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Orthopedics This Week

week in review

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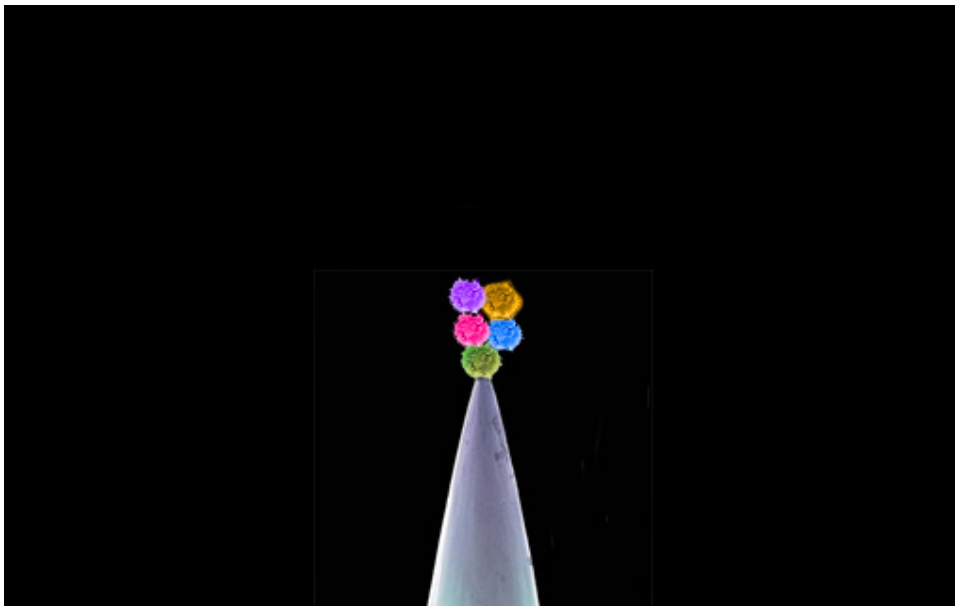

picture of success

26 **Dr. James Herndon** ◆ Dr. James Herndon, a former president of AAOS, has chaired the department of orthopedics at Harvard, Brown, and "Pitt." And his system-wide approach to patient safety continues to make a difference.

breaking news

16 AAOS Supports **Ryan Medicare Privatization Plan**

Prosthesis for the Poor—**A $20 Knee**

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Stanford Study IDs **Teratoma Cells**

DePuy Joins **Customized Knee Surgery** Club

OrthoSensor and **Stryker** Partner for "Smart" Knee Surgery

For all news that is ortho, read on.

Orthopedics This Week

VOLUME 7, ISSUE 27 | AUGUST 23, 2011

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Five of the top ten orthopedic companies have lost between 20% and 25% of their value in the last month. Are these firms really worth 20-25% less? Did their cash flows decline by that amount? Did their sales? Does any knowledgeable person really expect Stryker, Zimmer or Orthofix to sell 20% fewer implants? The answer is "no."

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Kensey Nash	34.24%	7.49%	By virtue of its cash flows and investor support, KNSY is the new #1 on the Orthopedic Power Rankings.
2	4	Johnson & Johnson	26.33	(4.68)	While the market may say that DePuy is a "slow grower" that steady dividend plus the pending Synthes add-in is building wealth.
3	7	Stryker	25.23	(23.04)	No way is SYK worth 23% less than it was 30 days ago. Huge overreaction. Up 4 spots this week.
4	1	Orthofix	14.72	(20.18)	Tough market to be the new CEO in. The market is just intolerant of even implied risk—like being the new top guy.
5	3	Zimmer	27.75	(20.17)	Standpoint Research upgraded ZMH to "BUY." Also oversold. Also not worth 20% less than it was one month ago.
6	NR	Medtronic	28.63	(14.79)	New CEO introduced himself to the Street this week and the reviews were upbeat. New leadership puts MDT at #6.
7	6	Smith & Nephew	22.80	(15.12)	While operating margins are still very respectable, they are the lowest of the big ortho companies.
8	9	ConMed	9.65	(21.91)	With the stock decline, CNMD is now the 2nd least expensive ortho stock in terms of its Price-to-Sales.
9	5	Wright Medical	8.76	(12.80)	Oooph! Compliance officer leaves WMGI. Is there any good reason for her to leave? Probably not.
10	8	Symmetry	7.64	(21.98)	Closes the Olsen buyout. But in this environment, which is about as short term as I've seen, SMA still drops 22%.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	RTI Biologics Inc	RTIX	$3.65	$201	18.12%
2	Kensey Nash	KNSY	$27.11	$231	7.49%
3	MAKO Surgical	MAKO	$30.60	$1,268	-3.20%
4	Synthes	SYST.VX	$172.85	$20,531	-3.35%
5	Johnson & Johnson	JNJ	$63.14	173,026	-4.68%
6	TranS1	TSON	$4.55	$95	-9.90%
7	Wright Medical	WMGI	$13.56	$534	-12.80%
8	CryoLife	CRY	$4.97	$140	-14.16%
9	Medtronic	MDT	$31.29	$33,198	-14.79%
10	Smith & Nephew	SNN	$45.08	$8,049	-15.12%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Alphatec Holdings	ATEC	$2.24	$200	-34.69%
2	NuVasive	NUVA	$21.08	$841	-34.66%
3	Tornier N.V.	TRNX	$20.11	$788	-27.22%
4	Bacterin Intl Holdings	BONE	$1.82	$72	-26.91%
5	Exactech	EXAC	$14.09	$185	-24.49%
6	Stryker	SYK	$43.80	$17,009	-23.04%
7	Integra LifeSciences	IART	$36.63	$1,008	-22.62%
8	Symmetry Medical	SMA	$7.56	$275	-21.98%
9	ConMed	CNMD	$21.90	$626	-21.34%
10	Orthofix	OFIX	$35.01	$644	-20.18%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$31.29	$33,198	9.54
2	Zimmer Holdings	ZMH	$50.98	$9,710	10.99
3	Stryker	SYK	$43.80	$17,009	12.44
4	Johnson & Johnson	JNJ	$63.14	173,026	12.91
5	Orthofix	OFIX	$35.01	$644	14.53

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$21.08	$841	26.35
2	Synthes	SYST.VX	$172.85	$20,531	21.88
3	ArthroCare	ARTC	$29.30	$804	20.49
4	Wright Medical	WMGI	$13.56	$534	19.37
5	Exactech	EXAC	$14.09	$185	18.54

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Integra LifeSciences	IART	$36.63	$1,008	0.69
2	Orthofix	OFIX	$35.01	$644	0.79
3	RTI Biologics Inc	RTIX	$3.65	$201	0.90
4	Exactech	EXAC	$14.09	$185	1.02
5	Kensey Nash	KNSY	$27.11	$231	1.14

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Alphatec Holdings	ATEC	$2.24	$200	6.69
2	ArthroCare	ARTC	$29.30	$804	3.28
3	Johnson & Johnson	JNJ	$63.14	173,026	2.33
4	CryoLife	CRY	$4.97	$140	1.94
5	Symmetry Medical	SMA	$7.56	$275	1.69

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$7.56	$275	0.76
2	ConMed	CNMD	$21.90	$626	0.88
3	Exactech	EXAC	$14.09	$185	0.97
4	Wright Medical	WMGI	$13.56	$534	1.03
5	Orthofix	OFIX	$35.01	$644	1.14

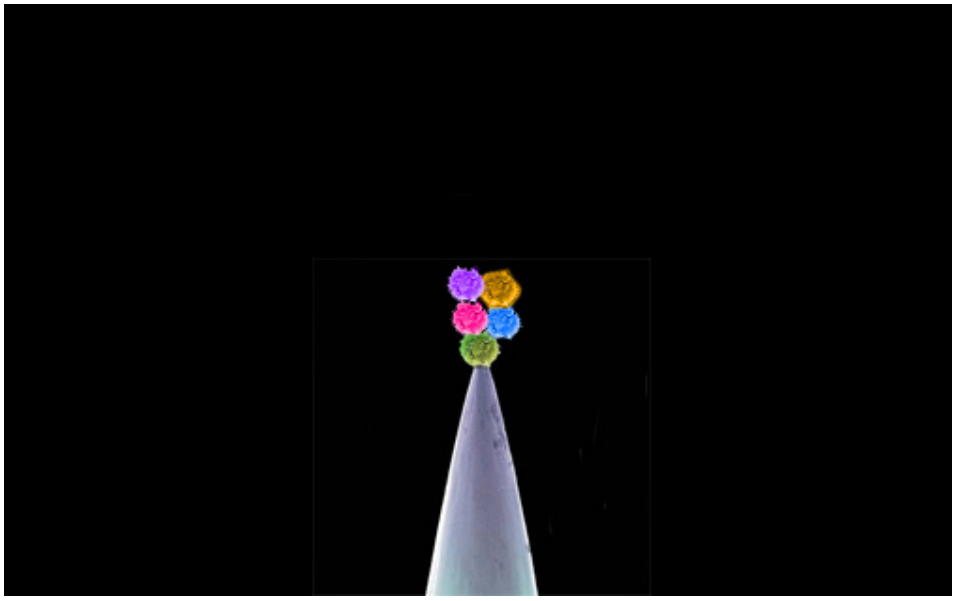
Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$1.02	$93	150.02
2	MAKO Surgical	MAKO	$30.60	$1,268	28.63
3	Synthes	SYST.VX	$172.85	$20,531	5.57
4	Bacterin Intl Holdings	BONE	$1.82	$72	4.68
5	TranS1	TSON	$4.55	$95	3.64

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

Five Stem Cell Companies in Orthopedics

By Robin Young



Wikimedia Commons and Marc Bessant, Steven Gschmeissner/RRY Image Creation

Five companies, we think, stand out when it comes to non-allograft stem cells. In reverse rank order, here is who we think are likely to make the biggest stem cell splash in orthopedics.

