VOLUME 11, ISSUE 38 | DECEMBER 1, 2015

Orthopedics This Week

WEEK IN REVIEW

BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: One highly reliable leading indicator of health care demand, aside from an aging population, is the financial health of the consumer. In 2008, when unemployment bounced up against the 10% rate, demand for orthopedic surgeries declined. Since then, unemployment rates have fallen steadily and this past October's 5% rate was the lowest since April 2008. This week a new report is due and it is likely to be down again. No surprise that demand for orthopedic services are at an all-time high. And should continue to rise for a long time.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer Biomet	31.22%	3.20%	ZBH and SYK are tied this week in terms of valuation. ZBH gets top billing with a higher operating profit margin.
1	4	Stryker	22.94	2.42	From an equity perspective, the prices for SYK and ZBH are ridiculously low. Especially given their dividend rates and their cash generating abilities.
3	3	Orthofix	2.35	14.74	The reason OFIX has performed so well is that analysts are moving sales and earnings estimates for 2016 higher. Also, Zacks put a "buy" rating on.
4	6	Integra LifeSciences	13.74	6.73	Q4's earnings are expected to be below last year but won't stop the full year from being solidly ahead of last year—say consensus of analysts.
5	2	Globus Medical	30.19	19.92	For the full year, most analysts think that GMED will report a very strong 14% jump in sales.
6	7	Medtronic	27.92	3.97	FDA approved MDT's app-based monitor. First in the world. Will control pacemakers from the smart phone. Functions can move to a variety of smart ortho implants.
7	5	NuVasive	13.25	10.23	While NUVA's sales won't be growing at the same rate as, for example, GMED, earnings are expected to double from last year—analyst consensus.
8	8	Johnson & Johnson	28.44	1.88	Why put money into the bank? JNJ has increased dividends for 50 consecutive years. The yield today is 2.95%. Can the banks beat that?
9	9	Exactech	10.26	(3.15)	Fact is, compared to all other orthopedic equities, EXAC is cheap—2nd least expensive, in fact.
10	NR	CONMED	11.10	4.65	CONMED returns to the Power Rankings by virtue of a reasonable valuation and an impressive strategic acquisition—SurgiQuest.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Globus Medical	GMED	$26.79	$2,551	19.92%
2	Orthofix	OFIX	$40.56	$766	14.74%
3	LDR Holding Corp.	LDRH	$26.33	$765	12.86%
4	NuVasive	NUVA	$52.35	$2,570	10.23%
5	K2M Group Hldgs	KTWO	$20.36	$839	9.17%
6	Wright Med. Grp N.V	WMGI	$20.95	$2,151	7.44%
7	Integra LifeSciences	IART	$62.68	$2,318	6.73%
8	SeaSpine Hldgs Corp.	SPNE	$16.32	$181	4.82%
9	CONMED	CNMD	$42.96	$1,190	4.65%
10	Medtronic	MDT	$76.46	$108,085	3.97%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$0.24	$24	-22.55%
2	Aurora Spine	ASG	$0.15	$3	-22.18%
3	RTI Biologics Inc	RTIX	$3.97	$229	-21.70%
4	Xtant Medical Hldgs	XTNT	$2.96	$35	-8.64%
5	MiMedx Group	MDXG	$8.73	$951	-8.01%
6	Smith & Nephew	SNN	$33.77	$15,106	-4.47%
7	MicroPort Scientific	853	$0.40	$568	-3.74%
8	Exactech	EXAC	$17.54	$247	-3.15%
9	Johnson & Johnson	JNJ	$102.37	$283,252	1.88%
10	CryoLife	CRY	$10.99	$313	2.23%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Exactech	EXAC	$17.54	$247	15.76
2	Johnson & Johnson	JNJ	$102.37	$283,252	17.84
3	Zimmer Biomet	ZBH	$101.00	$20,582	19.99
4	RTI Biologics Inc	RTIX	$3.97	$229	20.09
5	Globus Medical	GMED	$26.79	$2,551	20.67

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	$10.99	$313	72.11
2	NuVasive	NUVA	$52.35	$2,570	60.10
3	MiMedx Group	MDXG	$8.73	$951	48.50
4	Smith & Nephew	SNN	$33.77	$15,106	30.15
5	Integra LifeSciences	IART	$62.68	$2,318	27.55

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	RTI Biologics Inc	RTIX	$3.97	$229	1.34
2	Globus Medical	GMED	$26.79	$2,551	1.61
3	Exactech	EXAC	$17.54	$247	1.77
4	Smith & Nephew	SNN	$33.77	$15,106	1.96
5	Zimmer Biomet	ZBH	$101.00	$20,582	1.98

