surgery in Consumer Reports current issue on hospital surgery ratings. Officials at Christiana Care believe that their team-based approach to patient care results in clinical outcomes that are among the best in the nation.

"Through our new joint center, we are partnering with our neighbors to significantly enhance the patient- and family-centered experience when they are under our expert care," said Brian Galinat, M.D., chair of the Department of Orthopedic Surgery at Christiana Care. "Our patients can feel confident knowing that they will receive expert help through our innovative and effective systems of care."

The opening of the Center for Joint Replacement is part of the Wilmington Hospital Transformation Project, which, by 2014, will create a one million-square foot medical center. Christiana Care Health System ranks as the 21st leading hospital in the nation and 11th on the East Coast in terms of admissions. It includes two hospitals with 1,100 patient beds and an extensive range of outpatient services.

*—BY (September 6, 2013)*

*Courtesy of Christiana Care Health System*

## Integra Board Swap: Moszkowski Leaves, Morel Joins

Neal Moszkowski has retired from the Board of Directors of Integra LifeSciences Holding Corporation and has been replaced as a Director of the Company by Donald Morel. "Neal's service to Integra for a total of 13 years has been extremely valuable," said Stuart Essig, Chairman of Integra's Board of Directors. "We are thankful for his contributions to the Company during his tenure on the Board and its Nominating and Corporate Governance and Compensation Committees."

*Neal Moszkowski/ Courtesy of Towerbrook Capital Partners*

*Donald Morel/ Courtesy West Pharmaceutical Services*

Peter Arduini, Integra's President and CEO said of Morel, "He is a healthcare executive with extensive management and product development experience.

He has a particular interest and expertise in biomaterials. His tenure at West Pharmaceutical and broad experience in our industry will add a valuable perspective on Integra. I am delighted that he has agreed to join our Board of Directors."

Morel is currently the CEO and Chairman of the Board of Directors of West Pharmaceutical Services, Inc., a manufacturer of components and systems for the packaging and delivery of injectable drugs, as well as delivery system components for the pharmaceutical, healthcare and consumer products industries.

He also served as a Director of Kensey Nash Corporation, a medical device product development and manufacturing company and was a member of its audit and compensation committees. He is Chairman of the Board of Directors of the American Oncologic Hospital of the Fox Chase Cancer Center and is a member of the board of trustees of The Franklin Institute and of Lafayette College. Morel received a B.S. in Engineering from Lafayette College and an M.S. and Ph.D. in Materials Science from Cornell University.

*—BY (September 6, 2013)*

## Stryker Recalls Spine Plate

Stryker Spine has issued a Class I Recall of its OASYS Midline Occiput Plate.

The recall follows a July Hazard Alert for the device from Australia's regulatory agency, the Therapeutic Goods Administration.

On August 29, 2013, the FDA posted the recall on its Medical Device website. According to the FDA, the recall was initiated May 30, 2013 and affects products that were distributed from April 23, 2010 through February 12, 2013.

Stryker received reports indicating post-operative fracture of the pin that connects the tulip head to the plate body. This may cause serious adverse health consequences including blood loss, nerve injury, and the need for revision surgery to replace the fractured implant.

The Australian alert said the root cause of the problem is not yet known and Stryker is continuing to investigate reported cases from the U.S. and Belgium. At the time of the hazard alert, no cases of this problem had been reported in Australia.

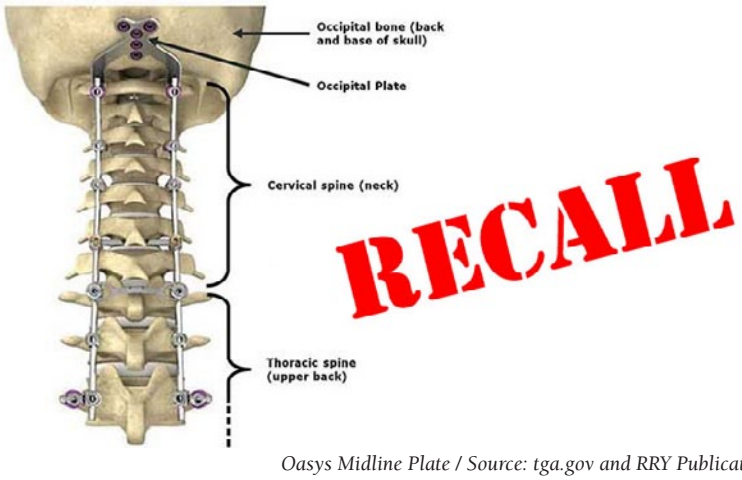
**Urgent Medical Device Recall**

The FDA commented that Stryker issued an Urgent Medical Device Recall on May 30, requesting medical facilities to examine their inventory and immediately stop distributing or using the recalled lots. If a medical facility has the affected product in stock, it should be returned to Stryker.

