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Orthopedics This Week

week in review

picture of success

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: The sorry spectacle of U.S. politics, at best, encourages the rest of the world to learn from Washington's mistakes. Orthopedics, a global industry that is largely U.S. based, embodies the best of this country. No surprise that it's roots are in rural America, far from Washington. So it's back to basics. Hips, knees,trauma, spine and extremities.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	14.72%	(7.94)%	New boss, Vaters, is one blunt guy. Want to know about OFIX? Watch the cash flow statement. Another reason OFIX still #1.
2	4	Kensey Nash	34.24	4.88	Speaking of cash—KNSY has more cash than quarterly sales. Also 30+% operating profit margin.
3	6	Wright Medical	8.76	(1.73)	Flat sales, but higher profit margins AND that ArthroCare deal. Good report considering the recent disruptions.
4	7	Johnson & Johnson	26.33	(7.17)	We just keep repeating—DePuy + Synthes, DePuy + Synthes. Like a mantra.
5	5	Zimmer	27.75	(10.83)	Anybody watching what ZMH is doing with its 28% operating margins? Buying back stock. That should tell you something.
6	8	Symmetry	7.64	(8.27)	Beats EPS estimate. Cash up 67%. Sales up 7%. Higher profit margins. UP 2 spots.
7	3	ConMed	9.65	(17.32)	Ugly sales number, but operating profit margins up. Cash going to debt pay down.
8	2	Smith & Nephew	22.80	(16.02)	Wasn't SNN supposed to raise profit margins? Gained market share last quarter, but investors looking for more.
9	10	Exactech	8.08	(10.08)	The cost of compliance hit EXAC hard this quarter, but those sales growth numbers were solid.
10	9	Stryker	25.23	(16.39)	SYK is taking the brunt of the market's anxiety over Medicare's ortho. To rebound, sales growth rate next six months may need to be double-digit.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	RTI Biologics Inc	RTIX	$3.43	$189	19.10%
2	Kensey Nash	KNSY	$26.43	$225	4.88%
3	Synthes	SYST.VX	$173.45	$20,602	-1.69%
4	Wright Medical	WMGI	$15.30	$603	-1.73%
5	TranS1	TSON	$4.47	$93	-3.04%
6	Johnson & Johnson	JNJ	$62.71	171,897	-7.17%
7	Orthofix	OFIX	$39.66	$730	-7.94%
8	Symmetry Medical	SMA	$8.54	$311	-8.27%
9	Tornier N.V.	TRNX	$24.48	$956	-8.96%
10	ArthroCare	ARTC	$30.61	$840	-9.97%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Alphatec Holdings	ATEC	$2.60	$232	-30.48%
2	Bacterin Intl Holdings	BONE	$1.93	$73	-29.56%
3	MAKO Surgical	MAKO	$24.03	$984	-27.75%
4	TiGenix	TIG.BR	$0.94	$86	-26.29%
5	NuVasive	NUVA	$24.90	$993	-25.96%
6	ConMed	CNMD	$24.16	$684	-17.32%
7	Stryker	SYK	$50.04	$19,432	-16.39%
8	Smith & Nephew	SNN	$46.30	$8,265	-16.02%
9	Medtronic	MDT	$33.31	$35,341	-12.53%
10	Integra LifeSciences	IART	$41.90	$1,153	-11.47%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$33.31	$35,341	10.16
2	Zimmer Holdings	ZMH	$57.56	$11,049	12.41
3	Johnson & Johnson	JNJ	$62.71	$171,897	12.82
4	Stryker	SYK	$50.04	$19,432	14.22
5	Kensey Nash	KNSY	$26.43	$225	15.02

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$24.90	$993	31.13
2	Synthes	SYST.VX	$173.45	$20,602	22.67
3	Exactech	EXAC	$16.94	$222	22.29
4	Wright Medical	WMGI	$15.30	$603	21.86
5	ArthroCare	ARTC	$30.61	$840	21.41

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Integra LifeSciences	IART	$41.90	$1,153	0.72
2	Orthofix	OFIX	$39.66	$730	0.86
3	RTI Biologics Inc	RTIX	$3.43	$189	0.95
4	Exactech	EXAC	$16.94	$222	1.06
5	Kensey Nash	KNSY	$26.43	$225	1.12

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Alphatec Holdings	ATEC	$2.60	$232	7.06
2	Johnson & Johnson	JNJ	$62.71	171,897	2.23
3	CryoLife	CRY	$5.26	$148	2.03
4	Wright Medical	WMGI	$15.30	$603	1.57
5	ArthroCare	ARTC	$30.61	$840	1.54

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$8.54	$311	0.86
2	ConMed	CNMD	$24.16	$684	0.96
3	RTI Biologics Inc	RTIX	$3.43	$189	1.14
4	Wright Medical	WMGI	$15.30	$603	1.16
5	Exactech	EXAC	$16.94	$222	1.16

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$0.94	$86	137.96
2	MAKO Surgical	MAKO	$24.03	$984	22.22
3	Synthes	SYST.VX	$173.45	$20,602	5.59
4	Tornier N.V.	TRNX	$24.48	$956	4.20
5	Bacterin Intl Holdings	BONE	$1.93	$73	3.93

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

The Debt Ceiling: "There Will Be Blood"

By Walter Eisner

"There will be blood in November."

That's what Bob Laszewski, a widely read insurance industry consultant had to say on his *Health Care Policy and Marketplace Review* blog after House Republicans, Senate Democrats and President Obama reached a deal on July 31 to raise the nation's debt ceiling by $2.8 trillion dollars. Congress passed the compromise and the President signed the legislation on Tuesday, August 2.

Wikimedia Commons

Device Makers' $13.5 Billion Carnage

Orthopedic device makers didn't have to wait until November for the bleeding to start. Their stocks took an immediate tumble as it became apparent that some of the $1.2 trillion in spending cuts will come at the expense of providers and future company profits

By the time some orthopedic company stock prices bottomed out later in the week, the stockholders of the following publicly traded companies saw the per-share prices of their stockholdings fall by: Stryker - $4; Zimmer - $3; J&J - $2.75; Smith & Nephew - $5.50; and Medtronic - $2.75. The market value of those five companies combined fell by over $13.5 billion in three days.

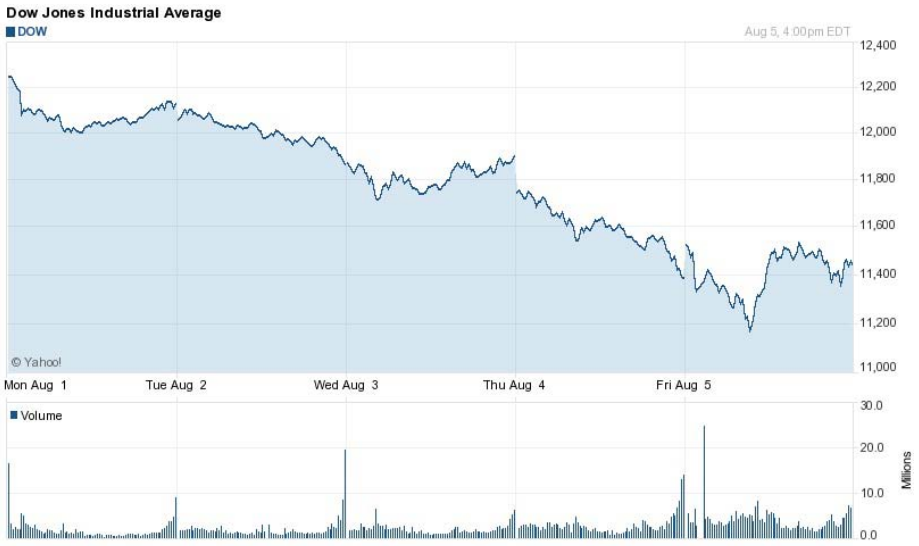
On August 3, Bank of America analyst Bob Hopkins wrote that Medtech is out of favor after having entered the second quarter earnings season with a 15% premium to the S&P 500 index valuation. The sector exited earnings season at just a 3% premium. He said that debt ceiling driven fears, among others things, and the likely resulting cuts to Medicare pointed to potential downstream pressure on pricing and margins which, in his view, accelerated the stock price declines.

By Thursday, August 4, the Dow had dropped around 750 points.

Provider Exposure

Hospitals, already on the hook for over $150 billion in Medicare and Medicaid savings over 10 years under the Accountable Care Act, warned against further cuts.

The American Hospital Association president said further funding reductions for hospital services translate into decreased access for our nation's seniors and said the Medicare program should be exempt from automatic cuts.



Yahoo Finance

The Cuts

However, it isn't just hospitals and the health care industry that are likely to get bloodied. Physicians, who are staring at a 29.5% Medicare payment cut on January 1, 2012, are also at risk. More on that later.

The debt deal calls for overall spending cuts of $917 billion and the creation of a congressional "super-committee" to find another $1.5 trillion in savings by November 23, 2011. If the committee can't agree on at least $1.2 trillion in savings, cuts would start automatically in 2013. The cuts are divided equally (50/50) between domestic and defense spending. Domestic spending cuts would include a 2% cut to Medicare and is required to be extracted from Medicare providers, not beneficiaries.