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$52.35	$2,570	3.93
2	Medtronic	MDT	$76.46	$108,085	3.73
3	Johnson & Johnson	JNJ	$102.37	$283,252	3.28
4	MiMedx Group	MDXG	$8.73	$951	3.23
5	Integra LifeSciences	IART	$62.68	$2,318	2.44

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.24	$24	0.12
2	RTI Biologics Inc	RTIX	$3.97	$229	0.87
3	Exactech	EXAC	$17.54	$247	0.99
4	Xtant Medical Hldgs	XTNT	$2.96	$35	1.00
5	SeaSpine Hldgs Corp.	SPNE	$16.32	$181	1.31

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.03	$182	29.03
2	MiMedx Group	MDXG	$8.73	$951	8.05
3	Wright Med. Grp N.V	WMGI	$20.95	$2,151	6.23
4	Globus Medical	GMED	$26.79	$2,551	5.38
5	Medtronic	MDT	$76.46	$108,085	5.33

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

Anti-Trust Alarms Sounding Over Humana/Aetna Merger

BY ROBIN YOUNG

If the $37 billion deal to combine Humana, Inc. with Aetna Inc. happens, as more than 99% of the shareholders of both firms hope with their approval last month, life will change for orthopedic physicians and their patients.

Immediately after the overwhelming shareholder approval of this merger, the American Medical Association (AMA) sent a letter to the U.S. Department of Justice (DOJ) saying that Aetna's proposed acquisition of Humana and Anthem's proposed acquisition of Cigna would create "a near total collapse of competition."

The letter went on also say: "The lost competition through these proposed mergers would likely be permanent."

Approximately 92% of orthopedic physicians are financially dependent on their contracts with health care plans. The rest are either concierge or cash-only practices (source: Orthopedic Surgeons: #1 in Pay, #11 in Satisfaction).

Health Insurer Monopsony

Said the AMA: "Health insurer monopsony, or buyer power, acquired through the proposed mergers would likely degrade the quality and reduce the quantity of physician services."

Monopsony is economics-speak for a buyer's monopoly.

The classic example of a monopsy is the relationship of farmers to food buyers. Hundreds of thousands of individual farmers sell to just a handful of food buyers. To level the negotiating playing field farmer cooperatives like the American Farm Bureau and the National Farmers Union (and later such co-ops as Land O Lakes, Ocean Spray, Sunkist, Organic Valley and Michigan Sugar) organized in the 1900s.

Courtesy of U.S. Department of Justice

With only four or five buyers, individual farmers had no negotiating power. But when they combined into co-ops, they had leverage.

The five major health insurers in the U.S. purchase the services of a vast majority of orthopedic physicians. And orthopedists typically work in small practices with 10 or fewer colleagues.

This creates a classic monopsony. And the American Medical Association is raising the alarms.

In their November 11, 2015 letter, the AMA said the current wave of mega-insurer mergers is creating a textbook monopsony scenario where dominate health insurers will be able to dictate pricing to the hundreds of thousands of physicians in the U.S.—including the 15,000 orthopedic physicians.

"If physicians were to refuse the terms of any health insurer, they would likely suffer an irretrievable loss of revenue. That is because medical services can neither be stored nor exported."

Orthopedic physicians have no individual leverage against mega-insurers. If they are unhappy about low payment rates what are they going to do? Terminate the contract?

Not likely.

Raising the Anti-Trust Alarm

A July 2015 analysis from the Kaiser Family Foundation (KFF) said that a merger of Aetna and Humana would

create a mega insurer covering 26% of all Medicare Advantage enrollees.

When they looked at specific markets, the coverage percentage jumped significantly. Humana, for example, covers more than 50% of the Medicare Advantage patients in Kentucky, Louisiana, and Virginia, and more than two-thirds of the patients in Mississippi and West Virginia.

Aetna covers approximately 25% of the quarter of enrollees in eight different states. Add these two firms together and they now control coverage for more than 50% of the Medicare Advantage patients in 39 counties out of the 335 counties with at least 10,000 Medicare Advantage enrollees.

The Big Five Become the Big Three

In September 2015, Republican Senator Mike Lee of the Utah, the Chairman of the Senate Judiciary Committee's Subcommittee on Anti-trust, Competition Policy and Consumer Rights, said that the relevant "antitrust inquiry" is "whether the combination [of insurers] will lead to a market concentration that may substantially lessen competition." If the DOJ approves the Aetna–Humana deal and another pending merger between Anthem and Cigna, Lee stated that the "big five" in the health insurance industry will be reduced to the "big three."