On June 20, 2013, Stryker notified spinal implant surgeons recommending routine clinical and radiographic post-operative evaluation for patients with an implanted OASYS Midline plate. If a patient begins experiencing symptoms including pain, weakness, or numbness, more urgent evaluation is needed. For patients who have had a revision surgery, Stryker recommends routine post-operative care and follow-up.

The OASYS Midline Occiput Plate is part of the OASYS Occipito-Cervico-Thoracic System used to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3). The OASYS Midline Occiput Plate provides stabilization at the junction

| Manufacturing Part Number | Product Description |
|---|---|
| 48551044 | OASYS MIDLINE OCCIPUT PLATE, SMALL |
| 48551045 | OASYS MIDLINE OCCIPUT PLATE, MEDIUM |
| 48551046 | OASYS MIDLINE OCCIPUT PLATE, LARGE |
| 48551047 | OASYS MIDLINE OCCIPUT PLATE, LARGE LONG |
| 48551048 | OASYS MIDLINE OCCIPUT PLATE, MINI |




*Oasys Midline Plate / Source: tga.gov and RRY Publications LLC*

between the occipital bone and the vertebrae in the cervical spine.

Class I Recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Questions should be directed to Michelle Barry, Stryker Regulatory Compliance Manager at 201-760-8287 or by email at michelle.barry@stryker.com.

Click here for the FDA posting: http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm366713.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

*—WE (August 29, 2013)*

## J&J's New Chinese Chairman Wu

Meet Chairman Wu.

On August 27, 2013, Johnson & Johnson announced that Jesse Wu, the company's worldwide chairman of consumer business, will fill the newly created role of chairman of J&J China.

Wu will report to J&J's Chairman and CEO Alex Gorsky. The business heads of J&J's three Chinese operations will report to Wu.

**Pendergrass Heads Global Consumer Business**

The company also announced that Lynn Pendergrass, a Hewlett-Packard senior VP overseeing the printing and personal systems businesses for the Americas, will join J&J, taking over Wu's job as head of the global consumer business.

The reorganization comes in the midst of a major Chinese reform effort to clean up business practices and enforce new anti-trust and corruption laws. The company was recently ordered by a Chinese court to pay $85,000 to a distributor who had sued the company for setting a minimum price the distributor could charge for surgical sutures. The company was found guilty of "vertical monopoly."

**Wu Highlights**

Wu graduated with a major in Economics from National Chengchi University, Taiwan and received his MBA from Duke University.

He started with J&J in 1989. His career highlights, in addition to his current worldwide chairman role, include: company group chairman, global markets organization; international vice president, Asia-Pacific; president, Greater China; and, finance director of both China and Taiwan.

He is the recipient of the Magnolia Award from the Shanghai municipal government, given in recognition of his contributions to Shanghai's development. He also sits on the board of directors of the Consumer Goods Forum, a global industry network of more than 650 retailers and manufacturers.

**"Don't Touch the Juice"**

In a 2012 McKinsey & Company interview, Wu talked about the company's products in emerging markets. Wu said it was important to always keep in mind in emerging markets that consumers are looking for good value, but they don't want cheap. "As we've expanded our lines to reach more consumers in the middle of the pyramid, we've been careful to keep product quality as high as in our higher-end brands. I always tell our new-product development teams 'Don't touch the juice.'"

Maybe we've heard the first quotation from Chairman Wu. We look forward to others.

*—WE (August 28, 2013)*

*Jesse Wu/Courtesy of Johnson & johnson*

LEGAL

# Biomet Owes Former NASS President $2.7 Million

*Dr. Neil Kahanovitz, M.D./Center for Orthopaedics*

Biomet Inc. has to pay Neil Kahanovitz, M.D., a former president of the North American Spine Society $2.7 million in past-due royalties.

Kahanovitz sued Electro-Biology Inc. and EBI LLC, two Biomet subsidiaries in 2011, after the companies stopped paying him $250,000 in royalties from an agreement signed in 1992. He eventually stopped providing consulting services to the company. The contract had an expiration date of November 2008 and the company then stopped paying the surgeon. However, the contract also said payments would continue "during the term of this agreement and for so long as Kahanovitz is performing services within the agreement field.