5 **RNL BIO Co., Ltd.** — Presidential candidate (and Governer of Texas) Rick Perry received stem cells for back pain using RNL BIO's system earlier this year. Stanley Jones, M.D., associate clinical professor at the University of Texas Medical School at Houston was Perry's doctor. What makes this story so compelling is that Dr. Jones had first tried the therapy on himself.

In September 2009, Dr. Jones was operating on a very long case when "My right wrist started to swell and I'd never had such severe pain in my life. I really had no idea what was wrong." So Dr. Jones asked his wife, who is a nurse, to inject his wrist with cortisone. "Two days later the pain was gone so I thought 'the cortisone did it! This is great.'"

But the pain soon returned. "My knee started to swell. I had never had so much pain. Wow, I thought, I had it in my wrist now I have it in my knee." Dr. Jones immediately went to his rheumatologist and was told that he had autoimmune arthritis.

Recalls Dr. Jones: "He (the rheumatologist) was quite frankly amazed at how much pain I was having. My physician assistant had to carry me into the office the pain was so bad. So I was pretty distressed. I just imagined that my practice in medicine was gone."

Dr. Jones contacted RNL BIO and signed up for its stem cell therapy program. "We went to our medical spa and we had fat taken from our abdomen, our own fat. Our own fat cells were then sent to Korea and they were put in tissue culture. Two months later, glory be, we were in Japan getting stem cells. I was overwhelmed by how easy it was, by the cleanliness and the professionalism of the hospital in Kyoto. By the middle of October, I no symptoms at all and I've not taken anything since September. Thank God I got well."

Link to video of Dr. Jones is here: http://www.youtube.com/user/rnlbio#p/u

Korean based RNL BIO's system, as Dr. Jones described, harvests adipose tissue, isolates the stem cells, cultures them into larger quantities and then, because treating patients with stem cells is not

approved in South Korea, injects those cells into patients at affiliated clinics outside Korea. In the U.S. RNL BIO has opened clinics in Los Angeles and San Diego. Tissues extracted from patients in the U.S. are sent to labs in Maryland or Korea for expansion. The cultured cells are then injected back into the patients in RNL BIO's partner facilities in China, Japan or Mexico.

Courtesy of Governor Rick Perry, RNL BIO's stem cell system for treating back pain or, indeed, any orthopedic procedure has been thrust into a presidential campaign spotlight.

4 **SpineSmith (aka Celling Technologies)** — *Every month* Celling Technology's (based in Austin, Texas) systems are used to treat about 350 orthopedic patients with stem cells. Roughly 200 patients are in Texas.

The company introduced its line of point-of-care, advanced bone-marrow-derived stem cell concentration systems in 2006. Today the company markets the ART 21, the Fusionary system and the MarrowXpress system.

Celling's technologies work at the point-of-care. It's an automated, closed system that concentrates bone marrow to a user-defined volume in about 30 minutes. The system retains more than 90% of the patient's mononucleated cells. It's self-powered and microprocessor-controlled. So it's very precise.

Celling also provides a service delivery team staffed with trained registered nurses to operate the systems. Most of Celling's sales are to surgeons performing lumbar or cervical fusions. Coming on strong are soft tissue knee and shoulder repairs and trauma.

Dr. Lee at University of California - Davis and Dr. Rodeo at Hospital for Sspecial Surgery (HSS) are studying the use of Celling's systems for long bone non-unions and a rotator cuff repair.

Bottom line: Celling Technologies is putting the ability to harvest autologous stem cells into the orthopedic surgeons' hands.

3 **Aastrom Biosciences, Inc.** — The first clue something was up was when Aastrom's CEO bought stock. On August 5, 2011, Tim Mayleben, CEO, filed a notice with regulators to buy 20,000 shares for around $2.36 per share. Then, three days later, he bought 10,000 *more* shares at $2.11 per share.

Two days after that (August 10) Aastrom's CFO, Scott Durbin, bellied up and bought 10,850 shares for $2.18 - $2.24 per share. Not to be left out, Aastrom director Ronald Cresswell filed his papers and purchased 20,000 shares at $2.22 per share.

All this buying happened in the middle of one of the broadest stock market sell offs ever. It reminded us of the Dan Akroyd and Eddie Murphy scene in "Trading Places" where the two men stand in an emotional selling frenzy buying everything they can.

What did Mayleben, Durbin and Cresswell know? Could they know something all of those big, smart institutional sellers didn't?

On August 15, Aastrom held a conference call with Wall Street analysts

and announced the FDA had reached an SPA agreement with the company regarding its Phase 3 Critical Limb Ischemia (CLI) trial. The trial is testing Aastrom's expanded multi-cellular therapy for no-option CLI patients. Under the agreement, Aastrom could start the final phase of its CLI trial in 4Q11.

Ah yes, THAT CLI trial. It had been about a year since Aastrom announced Phase II results. Those results (multi-center, randomized, double-blind, placebo-controlled trial) showed that Aastrom's autologous cells prevented amputations better than a placebo ($P<0.05$). Aastrom's trial is the largest blinded, randomized cell therapy study currently being conducted for CLI.

People with CLI face a high risk of leg amputation and in some cases death. Approximately 1 million patients in the U.S. suffer from CLI. The disease results in more than 160,000 amputations each year.

One Wall Street broker, Needham & Company, immediately reiterated its long time "Buy" rating and a $6.00 price target. The stock? The day after Aastrom's' announcement it fell by a penny to $2.61 a share. The astute masters of Wall Street rendered their judgment. They yawned.

We noticed.

2 **Osiris Therapeutics, Inc.** — The U.S. Government is about to be the largest purchaser of stem cell products in the world. Three years ago the Department of Defense gave a $224.7 million contract to Osiris for its adult mesenchymal stem cell (MSC) therapy as a medical countermeasure to nuclear terrorism and other radiological emergencies. Upon FDA approval of Osiris's product (in Phase 3 Animal Rule trials), the U.S. Government will purchase at least 20,000 doses at $10,000 per dose. And then stockpile these doses in freezers around the United States.

(The FDA Animal Rule states that the FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug or biological product is reasonably likely to produce clinical benefit in humans.)

The reason this matters to orthopedics is because the underlying etiology of radiation sickness is almost identical to the underlying etiology of arthritis and other autoimmune diseases.

MSCs are stimulated by biochemical stimuli and move through the blood stream to points of inflammation (like arthritis). Once there, MSCs coordinate healing and tissue regeneration at that point of injury or inflammation by producing growth factors, blocking inflammation and reducing scarring. Importantly, MSCs do not trigger the patient's immune system.

Soon the U.S. Government will begin to stockpile injectable doses of stem cells around the U.S. Why? Because the government is convinced that mesenchymal stem cells treat the kind of systemic inflammatory responses that occur due to radiation exposure—but also occur due to arthritis—and do so safely.

1 **Mesoblast Limited** — No stem cell company has launched more clinical programs aimed at the orthopedic surgeon than Australia's Mesoblast. Over the course of the last three years Mesoblast has:

1. Received FDA's clearance to begin Phase 2 clinical trials of its stem cell product NeoFuse for fusion of the cervical spine in the neck. The study compares two doses of NeoFuse against standard-of-care in 36 patients requiring bony fusion at 2 or more levels in the cervical spine. Mesoblast's preclinical trial results for NeoFuse showed earlier and more robust bony fusion of the cervical spine over a three-month period than either a recipient's own bone (autograft) or synthetic material, with no cell-related adverse events.
2. Completed a pilot clinical trial for non-healing, long bone fractures in the legs. Using Mesoblast's stem cell product, physicians were able to achieve bony union and healing within a median time of approximately four months versus what otherwise would have been permanent non-healing of the fractures in the absence of cell therapy.
3. Reported exceptional results of a preclinical cartilage trial which showed that a single injection of Mesoblast's allogeneic cell product, RepliCart, into knee joints damaged by osteoarthritis can prevent further deterioration and regenerate and regrow cartilage tissue lining the damaged joint.
4. And finally, as reported at the New York Stem Cell Summit two years ago, showed in a preclinical trial that a single, low dose of Mesoblast's allogeneic adult stem cells into severely damaged intervertebral discs could dramatically reverse the degenerative process, regrow disc cartilage and normalize the disc anatomy and function.

All of this was, in effect, captured when pharmaceutical firm Cephalon agreed to pay Mesoblast $130 million upfront and another $220 million to acquire a nearly 20% stake in the company. With regulatory milestone payments Mesoblast could receive up to $1.7 billion from Cephalon.

These firms either have stem cell products on the market or are in the advanced stages of bringing therapeutic stem cells to rank and file orthopedic surgeons.

So, now that you've read our picks, let us know what you think. ◆

Outing the AMA/CMS Sweetheart Payment System, Part II

By Walter Eisner

Is the American Medical Association's (AMA) Relative Value Scale Update Committee, known as RUC, a Federal Advisory Committee (FAC) or isn't it?

That's what The Georgia Six, a group of primary care physicians who filed a lawsuit against the Centers for Medicare and Medicaid Services (CMS) on August 5, want a judge to decide.

If the RUC is a FAC, then the entire process used by the AMA to develop the RBRVS (Resource-Based Relative Value Scale) used by CMS to set the Medicare physician fees, will have to change dramatically to comply with the Federal Advisory Committee Act (FACA).

"Breaking Up a Sweetheart Deal" /Wikimedia Commons/RRY Image Creation

It Walks Like a Duck

The AMA says the RUC is simply an independent group exercising its First Amendment Rights to petition the federal government.

Nope, say the primary care docs. It walks like a duck. Quacks like a duck. Looks like a duck. It should be treated like what it is—a regulatory duck that must meet the requirements of the FACA.

The Spark

Last week *OTW* brought you the details of the lawsuit. But what was the straw that broke the camel's back for Paul Fischer, M.D., the primary care doc leading The Georgia Six's assault on the AMA's unique relationship with CMS? Money and respect

Fischer told *OTW* that one day a third-year medical student on his family medicine rotation came to see him for a recommendation…to go into dermatology.