Other Medical Associations Step Up

The Texas Medical Association (TMA) wrote in a recent letter to the DOJ that Texas' health insurance market would suffer due to the decreased competition, potentially resulting in higher prices for plans and lower prices for services. Specifically, TMA pointed to more concentrated market power in several major Texas cities in health maintenance organizations (HMO), preferred provider organizations (PPO), and point of service plan markets.

The Texas doctors went on to raise concerns about the new mega-insurer's ability to unilaterally reduced prices below the actual service costs or to exclude physicians below the plan network and force those practices out of business.

AMA President Steven J. Stack, M.D., chimed in saying that the AMA has "long cautioned about the negative consequences of large health insurers pursuing merger strategies to assume dominant positions in local markets." And added: "We could have 42% of the U.S. population covered by three companies. Staggering, right?"

The American Academy of Family Physicians President, Robert Wergin, M.D.,

lent his voice to the growing chorus saying, "Your grandmother may have seen me for 20 years. Then she signs up for Medicare Advantage and I have to tell her that I'm not in the network and she'll have to pay for me out-of-pocket."

Are These Insurance Mega-Mergers Inevitable?

More than 99% of the shareholders of both firms approved the Humana/Aetna merger.

On July 3, 2015, when Aetna announced its plans to acquire Humana, it assured the public and the government that the transaction would be good for physicians and patients and have no effect on competition.

Aetna and its CEO, Mark Bertolini, are moving quickly to establish a sense of inevitability for the merger saying that he "took a conservative view" of what his company might need to divest in order to comply with any Department of Justice anti-trust concerns in merging with Humana.

Furthermore, Bertolini noted in discussions with Wall Street analysts, this transaction would be the first among the biggest insurers to merge and that would give them an edge in a review by anti-trust regulators. Aetna is the third largest insurer and Humana is the fourth, respectively by revenue. Combined they would have about a million more members in Medicare Advantage—the private insurance version of the federal program for seniors and the disabled than UnitedHealth, the next closest competitor.

Bertolini and his counterpart at Humana, CEO Bruce Broussard, also mentioned that the two insurers have complimentary rather than overlapping strengths—Aetna's is in commercial coverage and sells insurance primarily to employers while Humana's is in Medicare.

The Department of Justice Review

In what may well be signaling the Department of Justice's take on the Aetna/Humana merger and the other mega insurer mergers in the works, Assistant Attorney General Bill Baer—the DOJ's top antitrust enforcer—expressed concern about consolidation in the health insurance industry.

In a keynote address at a health care industry conference at Yale Law School, Baer said:

> "Competition is central to the provision of affordable quality health care in the U.S. It promotes innovation and helps deliver the best health outcomes for the lowest prices. Consumers benefit when they have

meaningful choices among insurers and hospitals, physicians and therapists, prescription drugs and medical devices."

And then he specifically talked about anti-trust issues with insurers:

"Over the last decade and a half, the division has either blocked outright or required divestitures from seven health insurance mergers. We did this to protect individual purchasers, employers buying small and large group insurance, Medicaid managed-care enrollees, and seniors who rely on Medicare Advantage."

"We don't pick winners and losers. Our job is to block mergers that threaten to reduce competition; our job is to challenge competitors who want to conspire rather than compete; and our task is to ensure that companies do not raise barriers that deny competitors the opportunity to enter new markets or expand their existing market presence."

"As my friend and mentor Bob Pitofsky said about this argument some years ago, the antitrust laws 'reflect a fundamental premise that consumer choice, rather than the collective judgment of sellers, should determine the mix of price and quality options available in the market place.' This is still true. Consumers do not benefit when sellers—or buyers—merge simply to gain bargaining leverage. Consumers benefit when there is entry, expansion, innovation and competition."

What Happens Next?

There is much discussion about how the changing landscape of health care service delivery is forcing insurance companies to consolidate. But, based on Assistant Attorney General Baer's comments at Yale, that may ultimately be irrelevant to the staff economists at the Antitrust Division.

Those lawyers and economists are studying these mergers carefully and the AMA and other physician groups are making it abundantly clear that the harm to individual physician practices is serious and no manner of legal maneuvering, political deal making or even corporate restructuring through divestitures may overcome it.

In many respects, a soft ruling on the Aetna/Humana deal opens the door to other mega mergers so it may well be the DOJ that draws the line in the sand—with support from the physician community. ♦

Medacta International: Founded by a Patient, Exceptional Through Training

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

There is training…and there is Medacta training.

You might even say that, 'spare the muscle, spoil the surgeon' is their motto.

Born out of a less-than-stellar total hip replacement (THR), Medacta International was created by Alberto Siccardi after he was dissatisfied with his surgical experience. Medacta, the only orthopedic company founded by a patient, is laser-focused on improving patient outcomes via superb surgeon training. Now, the company is celebrating its 200th Learning Center, a course where surgeons learn the company's proprietary approach.