Kahanovitz won the suit in 2011, but the company appealed. A New Jersey appeals court confirmed the lower court ruling.

**Pastena Testimony**

According to published reports, when the lower court decided Kahanovitz was still owed royalties, it took into consideration testimony from current and former executives from Electro-Biology and EBI who signed the original deal. Former EBI CEO James Pastena reportedly testified that the agreement was meant to reward Kahanovitz as long as he continued to practice orthopedic surgery, whether he was consulting for the companies or not.

*Mass Device* reported on August 27, 2013, that Pastena testified that the underlying purpose of the agreement "encompassed a number of factors: '1) To take a leading light, a world renown figure . . . and lock him into the corporation . . . so nobody else could take advantage of his input' and 2) 'because of the exclusivity' of the agreement, to 'use him as an advisor' more generally. According to Pastena, 'this royalty was to continue for as long as he was in the practice of medicine' and EBI 'would have stated exactly if [it had] wanted it to end,'" according to the documents."

Pastena also testified that Kahanovitz's consulting agreement would be reviewed and modified at the end date if necessary. Pastena explained that as long as Kahanovitz "was working as a spine surgeon with his image, with his contacts, with his advice that's how long this would last."

**Neil Kahanovitz, M.D.**

Kahanovitz is the director of spine surgery at the Center for Orthopaedics in West Orange, New Jersey.

His professional distinctions include:

- Director of Spine Surgery, Washington Hospital Center 1989-2002
- President, North American Spine Society 2000
- Volvo Award for Low Back Pain Research 1998
- International Society for the Study of the Lumbar Spine research award 1998
- Chief of Back Surgery, Hospital for Joint Diseases, New York City 1982-1989
- Fellowship, Hospital for Special Surgery: Specialty - Spine Surgery 7/1/80-6/30/81

He has published over 50 scientific articles, 12 book chapters and the book *Diagnosis and Treatment of Low Back Pain*. He served as deputy editor of *The Spine Journal* from 2001 to 2004 and currently serves on the editorial boards of *Spine, Orthopedics Today* and *Mosby Spine Surgery*. At present, he is writing a book for the general public on the care and treatment of the lower back.

*—WE (September 4, 2013)*

LARGE JOINTS

# $40,000 in Economic Benefits From Knee Replacement Surgery

Despite its cost of more than $20,000, knee replacement surgery more than pays for itself for most patients.

That is the conclusion of a study conducted by John R. Tongue, M.D., a researcher for the American Academy of Orthopaedic Surgeons (AAOS). Amir Khan, staff writer for *Everyday Health* wrote that the study estimated the economic benefits of the surgery to be up to $40,000. Patients who undergo knee replacement surgery miss fewer work days, experience a better quality of life and, in many cases, are able to pursue their careers until later in life. Most of the pay-off, Khan wrote, came from increased productivity.

"We know that when a knee replacement is done on patients at the appropriate time, it adds tremendous value to their lives," Tongue said in a statement, quoted by Khan. "It gets them back to work and back to their families. It improves their quality of life and allows them to be productive and active again. But until now, that value has been hard to quantify. This study allows patients to see the big picture of the effect on their daily lives and in the long term."

Barry Waldman, M.D., a clinical instructor of orthopedic surgery at the Johns Hopkins School of Medicine in Baltimore, said those patients whose osteoarthritis seriously limits their mobility should no longer look on knee replacement as an elective procedure. He said while that they used to tell patients to put off surgery until they couldn't walk, that is no longer the case. "Now we advise patients to think about surgery when there's something major they can't do any more, like go to work," he said.

*Wikimedia Commons and David Stanley*

Ambivalence about the surgery remains. Kahn quoted William Macaulay, Jr., M.D., Director, Center for Hip & Knee Replacement in New York City, who said that patients need to be aware that knee replacement surgery is not a panacea. "One must realize that total knee replacement, as good as it is, does not restore completely normal knee function," he said. "It can make a very arthritic and painful knee much better, but not 100 percent." Preventing osteoarthritis and the need for knee surgery in the first place could save even more money. Kahn quoted Daryl Osbahr, M.D., an orthopedic surgeon at MedStar Union Memorial Hospital in Baltimore, as saying. "And that begins by losing weight."