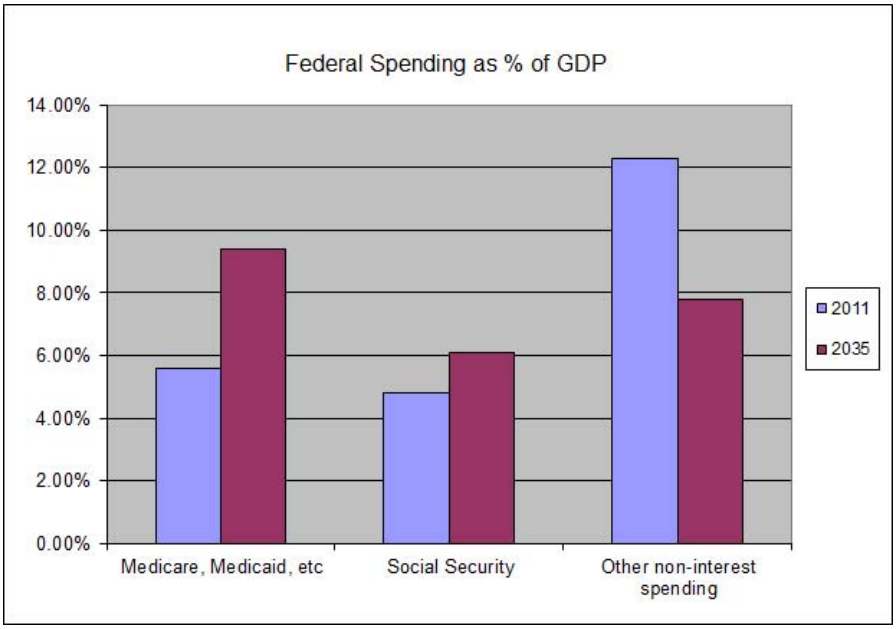
"There's a lot of uncertainty about the [super-committee] and the Medicare cuts, which is why everything is cratering," Ipsita Smolinski, an analyst at Capitol Street in Washington, told *Reuters* on August 1. "People didn't think Medicare would be included [in the cuts]. And now they're trying to absorb that...plans and providers could get cut in the second round," Smolinski said.

While there were no health care cuts in the first $917 billion of spending cuts, the second $1.2 trillion tranche is where health care will make its contribution, according to Laszewski. That's where all federal spending, including Medicare, Medicaid, the Affordable Care Act, benefits and provider payments are on the table.

"Since the budget window for the deal is ten years, it is not likely that any changes will be made to entitlement eligibility—such as delaying the Medicare eligibility age from 65 to 67. It just wouldn't be fair to tell a 60-year-old their Medicare eligibility age is being raised. But we could see more means testing of Medicare premiums," said Laszewski.

Health Care's Runaway Tab

To reach $1.2 trillion in cuts, it's hard to see how health care spending can be ignored. Health care spending, including Medicare, Medicaid and the child health program CHIP, will expand to nearly 7% of the gross domestic product (GDP) from 5.6% today—and keep rising sharply to 9.4% of GDP by 2035, according to the Congressional Budget Office (CBO). It is the fasted growing part of the federal budget and is exceeding inflation.



Source: Congressional Budget Office

Laszewski said it is possible that the super-committee could deal with real systemic health care reform—particularly in the way we pay providers. "But I doubt it. The committee isn't going to have a lot of time to take up so complex a matter as systemic health care payment reform given that they will have to deal with hundreds of billions more in cuts from lots of federal programs. I don't see the committee as having the expertise, will, or the time to tackle real health care reform.

"The real potential for cuts will be to provider reimbursement.

"So, all of those provider organizations that thought they scored big by limiting their contribution during the health care reform debate are likely be on the defensive in ways they could not have imagined 18 months ago," wrote Laszewski.

The Doc Fix Conundrum

Laszewski said that physicians, facing the 29.5% sustainable growth rate (SGR) fee schedule cut on January 1, 2012, need to be really worried because the SGR cut is part of the existing budget baseline from which the super-committee needs to cut hundreds of billions more. They would need to find tens of billions of dollars after the cuts to put the physician cuts off again. According to the Congressional Budget Office, the cost of a ten-year Medicare pay freeze and the cost of scrapping the sustainable growth rate formula would be more than $350 billion.

Some analysts argue that the debt reduction efforts and the need to fix the doctor reimbursement formula could collide, especially because of the cost of fixing the physician fee schedule. Pushing the issue off for another year would cost about $25 billion, although physicians have been pressing for a two-year fix at a cost of roughly $50 billion. These fixes would add to the nation's deficit and complicate the super-committee's work.

In the Bull's Eye

Laszewski noted that hospitals that got off with a $150 billion contribution to the Affordable Care Act have to be in the bull's eye this time. "Drug companies are a particularly juicy target for liberals who don't like them and conservatives who wish the Part D program had never been passed. Medicare Advantage insurers have recently been reporting record profits—not something you want to be doing when the Congress is looking for lots of cash."

Kaiser Health News analyst Mary Agnes Carey, addressing the "doc fix" on August 2, said that if Congress can't find money to offset mandated payment cuts, they will be cut.

"So you're going to have lawmakers looking for money in Medicare in a variety of areas. They'll have the pressure of either producing this report and having it passing, or if it's not, the across-the-board cut. And no one wants to see a Medicare physician payment cut. So you can imagine what December is going to be like on Capitol Hill."

Laszewski notes that while there is a 2% cap on any cuts that could occur to Medicare, there are no limits to what the super-committee can cut. "As an order of magnitude, it looks to me like the cuts Medicare will have to eventually sustain from the super-committee will have to approach the cuts the program saw under the new health care law—largely because of the impact the SGR formula has on the baseline the committee will have to use."

The debt ceiling formula is a particular problem for the physicians said Laszewski. "They are the ones who agreed to support the new health care law (the AMA anyway) without getting a fix to the SGR dilemma."

Wikimedia Commons

He asks, given how reluctant Congress has been to cut the docs in past years, just how the heck are they going to accomplish net Medicare cuts and take care of the docs this time?

"[J]ust think of the impact big provider cuts could end up having on health care cost trends as providers attempt to shift the impact of these cuts to the entire health care system—just as health care cost trend has finally been slowing down," added Laszewski.

Winners, Losers and the Battlefield

So are there any winners in this deal?

K Street of course. Lobbyists make money on complexity, and the debt ceiling law is nothing if not complex, with multiple phases, conditional phases, nonspecific spending caps and the prospect of a tax code revamp.

There will be legislative fights involving just about every deep-pocketed interest in Washington: hospitals, doctors, military contractors, big business, small business, seniors, investors, hedge funds, etc. President Obama has vowed to find extra revenue and these groups will not only be fighting to be spared cuts, but spared higher taxes.

The required spending cuts have the potential to pit the health care provider community against their patients as seniors fight to preserve their Social Security payments and Medicare benefits. The Democrats have put providers on the chopping block while Republicans have put seniors on notice they want to change Medicare to a voucher-type system where seniors will have to pay more.

There Will Be Blood

Concluded Laszewski: "If you thought we had a tense few weeks over the debt ceiling, you had better clear your calendar for the weeks leading up to the November 23rd super-committee deadline. The debt deal was only about process, this next big fight is going to be about real and significant cuts and there will be some significant blood on the floor when it is over!" ◆

From Your Lips to the Machine's Ear

By Robin Young

If you can think of it, these guys can make it—right now. Give them your dreams, your X-rays, your MRIs, your sketches on napkins and they will give you back an implant, an instrument or pretty much anything you've imagined. In short, they can plug your mind into a fabrication machine.

Welcome to a revolution called e-manufacturing. One small Connecticut-based company has just made a big bet on this concept. The company, Oxford Performance Materials, LLC (OPM), began a multi-million dollar program earlier this year to, literally, take anything a surgeon or engineer dreams of: X-rays, MRIs or napkin sketches, and produce exactly that part—right now.

Source: EOS, GMPH

Plugging Your Mind Into the Machine

The e-manufacturing process that OPM is building has been revolutionizing the aircraft, auto and other manufacturing industries and is now about to (FDA willing and the CMS don't rise) accelerate innovation and time to market in orthopedics.

E-manufacturing is the system for taking any kind of digital input from any source and then sending it directly to a machine via the Internet (or Intranet). E-manufacturing effectively makes the thoughts of an inventor transparent to the fabricating machine.

For years, the electronics of e-manufacturing have been running far ahead of the fabricating machines. Up until just recently, e-manufacturing machines created prototype products from low temperature, low performance polymers. Then a German company named EOS presenting at the Euromold plastics convention introduced a digital laser sintering machine (like a 3D laser "printer") which can melt high performance polymeric powders and fuse them into solid shapes. We're talking melting points as high as 380°C (716°F) degrees. This was a huge innovation. With the EOS printer, e-manufacturing systems could now move to high performance, medical grade polymers like PEKK.

It took one full year to sell the first machine. That was two years ago.

Even now, there are barely a handful of these machines in use around the world—including, of course, the one operating at 30 south Satellite Road in South Windsor, Connecticut (OPM's corporate headquarters).

OPM's system is in fact the world's first system that can plug into an e-manufacturing system and laser-sinter PEKK

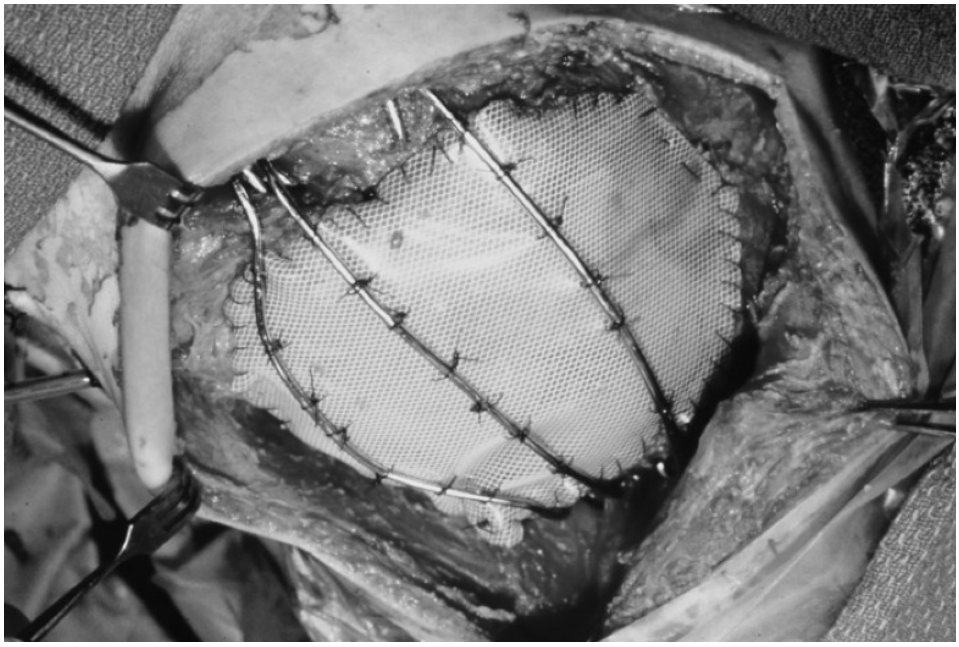
Mastoid form created through the OXPEKK® Osteo-Fab™ *manufacturing process*

polymers. OPM can fabricate virtually any implant or instrument imaginable.