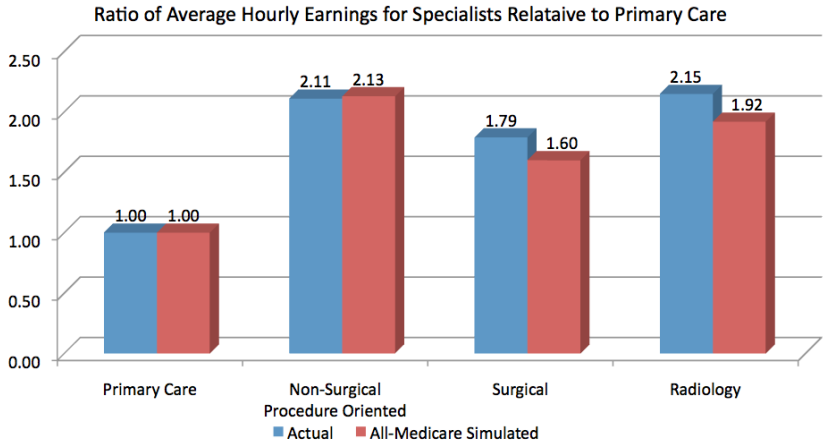
Paul Fischer, M.D./Courtesy Dr. Fischer

The student told Fischer he really liked the work, but just could not afford to go into family practice. Fischer said he realized by "afford," the student was referring not only to finances but also to the expectations of his parents, friends, and medical school. "After spending 35 wonderful years as a family doctor, I have been 'dissed' by a kid who wants to become a dermatologist," said Fischer.

Income Disparity

Who can blame the student? Data from the Department of Labor Statistics and the Medical Group Management Association show that primary care physicians earn a cumulative average lifetime net income of nearly $6.5 million compared with more than $10 million for subspecialists.

Fischer and his colleagues blame the AMA and CMS for this situation.



Source: Berenson et al. "What if All Physician Services Were Paid under the Medicare Fee Schedule? An Analysis Using Medical Group Management Association Data." Report No. 10-1 to MedPAC, March 2010/RRY Image Creation

AMA: "Don't Blame Us"

But the AMA says it's not their fault.

The AMA says CMS is entirely responsible for the RBRVS, where all modifications are made through rulemaking and, unlike RUC meetings, are open to the public.

But at the same time the AMA declares that CMS has recognized the expertise of the RUC by adopting 95% of its work relative value recommendations.

The AMA acknowledges that CMS has observers at each RUC meeting and if a concern is expressed the RUC responds accordingly.

The meetings are not a closed process, says the AMA. The RUC Chairman accepts requests for attendance at each meeting. However, the RUC has a strict conflict of interest policy and does not want the influences of industry involved in the process.

Still, the AMA grants that the RUC activity provides the Medicare program with the ability to issue "timely updates" to the physician fee schedule. "Even with input from an advisory board or consultants, CMS could not replicate the resources to duplicate this process," according to the AMA website.

Quack. Quack. The RUC certainly looks like and walks like a duck, suggests Fischer's lawsuit. If a federal judge agrees, the RUC could be required to abide by FACA laws that require among other things, open meetings, balanced composition and financial disclosures by committee members

Advisory Committee Precedent

There are a couple of recent health care judicial precedents relating to the Federal Advisory Committee Act.

On August 12, a federal judge threw out a government request to dismiss a lawsuit claiming the Obama Administration had violated FACA by setting up a de facto advisory committee of lobbyists from the pharmaceutical industry, the U.S. Chamber of Commerce, the AARP, AMA and others to build support for passing health care reform legislation.

The Clinton administration's health care reform efforts were also the subject of a suit under FACA. The administration eventually conceded the case and released all the records of committees it set up to work on reform legislation. That suit was brought by the American Association of Physicians and Surgeons.

Quitting the RUC?

The disenchantment by primary care physicians over the perceived favored treatment of their specialty colleagues has been going on for two decades and has brought the American Academy of Family Physicians (AAFP) Board to reconsider its longstanding participation in the RUC. At the AAFP's May 5th meeting, the Board decided to continue studying the implications of abandoning the RUC. They intend to announce a final decision before their next meeting in September.

"The mechanism for how (Medicare payment) codes are evaluated has contributed to the devaluation of family medicine and primary care through the years," said AAFP President Roland Goertz, M.D., M.B.A., of Waco, Texas. He added that it doesn't seem likely the current RUC process will change this imbalance. The AAFP is not calling for the elimination of the RUC, said Goertz. He noted that the AAFP has for years asked the AMA to provide more primary care physician representation on the RUC and to provide greater transparency in terms of how the RUC's votes are taken. "But there does not appear to be movement in that direction," he said.

Brian Klepper, Ph.D./Courtesy of Dr. Klepper

Brian Klepper, Ph.D. is the Managing Principal of Healthcare Performance Inc., a business development practice based in Atlantic Beach, Florida, and Chief Development Officer for WeCare TLC, LLC, an onsite clinic firm based in Longwood, Florida.

Admitting that he has a dog in the fight, Klepper and David Kibbe, M.D., MBA write there is a more insidious and destructive issue at hand in a July 20, 2011 *kaiserhealth.org* article titled, "*Quit the RUC.*"

RUC: Principle Driver of Excess

"The perverse incentives that are embedded in fee-for-service physician payments influence care decisions and are a principal driver of the health system's immense excesses.

"Encouraged by the RUC, sometimes unnecessary specialty procedures may appear more valuable and appropriate than primary care services. The system pays more for invasive approaches, so conservative treatment choices that are lower cost and lower risk to the patient may be passed over, especially near the end of life. The resulting waste, half or more of all health care dollars, has fueled a cost explosion that has led the industry and the larger economy to the brink of instability."

Klepper says there is overwhelming evidence that the RUC has used flawed and capricious methodologies.

"It has systematically under-valued primary care and operated without regard for financial conflicts of interest. Its influence has compromised care quality and facilitated the primary care labor shortage.

"The Chair of the Medicare Payment Advisory Commission (MedPAC) is on record before a Congressional Committee describing its harmful characteristics. We know that the valuations it recommends—and CMS accepts—are major contributors to unnecessary utilization and cost. Former CMS Secretary Tom Scully has publicly condemned it as 'indefensible'."

Klepper told *OTW* that the RUC is a small group that was able to gin up health care costs to the point of the U.S. spending twice what our nearest industrialized colleagues around the world pay.

Kathleen Behan, the constitutional lawyer who filed the lawsuit for The Georgia Six saw the story and called Klepper. Klepper hooked her up with Fischer and the lawsuit was on.

Courts Over Politics

Fischer says he and the other plaintiffs decided to go to court instead of Congress or CMS because the AMA, which spent $8.5 million lobbying Congress and federal agencies during the first six months of 2011, has built strong ties in Washington.

"We certainly don't have the money that the AMA has," Fischer said, "but we have the law on our side. At some point you have to rely on being right instead of being rich."

Not surprisingly, the AMA disagrees with Klepper and Fischer about claims of specialty bias.

AMA Defends RUC

On their website, the AMA states, "One of the common criticisms of the RUC

has been a purported bias to non-primary care specialties. However, it is important to note that the RUC does not review "primary care" or any specific specialty in terms of relative value. Rather, it reviews the relative value of individual services that physicians perform—regardless of specialty.

"Even as Medicare payments for many physician services have steadily declined over the past two decades, the RUC has taken significant steps to improve reimbursement for services that are performed by primary care including:

- Recommended increases in 1995 for evaluation and management services that resulted in a shift of $2.7 billion and net increases for family practice and internal medicine of 2.0% to 2.5%.
- The shifting of more than $4 billion to evaluation and management (E & M) codes—which are largely provided by primary care practitioners—from other physician services in the 2007 Fee Schedule.
- A 37% increase in the work values associated with an intermediate office visit (CPT 99213), the most frequently billed Medicare physician service for family practice and internal medicine physicians
- A 22.5% increase in payments to primary care between 2006 and 2011.

The AMA says that last increase was a result of the RUC recommendations. (Was that a "Quack"?)

Shrinking Pies and Ducks

The health care piece of the federal spending pie is under extreme pressure as Congress looks for spending cuts and a mandated 29.5% cut to physician payments by the end of the year. Is The Georgia Six challenge going to set the stage for other competition between physicians over a shrinking pie? We'll soon know if the AAFP withdraws from the RUC and if a judge decides the RUC is a duck. ◆

Orthopedics in Medical School? 'Bout Time

By Elizabeth Hofheinz, M.P.H.

Orthopedic surgeons are tough… but even they can get tired of hitting their heads against a brick wall.

Alas, it's an old tale of woe for the field… insufficient exposure to musculoskeletal issues in medical school. There have been numerous calls for action, as well as a 2004 National Ambulatory Medical Care Survey indicating that musculoskeletal conditions were the number one reason for visits to physicians' offices.[1] *Why* has this situation not been addressed? "Politics," says our expert, "…*some* physicians are playing politics with the medical school curriculum." This orthopedist decided to do something about it.

Wikimedia Commons and Ed Edahl

Our expert is Dr. Charles Day, Associate Professor of Orthopedic Surgery at Harvard Medical School and Chief of Hand and Upper Extremity Surgery at Beth Israel Deaconess Medical Center. Alarmed by the fact that medical students were showing up at the Harvard clinic in their third year with little understanding of what actually causes orthopedic injuries, Dr. Day embarked on a study to examine whether medical students have sufficient skills to handle even routine orthopedic cases.

Dr. Day: "I saw that our medical students had no exposure to orthopedics until they chose it as an elective in their third year. This can be very dangerous for patients. These young doctors 'hit the wards' in their third year with no understanding of the pathophysiology of certain diagnoses. They are learning things by rote memory and don't grasp the underlying mechanisms at play. Let's say someone comes in with wrist pain and the student doctor orders a brace. What he or she doesn't know is that there may be a scaphoid fracture, something that has a high rate of avascular necrosis. If the patient is young then all of a sudden this person is doomed to early arthritis in his early 30s because the medical student didn't understand the pathology."

Delving into the "back story," Dr. Day states, "Our medical school had a musculoskeletal block for 30 years but it was 95% rheumatology. The problem is that most of what doctors are seeing in clinic isn't rheumatology…it's run of the mill orthopedics (sprained ankles, carpal tunnel, etc.)."