The number of candidates for knee replacement surgery is expected to rise from 600,000 to more than 3 million per year by 2030, according to the study. If those patients actually receive the treatment, Kahn wrote, millions of dollars could be saved in lost productivity.

The study findings may help provide a better way for assessing the value of what has become an increasingly common surgery. Khan noted that, with the baby boomer generation reaching the age where this surgery can become necessary, better understanding the risks and benefits can help doctors and patients with balky knees make the best decision possible.

*—BY (August 29, 2013)*

## Running Not to Blame for Arthritis

Can a study of 70,000 runners be wrong? Paul Williams, exercise scientist at Lawrence Berkeley National Laboratory in California, has studied that many runners over 22 years and says that running long distances does not cause repetitive-stress injuries such as arthritis and joint damage.

"There's a perception out there that somehow you're wearing out your joints if you're out there running," Williams told Christie Aschwanden, writing for the ***Washington Post***. "I've recruited people who were doing 60 or 70 miles per week, and we've followed them over time. If there had been an effect, we would have seen it." Williams believes that running can inhibit joint damage. As leader of the National Runners' Health Study, he has studied thousands of runners since 1991 and says that he has yet to see any convincing evidence that links running to osteoarthritis.

Major risk factors for osteoarthritis are obesity and family history, according to experts. Patience White, vice president of the Arthritis Foundation, says that people with a family history of osteoarthritis are at a greater risk for joint damage than are distance runners without such a genetic predisposition.

"If you have osteoarthritis in your family, you're more likely to get it no matter what you do," said White. Similarly, carrying excess weight is far more stressful for joints than running. "If you lose five pounds, that's like 20 pounds across your knees," said White.

*—BY (August 26, 2013)*

*Wikimedia Commons and Ernst Vikne*

**TRAUMA**

## Broccoli to the Rescue for OA?

Greens to the rescue…A laboratory study from the U.K. has found that sulforaphane, a compound found in broccoli, could be key to preventing or slowing osteoarthritis (OA). The research is being led by a team at the University of East Anglia (UEA) and is the first major study looking into the effects of sulforaphane on joint health.

*Wikimedia Commons and cyclonebill*

Results from the laboratory show that sulforaphane slows down the destruction of cartilage in joints associated osteoarthritis. The researchers found that mice fed a diet rich in the compound had significantly less cartilage damage and osteoarthritis than those that were not.

Sulforaphane is released when eating cruciferous vegetables such as Brussels sprouts and cabbage, but particularly broccoli. The researchers discovered that sulforaphane blocks the enzymes that cause joint destruction by stopping a key molecule known to cause inflammation. They wanted to find out if the

compound got into joints in sufficient amounts to be effective and their findings are published today in the journal *Arthritis & Rheumatism*.

Researchers from the School of Biological Sciences and Norwich Medical School are now embarking on a small scale trial in osteoarthritis patients due to have knee replacement surgery, to see if eating broccoli has similar effects on the human joint. If successful, they hope it will lead to funding for a large-scale clinical trial to show the effect of broccoli on osteoarthritis, joint function and pain itself.

Ian Clark, professor of musculoskeletal biology at UEA and the lead researcher, said in the August 27, 2013 news release: "The results from this study are very promising. We have shown that this works in the three laboratory models we have tried, in cartilage cells, tissue and mice. We now want to show this works in humans. It would be very powerful if we could."

For the small-scale trial, funded by DRINC, half the 40 patients will be given 'super broccoli' - bred to be high in sulforaphane - to eat for two weeks before their operation. Once the surgery has taken place the researchers will look at whether the compound has altered joint metabolism and if it can be detected in the replaced joints.

Dr. Clark told *OTW*, "At the moment, the most important message is that we are following up on the laboratory evidence to examine the question: is consumption of broccoli good for joint health in man? We will continue to publicize our research so that everyone is informed of the outcomes."

*—EH (September 3, 2013)*

**REIMBURSEMENT**

## Joint Replacement Readmission Penalty $265,000

Medicare pays for hospital stays. Medicare also counts how many patients are readmitted within 30 days after the end of their initial hospital stay. If readmissions are above the national average, adjusted for patient mix, Medicare will charge the hospital a penalty.

According to PR Newswire, Medicare will begin charging hospitals $265,000 for each excess readmission (patients who come back within 30 days) after knee or hip replacement surgery that is above the U.S. average. The article states that half of all hospitals have above-average numbers of Medicare patients who return within 30 days after their joint replacement surgery.