Since the OPM's new EOS machine is also on the Internet, it can be tether-free (i.e., wireless) and can make use of advanced predictive technologies. In the jargon of manufacturing, OPM's system pushes surgeon, engineer or inventor data (typically images) through a distributed, flexible, open, reconfigurable, scalable and extendable communication network which spits out, at the end of it all, a fabricated PEKK polymer implant or instrument.

Need for Speed

Probably e-manufacturing's biggest revolution is its ability to create bionic structures which, up until now, would have been inconceivable using conventional manufacturing methods(try making that mastoid form in the attached image without e-manufacturing capabilities).



AAOS

Here's what implant creation was like many years ago.

(The following account comes from AAOS's inspiring history of orthopedics book "Moving Stories: 75 Years of Orthopaedics" available at http://www.aaos75th.org/stories/.)

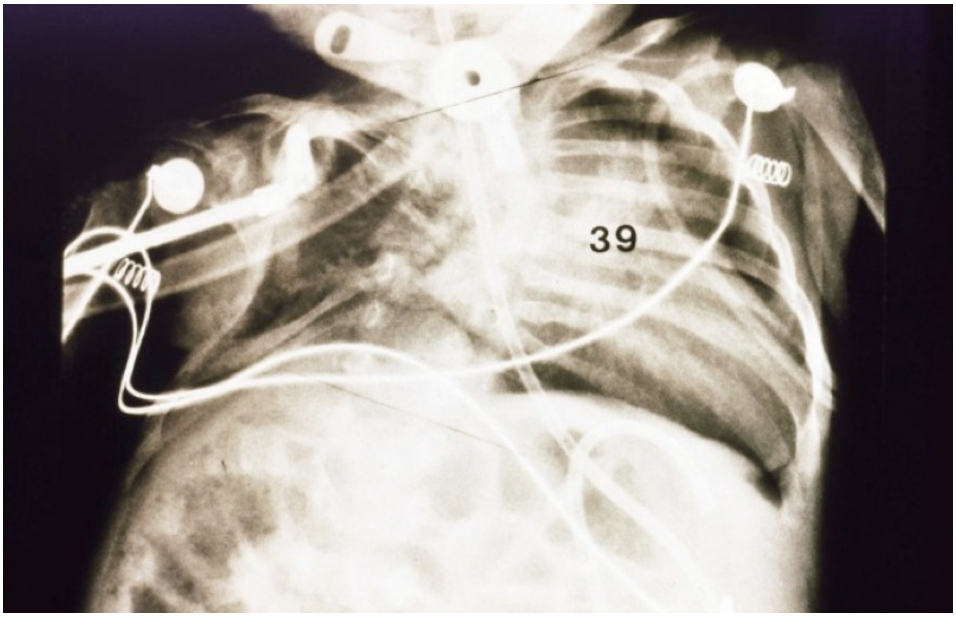
In late September 1987 a six-month-old boy arrived at Christus Santa Rosa Children's Hospital with seemingly irreversible defects—the most severe of which was a missing left chest wall. Seven of the twelve ribs were gone, so there was no support for the lung. The child also had severe scoliosis. Doctors in Houston had tried to treat the chest wall defect with a splint, but had been unsuccessful. The child was out of options and had been sent home to die.

Robert Campbell, M.D. was the orthopedic surgeon and Melvin Smith, M.D. was the pediatric general surgeon in charge of this young boy's case.

"I didn't know it at the time, but I was about the third orthopod Dr. Smith had asked and the other two had said sorry, but there's nothing to be done," Dr. Campbell recalls with a slight smile. While that may be true, Dr. Smith remembers he was just trying to find help from "somebody who had as wild ideas as I did."

Dr. Smith suggested using some plates or rods that could be screwed into place, but any screws used around the chest would work loose and perhaps go into the heart. Dr. Campbell went home that night and after a bit of doodling, settled on using fracture pins—metal pins used to stabilize and realign broken bones.

But it was one thing to make some doodles but quite another to make those doodles real—inside a sick infant's chest.



AAOS

The two surgeons went to work. As Dr. Campbell recalled; "I stuck the first Steinmann pin up there, got sterile vice grips, and started bending them around the ribs of this six-month-old infant. It was just terrible because I had to use tremendous force. One slip and I would have torn the axillary artery or damaged the spinal cord…my shoes were filling up with sweat."

Despite everything, the surgery was successful. They had saved his life. But very soon new problems emerged. The pins wouldn't grow as the boy matured and therefore the makeshift device would end up harming the patient.

Dr. Campbell decided he needed to invent a device to replace the Steinmann pins.

He approached a large orthopedic implant manufacturer and after two months of negotiating the confidentiality agreement he moved on. The second company he approached took a month before telling him that they couldn't do it but referred him to a custom prosthesis firm in California called Techmedica.

Dr. Campbell sketched his designs out for Techmedica on children's construction paper. He then transferred those sketches to an actual blueprint. His invention was an expandable rib—kind of like a curtain rod for the chest.

Nearly a year after the original surgery, with the original patient starting to outgrow the Steinmann pins and with the scoliosis returning, Dr. Campbell sat down with Techmedica's engineers and got to work. It would take another half year of trading blueprints back and forth for the company to create the first prototype.

Time was running out for his patient. On April 18, 1989 the first fabricated expandable child's ribs arrived at Dr. Campbell's office and the very next day he implanted his Vertical Expandable Prosthetic Titanium Rib (VEPTR)—which performed as hoped for, for his young patient.

The process with everyone working as fast as they could, took from September 1987 to April 1989—18 months.

Fast forward to mid-2011. Today, with e-manufacturing systems in place, Dr. Campbell's options change dramatically. With the Internet, Dr. Campbell would email his patient's X-ray or MRI as well as digital images of his sketches to, for example, OPM. Before the week was out, a PEKK 3D fabricating machine would have "printed out" the first of several prototypes of the VEPTR and then ***the implant itself.***

Just like that.

Information Transparency

When the information residing in the head of a surgeon or inventor becomes transparent to the fabricator, a new roadmap opens up for innovation and patient care.

It cost OPM more than $1.2 million to install the centerpiece of this e-manufacturing system—the EOSINT P 800 SLS machine for fabricating medical implants and instruments. OPM secured its funding from Connecticut Innovation's BioScience Facilities Fund in the form of a special debt instrument. The machine is but one part of a multimillion dollar project to make next generation orthopedic implants through additive fabrication using OPM's proprietary OXPEKK materials.

OPM, which was founded in March 2000, operates out of an 18,000 square foot facility in South Windsor, Connecticut. OPM currently sells its biomedical polymeric OXPEKK products throughout the world and their customers have received regulatory approvals from the FDA, KFDA, ANVISA, COFEPRIS, and several CE Marks: OPM is ready for business anywhere.

OPM has traditionally sold its OXPEKK products as raw materials. But with the addition of the EOSINT P 800, the company will now be able to provide value-added manufacturing in-house. As we've been describing, the new remarkable fabricating machine opens up the possibility of direct digital additive manufacturing through selective laser sintering (SLS), which means that nearly anything that can be designed can be built with the firm's implantable polymer.

We were so taken with this new technology and what it means for orthopedics, that we called OPM's president, Scott DeFelice, and interviewed him via Skype. Sorry about the quality of this interview, BUT please listen carefully. This enhanced capability positions the firm to lead innovation in biomedical technologies and the polymer market. OPM's initial focus is on the production of custom cranial and maxillofacial implants which are anatomically identical implants derived directly from a CT scan or MRI.

Seriously, this is remarkable and we hope that OPM's phones start ringing off the wall from surgeons and engineers who want to get on the e-manufacturing wave. ◆

Patient Safety on the Wane?

By Elizabeth Hofheinz, M.P.H., M.Ed.

When Dr. James Herndon, a former president of the American Academy of Orthopaedic Surgeons (AAOS) and Chairman Emeritus of orthopedics at Harvard, had surgery recently, he wasn't taking any chances. A resident came in and did the "sign your site" drill, at which point Dr. Herndon said, "Go get the surgeon…I want his signature too."

Why the extreme caution? Because Dr. Herndon has the facts. And the overarching, disturbing fact is that patient safety among orthopedic surgery residencies has declined. Dr. Herndon, whose article on this topic was recently published in the *Journal of Bone and Joint Surgery*, explains, "We surveyed 169 residents and found that despite having been exposed to formal educational events on safety in the last ten years, the patient safety climate has decreased. Unfortunately, the culture of many hospitals is such that they don't want to recognize mistakes. Couple that with the fact that most doctors don't believe that near misses and mistakes are as common as they are, and the fact that people don't often recall their mistakes, and you have a good picture of the challenge we're up against."