Francesco Siccardi, executive vice president of Medacta International—and son of the founder, tells *OTW*, "Years ago I watched my father suffer after undergoing a total hip replacement. He and I both knew that there had to be a better way."

Enter the anterior approach.

"We could see the advantages of the anterior hip approach, and we were personally motivated to find a way to give patients a superior surgical experience. To that end, we partnered with esteemed French surgeon Frédéric Laude, M.D., one of the original innovators of the anterior approach. Together, we created the AMIS (anterior minimally invasive surgery) Technique, a muscle-sparing approach that has resulted in shorter hospital stays, faster rehabilitation time, and a quicker return to daily activities."

Courtesy of Medacta International

Working alongside Dr. Laude, Medacta poured its resources into developing a training program with an unprecedented level of support and resources for surgeons.

"Medacta has an educational program that allowed me to learn this technique comprehensively and implement it in a safe manner. The anterior approach does have a steep learning curve and it can be frustrating. With the Medacta program, the surgeon first goes to a Reference Center to observe a surgeon who is proficient in the technique. After the Reference Center visit, the trainee can then participate in an introductory course with didactic classroom sessions and cadaver lab sessions. If he or she decides to adopt the technique, Medacta arranges for a proctoring surgeon to be on hand in the OR for their first cases and as many times after this as the trainee feels is necessary," says training participant-turned-AMIS educator, Peter Thadani, M.D., who is with the Illinois Bone and Joint Institute.

He tells *OTW*, "Typically, the way a surgeon learns how to implement the anterior techniques is through reading, video, or a weekend course where the surgeon listens to lectures and does a little cadaver practice. In my opinion, that is insufficient."

200 AMIS Learning Centers, 3,500 Surgeons

Medacta, headquartered in Castel San Pietro, Switzerland, recently hosted a series of events across five U.S. cities that included a live international webcast panel, and the commencement of Medacta's 200th AMIS Learning Center.

To enhance and solidify the learning experience, surgeons can access the M.O.R.E. (Medacta Orthopedic Research and Education) Institute pro-

grams, an important resource for surgeons as they learn and adopt the AMIS technique. "The M.O.R.E. Institute was created to provide continuous support to professionals in the field of research and education and to improve patient outcomes. This is supported through effective training programs, surgeon to surgeon education, and a forum to share experiences."

To date, more than 3,500 surgeons in over 30 countries have been trained in the AMIS Education Program, which is only a small portion of the programs provided by the M.O.R.E. Institute.

Francesco Siccardi tells *OTW*, "We feel that the most important thing in orthopedics and joint replacement is not only to improve implant design, but how to elevate design standards. Given this, we focus substantial attention to hip and knee surgical techniques. These, along with additional methodology and improvements in pain management will move the field forward. The anterior approach plays a key role because it involves a faster recovery and is highly reproducible."

"Surgeons want to know how to learn the new technique without putting their patients at risk. To ensure safety, we focus on minimizing complications during the learning curve; that is why we take a step-by-step approach. The key aspect to supporting the surgeon during the learning curve is our proctoring service…we promise the surgeons that they will never be left alone."

"We estimate that it takes performing a minimum of 25-30 of these surgeries in order to go through the learning curve. At 100 surgeries the surgeon has fully mastered the technique and can operate on all comers."

Eric Fontenot, product director for Medacta, tells *OTW*, "At present we have ongoing learning centers in the U.S., Australia, Singapore, France, and Switzerland. In April 2016, we will also conduct our 8th M.O.R.E. Symposium, a semi annual event, focusing on techniques in hip and knee arthroplasty. In addition to the symposium and the ongoing learning centers, our educational activities have to grow with our growing user base. The more surgeons become proficient in our technique, it is even more important that we add masters and revision level courses. The revision market is a burgeoning area and there is a lot to develop in terms of new instruments and techniques to preserve muscle in this setting. In revisions the dislocation rate is disproportionally

high. If we can address this issue by improving the surgical approach and leaving the hip more stable, then we will have gone a long way toward serving our mission."

The Product Is Education

Tyler Goldberg, M.D., U.S. medical director for Medacta, helped bring the technique to the United States in the 2008. "My message about Medacta is this: It is an educational company that just so happens to sell implants. They are in the business of educating surgeons on the safe way to pursue this innovative technique. The main difference in the way most surgeons are trained compared to the way Medacta surgeons are trained is that the latter is anatomically based. Medacta makes hip replacement about surgical dissection and appreciation of the anatomy. With other training, it's often about retractor placements and moving the tissue forcefully out of the way to get to the fun of reaming and broaching. After Medacta training, several surgeons have told me things to the effect of, 'I have been doing the anterior approach for years and it is nothing like *this* operation.'"