Hospitals already pay $35,000 to $55,000 penalties for any readmission above the U.S. average for heart attacks, heart failure and pneumonia. The PR writer suggests that hospitals can reduce the possibility of readmissions by better care and also by refusing to treat patients who are seniors. In a letter to Medicare in June 2013, the American College of Surgeons warned about "the potential that these hospitals will decrease their care for such patients, thereby creating an access issue."

The watchdog site Globe1234.com states that hospitals will start paying in October 2014, based on knee and hip replacements installed since July, 2010. The amounts of the penalties are expected to be officially published in the Federal Register later in August.

Penalties are the initial payment times "1/ national readmission rate" The national readmission rate for knee and hip replacements is 5.7%; one over it is 18. This factor times the average initial Medicare payment of $15,000, is $265,000.

*—BY (August 26, 2013)*


*Source: Wikimedia Commons and Jeramey Jannene/ Source: Wikimedia Commons and Jon Eban Field*

PEOPLE

## Kevin Klingele, M.D. Is New Ortho Chief at Nationwide Children's

Kevin Klingele, M.D. has just been appointed chief of Orthopedics at Nationwide Children's Hospital.

In his previous role, Dr. Klingele was the interim chief of Orthopedics. He will continue to serve as the surgical director of Sports Medicine at Nationwide Children's. Dr. Klingele is director of Orthopedic Education and Clinical Research at the hospital, and is a clinical assistant professor of Orthopedics at The Ohio State University College of Medicine.

"We are grateful for Dr. Klingele's leadership during the interim and, with this new appointment, look forward to what his expertise will bring to our orthopedic patient families and to our staff," said Lawrence Moss, M.D., surgeon-in-chief at Nationwide Children's Hospital in the August 26, 2013 news release.


*Kevin Klingele, M.D./Nationwide Children's Hospital*

Dr. Klingele received his medical degree from The Ohio State University College of Medicine. He completed his residency at Indiana University and followed with a fellowship at Boston Children's Hospital. His clinical interests include adolescent and children's sports medicine, pediatric trauma, hip and pelvis reconstruction and lower extremity reconstruction. Dr. Klingele is a member of the American Academy of Orthopaedic Surgeons, The Columbus Orthopaedic Society, The Ohio Orthopaedic Society, The Pediatric Orthopaedic Society of North America and Gillespie Pediatric Orthopaedic Study Group.

Dr. Klingele told *OTW*, "My main early focus in this role is to expand upon the recent momentum of departmental growth which includes the addition of three new partners within the past six months. Subspecialty interests and focused program growth within pediatric spine surgery, pediatric hand surgery, sports medicine, and limb deformity will enhance the department's past success in providing state of the art care to the pediatric orthopedic patient. Building a foundation for clinical and basic science research is also a top priority. I hope to bring the department of pediatric orthopedics at Nationwide Children's Hospital to the forefront of our field, both clinically and academically."

*—EH (August 30, 2013)*

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## Sidow Joins Pivot Medical Board

Pivot Medical, Inc, a device company focusing on hip arthroscopy, has named Kevin Sidow to the company's Board of Directors. Sidow, who is president and CEO of Moximed, Inc, has worked for more than 20 years in the orthopedic medical device market.

Prior to running Moximed, he was president and CEO of St. Francis Medical Technologies, Inc. a firm that developed treatments for degenerative spinal disorders. Kyphon purchased St. Francis Medical for $725 million in January 2007. Before joining St. Francis Medical, Sidow was the Worldwide President of DePuy, Inc. where he oversaw the global orthopedic, spine, trauma and sports medicine business.

"We are delighted to attract someone with Kevin's experience and expertise in orthopedics to join the board of Pivot Medical. His insights will contribute substantially to Pivot's commercial growth," said John J. Savarese, M.D., Chairman of Pivot. Other members serving on the Pivot Medical board are, Jack Giroux, Julian Nikolchev, John J. Savarese, Michael Lynn, John F. Maroney, and Guy L. Mayer.

*—BY (August 29, 2013)*


*Kevin Sidow and Moximed, Inc.*

## Dwayne Montgomery Joins IlluminOss Medical

IlluminOss Medical, Inc., a privately held medical device company in East Providence, Rhode Island, has named Dwayne Montgomery its Senior Vice President of Sales and Marketing. Montgomery, who has 20 years of experience in orthopedic, spine and cardiac markets, was most recently Vice-President of Commercial Operations at TranS1, Inc. (now Baxano Surgical, Inc.) where he was responsible for North American sales and operations.