Source: MorgueFile and Clarita

To assess the status of safety, Dr. Herndon and his colleagues looked to the skies. An OR is a high pressure environment…so is an airplane cockpit. If the plane goes down, it's all over. At the risk of stating the obvious, pilots are highly motivated to take every appropriate safety measure. "We used the Patient Safety Climate in Healthcare Organizations (PSCHO) questionnaire, a tool that was adapted from a survey that is used with aircraft fighter pilots. The PSCHO was developed by the Patient Safety Culture Institute at Stanford University and the Palo Alto Veterans Affairs. For this study, conducted over six years, we used a version modified by George Bilke, M.D. of the Dartmouth-Hitchcock Medical Center."

And their eye-opening finding? "Whereas 6% of aviators assessed safety as being a problem," says Dr. Herndon, "between 13 and 15% of orthopedic

"Whereas 6% of aviators assessed safety as being a problem," says Dr. Herndon, "between 13 and 15% of orthopedic residents answered questions implying that safety was a problem. So our problems with safety could actually be twice as high as those of military pilots."

"Perhaps most alarming was our finding that en masse respondents were unwilling to report unsafe situations because they were afraid of retribution."

residents answered questions implying that safety was a problem. So our problems with safety could actually be twice as high as those of military pilots."

Delving into the survey itself, Dr. Herndon states, "We examined several safety related topics, communication up and down the chain of command, management's ability to respond to safety issues, safety reporting, and concerns of safety at the point of care. Perhaps most alarming was our finding that en masse respondents were unwilling to report unsafe situations because they were afraid of retribution. And this is an issue that exists across the medical world—not only orthopedics. But we still have to find ways to deal with this. One possibility is to place boxes around the hospital where people can report situations anonymously."

An example of a communication error is as follows: a doctor who is leaving his/her shift says to a colleague: "Surgery went well. I just gave Mrs. Jones the pain medication. I've got to go now." The physician or nurse receiving the information may have important questions, but, sensing that the departing doctor isn't open to inquiry, thinks, "Well, I guess everything is in the chart." Dr. Herndon: "One thing we assessed was the degree to which good communication flow exists down and up the chain of command regarding patient safety issues. The major issue here is the frequency in the change of providers. There are more personnel involved in one person's care than ever before. Some patients have five or ten doctors involved, not counting nurses and other personnel. That is a lot of room for communication errors."

"The point at which residents sign in and out of shifts is critical because that space of time is ripe for mistakes. Fatigued residents are being interrupted by the staff and they are getting paged to answer questions, etc. This could lead to someone forgetting to chart an issue, or be less comprehensive than they normally would be. If the doctor leaving the shift appears hurried, he may signal to those still on duty that he is not especially open to questions. And one alarming study—one conducted with pediatric residents—found that despite the residents' perception that their patient handoffs were solid, they actually failed to note a diagnosis nearly 40% of the time."

Sometimes, a culture of safety collides with a wider cultural phenomenon of wanting to be seen as someone who can "tough it out." "One of the issues we looked into was whether or not senior management would readily restrict personnel who were under a lot of stress. The residents in this survey overwhelming said, 'We don't see that happening.' In many cases it may be that surgeons don't want to reveal that they are overly stressed, thus management wouldn't be in a position to respond. Whatever the situation, it often takes some form of acting out on the part of the surgeon until management does something about the problem."

A scientist, Dr. Herndon doesn't give in to suspicions…but he wonders when the evidence hints at things. And now, he just may be thinking that students are taking notes in invisible ink. Dr. Herndon explains, "The fact that patient safety was formally and repeatedly emphasized over several years, and that things actually got worse, makes me wonder if something else is going on. I have come to believe that even though residents sit in lectures and hear all the right things, once they begin their workday in the hospital, there is a shift of emphasis to what is unspoken."

"I think that these young trainees fall into step with the 'hidden curriculum,' i.e., how people around them behave. They learn one thing in lectures and go to the floors and see their superiors

doing something else. What are they to think?"

If, that is, they can think clearly at all. "Resident burnout is a real issue, and is one that is strongly related to surgical errors. Brigham and Women's Hospital just published a paper on surgeons and fatigue (which is just one aspect of burnout). Their findings led them to say that if a surgeon has been up 24 hours before surgery (for example, they were up all day and all night Wednesday, and have an elective case Thursday morning) then they have an obligation to tell the patient that they have not slept in 24 hours. Many surgeons don't schedule elective surgeries in such a situation, but that is not always true. You can imagine the disincentives… scheduling problems for the doctor, the patient, and the hospital, loss of money for the hospital. Ideally, hospitals would have a mechanism to make up for such a situation."

Those fighting the good fight say there is hope. "Change has come," says Dr. Herndon, "and things will continue to evolve as we obtain more evidence of what is working and what is not. We have improved systems that can help avoid errors, such as color coding of medication vials. In the future, the most important weapon we have in the fight for safety is the checklist. Those institutions that have implemented checklists have demonstrated a significant reduction in mortality and surgical errors."

"Many organizations are involved in advancing patient safety, including the World Health Organization, which has

Source: MorgueFile

extensive pre-, intra-, and postoperative checklists. Nationally, both AAOS and The Joint Commission support preoperative time outs…brief periods where anyone in the OR can raise concerns before the surgery gets underway. As for the 'Sign Your Site' program, AAOS has been a major leader in making that more common around the country."

Checklists…they sound quite helpful. But they take time. And, says Dr. Herndon, there is another reason that surgeons may not want to pick up that pencil. "Some doctors are going to be concerned that if they forgot to check something off then that could result in a malpractice suit. To my colleagues I say, 'Prepare yourself…mandatory checklists are not too far down the pike.'"

To those who groan, Dr. Herndon says that such a systematic approach may be the only way to rectify such a widespread problem. "Earlier this year a paper on adverse events was published in ***Health Affairs***. The study was undertaken under the auspices of the Institute for Healthcare Improvement, a nonprofit headed at the time by Donald Berwick, M.D., the new director of the Center for Medicaid and Medicare Services. The researchers looked at two ways that adverse events are tracked: the first is voluntary reporting and patient safety indicators. When that was compared to chart reviews they found that traditional reporting (voluntary and safety indicators) missed 90% of the adverse events. Chart reviews were much more effective at catching patient safety issues."

To hospital administrators who may not be ready to deal with this issue, Dr. Herndon says that there is incentive for

"I think that these young trainees fall into step with the 'hidden curriculum,' i.e., how people around them *behave.* They learn one thing in lectures and go to the floors and see their superiors doing something else. What are they to think?"

them…budgetary incentives and marketing incentives. "One study examined heart attacks, respiratory problems, and heart failure, and found that those organizations that had a safety culture *at every level of personnel*, had significantly lower readmission rates. That is better for the bottom line, not to mention the reputation of the hospital."

And these issues are being closely watched by external parties. "The media is routinely reporting what hospitals are doing well, and where they are coming up short. In addition, insurers are providing external pressure. One large national insurance company has recently determined that instead of standard payments to hospitals, going forward they are only going to pay hospitals based on quality. Hospitals that don't meet their criteria will not receive the yearly increase in payments they are accustomed to. This will be replaced with an increase based solely on quality performance measures. Their gold standards? Readmission rates and the use of checklists."

"All doctors must recognize that medical errors are a very real problem. We are all human and make mistakes… but we must go through the process of learning how our errors develop. My hope is that more orthopedic surgeons become active in attempts to change the culture and systems so that errors don't occur. Have the heart, as it were, to step forward and say, 'There was a near miss.'" ◆

company

Alphatec 2Q11: Rock-in' the U.S.A.

Alphatec Spine, Inc. reported a whopping 17.8% rise in sales in the U.S. during the second quarter. Total worldwide sales were $50.9, while U.S. sales were $34.5 million and international sales came in at $16.3 million. International sales were up 1.3%

Dirk Kuyper, company president and CEO, told analysts during an August 4 conference call that the spine market is stabilizing in 2011 and will grow 2-3% over the next year. He expects the market to remain flat in Europe.

Kuyper said the company's U.S. and global revenue growth "significantly" outpaced competitors. Cash flow was break-even for the quarter.

Second quarter highlights included receiving Pharmaceuticals and Medical Devices Agency (PMDA) regulatory approval of Illico in Japan and continued market penetration of OsseoFix and OsseoScrew in Europe. OsseoFix sales grew by 32% in the quarter and the company resubmitted its 510(k) OsseoScrew application to the FDA.

Alphatec also announced a 10% reduction in staff at their headquarters. None of the reductions were in the sales force, which now numbers between 270-280 reps.

PureGen and PODs

But analysts primarily wanted to talk about PureGen, the company's Osteoprogenitor Cell Allograft and PODs (physician-owned distributors).

Statue of Liberty/Wikimedia.org

Alphatec Spine, Inc. 2Q11	Sales ($ in millions)	% Change
Total Reported Sales	$50.9	12.0%
U.S.	$34.5	17.80%
International	$16.3	1.3%

Source: Alphatec Spine, Inc.

Kuyper said the company was not aware of any significant impact on PureGen sales in light of the FDA's June 23 warning letter that the product was miscategorized. Even a worse case scenario, Kuyper said sales were not significant at this point.

Regarding PODs, Kuyper said that most of the company's relationships with stocking distributors are not with PODs. He said the percentage of sales to PODs was "comfortably below a level of materiality in terms of contributions to U.S. and global revenue." He said the company requires PODs to comply with stringent legal criteria and has walked away from distributors that did not meet Alphatec criteria.

Looking Ahead

Kuyper concluded, "While we are pleased to have reported record revenue results and break-even cash flow in the quarter, we have turned our focus to our U.S. gross margin, which we expect to meaningfully improve throughout the remainder of 2011 and 2012. We have initiatives underway that aim to reduce costs, better utilize our in-house manufacturing capacity and improve manufacturing efficiencies. We continue to be laser-focused on driving our differentiated technologies in Aging Spine, MIS and Biologics to gain market share globally."