"While the learning curve can be intimidating, it can be shortened by teaching the surgeons *through* it and letting them know what to expect and how to handle different situations. By sending in surgeons like myself who have a vast amount of experience, the company ensures that the surgeon is never abandoned on their own 'island.'"

"The company's definition of success is, 'What is the rate of conversion to the anterior approach after a surgeon undergoes Medacta training?' We have evidence showing that 85% of surgeons who receive the AMIS training continue to do this approach after the training."

Courtesy of Medacta International

Just what Medacta's original patient, Alberto Siccardi, would call a success indeed. ♦

Cornstarch and Ash Promote Healing? // SF-36 Scores Don't Predict Ankle Surgery Outcomes // John Feagin, Jr., M.D. Wins Dr. Ernst Jokl Sports Medicine Award

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

Cornstarch and Volcanic Ash = Orthopedic Healing? While it sounds like something a 7-year-old might concoct from the fridge and the playground, a new plastic just might help in healing orthopedic injuries. Researchers from Beaumont Health in Royal Oaks, Michigan, have put together a new material made of cornstarch and a volcanic ash compound (Montmorillonite clay). Kevin Baker, Ph.D., director of the Beaumont Orthopaedic Research Laboratories, worked on the study with Rangaramanujam Kannan, Ph.D. of Johns Hopkins University. Dr. Baker tells *OTW,* "The idea for this project actually began as a conversation between our late chairman—Harry Herkowitz, M.D.—and me regarding the need for a synthetic graft material that could replace the use of autologous iliac crest bone graft. The material needed to be highly porous like native bone, but also be able to withstand significant biomechanical loading. Dr. Kannan (then at Wayne State) was leading the field in the development of polymer nanocomposites for primarily non-medical applications. We discussed the project with Dr. Kannan and he felt that his supercritical CO_2 processing would be an excellent match."

Kevin Baker, Ph.D. / Courtesy of Beaumont Health

Pixabay

"We started the initial work in 2007 and found that we were able to significantly increase the compressive strength of resorbable polymers (poly-d-lactide) by adding organically-modified Montmorillonite clay and processing the mixture in supercritical CO_2. So we ended up with a synthetic, resorbable construct that looked like bone and behaved mechanically like bone. And it dissolves in the body within 18 months."

The material is still in the research phase, say the researchers, and likely won't be available to patients for several years. "It's always important to know the limitations of the material. First of all, we are still quite a ways away from seeing this in human patients. There is a strict FDA pipeline for this type of technology, though we are using constituents that have FDA approval for other uses (PDLA [polylactic acid] is an approved polymer used in medical applications; Montmorillonite clay is used in pharmaceutical and cosmetic applications). Second, we believe that the supercritical CO_2 process will allow for the incorporation of growth factors and small osteoinductive molecules which can be slowly released from the constructs upon implantation. Most other porous polymer technology relies on the use of volatile organic solvents which have the ability to denature proteins, and stimulate an inflammatory response. Since we are using CO_2 for processing, we avoid these issues."

"We were fortunate that the translational aspects of our research were funded

by a Seed/Starter research grant from the Cervical Spine Research Society. And to honor Dr. Herkowitz, we have dedicated the manuscript to him."

SF-36 MCS Does Not Predict Functional Outcome After Ankle Arthritis Surgery Does mental health status point towards certain outcomes after surgery for ankle arthritis? A team of American and Canadian researchers wanted to find out. Stephen Kennedy, M.D. is a hand and upper extremity surgeon in the Department of Orthopaedics and Sports Medicine at the University of Washington in Seattle. He tells *OTW*, "This study was prompted by discussions at orthopedic grand rounds about the role of psychosocial factors on outcomes in orthopedics. Researchers and health care organizations are increasingly demonstrating that psychological factors like depression and anxiety can predict functional outcome after surgery. For example, the World Health Organization has found that depression better predicts general health status than angina, asthma, diabetes, or arthritis. We were interested in whether there was an effect on ankle osteoarthritis surgery."

The researchers gathered preoperative and postoperative patient scores on the SF-36 MCS and Ankle Osteoarthritis Scale questionnaires from the Canadian Orthopaedic Foot and Ankle Society (COFAS) End-Stage Ankle Arthritis Database. "We reviewed 337 surgeries (95 arthrodesis and 242 arthroplasties) and found, surprisingly, that the preoperative SF-36 MCS doesn't actually predict functional outcome after surgery for ankle arthrodesis or arthroplasty, at least not at the two-year mark or the five-year mark. Based on the existing literature in other areas supporting a link, we thought there might be an effect. However, although depression, anxiety, and other factors can have an impact on function, pain, and wellbeing, this impact may dissipate with time after the underlying biomedical problem improves. It probably effects how patients perceive pain and function in the present, but may not be as helpful at predicting the future response to medical treatments. In the long run, the benefits of ankle arthroplasty or arthrodesis surgery, as measured by Ankle Osteoar-

thritis Scale, are not limited by the preoperative MCS."