Formerly, Montgomery was the Global Vice President and General Manager for Smith & Nephew, Inc's Orthopedic Trauma Division where he was responsible for global strategic directions, including a $400M sales business. He holds a BS Degree in Chemistry from the University of North Alabama, an MBA from the Jack C. Massey School of Business at Belmont University and strategic marketing certificates from University of Michigan and University of Texas Schools of Business.

*Dwayne Montgomery*

"Dwayne has an exceptional track record in orchestrating winning sales strategies for companies in some of the most competitive healthcare markets and has vast commercial experience centered on quickly developing strong surgeon relationships," said Dirk Kuyper, president and CEO of IlluminOss. "He is well respected by his colleagues for possessing exceptional business acumen. Dwayne is exactly the addition our team needs to reach our sales goals as we move into the commercial ramp phase of the company."

IlluminOss maintains CE Mark for clinical applications in light to low load bearing bones and is extending the platform technology to other extremities and applications. The company has direct distribution in Germany and is expanding in Europe with the recent addition of exclusive distribution in several key markets. The IlluminOss products are Investigational Devices; limited by U.S. Federal law to Investigational Use and are not approved for sale in the USA.

Company officials say that the global bone fracture repair market amounted to $5.5 billion in sales in 2010 and is growing at the rate of approximately 6% per annum, driven by population growth and aging populations around the globe.

*—BY (August 29, 2013)*

## Kevin Black, M.D. Elected Second President-Elect of AOA

The American Orthopaedic Association (AOA) has announced that Kevin P. Black, M.D. has been elected to the position of Second President-Elect. Dr. Black will become First President-Elect at the 2014 Combined Meeting of The American Orthopaedic Association and the Canadian Orthopaedic Association in Montreal, Canada, June 17-21, 2014, and will assume the role of AOA President in June 2015.

*Kevin P. Black, M.D./ American Orthopaedic Association*

Dr. Black is the C. McCollister Evarts Professor and Chair of the Department of Orthopaedics and Rehabilitation at Penn State Milton S. Hershey Medical Center. He came to Hershey in 1993 and in September 2001, became Chairman of the Department of Orthopaedics and Rehabilitation—a position he still currently holds. On July 1, 2013,

he was also appointed to the role of Vice Dean for the Penn State University College of Medicine University Park Regional Medical Campus in State College, Pennsylvania.

Dr. Black has a special interest in orthopedic resident education and has been active with the AOA's Academic Leadership Committee and Council of Orthopaedic Residency Directors (CORD) program. He served as Co-Director of the AOA's Effective Orthopaedic Educator Course, and chaired the 2010 Resident Leadership Forum, which provides PGY4 (post graduate year 4) residents with an introduction to orthopedic leadership concepts. His expertise as an orthopedic educator was acknowledged by Penn State Hershey Medical Center, where he was presented with the Distinguished Educator Award in 2011.

Hershey also recognized Dr. Black with the 2008 Steven Baron Leadership Award for his exceptional professional achievement and exemplification of cooperation and teamwork. Dr. Black is the recipient of two Traveling Fellowships: a European Traveling Fellowship from the American Orthopaedic Society for Sports Medicine (AOSSM) in 2000, and a Traveling Fellowship from the Clinical Orthopaedic Society in 1992. He carries his interest in Traveling Fellowships into his volunteer work with the AOA, having served on a number of the AOA's Traveling Fellowship Committees.

Dr. Black will also serve as 2013 President of the Pennsylvania Orthopaedic Society. He is also a member and has served on the Board of Directors of the American Academy of Orthopaedic Surgeons (AAOS), and the AOSSM.

His clinical interests and associated research interests include knee ligament injuries, osteochondritis dissecans, patella instability, and meniscal injuries. His research interests are in the areas of orthopedic resident education, medical student education, knee ligament instability, and articular cartilage injury.

Following his residency training at the University of Rochester, School of Medicine & Dentistry, Dr. Black held a Fellowship in Sports Medicine at the Cleveland Clinic Foundation. He began his career at the Medical College of Wisconsin in 1987, where he developed the Sports Medicine Program.

Dr. Black told *OTW,* "My initial efforts will focus on continuing to support the mission of the AOA and the needs of our members, helping them develop the requisite skills to provide the necessary leadership to our profession amidst the myriad of changes we are confronted within health care and education."

*—EH (August 23, 2013)*




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