Jefferies Research analyst Raj Denhoy said that new product launches and SG&A investments should continue to propel above-market revenue growth, but at the price of continued anemic profitability.

—WE (August 5, 2011)

Biomet Confirms Job Cuts

Biomet, Inc. is cutting jobs in its knee and hip divisions to "increase manufacturing efficiency."

That's according to a July 30 story in the Ft. Wayne *Journal Gazette* where the company confirmed that up to 200 jobs will be lost by September 1

The company is reorganizing its global reconstructive business in a bid to boost growth to above the market average, according to a company statement noted in the story. The reorganization calls for eliminating unspecified 21 positions in the U.S. and 60-80 positions in Europe. The company also acknowledged it was reviewing an additional 99 positions in Great Britain for potential cuts, "as a result of softness in the worldwide orthopedics market."

The *Journal Gazette* noted that Biomet has struggled in recent quarters. On July 12 the company reported a preliminary annual loss of $843.5 million for the fiscal year ended May 31. The loss was almost $800 million more than the $47.6 million loss reported for fiscal 2010. Special items included a $941.4 million charge for goodwill and intangible assets impairment, an expense that wasn't listed in fiscal 2010, related to a continued slowdown in the European market.

Biomet Headquarters

"These decisions have been very difficult ones for the management team to make," the company said in a statement. "Where possible, the company will explore other options for these team members."

Those employees who cannot transfer to another position will be paid severance and given outplacement assistance.

Biomet had 7,400 global employees as of March, with 1,700 of those in Indiana.

—WE (August 2, 2011)

SNN Restructuring; DeVivo Departs

According to a recent article in the *Memphis Business Journal*, ("Joe DeVivo out as Smith & Nephew merges operating divisions," Andy Ashby, July 25, 2011), there are major restructurings going on at the London-based device giant. The Memphis-based Orthopaedic Reconstruction division and the Andover, Massachusetts-based Endoscopy unit will combine forces. Mike Frazzette, president of Smith & Nephew's Endoscopy division, will lead this new business unit, called the Advanced Surgical Devices Division.

"We're the same company," said Andrew Burns, spokesman for Smith & Nephew's Orthopaedic Reconstruction division, in the article. "This is an internal integration. We're not looking at anything like site closures or layoffs. This is about achieving more internal focus on the marketplace. They're looking at how we might adjust our strategy with these two divisions together."

A spokesperson for the company told *OTW*, "Smith & Nephew has a great foundation with many innovative products, a strong focus on customers, and talented people. But in the last few years we have seen the markets around us change, some significantly. Our established markets, especially in North America and Europe, are under pressure. At the same time emerging mar-


Source: Wikimedia Commons and US FHWA Manual on Uniform Traffic Control Devices

kets have huge potential. We are going to ensure we have a focused organization and allocate appropriate resources to seize these opportunities. As part of this strategy, our organizational changes will enhance our focus on key global markets and the needs of our customers worldwide."

Regarding DeVivo, a quote from an internal memo states, "Joe has made significant contributions to our organisation over his four years with the company. Joe successfully led the organization through a difficult period which prompted a refocusing of our commitment to ethics and compliance, was instrumental in establishing market leadership for VERILAST, and championed the expansion of Orthopaedics globally—most recently in China."

—EH (August 1, 2011)

Orthofix's Vision For Recovery

Orthofix Headquarter/Orthofix International N.V.

The story on Wall Street about Orthofix International N.V.'s second quarter was that the company didn't meet expectations for sales but beat expectations for earnings.

But the real story was about the vision of the company's future articulated by the incoming President and CEO, Bob Vaters.

Orthofix International NV 2Q11	Sales ($ in millions)	% Change
Total Reported Sales	143.6	down 0.2%
Spine Stimulation	39.7	down 12%
Implants/Biologics	36.9	9.0%
Total Spine	76.5	down 3%
Orthopedic	40.1	7.0%
Sports Medicine	25.2	9.0%

Source: Orthofix International NV

Reported sales of $143.6 million for the quarter were down 0.2% from the second quarter of 2010. Total spine revenue was down 3%, orthopedic products were up 7% and sport medicine rose 9%

Vaters, the company's former chief operating officer said sales were below expectation but described an environment where he believed sales will accelerate in the near future. He said an expected resolution with the government over spine stimulation devices will "clear the deck" of disruptions that have suppressed sales. He sees expanded distribution opportunities with the disruptions that have been in the market with the controversy over InFuse and the Synthes/Johnson & Johnson merger. Vaters also believes that Orthofix will not be at risk for possible disruptions from selling to physician-owned distributors.

Spine Stimulation

Orthofix's spine stimulation device sales have declined for three consecutive quarters of 4-9% sequential declines. But in the second quarter the company was able to reverse that trend, with revenues of $39.7 million. However, Vaters said he wasn't ready to do a "victory lap," a couple of days before officially becoming president and CEO. He was quick to not classify the quarterly performance as a trend reversal on the grounds that the spinal stimulation business continues to suffer from a combination of the DOJ investigations, anemic surgical volumes, and pricing and reimbursement pressures.

When asked during a conference call with analysts on July 28 how a relatively small player like Orthofix can take advantage of distribution opportunities from the Synthes deal, he said, "I'll let you know after I go through the pile of resumes on my desk."

Implants and Biologics

Vaters was particularly bullish about the 9% increase in the company's implants and biologics revenue driven by Trinity stem cell and Collage synthetic biologics. In addition to an opportunity to

take advantage of Medtronic's InFuse disruption, company management told analysts that recent FDA concerns over classification of Alphatec's PureGen Osteoprogenitor Cell Allograft do not impact Orthofix's biologic products.

2011 Outlook Update

The company reiterated its sales guidance, which is expected to be between $580-590 million for the full year 2011.

Vaters ended his remarks by thanking his predecessor, Alan Milinazzo, who will continue to serve on the company's board of directors. The two leaders seem to have executed a seamless transition with a clear vision of the company's place and opportunities in the orthopedic and spine industry.

—WE (July 29, 2011)

Zimmer Sales Rise 7.5% - Keeps Chuggin'

Despite a global slowdown in orthopedic procedures, Zimmer Holdings, Inc.'s President and CEO David Dvorak reported a 7.5% sales increase to $1.137 billion for the second quarter of 2011. Earnings rose by 11%.

Dvorak said the results "reflect improved sales execution in support of new product introductions across our diverse geographic channels, as well as the positive impact of operational improvement initiatives and continued disciplined capital deployment."

Zimmer Holdings 2Q11	Sales ($ in millions)	% Change
Reported Sales	$1,137.0	7.5%
Reconstructive	$857.0	6%
Hips	$345.0	9%
Knees	$471.0	4%
Spine	$56.0	down 3%
Extremities	$41.0	7%
Trauma	$69.0	20%

Source: Zimmer Holdings

Photo manipulation by RRY Publications. Source: Zimmer Spine and Wikimedia

Hips and Knees Shine - Spine Swoons

Every product category, except spine, reported an increase in sales: hips up 9%; knees up 4%; extremities up 7% and trauma up 20%. Spine reported a 3% drop in sales. Currency impacted revenue numbers by about 5.5%. Knees did particularly well in Europe, rising 21%.

Maintaining Momentum

Questions from analysts on the July 27 call with the company were prefaced with the characterization that the company was "maintaining momentum."

Dvorak told analysts that the market slowdown was not permanent and he fully expected people who have deferred procedures due to unemployment concerns and loss of insurance to return when the economy recovers.

The company updated its guidance for the remainder of the year and now expects reported revenue to increase 5.5% to 6.5% over 2010. Currency is expected to be about 3% of that increase.

Recon Market Stable

Mizuho Securities analyst Mike Matson said based on actual results from Biomet, DePuy, Stryker and Zimmer, the reconstructive market appears stable in the second quarter. He estimates that global constant currency reconstructive growth was 0%, in-line with the first quarter. He believes that global knee growth, on a constant currency basis, was -1% and global hip growth was 1%.

"Zimmer's competitive position in the market remains the strongest it has been in several years," concluded Matson.

—WE (July 27, 2011)

NuVasive 2Q11: Taking Share, Lower Profits

On July 25, NuVasive, Inc. reported $133 million in sales for the second quarter of 2011. That was an increase of 11.2% over the second quarter of 2010.

Alex Lukianov, Chairman and CEO , told analysts that the financial performance was "excellent" and suggests the company was continuing to take market share. Lukianov said the revenue increase was "industry leading" in spite of challenging spine market growth dynamics.

"We are exceptionally pleased with the outcome of our recent convertible notes offering, which bolsters our balance sheet and significantly enhances our financial flexibility. As our focus shifts toward the achievement of our next milestone, the evolution of NuVasive into a $1 billion revenue company," added Lukianov.

Wall Street wasn't quite as happy because the company reported higher expenses due to costs associated with higher revenues and infrastructure expansion. The higher costs dropped profits from a year earlier and, because of the new convertible notes, caused the company to lower earning projections for the remainder of the year by around $0.11 per share. NuVasive's stock dropped by about 10% on that news. The company maintained its 2011 financial guidance of revenue of $530 million to $540 million.

Lumbar

Responding to repeated questions from analysts as to why revenue and growth projections weren't stronger, management cited a challenging reimbursement environment and a languishing spine market. The company noted that some 15% of U.S. lumbar procedures for DDD (degenerative disc disease) continue to experience payor reimbursement denials.

Jeffries analyst Raj Denhoy noted NuVasive continues to show resiliency in lumbar, which accounts for about two-thirds of revenue. "Despite market contraction, the company has grown lumbar over 10% year to date. Full-year U.S. lumbar growth is now expected to be 3% to 6% (versus prior guidance of 1% to 4%), which still appears conservative," wrote Denhoy in an investor note on July 25.