When he brought his concerns to those in charge, Dr. Day says he received a response that is typical around the country: 'Well, they do fine.' Not so much, it turns out. Dr. Day: "We compared the students' confidence in performing history and physical exams to their confidence in handling pulmonary problems—we found a statistically significant difference. Here is how

"These young doctors often have a kneejerk reaction to send someone to PT for musculoskeletal pain…but they really don't know what they are sending them for."

this might play out clinically: a patient comes in with 'hip pain,' which, many times can be solved with a round of physical therapy (PT) and anti-inflammatory medication. But if you do not know how to look for the underlying issues, you may miss, for example, that there are some lumbar radicular nerves being pinched. These young doctors often have a kneejerk reaction to send someone to PT for musculoskeletal pain…but they really don't know what they are sending them for."

The good news? The student doctors think musculoskeletal medicine is important. Dr. Day says, "We asked 450 Harvard medical students how important musculoskeletal medicine was to their careers (regardless of what specialty they were going into). The majority indicated that on a scale from 1 to 5 with five being 'most important,' musculoskeletal medicine was a '4.' When we asked them to rank musculoskeletal medicine compared to seven other organ systems, it went as follows: number one was cardiology, followed by pulmonary medicine…musculoskeletal medicine was number three."

When strategizing about how to use this data for change, the savvy Dr. Day knew enough not to sing to the choir. "Most studies demonstrating that there is insufficient attention to the musculoskeletal system in medical school are published in the *orthopedic* literature. Given that most of the senior leadership in medical schools are *not* orthopedists, I decided to publish my results in a journal read by most senior medical educators in the country—*Academic Medicine*."

Stirring the pot, he was. "I wandered the halls and met with several Harvard Medical School course directors asking, 'Could I administer this survey to your students?' This created a buzz about the topic, several senior medical educators got involved, and that led to the creation of a task force that was appointed by the Harvard Medical School curriculum committee. In 2006, this group of orthopedists, rheumatologists, radiologists, anatomists, and primary care physicians all came to the conclusion that there was, in fact, a deficiency in musculoskeletal medicine at Harvard."

Then, they gave him the keys to the kingdom. "The task force selected me to be the one to create a four-year musculoskeletal curriculum. I began by focusing on the most common diagnoses that a primary care doctor would encounter…and then I worked backwards to include the pathophysiology and relevant anatomy of those diagnoses. The curriculum includes carpal tunnel syndrome, rotator cuff impingement, among other common conditions. I also cover things that are uncommon but are so serious that you can't afford to miss them (tumors, infections, compartment syndrome)."

"As part of this curriculum, first-year medical students at Harvard are exposed to significantly more anatomy than in the past. It used to be that as part of an anatomy course, students dissected *either* an arm or a leg, but not both. Now, we have increased the orthopedic anatomy dissection time by 40%—and they dissect both an arm and a leg. Also, these students are now exposed to orthopedic surgeons in their lectures; before this program, there were no orthopedic surgeons engaging with them in year one."

Year two is the heart of the matter, says Dr. Day. "Traditionally, it is year two when students are introduced to the

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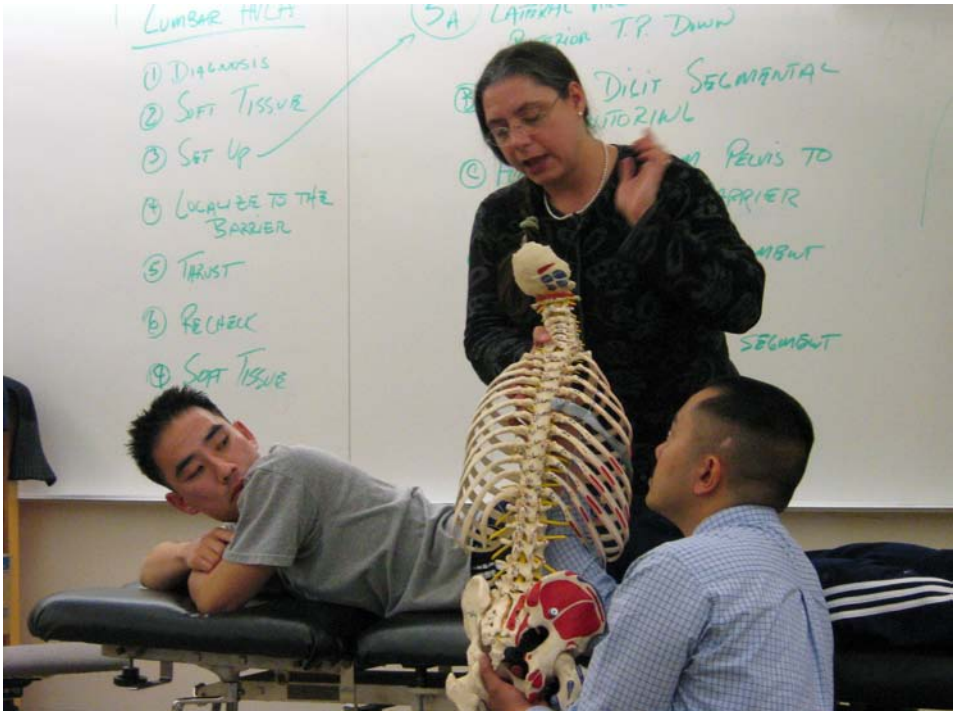


Wikimedia Commons and Ed Edahl

pathophysiology of different organ systems, thus that is where the majority of our additions were. The 'old' musculoskeletal course was six days long and 95% rheumatology. Now, rheumatology has four days and orthopedics has four days."

"There are 20 hours covering the pathophysiology of orthopedics, along with a physical exam course that includes two afternoons dedicated to orthopedic physicals. We spend eight hours on the knee, low back, hand, and shoulder exam; unfortunately, we don't have time to cover the hip, elbow, ankle, or neck." This past January, Dr. Day "went to press" with an assessment of the results of this curriculum. The study, published in the *American Journal of Orthopedics,* found that medical students at Harvard did in fact report significantly higher levels of clinical confidence in performing orthopedic physical examinations.

If you're wondering how to get your institution on board with such a program, says Dr. Day, you have to be comfortable with the role of persistent lobbyist. "Getting musculoskeletal medicine into years one and two has been such a big political battle that a lot of people have just given up. Take heart, though…it is possible if you approach things—and people—in the right way. First of all, in approaching the Dean you will likely encounter a response along the lines of, 'Everyone else wants more time for their subspecialty so whose curriculum do you want me to cut?'"

But let's assume that you're guided by the principle that the curriculum should be dictated by patient needs. "You can point to the vast array of studies out there, including mine and some great work from Washington University in St. Louis or the University of Pennsylvania. You must first have a clear understanding of the current curriculum at your medical school…don't be fooled by the name of the course. As we have seen, something called 'musculoskeletal medicine' may be nearly all rheumatology."

"If you find a deficiency then you must prove to medical educators (most of whom are internal medicine doctors) that change is necessary. And, if you are going to go through the evaluation process then you may as well publish the results of your effort."

Dr. Day continues to lead this charge, expanding his efforts to help other medical schools around the country. "Those at the leadership level of the American Orthopaedic Association are very invested in this movement, and in fact have recently hosted a symposium that was chaired by Dr. Martin Boyer of Washington University in St. Louis. On

"Getting musculoskeletal medicine into years one and two has been such a big political battle that a lot of people have just given up. Take heart, though…it is possible if you approach things—and people—in the right way."

a Saturday morning at 7am we had over 50 faculty members show up to learn how to bring a musculoskeletal curriculum to their institution."

"For years orthopedic surgeons have known that our specialty was being left out of medical schools. The overarching problem is that it is rare for orthopedic surgeons to be in senior leadership positions at medical school. I don't know if that part is going to change any time soon, but in the meantime, we can't let politics interfere with patient care. We have to lead this charge and get the medical students the education they need to help our patients." ◆

[1]*Hing E, Cherry DK, Woodwell DA. National Ambulatory Medical Care Survey: 2004 summary. Adv Data. 2006;(374):1-33.*

company

Zimmer Closes North Carolina Plant

Zimmer Holdings, Inc. is closing its surgical products plant in Statesville, North Carolina.

The Charlotte Business Journal reported on August 16 that the company had notified the State of North Carolina that it was permanently closing the plant which makes tourniquets and slings.

Source: Wikimedia Commons

The closing will eliminate 124 jobs by the end of the first quarter of 2012.

The article states a Zimmer spokesperson said the company is streamlining its operations and will produce goods made at the Statesville plant at other locations. Zimmer Surgical manufactures surgical products in Statesville and Dover, Ohio.

According to Zimmer's web site, the Zimmer A.T.S. 3000 Automatic Tourniquet System is a dual-port, dual-cuff system with microprocessor controls and dedicated ports for supplying and measuring pressure independently.

The Statesville plant received a National Safety Council award for Occupational Safety Excellence and its Lift Truck Operation Program and achieved 1,000,000 safe hours (approximatly 2-1/2 years) in March 2005.

Statesville, home of the CrossRoads PumpkinFest and the Carolina BalloonFest, is located at the intersection of Interstate 77 and Interstate 40.

—WE (August 17, 2011)

legal

U.S. Joint Registry Completes Pilot Phase

The pilot phase of the AJRR (American Joint Replacement Registry) project has been completed.

Hospitals from eight different reporting sites in the U.S. submitted data on more than 3,600 primary and revision hip and knee replacements over a period of a few months.

The AJRR board of directors received an update report on the pilot project, covering lessons learned and data analysis, at their July 9, 2011 meeting, according to the August issue of *AAOS Now*. The board also began to formulate strategies for outreach recruitment, expansion of registry staff, and efficient data collection methods as the registry moves from the data trial to full production.

"The AJRR has an aggressive timetable," said David Lewallen, M.D., chair of the board. "We hope to achieve 90% participation by hospitals by October 1, 2013, so we are actively recruiting

morgueFile/AAOS/RRYImage Creation

surgeon and staff champions across the country. We are also proceeding with plans to hire a medical director and to expand our support staff who will work with participating hospitals."