"For the day-to-day work of orthopedic surgeons, this means that mental health scores may not be helpful in determining whether a patient will benefit from either ankle arthrodesis or ankle arthroplasty. It may influence their experience of their osteoarthritis, or coping around the time of the actual surgery, but it likely has little or no effect on the long term benefit of the surgical procedure. Of course, there are limitations to the study, and more studies are needed. Future studies will need to be prospective, use better validated measures of psychosocial factors, and have a design that follows patients through multiple time points in their recovery."

John Feagin, Jr., M.D. Wins Dr. Ernst Jokl Sports Medicine Award Dr. John A. Feagin, Jr. has been honored with the 2015 Dr. Ernst Jokl Sports Medicine Award by the United States Sports Academy. A former West Point athlete who was commissioned to the Artillery Branch of the U.S. Army, John Feagin rose to become a peerless leader in the field of sports medicine. The award Dr. Feagin is receiving is named for Ernst Jokl, M.D., a former Olympic athlete, international sports medicine scholar and Director of the University of Kentucky Rehabilitation Center.

Following graduation from Duke University in 1961, Dr. Feagin returned to active duty, and then began a residency at Walter Reed Army Medical Center. He would go on to participate in the founding of a number of orthopedic organizations, including the Society of Military Orthopaedic Surgeons, the American Orthopaedic Society of Sports Medicine, and the International Society of Knee Surgery and Arthroscopy.

Later on, Dr. Feagin returned to Duke University, and spent 10 years leading and following his own personal star of excellence. Over the years he has worked closely with Blue Devils basketball coach Mike Krzyzewski, and became team physician. Dr. Feagin gave so much to the university that Duke's Sports Medicine Leadership Program is named after him.

Asked what this honor means to him, Dr. Feagin told *OTW*, "I met Dr. Jokl one time. He was a giant of a man. I learned of his life's work, reputation and accomplishments from his son Dr. Peter Jokl an orthopaedic colleague on the faculty at Yale. That was early in my sports medicine career and it gave me a sense of what could be accomplished even in the face of adversity. To be honored for contributions to Sports Medicine by the U.S. Sports Academy, in the name of Dr. Jokl, makes the work of a career especially meaningful."

Asked about the most important areas being explored in sports medicine, Dr. Feagin told *OTW*, "The STOP program instituted by Dr. Andrews and the American Orthopaedic Society for Sports Medicine is our most important work because it emphasizes prevention of injury early in sports. The concussion work is also important. A review of rule change opportunities in the collision sports at the level and with the import that President Theodore Roosevelt accomplished many decades ago is a must. The game has changed and so must the rules.

"Lastly, the value of sports to our country, to the family and individually needs to be revisited. The work of Dr. Bruce Ogilvie, a sports psychologist at San Jose State, was seminal and every parent should have a grasp of what sports can mean in a young life. The good and the not so good, and the critical role of coaching the young athlete."

"The role of sports and sports as a business has grown exponentially in my lifetime. The leadership requisite to this development in business, on the field, philosophically and physiologically is critical if we are to preserve the values we knew and believed. Coach Krzyzewski is a great example of what that leadership can accomplish. The U.S. Sports Academy is a degree-granting institution with the same commitment as our Duke Leadership Program." ◆

James Andrews, M.D. Breaks Ground on New Facility in Texas // Fewer Falls, Reduced LOS With Bupivacaine Liposome! // Articulation *Doesn't* Cause Wear?!

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

"Jimmy" Andrews Breaks Ground on New Institute in Texas Famed orthopedic surgeon James Andrews, M.D. hauled a few shovels of dirt on November 6 in order to celebrate the opening of the Children's Health Andrews Institute for Orthopedics & Sports Medicine. Dr. Andrews told *OTW*, "The Children's Health in Dallas, Texas has a boutique hospital in Plano that is a general children's facility. They decided they wanted to develop an orthopaedic section, particularly to get involved with youth sports medicine. There are some two million children in the Dallas area and a high percentage are active in youth sports. Such activity brings with it an epidemic of youth sports injuries. They contacted me and asked if I would help develop a sports medicine complex at the Plano facility in the Dallas area. That came to fruition, and we had the groundbreaking for the Children's Health Andrews Institute last Friday."