Cervical

In the cervical product area, the company is waiting for FDA approval of the PCM cervical disc replacement system and projects $100 million in potential revenue within three years of launch of the product. The company also noted "very good early adoption" of the Helix R anterior transitional cervical plate.

Biologics

In Biologics, Progentix, now named AttraX, is only expected to increase sales by 15% in 2011. Due to delays at the FDA, this was lower then previous expectations for a 20% rise. BMO Capital Market analyst Joanne Wuensch noted that while AttraX could hit

Wikimedia Commons

later in the year it is more likely it will be 2012 for a full-year contribution. Wuensch said how much market share the product takes given the Medtronic, Inc. InFuse furor is a very good question.

Medtronic Lawsuit

Lukianov also updated analysts on the company's patent lawsuit with Medtronic. The first set of claims is scheduled to go on trial on August 30 and will cover three of the nine patents under dispute (three covering pedicle screws were dropped and six have been set aside until a later date). The three patents relate to:

1) a cervical plate
2) the MaXcess retractor
3) a lateral inter-body implant. Also to be heard in this phase of the trial is part of NuVasive's counter suit over Medtronic's NIM-Spine System Neural Integrity Monitor.

Expanding Markets and Share

The company remains on track to enter Japan in 2012, and announced that it has opened its fifth international facility in Puerto Rico and plans to open its sixth in Tokyo by the end of the year.

"Overall, while the spine market remains quite challenging owing to continued pushback on lumbar procedure volumes and price pressure, we remain confident in NuVasive's ability to continue to grow well above market rates," concluded Denhoy.

—WE (July 26, 2011)

legal

Synthes/Globus Patent Feud Resumes

Synthes USA, LLC is suing Globus Medical, Inc. again.

The latest suit is after Globus paid Synthes $13.5 million in 2007 to settle allegedly infringement claims. This time Synthes is suing Globus over U.S. Patents '207, '616 and '076.

The '207 patent, issued in December 2010, the '616 patent issued in January 2011 and the '076 patent also issued in January 2011, are entitled "Intervertebral Implant." Synthes claims the patents cover the following Globus products: Independence ALIF System, Coalition ACDF System and the Inter-Continental Plate-Spacer. According to Globus' website, the Independence combines a stabilization plate and a PEEK interbody spacer. The Coalition is an ACDF spacer system. The Inter-Continental is a plate-spacer designed for minimally invasive lateral fixation. The '027 and '616 inventors are Beat Lechmann, Dominique Burkhard, Chris M.J. Cain and Claude Mathieu. The '076 inventors are only Mathieu and Cain.

The case is Synthes USA v. Globus Medical Inc., 11-cv-652, U.S. District Court, District of Delaware (Wilmington).

Synthes Seeks Relief

Synthes wants the court to declare that Globus has willfully infringed the three patents, enjoin Globus from further infringement and award treble damages. Synthes is also asking for interest on the damages and all legal costs. In addition Synthes wants Globus to recall and destroy the entire stock. They also want a jury trial. No specific monetary damages were sought in the suit.

Globus Lawsuits

Earlier this year, Medtronic Inc. won a partial victory in a federal appeals court against Globus over a spinal sta-

Source: Wikimedia Commons

bilization technology. That case was returned to a lower court for reconsideration of a $2.7 million judgment against Globus.

In October 2010, NuVasive, Inc. filed a patent infringement lawsuit against Globus, contending that Globus' LLIF lateral fusion product, including instruments, implants and techniques sold under the trademarks TransContinental, MARS 3V, and LLIF, infringed NuVasive's XLIF intellectual property.

Globus has a reputation in the industry for successfully fending off lawsuits.

Festering Feud

Synthes and Globus have been at odds ever since Globus was founded in 2003 by David Paul, a former Synthes employee. While as Synthes, Paul served as Director of Product Development for Synthes Spine. According to Globus, he was named inventor on approximately 25 patents while at Synthes. Globus is now the world's largest privately held spinal company. In previous lawsuits, Synthes accused Globus of improperly using confidential information about Synthes, recruiting Synthes employees and passing off Synthes products as their own.

With Synthes having agreed to be acquired by Johnson & Johnson, this may be last shot in the long running feud by former colleagues.

Click here to view the complaint in its entirety.

—WE (July 28, 2011)

extremities

Remarkable Polymer for Osteoporotic Wrist Fractures

IlluminOss Medical Inc. has done it again. The company announced the first use of its product to repair a distal radius fracture in an 80-year-old female patient in Germany. Doctors had originally treated the fracture with a conventional open surgical fixation using a locking plate. This failed when the screws that secured the plate pulled out of the osteoporotic bone.

Dr. Frank Hoffman, a leading trauma surgeon in Germany, then implanted the IlluminOss Photodynamic Bone Stabilization System to repair and stabilize the wrist.

Hoffman stated, " In using the IlluminOss System to both stabilize the fractured radius and provide reinforcement for the continued use of locking screws and the plate, I was able to achieve a rapid repair of the wrist with a security of screw retention that is now independent of the patient's osteoporotic bone. Without this internal IlluminOss implant, I doubt that I would have had a means to ensure secure screw engagement in this patient's bone."

The Bone Stabilization System is used to treat fractures through a small entry into the bone. The flexible balloon catheter is inserted into the bone and placed across the fracture site. A proprietary liquid monomer is then infused through the catheter, expanding the balloon that assists in the alignment of the fractured bone. A special light source is used to convert the monomer inside the balloon into an exceptionally tough, hardened polymer implant.

Hoffman said that he was "amazed at how easily I was able to gain access to the radius with only a small incision. The incision I made was dramatically smaller compared to the traditional plate implant that was used originally. After closing the tiny skin incision, the patient had mobility of her wrist without the need for heavy external plaster casts after a rapid 35 minute procedure.

IlluminOss Medical is a privately held medical device company dedicated to the development of minimally invasive orthopedic systems for the stabilization and treatment of bone fractures.

—BY (July 25, 2011)

IlluminOss Medical Inc.

Hospital for Special Surgery Champ

Once again *U.S. News and World Report* has named the Hospital for Special Surgery (HSS) of New York the top hospital for orthopedics in its 2011 issue of "America's Best Hospitals."

The hospital came in second as a leader in rheumatology. *Consumer Reports* rated it best in New York City for patient satisfaction in a survey of 43 hospitals in the metropolitan region.

Last year, more than 25,000 surgeries were performed at HSS. Areas of expertise include joint replacement, spine surgery, sports medicine, orthopedic trauma, hand surgery, foot and ankle surgery, pediatric orthopedics, limb lengthening, osteoporosis and metabolic bone disease

Of the 169 hospitals in New York State that performed hip replacement/revision surgery in 2009(the most recent data available) the New York State Department of Health found that HSS was the only hospital with a statistically lower rate of surgical site infection compared to the state average.

Physicians from Hospital for Special Surgery's Sports Medicine and Shoulder Service perform in official capacities for major professional sports teams including the Giants, New York Mets, New York Knicks, Nets Basketball, New York Liberty Basketball and New York Red Bulls Soccer. HSS sports medicine specialists also served on the U.S. Olympic Committee medical staff team that covered the Beijing Games in 2008.

"We are deeply honored to be recognized nationally as the best in our specialized fields," said Louis A. Shapiro, president and CEO of Hospital for Special Surgery. "Our hospital staff consistently exceeds the high standards that we set for ourselves, providing an environment for excellence in patient care and safety."

—BY (July 25, 2011)

Hospital for Special Surgery

spine

Yale University to Conduct Comprehensive Review of rh-BMP-2

On the evening of August 3, Medtronic, Inc. announced that Yale University has agreed to conduct a comprehensive review of rhBMP-2 (sold by Medtronic under the brand name InFuse). Medtronic will fund the study with a $2.5 million grant. This study is notable for several reasons the first of which is that its impetus was *The Spine Journal*'s (*TSJ*) June 2011 critical review of several early rhBMP-2 studies. Specifically, the journal uncovered numerous flaws in the early studies and then linked those flaws to royalty and consulting fees that were paid to the authors of those studies.

Image courtesy of Yale University

While *TSJ*'s review was itself also flawed, it did successfully raise new concerns about the safety of InFuse. Medtronic's Doug King, president of Medtronic Spinal, responded at the time by writing to surgeons: "Needless to say, we were

shocked and also puzzled about many of these allegations, especially the allegations that zero adverse events were reported, cumulatively, in these studies of rhBMP-2." King then announced that Medtronic would launch its own independent review of *TSJ* articles and commission an independent, formal systematic review of InFuse Bone Graft published literature.

This is that independent review. But, Yale and Medtronic have agreed to a more comprehensive study than the "formal systematic review" mentioned in King's earlier statement.

ALL available patient level data on rhBMP-2, both published and unpublished, as well as all FDA-filed adverse event reports are being provided by Medtronic.

Furthermore, Yale will assemble a panel of experts and will commission **two** academically recognized, publicly trusted clinical research organizations specializing in systematic reviews to conduct the analyses and ensure the findings are reproducible and of the highest integrity.

While Medtronic is funding the study, *it will not participate in any manner in the selection of the research organizations or the steering committee, the reviews, or the manner of the data release.*

ALL the clinical-trial results will be posted on ClinicalTrials.gov, the clinical-trial registry managed by the National Library of Medicine. Under Yale's direction, Medtronic will retroactively register all pre-market-approval and post-market clinical trials on the product that were completed before the September 2007 requirement for registering such trials on the site.

Finally, in a move unprecedented in the medical industry, Yale and Medtronic agreed to provide researchers access to all data on rhBMP-2 by means of a defined registration process and website. This is not like clinical trial publications or other data sources. This **is complete access to the full patient-level data sets possessed by Medtronic, including independent de-identified patient level data,** not just the data summaries that are commonly used in meta-analysis and systematic reviews.