Lewallen said the greatest value of registries "is in their ability to identify outliers in implants, hospitals, and surgeons. Registry data typically enable us to ask intelligent questions that require more study; they don't give us answers."

Date Collection Strategy

The AJRR data collection strategy, according to Lewallen, is to start with level one data and add data elements incrementally.

Level-one data collection at this level is an institutional responsibility and includes several core data elements, such as:

- patient data (name, sex, date of birth
- social security number
- ICD-9 code for diagnosis)
- surgeon data (name, number of surgeries performed)
- procedure data (ICD-I code for type of surgery
- date of surgery
- patient age (at surgery, laterality, implant)
- and hospital data (name, address, number of surgeries performed there).

Each patient, surgeon, and hospital has a unique identifier, which enables index procedures to be linked to subsequent events, permits patients to access their own information, allows data to be linked to other databases, and helps maintain confidentiality.

Level-two data include variables such as the patient's body mass index and any comorbidities, as well as process of care data such as antibiotic prophylaxis. Level-three data focus on outcomes and patient satisfaction, while level-four data (such as radiographs) provide a more in-depth analysis of why and how implants or procedures fail.

Next Step

The next step is for the registry to hire a medical director to supervise operations. Lewallen said the board is also moving toward to implement systems that will enable a wide range of hospitals and systems to participate and submit data.

—WE (August 16, 2011)

AAOS Supports Ryan Medicare Privatization Plan

The American Academy of Orthopaedic Surgeons (AAOS) wants to privatize Medicare and loves the plan to change Medicare put out earlier in the year by Wisconsin Republican Congressman, Paul Ryan, chair of the House Budget Committee.

In the August 2011 edition of AAOS Now, John T. Gill, M.D., chair of the AAOS Advocacy Resource Committee, writes in a column titled, "Is Congress Finally Listening?" that Congressman Ryan's plan to privatize Medicare reflects many positions held by AAOS.

The Ryan plan passed by the U.S. House of Representatives in April, but not acted on by the U.S. Senate, called for "the most significant changes to Medicare since its inception in 1966," according to Gill.

Voucher or Premium-Support

Ryan's plan was highly controversial as Democrats characterized the plan as a voucher system for Medicare recipients that would end Medicare as we know it and put seniors at the mercy of insurance companies and make them pay more for of their own healthcare bills. Republicans rejected that characterization, saying the plan, starting in 2022, would provide Medicare beneficiaries with a premium-support payment, which they could use to choose a healthcare plan from a variety of private options.

The plan was also controversial with some Republicans, as former House Speaker and presidential candidate Newt Gingrich called the plan, "too big a jump," and said he would be against a conservative imposing "radical change."

Eligibility, Payment, Tort Reform and More

The Academy also supports Ryan's proposal to incrementally raise the eligibility age for Medicare to be consistent with Social Security. Under the Ryan plan, writes Gill, the age of eligibility for Medicare would increase by two months per year, starting in 2022, until it reaches age 67 in 2033.

On a number of other issues, including: Medical Savings Accounts; SGR (Sustainable Growth Rate), Tort Reform and Managed Care, Gill notes the Academy's agreements with Ryan's plan.

Congressman Paul Ryan Source: Wikimedia Commons

AAOS strongly supports the concept of a Medicare Medical Savings Account (MSA). In such a system, Medicare would deposit a certain amount of money into an MSA at a bank chosen by an insurance plan. Critics say the amount deposited into the account will generally result in beneficiaries having high out-of-pocket costs to pay until deductibles are met.

On tort reform, the Academy likes the Ryan plan's cap on noneconomic damages in medical liability lawsuits.

The Academy also likes Ryan's plan to eliminate fraud and abuse by transferring the responsibility for benefits and claims to private insurers.

Successful AAOS Advocacy

"The Ryan plan is, in part, a result of the AAOS's persistent advocacy efforts on Capitol Hill. It is consistent with the AAOS principles that the Medicare program should move toward privatization, engender more individual responsibility and cost sharing by beneficiaries, have a higher eligibility age, and correct the flawed SGR physician payment formula," writes Gill.

End-of Life Versus Life Improvement Care

As Congress' promised austerity budget pits more providers and new procedures against each other in a slower growing public funding pie, AAOS has staked out a position which points out that much of Medicare's spending is spent on patients in the last six months of their lives. It follows that the Academy sees a better chance of patients gaining access for life improvement procedures if Medicare is privatized and patients are forced to make their own decisions about where to spend scarce resources.

—WE (August 15, 2011)

biologics

Stanford Study IDs Teratoma Cells

A discovery by the Stanford University School of Medicine involving human embryonic stem cells may have significant benefits for pluripotent stem cells created in the laboratory from adult tissue. (Pluripotent cells are cells that have the capacity to become all types of human tissue.)

A continuing problem inhibiting the use of embryonic stem cells is that any cells that have not differentiated into the desired tissue may go on to become tumors, called teratomas, when injected into patients.

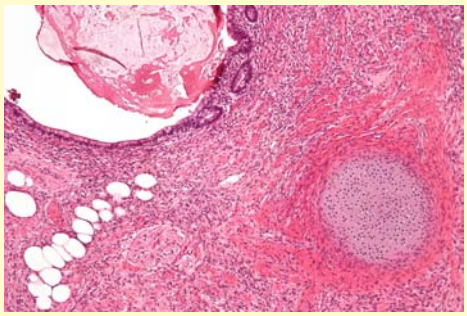
"Because even a single undifferentiated cell harbors the ability to become a teratoma, we sought to develop a way to remove these cells before transplantation," said Micha Drukker, Ph.D., the senior author of the research, which will be published online August 14 in *Nature Biotechnology*.

"The ability to do regenerative medicine requires the complete removal of tumor-forming cells from any culture that began with pluripotent cells," said Irving Weissman, M.D., director of the Stanford Institute for Stem Cell Biology and Regenerative Medicine. "We've used a combination of antibodies to weed out the few undifferentiated cells that could be left in the 10 or 100 million differentiated cells that make up a therapeutic dose."

The researchers studied two sets of antibodies—one commercially available and one they generated themselves—to identify which among them bound most strongly to pluripotent, but not differentiated, cells. They found one newly generated antibody that was highly specific for a previously unknown marker on undifferentiated cells.

Stanford University has filed for patent protection for the use of monoclonal antibody-based protocols to remove teratogenic pluripotent stem cells from a cell mixture.

—BY (August 18, 2011)



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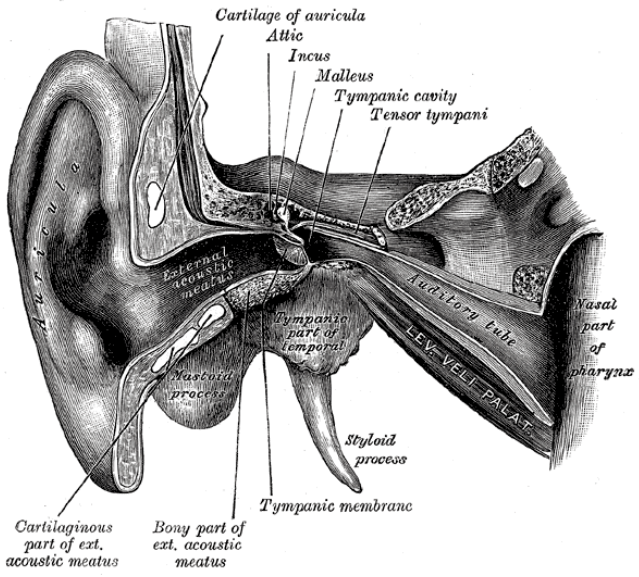
Ear Stem Cells for Cranial Maxillofacial Repair

A team of Japanese scientists has successfully grown chunks of cartilage from stem cells in the ear, which could replace the synthetic materials currently used in surgery.

Takanori Takebe at Yokohama City University in Japan and Professor Shinji Kobayashi, lead authors of the study published in the August 11 issue of *Proceedings of the National Academy of Sciences* confirm that the ear contains a source of stem cells, hidden in tissue



Wikimedia Commons and Grays Anatomy

called the penchondrium. The penchondrium is a thin layer of connective tissues that covers and protects cartilage in the human body. His team removed part of the penchondrium from human ears and injected it into mice where they successfully grew cartilage.

"We are now preparing for the first clinical application [of the technique] in our university hospital," said Takebe.

Researchers had already discovered the regenerative potential of stem cells taken from the ears of adult rabbits but this Japanese study is the first to find these stem cells in the human ear.

Kobayashi and his associates developed a technique to grow the stem cells efficiently and report that the stem cell-derived cartilage they grew and transplanted under the skin of mice has been stable for ten months. The authors note in their paper that there is demand for more effective treatments for craniofacial injuries or abnormalities. Their discovery of this new, easily-accessible source of adult stem cells together with their technique for efficient growth of cartilage would allow patients suffering from craniofacial deformities to be treated with reconstructive material grown from cells collected from their own ears. The researchers hope to start a clinical study as early as 2012.

—BY (August 18, 2011)

large joints

OrthoSensor and Stryker Partner for "Smart" Knee Surgery

OrthoSensor, Inc. and Stryker Corporation's Orthopaedics Division have announced an agreement whereby the former will provide its OrthoSensor Knee Trial for use with latter's Triathlon knee system.

The announcement on August 17 said the OrthoSensor Trial provides quantitative, intra-operative feedback to surgeons to optimize joint balance during total knee replacement surgery.