Watch the video: https://www.childrens.com

"The vision for the facility is to provide a first-class treatment facility for injuries in youth sports at all levels, and to become a national leader in research and education for the prevention of injuries in youth sports."

"The reason that I am involved in this project is primarily because of my passion for the prevention of injuries in youth sports. The Children's Health of Dallas is going to provide a research and education foundation at the facility in Plano to conduct research which would improve the prevention of youth sports injuries as well as provide an educational platform for prevention at the grassroots level."

"It appears that we have 100% cooperation with the parent organizations which will make a difference with prevention—not only locally, but nationally. Children's Health have become a collaborative partner with our national initiative which is entitled, 'The STOP Program' (Stop Trauma and Overuse Prevention in Youth Sports). STOP is an initiative which is led by the American Orthopaedic Society for Sports Medicine. I am very excited about this opportunity and I think we can make a difference, not only in that region, but nationally, due to the backing of the Children's Health program in Dallas."

Fewer Falls, Reduced LOS With Bupivacaine Liposome! With the groundswell of attention on opioid problems in the orthopedic realm, it is timely that new research has found an alternative. Richard Iorio, M.D., professor of orthopaedic surgery at NYU School of Medicine, was lead author on a study comparing bupivacaine liposome and femoral nerve blocks after total knee arthroplasty (TKA). Dr. Iorio tells *OTW,* "Liposomal bupivacaine has been highly controversial because it is expensive and because the FDA reprimanded the manufacturer for claiming that the length of action was 72 hours rather than a demonstration of 48 hours for bunionectomy and hemorrhoidectomy. The manufacturer was reprimanded for making claims related to non-investigated procedures as well."

"Our study found that this drug resulted in a shorter length of stay [LOS], a lower 30-day all-cause re-admission rate, a reduced inpatient fall rate, and an increased rate of discharge to home. Specifically, we were able to show a meaningful increase in patient milestones such as walking 100 feet sooner and climbing stairs sooner than those who received femoral nerve blocks.

Even the decreased amount of narcotic use was statistically significant."

"When you do femoral nerve blocks with a catheter it knocks out the femoral nerve and thus the patient has poor motor and sensory functioning. When you use liposomal bupivacaine without a femoral nerve block then there is no motor weakness and the person can get up and walk on the same day of surgery. At our institution we were able to completely stop using femoral nerve blocks in total knee replacement patients."

"While some studies have shown negative results with this drug, they are comparing them against conventional local anesthesia, which is not long acting. And in my opinion, if you don't do *any* injection correctly then of course you will have equal results. If the doctor exits the OR and leaves the injection to the trainees then you are not likely to see a benefit. We need a non-conflicted prospective randomized study. I am conservative with regard to implementing new paradigms, but this is a winner and we are not going back to femoral nerve blocks."

"My recommendation is that if you choose to use liposomal bupivacaine, then study the technique with someone who is experienced with these injections. You need small aliquots, a small gauge needle, and small amounts in contiguous areas. It doesn't diffuse as much as a local anesthesia, so if you have large globs of the drug in different areas then you will get large, numb areas, but no continuous pain relief throughout wound. If you don't study the technique with someone who knows what they are doing then you will have wasted time and money."

Articulation DOESN'T Cause Wear?

Researchers from the University of Delaware wanted to know why the cartilage in our joints doesn't deflate over the course of days, months or years. Their answer? Movement. David Burris, Ph.D., an assistant professor in the Mechanical Engineering Department at the University of Delaware, led the research.

Dr. Burris told *OTW*, "From biphasic modeling, we know that cartilage loses fluid during loading over time, but in-vivo measurements show that although this is true in static conditions, *articulation actually drives fluid back into the tissue*. The community has not understood this mechanism and given the importance of the fluid in the tissue for mechanical and biological function, we felt this was an absolutely critical scientific question to answer. To date the only hypotheses have been that migration limits time in contact and articulation exposes the contact to the bath, which enable it to imbibe fluid to recover. We were shocked to find the same recovery mechanism others observe in the natural joint in a contact that did not involve migration and bath exposure. The results suggest that hydrodynamic pressure develops dur-

ing articulation, but instead of creating fluid films as described in biomechanics textbooks, these external pressures combat the exudation process associated with interstitial pressurization. We believe this 'tribiological rehydration' mechanism is critical for sustaining joint function and health and can be leveraged to provide unprecedented control in cartilage studies while maintaining physiological fluid pressures."

"Firstly, the results contradict the conventional wisdom that articulation causes wear. The mechanism we propose based on our results suggest that the mechanical intensity felt by the solid is far less when active than when inactive. It suggests that obesity, inactivity, and low amplitude oscillations are more damaging mechanically than normal activity. In other words, we expect recommendations of 10,000 steps per day to also benefit joint health (in addition to cardiovascular, etc.)."