Eugene Carragee, M.D., the editor of *TSJ* and the driving force behind the journal's attack on the rhBMP-2 studies, sent out a competing press statement at precisely the same time as Medtronic's release went out the evening of August 3. In it he reminded the media that the U.S. Senate and the Department of Justice had previously launched investigations into Medtronic's marketing of InFuse. Dr. Carragee also took credit for Medtronic's funding of the Yale study saying "In response to research published in the June 2011 issue of *The Spine Journal*, Medtronic, Inc. has announced a $2.5 million grant to Yale University". Dr. Carragee then went on to offer his services to Yale's principal investigator—Harlan Krumholz, M.D., the Harold H. Hines Jr. Professor of Internal Medicine, Epidemiology and Public Health at Yale School of Medicine.

You know, in case he needs it.

—*RY (August 4, 2011)*

Vertebral Technologies Implants InterCushion

There's a really happy spine somewhere in Venezuela…Vertebral Technologies, Inc. (VTI) has announced that its InterCushion System was implanted successfully in the first surgery done with the product. The lucky recipient? A patient who entered a clinic with incapacitating pain from a herniated disc after having failed three months of conservative treatment. Twenty-four hours after the surgery, the patient was discharged with no pain.

"Vertebral Technologies is pleased with the successful implantation of the InterCushion device. It is an innovative product that replaces the disc nucleus and provides excellent disc stability while preserving motion at the operated segment. The InterCushion is a much more physiologic solution than fusion," said Jeff Felt M.D., chairman and CEO of VTI in the July 26, 2011 news release. "We are thrilled with the success of the first implant in Venezuela. Dr. Pino and his team did an excellent job with patient selection and with the surgical technique."

Dr. Felix Pino, an orthopedic spine surgeon of Tensegrity Spine and Vertebrology Unit, Maracay, Venezuela, conducted the surgery. Orthopedic spine surgeon Paul Asdourian M.D., of Greater Chesapeake Orthopaedics Associates in Baltimore, and orthopedic spine surgeon Arnold Schwartz M.D., of Orthopedic Spine Care of Long Island in New York, assisted with the surgery.

"The InterCushion was able to provide the patient with pain relief, something months of therapy could not accomplish," added Dr. Pino. "We are very impressed with the method of the implantation and the positive patient result."

Source: Vertebral Technologies, Inc.

When asked about patient follow up and where the company goes from here, Dr. Felt told *OTW,* "We plan to continue implanting the InterCushion in Venezuela. The study we began there will be expanded to include three sites in Canada. Patients will be evaluated at 2 weeks and at 3, 6, 12, and 24 months."

He added, "The InterCushion provides the spine surgeon with a new therapeutic tool to interrupt the degenerative cascade before fusion becomes necessary."

—EH (July 29, 2011)

people

Spine Industry Pioneer Dr. Charles Ray Dies at 83

Charles Ray, M.D., who played a larger-than-life role in shaping the surgical treatment of debilitating back pain, died peacefully in his sleep—no doubt dreaming of his next invention—on July 21, 2011 in Santa Barbara, California at the age of 83. Dr. Ray, whose long list of inventions, patents, students and surgical techniques only begins to hint at his impact on spine surgery, was active to the very end.

"Dr. Ray was one of the most creative men I ever met. He was not only a fantastically innovative and creative personality but most gracious and open to any and all queries. He would always be available to help with any and all ideas and always contributed more than his fair share. It was an honor to know Charlie and be able to call him a friend." *— Stephen Hochschuler, M.D.*

Inventor

Charlie, as he was known by virtually everyone he came into contact with, held 53 U.S. patents and over 100 foreign patents, wrote over 365 articles and books and his bibliography lists 340 entries. He was the inventor of the Ray Threaded Fusion Cage, as well as the prosthetic nucleus to restore degenerative discs. For this work he was declared the Gold Medal Winner of the Medical Design Excellence Award for the year 2000. He was also awarded one of the three R & D 100 (along with NASA and DuPont Inc.) Best of the Best Awards—his for the development of this product having the most humanistic application.

Dr. Charles Ray; courtesy of ISASS

Charlie was born on August 1, 1927 in Americus, Georgia. a very small town about 130 miles southwest of Atlanta. In addition to Charlie Ray, Americus is the birthplace of Habitat for Humanity. Both Charlie and Habitat for Humanity would eventually become internationally known and renowned builders.

His parents, Oliver Tinsley Ray and Katherine Broadfield Ray, moved from Americus to Atlanta in 1937. There, Charlie attended the Technological High School and upon graduating in 1945 joined the U.S. Navy. With the Navy, Charlie began what would eventually become a lifetime of traveling the world. Over the course of the next 65 years he trained surgeons on every continent, in hundreds of countries and became fluent in eight languages.

Charlie earned an undergraduate degree from Emory University in Atlanta and then a Master's degree from the University of Miami in 1952. He earned his medical degree from the Medical College of Georgia in 1956 and completed his fellowship at the Mayo Clinic in Rochester, Minnesota. From there, Dr. Ray joined the staff at Johns Hopkins University taking the position of Assistant Professor of Neurosurgery and Bioengineering.

A Major Theoretical Influence

An expert in bioengineering, philosophy, medicine and biology, Dr. Ray was much more than just a surgeon engineer. He was a major theoretical influence on spine care because he championed arthrodesis and arthroplasty as treatment modalities for degenerative disc disease instead of fusion. Under his guiding hand, generations of surgeons around the world are more routinely successful and their patients are leading more pain free lives.

Courtesy of Anthony Yeung, M.D.

Eventually, Charlie would become the co-founder of the North American Spine Society as well as the founding President of the Spine Arthroplasty Society, co-founder of the both the American College of Spine Surgery and the American Board of Spine Surgery. Over his career Dr. Ray advised numerous firms including Hoffman-LaRoche in Basel, Switzerland, Medtronic, Inc. in Minneapolis, Minnesota and, of course, RayMedica Inc., in Minneapolis as well as InveRay, Ltd.

Charlie met his beloved wife, Christie Mae Ross, at the Medical College of Georgia in the early 1950s. She preceded him in death as did his daughter, Kathy Lynn Ray; and son, Thomas Ross Ray; as well as his sister, Katherine Olivia Ray Jones. Those left to cherish and honor his memory include daughter, Christie Marlene Ray and and son, Bruce Charles Ray, as well as Rod Pearson and two grandchildren, Ross Michael Pearson and Nancy Rose Pearson of Santa Barbara; brother and sister-in-law, Thomas Broadfield Ray and Jean Bodin Ray of Atlanta; and numerous additional family members.

Final Thoughts

"Dr. Charles Ray, beside his impressive CV and his documented achievements, was a very warm and attentive man. Always innovating and inventing, ready to listen to problems and looking for solutions, he took on challenges that are daunting but needed to be initiated to benefit patients. He built consensus and led by example. He was an inventor, artist, writer and lecturer in five languages. Most importantly he was my friend." — *Hansen A. Yuan, M.D.*

"Charlie was a thought leader in the world of contemporary spine surgery. The Ray TFC cage changed how fusion surgery was performed. He was the first to address disc degeneration with a replacement for the degenerated nucleus. He was truly a pioneer as evidenced by so many arrows in his back. He invented to help patients." — *John V. Viscogliosi, Viscogliosi Brothers, LLC*

"Charlie Ray remains in my memory as a great human and a true pioneer of devices for the spine. My first contact with Charlie was in 2002 when I received a welcome letter from him on becoming a member of the Board of Directors of the Spine Arthroplasty Society. The Society had been formed a year earlier. Later I had the honor of cooperating with Charlie to revise the Society's bylaws and create today's ISASS, the International Society for the Advancement of Spine Surgery. I had many meetings and conversations with Charlie. He was an enjoyable gentleman and a good advisor. I will never forget him. My deepest regrets to his family." — *Karin Buettner-Janz, M.D., Ph.D.*

Sign Dr. Ray's Guest Book

If you would like to contribute a comment to Dr. Ray's legacy Guest Book, please click here.

—RY (August 1, 2011)

THE PICTURE OF SUCCESS

Sandy Gordon

By Elizabeth Hofheinz, M.P.H., M.Ed.

Sandy Gordon / Hiking in Costa Rica

She has won an Emmy, helped research the Americans With Disabilities Act (ADA), and has taken the American Academy of Orthopaedic Surgeons (AAOS) by storm with her unusually innovative public relations initiatives such as Legacy of Heroes and Wounded in Action.

Sandy Gordon, now Director of Public Relations for AAOS, was raised a world away from surgeons, orthopedics, art exhibits and politics. She first worked as a special education teacher in Virginia, and was later scooped up by the Hubert Humphrey campaign to promote issues important to people with disabilities. Later, when directing public relations efforts for the American Academy of Dermatology, she convinced Dr. John Tongue that what she was doing for dermatologists could also be done for orthopedists.

The Journey From Fargo

Years ago, Sandy Gordon just wanted a Bat Mitzvah. It was only *fair*. And so, the little girl with curly black hair blew into the local rabbi's office in Fargo, North Dakota, and said, "All the boys in this town have Bar Mitzvahs. I want a Bat Mitzvah," the rabbi replied, "Sure. Why not?"

Even then, unfairness just made Sandy Gordon's hair curl.

But justice would be done…and would become the driving force in Sandy Gordon's eventful life story.

The fight for a Bat Mitzvah in 1950s Fargo was likely the easiest challenge she ever encountered. But even that required a budding sense of chutzpah. It also offered an early clue that her internal tuning fork for unfairness was sharp and her willingness to fight for others was always at the ready.

It is no exaggeration to say that Gordon has altered the history and stature of AAOS by applying her energy and sense of fairness to a cornucopia of inventive and inspirational public relations projects…efforts which have earned almost 200 national and international accolades for AAOS.