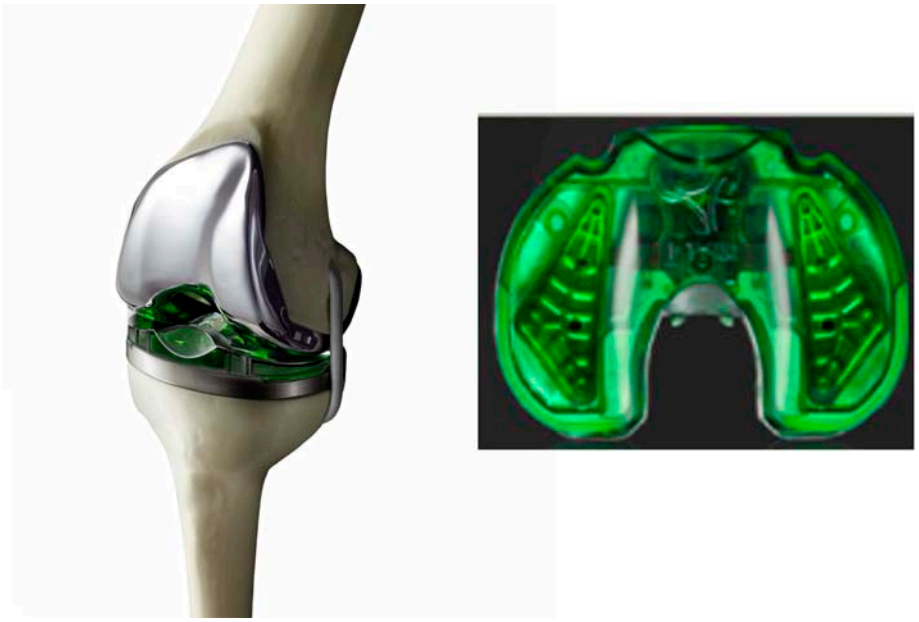
This is done through embedded microelectronics and sensors in single-use trial inserts, delivering data to optimize the final ligament balance and patients' specific joint kinematics. The sensor wirelessly transmits key information to a graphic display of real-time feedback, enabling the surgeon, according to the press release, to visualize and quantify joint loading and balance. The surgeon can then modify implant positioning, adjust legs alignment and optimize soft tissue balance through a full range of motion.

"The single radius design philosophy of Stryker knees is a perfect complement to OrthoSensor's innovative technology," said Doug Leach, vice president of global research and development, knee reconstruction at Stryker Orthopaedics.

OrthoSensor raised $21 million in a Series B round this past January. There was an undisclosed "major medical-device" contributor to that round of financing.

The company aims to bring integrated circuits, radio-frequency identification, accelerometers and other advanced sensor to implantable orthopedic devices, said OrthoSensor CEO Jay Pierce.

"This is a new category," said Pierce in a January 27, 2011 *Wall Street Journal* article, referring to converging consumer electronics with medical devices.



OrthoSensor Knee Trial/Stryker Orthopaedics

OrthoSensor is the only company adding integrated circuits to orthopedic devices, Pierce said. While pacemakers and other implantables feature some circuitry to communicate with doctors, orthopedic devices have so far never included advanced sensors, he added.

Once a doctor implants a high-tech hip, knee or other body part, the doctor can access real-time information about how the implant is performing, and how the patient is reacting to the operation, Pierce said.

"The plan is to monitor early signs of infection, bone ingrowth and other problems," he said.

While the company is selling its knee-balancing system today, the main effort is to get approval for smart devices that stay inside the body and constantly update orthopedic surgeons on how their patients are doing.

—*WE (August 19, 2011)*

DePuy Joins Customized Knee Surgery Club

DePuy Orthopaedics, Inc. has jumped into the customized knee replacement surgery market with the FDA clearance for the use of its TruMatch Personalized Solutions with the company's Sigma Fixed-Bearing Knee System.

The company joins Biomet, Inc. and Stryker Corporation, among others, with a personalized knee surgery system.

Reduced OR Time

The system, available immediately, is a surgical instrumentation and computer software system that, according to a company statement, is designed to aid in knee implant positioning and procedure efficiency. The company says the system will help reduce costs by decreasing OR time by an average of 35 minutes. The procedure will require less instrumentation and eliminate up to nine surgical steps compared to total knee replacement performed without the system.

DePuy's new president, Andrew Ekdahl, said the system has the potential to improve patient care while reducing costs.

Daniel Hoeffel, M.D., of Summit Orthopaedic Group in St. Paul, Minnesota, said the technology, "helps surgeons consistently provide knee replacement patients a customized fit and enables them to do the operation in less time. Patients, surgeons and the health care system all benefit from advancements in technology that provide greater efficiencies and individualize treatment."

Femoral and Tibial Cutting Blocks

The company says TruMatch is the first system to utilize CT scans and computer software to guide the development and production of femoral and tibial cutting blocks that are individually prepared to match the actual bone surfaces of each patient. Precise positioning of the knee implant is critical to its overall performance. Also, the use of CT scans, rather than MRIs, results in improved bone imaging, less scanning time and lower costs.

—WE (August 19, 2011)

TruMatch Personalized System/DePuy Orthopaedics, Inc.

Kneecap Reconstruction a Viable Option

Five percent of 500,000 is 25,000. That is the number of patients who got a knee replacement last year who might have been just as well served by having a smaller, more focused surgery. That surgery would have reconstructed just their kneecap—called the paellofemoral.

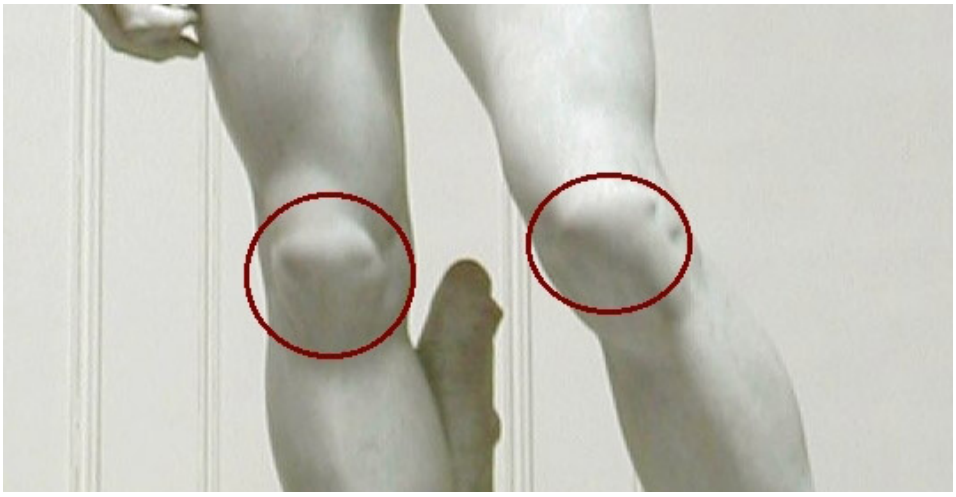
Dr. Ronald Grelsamer, chief of patellofemoral reconstruction at Mount Sinai Medical Center, says, "A type of partial knee replacement, called a patellofemoral replacement, is an option for patients with kneecap arthritis. It's a partial knee replacement that replaces only the kneecap and the underlying femoral groove, leaving all the healthy structures of the knee intact."

The kneecap is a bone with a thick undersurface of cartilage. "The kneecap glides within a groove, and that groove also has cartilage," says Grelsamer. "The cartilage is durable, but like the brakes in your car, it can wear down." When the undersurface of the kneecap wears out and a condition called patellofemoral arthritis develops, patients may benefit from a patellofemoral replacement. "The classic symptom is persistent pain at the front of the knee, often experienced as a painful catching or locking sensation," says Grelsamer.

Patellofemoral partial knee replacement is an option for patients with kneecap arthritis that hasn't responded to other therapies. "We're talking about a surgical procedure that is wonderful, but it's the last stop on the railroad track, not the first. We remove the worn out cartilage from under the kneecap and replace it with a plastic button, and we replace the groove's worn-out—cartilage with a small, thin, custom metallic piece."

It's a little like capping a tooth, he says. Compared to a total knee replacement, a patellofemoral replacement offers a quicker recovery and less blood loss.

"The operation takes about an hour, and people are usually in the hospital two days. Patients are usually on crutches for a week and a cane for two weeks, followed by two months of physical therapy," says Grelsamer. "The pain relief can be spectacular."



Michelangelo's David's Kneecaps/Wikimedia Commons and David Gaya

Patellofemoral partial knee replacement is a rare surgery in the U.S., though it is fairly popular in Europe. "This procedure has been a real research breakthrough," says Grelsamer. "It's appropriate for nearly all ages—in particular people who consider themselves too young, too old or too sick for a total knee replacement."

—BY (August 15, 2011)

Pirate Move Relocates Hip

Chris from Illinois and friends show off their Captain Morgan pose in Iraq

Need to wrestle a dislocated hip back into place in a hurry? According to a study posted online in ***Annals of Emergency Medicine*** one should use the "Captain Morgan Technique for the Reduction of the Dislocated Hip." Named for an 18th century English pirate, the technique involves the caregiver assuming a pose popularized in the advertisements.

"This novel technique based on a familiar advertising figure is a classic example of how emergency physicians are masters of improvisation when it comes to advancing emergency care," said study author Gregory Hendey, M.D., of the University of California San Francisco Fresno. Researchers reviewed case records for 13 patients on whom the Captain Morgan technique was

used. The only failure was for a patient who fell while roller skating, sustaining a fracture-dislocation of the hip that required surgical repair.

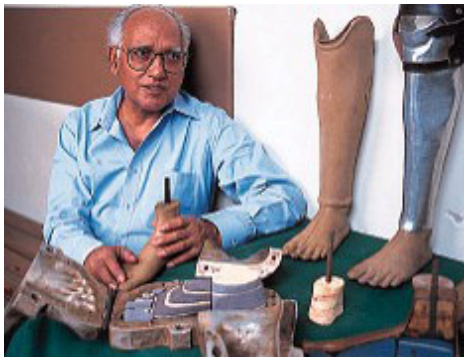
"The technique allows the physician to remain standing on the floor—as opposed to straddling the patient on a gurney—while easily and safely applying the necessary force to the patient's hip to pop it back into place," Hendry said.

The procedure is named for Captain Morgan because the physician stands with a bent knee and one foot up on the gurney—the classic Captain Morgan pose. The physician places his knee behind the supine patient's flexed knee and lifts and rotates the hip back into place. Other methods of hip reduction risk physician falls or back injuries as well as knee injuries to patients. "Physicians should consider the Captain Morgan technique first when treating a patient with a dislocated hip," said Dr. Hendey.

—BY (August 15, 2011)

Prosthesis for the Poor—A $20 Knee

It almost makes one believe in miracles. In 1967, in India, an orthopedic surgeon by the name of P. K. Sethi hired a craftsman named Ram Sharma to teach art as therapy to polio victims at the Sawai Man Singh [SMS] Hospital in Jaipur.



Dr. P.K. Sethi, Inventor of the Jaipur Foot/Courtesy of Rotary Clubs International

Sharma watched doctors fitting amputees with impractical, expensive, imported artificial limbs and thought that he could do better. He devised a vulcanized rubber foot hinged to a wooden limb that they called the Jaipur Foot. Dr. Sethi helped Sharma improve the limb and its low cost, lightness in weight and ease of fabrication made it suitable for working people in the Third World.

The process to make the device is a simple one. The amputee's stump is covered with a knitted sock and a plaster of Paris mold is made. From this socket a plug is made which is an exact replica of the limb. High density polyethylene pipe is warmed and stretched over the plug. A vulcanized rubber foot is attached and suitable straps provided to hold the leg to the body. The fitting of the limb is done on the same day it is made and, within hours, patients are comfortable with their new limbs.

The Jaipur Foot would have remained a purely local item in Jaipur if Devendra Raj Mehta, a graduate of MIT's Sloan School of Management, had not been involved in an automobile accident. He was hospitalized at the same SMS hospital and, while recovering, saw the hundreds of poor, maimed people who were thronging the hospital in search of legs. They lived on the streets while they waited their turn for a fitting.

Though Mehta had ridden through the ranks of India to hold major public positions, he also founded BMVSS, an organization dedicated to providing artificial limbs to the poor. Thanks to Mehta's organizational skills, patients who arrive in daily waves at the hospital no longer live on the street. Instead the hospital staff feeds and houses them while their limbs are being made. They are then sent home walking.

Since 1975, technicians have fitted over 300,000 limbs—every one of them given away free. Thanks to Mehta's efforts, India has become the world leader in practical, low-cost prosthesis. And the Jaipur Foot has become available throughout India and 18 other countries. Notable for its lightness and mobility, amputees who wear the foot can run, climb trees and pedal bicycles.

Now BMVSS is installing a new device, a $20 artificial knee joint. Developed in cooperation with Stanford University it was named one of the 50 best inven-

tions in the world by *Time Magazine*. The knee joint came about when teachers of a Stanford class titled Biomedical Device Design and Evaluation challenged their students to create a low-cost, high-performance prosthetic knee joint for amputees in the developing world. Old models of low-cost knee joints used a single-axis joint, which rotated like a door hinge. These were unstable and unsafe as the joint tended to buckle under weight, making them dangerous and painful for an amputee.

To build a better model, the students studied the mechanics of high-end titanium knee joints in the United States. After surveying the materials available they designed a versatile knee joint made from an oil-filled nylon polymer. The self-lubricating joint is claimed to have remarkable flexibility. To date, Mehta has fitted 43 of these joints in patients in India. His goal is to mass-produce and distribute 100,000 knee joints in the next three years. Mehta's BMVSS enterprise now staffs 20 centers across India and services 65,000 patients each year—20,000 of whom require new feet and leg replacements.

Some information for this article was supplied by Rahim Kanani, founder and editor-in-chief of *World Affairs Commentary* and the Stanford News Service.

—BY (August 16, 2011)

extremities

Genomics: How RA Develops

Scientists at Mount Sinai Hospital, in collaboration with researchers at the University of Toronto, University Health Network and McGill University have obtained a more accurate understanding of how autoimmune conditions such as rheumatoid arthritis (RA) develop. The findings are published online in *Nature Genetics*.

Dr. Katherine Siminovitch and her team identified the exact means by which an alteration in the gene PTPN22 increases risk for RA and other autoimmune disorders. The study used advanced genomics technologies that enable testing of millions of genetic markers in a single experiment to identify genes, such as PTPN22, that confer risk for disease. The team then generated a mouse genetic model to show how the PTPN22 gene mutation impairs immune cell function and then validating their findings in humans, taking their discovery from the laboratory bench to the clinic.

"Our findings are particularly exciting because this study sets a new precedent for studying arthritis and other autoimmune disorders," said lead author Dr. Siminovitch, Senior Investigator and the Sherman Family Research Chair in Genomic Medicine at the Samuel Lunenfeld Research Institute of Mount Sinai Hospital, in the August 14, 2011 news release. Dr. Siminovitch is a professor at the University of Toronto, and Director of the Fred A. Litwin & Family Centre in Genetic Medicine.

"This is one of the first studies in which we have traced the steps that connect a specific genetic lesion to the development of a common, complex autoimmune condition."

The group used genetically modified mice in which PTPN22 had been altered to mimic a genetic mutation found in many RA patients. The effects of this change on immune cells were observed in the mice, and the studies were then repeated in human blood

Wikimedia Commons and Aaron Logan

samples from patients with and without RA. By this means, the group honed in on the impact of a key protein called Lyp/Pep that—in healthy cells—prevents the hyper-immune responses that lead to autoimmune disorders. The group found that this gene mutation leads to decreased levels of Lyp, thereby removing a natural brake that normally prevents the inflammatory processes underlying RA and many other autoimmune conditions.

"Measuring levels of this protein will help us monitor disease severity in patients with autoimmune disorders, test the effects of various therapies including new drugs, and determine which treatments work best in specific patients," added Dr. Edward Keystone, co-author of the study and Director of the Rebecca MacDonald Centre for Arthritis and Autoimmune Disease at Mount Sinai Hospital. "We are truly seeing genomics in action with this study, and the results give us new hope for improving patient outcomes."

—EH (August 16, 2011)

RA and Cardiovascular Disease

Researchers from Sweden have some somber news for those who suffer from rheumatoid arthritis (RA)…a new study has shown that they are at an increased risk of dying due to cardiovascular disease. The five-year study published in *Arthritis Research & Therapy* showed that the risk of cardiovascular disease for people with RA is due to disease-related inflammation as well as the risk factors which affect the general population. Treatment of arthritis with disease modifying antirheumatic drugs (DMARDs) also reduced the patient's risk of heart disease.

Over 400 people with RA were followed from date of diagnosis. After five years, 97% of the patients had been treated with DMARDs, reducing both the chemical markers of inflammation and the physical appearance of their arthritis. Patients were also looking after themselves better—fewer patients were smokers and their BMI (body mass index), and blood pressure, had reduced (due in part to treatment for high blood pressure).

Analysis of the patient data revealed that a new cardiovascular event such as heart disease, stroke or DVT could be predicted by intensity of their arthritis and by presence of diabetes, high blood pressure, and the level of triglycerides. Encouragingly treatment with DMARDs decreased the risk but COX-2 inhibitors appeared to predict a new event.

Dr. Wållberg-Jonsson from University Hospital, Umeå, in Sweden said in the August 14, 2011 news release, "Inflammation associated with rheumatoid arthritis increases patients risk of heart disease and other cardiovascular events. However it is possible to reduce this risk in a two-pronged attack by treating both the inflammation and traditional risk factors for heart disease."

Dr. Wållberg-Jonsson told *OTW*, "It is well known by now from publications by us and others that cardiovascular disease (CVD) is increased in patients with RA. Traditionally, the established cardiovascular risk factors (like hypertension, lipid levels, diabetes, smoking, BMI) are not particularly striking in RA and other reasons have to be looked for. There have been implications that the inflammatory activity contributes to CVD in RA. Most previous studies in this field (including ours) are, however, cross-sectional or retrospective. The present study was designed in a prospective manner which makes blood sampling of all patients possible and info on i.e., pharmacological treatment more reliable. Only single studies of prospective nature have been published in this field up until now."

Looking forward, Dr. Wållberg-Jonsson commented to *OTW,* "Almost 1000 patients have been included in the present cohort, of whom over 600 have been followed for more than 5 years and around 300 for 10 years. Thus, we plan future follow-ups regarding progression of CVD and contributing factors. Hopefully, our results can be of use for the cardiovascular prevention in patients with RA. The aim is also to study other forms of comorbidities than cardiovascular disease. A study on the impact of gender and age at disease onset on cardiovascular and other comorbidity is under way."

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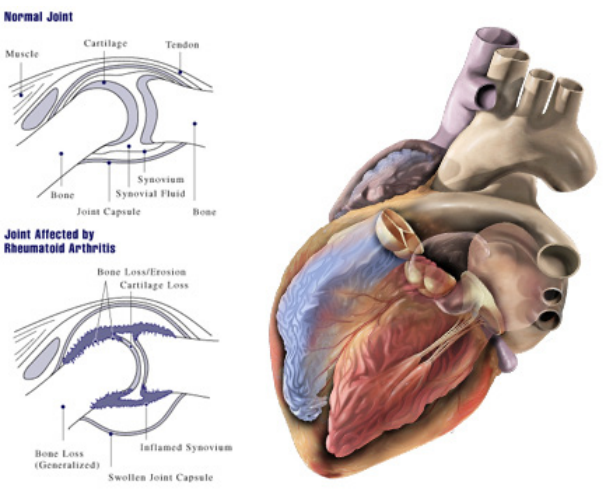

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THE PICTURE OF SUCCESS

Dr. James Herndon

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

Dr. James Herndon

His eye is on the sparrow—the Life of Dr. James Herndon.

For two years, the toddler's diagnosis had eluded his doctors. "I was examining this child. He was on the exam table with his back to me. There was a pile of books on the edge of the table. I turned around and mistakenly knocked the books over. They hit the floor with a 'bang,' but this young child didn't hear it. That's when I realized he was deaf. I actually made my reputation on the pediatric service at 'Penn' when I made that diagnosis."

Talking to Dr. Herndon is a wonderful experience and in his stories one theme emerges—the importance of the little things in medicine (if not also in life and faith).

Like preventable errors.