For Sandy Gordon, it started with a friend who had cerebral palsy. "One summer in high school I worked at a camp for children with disabilities, something that led to my interest in special education. I became friends with a local girl with cerebral palsy who—it seemed—had been sent to Jamestown, North Dakota, by her family because there were no accommodations for kids with handicaps where she lived. Her life situation led me to develop a strong sense of caring about people with disabilities. Several years ago I had an emotional reunion with her and over dinner I told her how being her

"We had just completed the enormous AAOS 75th anniversary project, and had some funding in reserve. I racked my brain to think of what good use might come of it. Eureka! Let's tell the stories of those doctors and civilians whose lives have been forever changed by war. Art can often draw people into the lives of those in pain when words cannot 'get through.'"

friend and knowing her experiences had shaped my entire life. She burst out laughing and said, 'That's not why I was in Jamestown. It was because my family was overprotective and my dad decided that the only way I would become independent was if I got some distance from them.' How odd it was to learn that the trajectory of my life had been based on something that didn't actually happen!"

Researching the ADA

This, of course, doesn't matter to the thousands of people whose lives she has changed. "In the 1980s I worked in rehabilitation centers in Minnesota and Chicago, during which time I helped research various portions of the ADA… and I was there for the signing of the bill. While it was thrilling, the enforcement side of things was tough. We could write this great bill, get it passed into law, but then you have the very real question of how to enforce it. How, for example, can you get small business to make their premises wheelchair accessible in a way that doesn't pose a huge financial burden for them? Over the years things have changed, however, and the funding has been made available. But, enforcement issues still remain."

Gordon, named 'PR Professional of the Year' by PRNews in 2004, says that leading the public relations effort for AAOS has been the zenith of her career. When she began in this position 12 years ago, Gordon brought with her a trail of experiences that ended up making orthopedics a perfect fit.

"I lived in Washington, D.C. when Hubert Humphrey was running for president, and I knew he had a grandchild with Down Syndrome. At that time no political figure seemed to care about handicapped people…no one was willing to tackle issues like accessibility, housing, and employment. I walked into his presidential campaign office and asked to speak with him—and I did. I told him, 'I know you have a grandchild with Down Syndrome and I am a special education teacher. Let's form a committee that will do things for the handicapped, such as organize people with disabilities so they can get to voting places. Not only was he very enthused about the idea, but I was hired on the spot."

Sandy after setting up for AAOS 75th Anniversary

The Sandy Effect

In just one example of "the Sandy effect," Gordon was the brainstorm behind the elegant and moving AAOS art exhibition, "Wounded in Action." Whether it's a civilian's lithograph depicting a Marine through a riflescope or an orthopedic surgeon's oil painting of a field of graves, the viewer has the opportunity to be deeply drawn into another's experience. Gordon states, "We had just completed the enormous AAOS 75th anniversary project, and had some funding in reserve. I racked my brain to think of what good use might come of it. Eureka! Let's tell the stories of those doctors and civilians whose lives have been forever changed by war. Art can often draw people into the lives of those in pain when words cannot 'get through.' The exhibit has been a huge success, and continues to travel the country and alter the lives of those involved."

Not "only" an observer of those who have faced chaos and uncertainty, Sandy Gordon has had her own experiences of heavy themes…death, loss, illness, divorce. "When I was 16 my world shifted, and the lives of everyone in my family were turned upside down. My dad had two business partners, his brother and my mother's sister's husband. We were all extremely close. While my father stayed home for one

particular trip, the other two partners went, and were killed in a car accident. My mom fell apart…she declined physically and sunk into a depression. My dad was also depressed, but he shouldered the responsibility of taking care of the two families who had lost dads. I took over so much at home, and out of that experience grew into a person who tends to have a substantial empathy for others and a deep desire to help those who are suffering."

It was one of the first times that Sandy Gordon realized that to make it through tough times she would have to dig deep inside…and find laughter. "My sense of humor has kept me going through difficult times—and through life in general. And I'm often my own target for the humor. For example, years ago I was walking with a good friend who was blind. We were exiting a building with a revolving door and I was chatting away and exited the door. I left him in the door and he has never let me forget it!"

"And when I took sign language classes I ended up getting myself into trouble. While introducing the governor of Minnesota at a conference, instead of signing that he was, 'My dear friend,' I signed that he was, 'My dear hamburger.' Another time I was trying to help a deaf student get coffee and I signed something so naughty that I totally embarrassed my teacher…and myself."

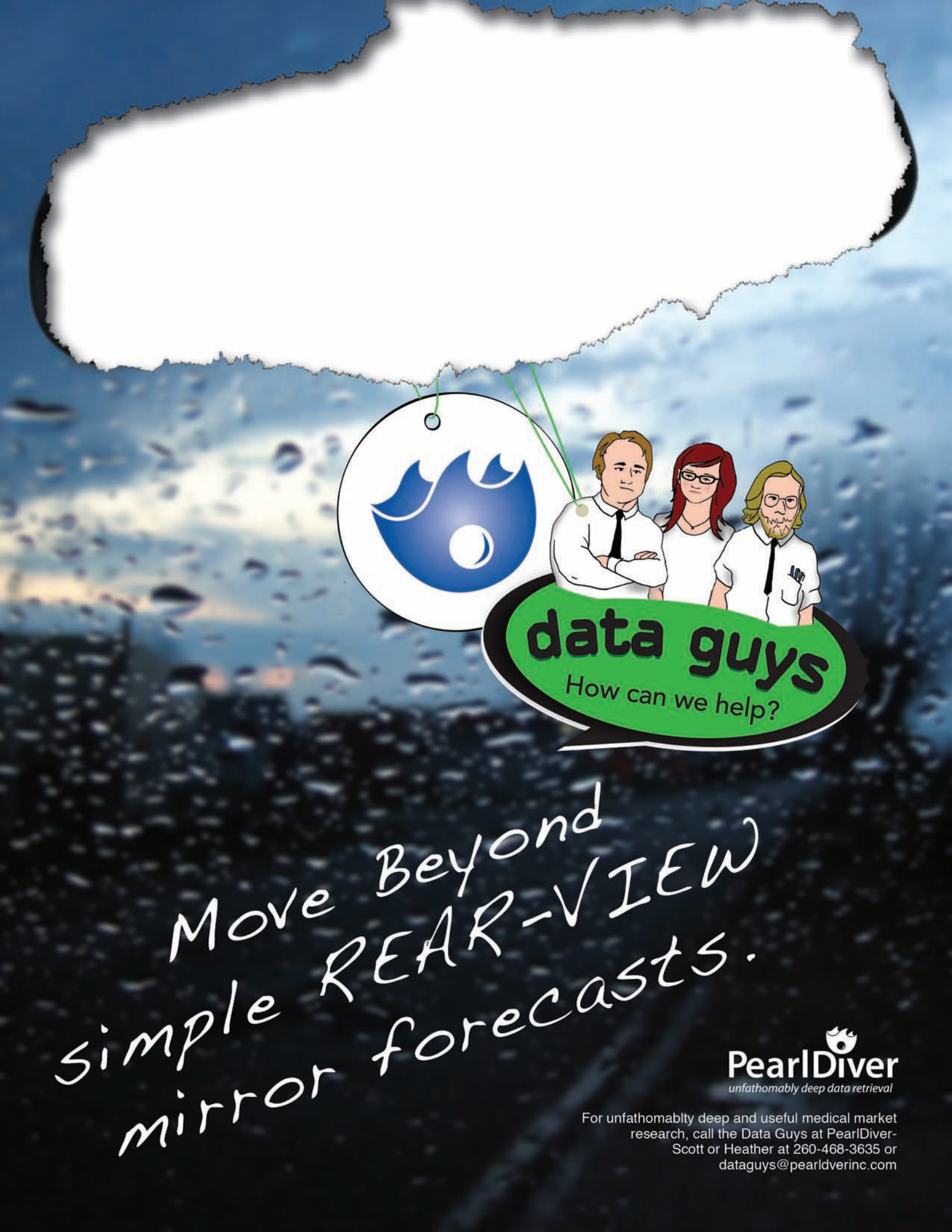
Gordon, who was brought on board at AAOS to let the public know the value of orthopedic surgeons, hasn't done any signing lately…she is communicating everything in her most familiar language…and doing so with a punch. Gordon, the genius behind AAOS' eMotion Pictures exhibit, says, "In 2001 we launched a truly moving art exhibit that included works from people from all walks of life—even children—who have had to contend with an orthopedic condition. I went to industry to raise the funding, then we opened at the AAOS Annual Meeting, the Chicago Cultural Center and then toured the exhibit nationwide. The art, which captured feelings involving healing, frustration, self-image, etc., was just extraordinary."

A Devastating Loss

Sandy Gordon, who has an extraordinary personal loss in her past, could have contributed artwork to the exhibit as well. "My second child was a little boy born with Osteogenesis Imperfecta (OI), known as 'brittle bone disease.' He only lived a few hours. Afterwards, nearly everyone came up to me and said that I was lucky that he didn't survive…that his life would have been so difficult. My only thought was, 'If anyone would have been a good mother to someone with a disability it would be me.' I became more determined than ever to do things for people with disabilities."

"In the ensuing years, people with OI have come into my life and I have been able do things for them. Several years ago I met a young girl with OI who wanted to compete in the Miss Teen USA contest, but was denied this opportunity. I was incensed. I called the media, they got their cameras, and we all went to the contest offices. This young girl in a wheelchair knocked on their doors and we caught it on camera when they slammed the door in her face. They were shamed into letting her compete. She died the following year." ◆

Next week, learn about Sandy Gordon's AAOS Legacy of Heroes project, her work on the AAOS Distracted Driving campaign, how she received a personal tour of the White House from President Clinton…and more.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