Each year 44,000 to 98,000 people die in hospitals as the result of preventable medical errors.[1]

After an illustrious career that included chair positions at Harvard, Brown and "Pitt" and as he was waiting his turn in the Presidential line of succession at the American Academy of Orthopaedic Surgeons (AAOS), those words from an Institute of Medicine (IOM) report really hit home. "Here," thought Dr. Herndon, "is an opportunity for change."

"I read the entire Institute of Medicine report, and I began to think more deeply about making hospitals safer for patients. It was evident that my colleagues and I were getting caught up in the intricacies of our days; we were not making time to look at how the flaws in our system put patients in jeopardy."

Leading AAOS, Teaching Residents

Dr. Herndon was a natural fit for the helm of AAOS. But once the membership learned of his "theme"—patient safety—did they groan? "I had spent a lot of time at meetings about wrong site surgery, time outs, etc., and I felt like we should be a leader in patient safety. And, I felt strongly that if we were going to advocate on 'the Hill' for malpractice and Medicare reform, we should have patients with us to advocate for our joint interests. Otherwise, we would be viewed as fat cats. There was some grumbling, however, because the fact is that you can't discuss patient safety without talking about mistakes. And who is fond of that?"

"Most of us go along and think that we are doing a good enough job of discussing complications, consulting with other doctors, etc. The problem is that we usually don't look at the system wide issues. For example, is the culture of the institution such that residents feel comfortable reporting a near miss or are they fearful of being a whistle blower? My recent research on residents shows there is great deal of concern about the repercussions of reporting."

And, having trained over 300 residents as they rode the roller coaster between exuberance and reality, Dr. Herndon has a good sense of their needs and concerns. He listens, and he counsels.

"There was some grumbling, however, because the fact is that you can't discuss patient safety without talking about mistakes. And who is fond of that?"

"I tell them, 'Look, in the first two years out of residency you will feel very confident and on top of the world. The next year you will see things in a different light, and realize that there is always something that you don't know. Part of the challenge is that musculoskeletal medicine is a huge field, but doesn't get much attention in medical school. My early family experiences rear their head as well…I tell residents that instead of moonlighting they need to spend time with their families."

And, advises Dr. Herndon, watch for hubris. "Leaders must do the work themselves…not just tell others what to do. I have seen some individuals get overly impressed with themselves and take advantage of the benefits offered by their leadership role. When I see this, I just may pull a colleagues aside and point out the errors in their thinking."

Hard Earned Lessons

"I was born in Los Angeles, where I lived with both of my parents until they divorced when I was six. I think we never know the exact effect of these things…over the years my wife and kids have asked me about this period in my life, but frankly, I have probably repressed a lot of it. The only positive thing about being a child of divorce is that it has given me a sensitivity to the concerns of patients and families. For example, during my internship at the University of Pennsylvania I had a child die of leukemia. I will never forget the pain involved when I had to tell his family…it was the first time that I had had the full responsibility for someone who died."

Dr. Herndon's ability to tune into all aspects of patient care—no matter how small—did not come easily. Before entering medical school a gravely injured Jim Herndon lay in a hospital bed. He, of course, recovered fully but that experience of facing death and recovering changed him more than anything else. "I was a senior in college when I had a catastrophic car accident; I spent several weeks in the hospital with a crushed chest. Although I had lost my (fully completed) medical school applications in the wreck, I persisted, and received significant support from my biology professor, who allowed me to return to school. Throughout this experience I benefitted from the skill and compassion of my doctors, and I came to see that I wanted the challenge of caring for people with major problems."

For Jim Herndon, this definitely trumped being a butcher. "I was fascinated with anatomy from an early age, and I even worked as butcher in high school and college. I did not, however, advertise this to my patients."

The Lessons of Chairmanship

Years later, Dr. Herndon was recruited back to his Harvard alma mater, where he distinguished himself as a leader. "I was brought in at the height of managed care to develop an integrated delivery system model for orthopedics at Massachusetts General and Brigham and Women's Hospital. I created a practice plan at each hospital but could not merge the doctors because the hospitals' cultures were too different. They have both improved because of the competition, but work remains to be done as far as speaking and acting with a unified voice. For one, I had hoped that we could make it easier to get patients into the hospital. So, for example, if orthopedics was full at Mass General, wouldn't it be ideal if we could admit

"I tell them, 'Look, in the first two years out of residency you will feel very confident and on top of the world. The next year you will see things in a different light, and realize that there is always something that you don't know."

patients to Brigham and have the doctor from Mass General come over? I pushed the envelope too far, however…that wasn't going to happen."

But he had accomplished his mission, in part thanks to some tough lessons from another university. When Dr. Herndon took the orthopedic reigns at Brown, he encountered resistance. "I was the first full time orthopedic surgeon…and I was young and naïve. There were 80 orthopedists on staff, but nobody was teaching, and nobody was covering the ER or clinics. Over ten years I recruited numerous staff, started labs, and fought with the head of the department of surgery about orthopedics becoming a department. I finally won this battle by going to the university's board of trustees. After two years of wrangling with the part time orthopedists I just declared that we would *all* take call, cover clinic, and teach. Twenty orthopedic surgeons got on board while the other 60 said, 'Go to hell.' But I received the full support of the trustees and the remaining part time clinicians and additional full time recruited faculty worked well together as the department flourished clinically and academically."

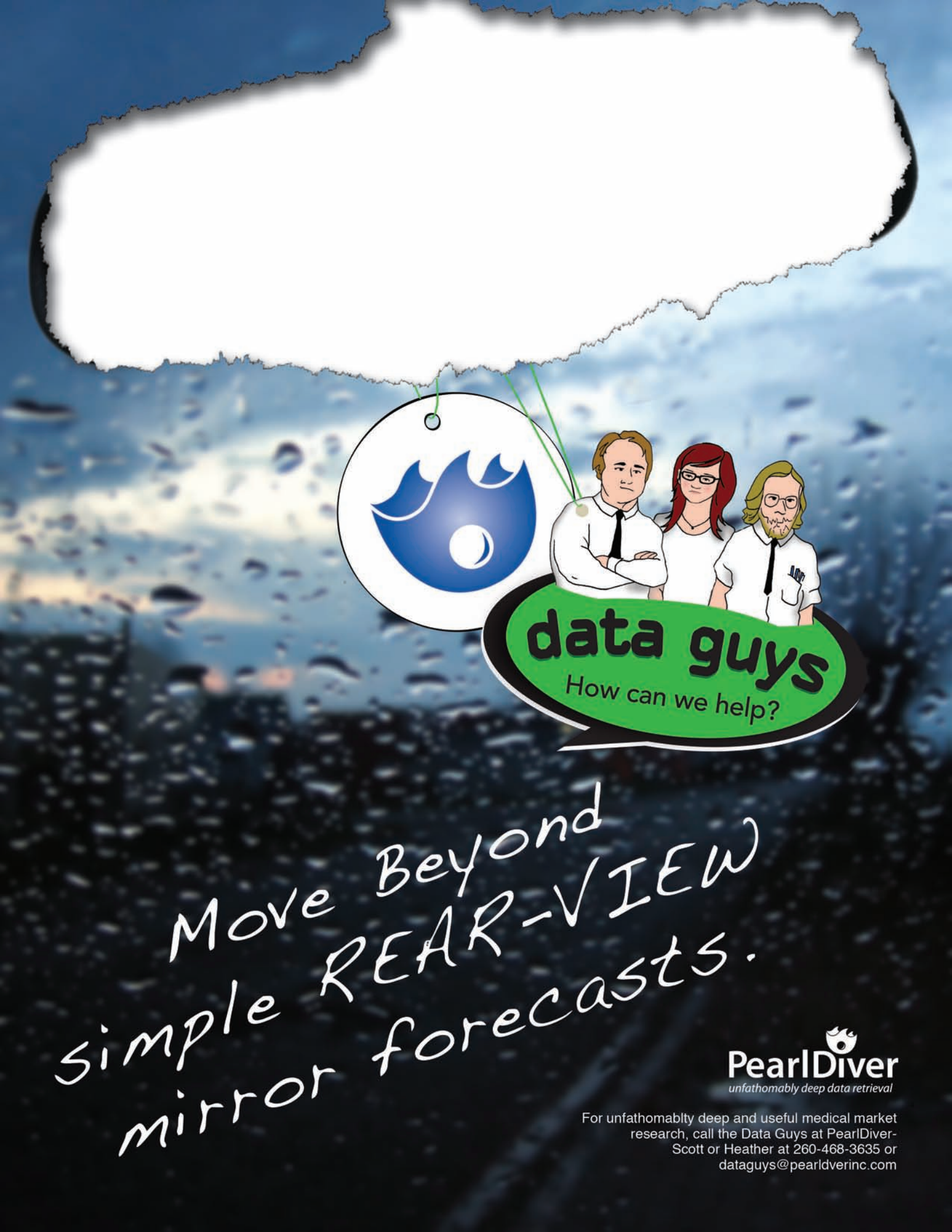
Once the chair at "Pitt," Dr. Herndon also served as Associate Senior Vice Chancellor of the university. "I worked with outside consultants to put together an academic practice plan, mainly because I saw that with all of the evolving issues—physician loss of control, etc.—doctors would have to be more organized. This resulted in great progress for the doctors, and they have been successful in several ways, including in the negotiation of contracts with third party payers."

Life Outside of the Hospital and Societies

Leading by example, Dr. Herndon has left the comforts of U.S. medicine and gone abroad to help those with severe problems. "I have traveled to Honduras and the Dominican Republic (DR) with the Scoliosis Research Society; in Honduras I also did hand surgery. There was a man who had lost his thumb and couldn't work; we transposed his index finger into the position of thumb… he only had three fingers but he had a thumb and he could work. In the DR I removed a spine tumor from a teenage girl; soon after, the respirator failed, and the resident and I sat and bagged her for 24 hours."

Through all of the changes, projects, and frustrations, there is one constant at home…a loving wife of 44 years. "My wife and I met when she was working as a nurse at the University of Pennsylvania. We raised two children, who are now 39 and 35. Our son lives nearby, and works as a businessman; our daughter is an attorney in Alabama. It's a good life." ◆

[1] "To Err Is Human: Building a Safer Health System," Institute of Medicine, 1999.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