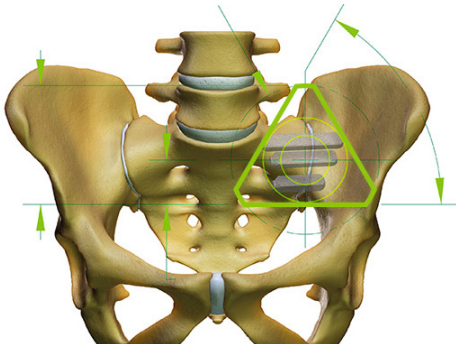
"Secondly, most textbooks focus on lubrication during articulation and suggest that fluid films are responsible for exceptionally low friction and wear. The problem with this mental model is that it fails to address how our joints deal with static conditions in which there are no fluid films. This is critical since our joints are static ~95% of the time. Our research suggests that the joint excels because it is designed specifically to address inactivity. Cartilage acts as a buffer to the inevitable 'crash landing' when motion stops. The extremely slow exudation process ensures negligible losses of lubrication over ~1 hour of inactivity. When activity resumes, this buffer is quickly refilled to prepare cartilage for the next crash landing. Joint replacement devices do not possess such a buffer and therefore experience the full brunt of the crash landing, poor lubrication, surface damage, wear, and the biological consequences thereof. If we want reliable joint replacement devices, we must stop striving to create fluid films during articulation at all cost and start focusing on mitigating stresses and damage during long periods of static loading; we need to leverage the interstitial lubrication that nature exploits so effectively."

Asked what kind of movement might be best and why, Dr. Burris commented to *OTW,* "Static conditions are the enemy in my opinion and cartilage deals with them effectively for long periods when cartilage is fully hydrated. High speeds, light loads and longer distances maximize rehydration after static exudation and are therefore the most effective way to prepare the joint for subsequent inactivity. I believe this is one reason OA [osteoarthritis] correlates so strongly with inactivity and weight. Unloaded or deloaded articulation would drastically accelerate the rehydration process; once the buffer is full, any additional input would create fluid films. ♦

COMPANY

iFuse: FDA OKs Language Supporting Clinical Improvements

Makers of the iFuse Implant System—SI-BONE, Inc.—have announced that the FDA has cleared the iFuse Implant System to include in its indication statement that, "Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function and quality of life at 12 months post-implantation." According to the company, this addition was based on prospective and retrospective clinical studies demonstrating consistent improvement in pain, patient function and quality of life at 12-months in patients treated with iFuse.



Courtesy of SI-BONE, Inc.

"We are pleased with the FDA's review of our clinical data supporting this 510(k) clearance and look forward to additional filings as SI-BONE continues to conduct studies and follow-up on patients treated with the iFuse Implant System. Data supporting these claims came from retrospective and prospective studies, including INSITE (Investigation of Sacroiliac Fusion Treatment; 148 patients), SIFI (Sacroiliac Joint Fusion with iFuse Implant System; 172 patients) and additional studies reviewed by the Agency," said Roxanne Dubois, Vice President of Quality and Regulatory Affairs at SI-BONE, Inc., in the November 9, 2015 news release.

"Over 20 clinical studies demonstrating safety and effectiveness with the iFuse Implant System have been published in peer reviewed journals including studies with follow up out to as much as five years. Over 18,000 iFuse procedures have been performed worldwide making it the leading minimally invasive solution for these patients," commented Jeff Dunn, President and CEO of SI-BONE, Inc.

Asked how they plan to grow the company, Dunn told *OTW*, "We're focused on moving our business forward quickly with the right partnerships and right financing. As always, we're continuing our deep commitment to evidence and education. The diagnosis of SI joint dysfunction is as equally, if not more, important than the treatment. In anticipation of increased global demand for the procedure and the evolving reimbursement conversation, educating physicians at all levels of the care continuum continues to be key."

As for the next 6-12 months, he added, "iFuse is now the only MIS SI joint fusion device whose FDA clearance includes improved pain, patient function and quality of life at 12 months post-implantation. This is a significant competitive differentiator, which we expect will further contribute to our long-term market leadership. And, it's a reflection of our ongoing commitment to rigorous clinical studies—without the supporting safety and effectiveness evidence, this milestone would not have been possible. Over 18,000 iFuse procedures have been performed to date, and we anticipate our expanded application approval will further drive procedural growth and revenue." — *EH*

Collagen Meniscus Implant Reaches U.S. Patients

It's hard to kill a good idea. Even for the FDA.

On November 12, 2015, Ivy Sports Medicine, LLC announced the first implantation of its Collagen Meniscus Implant (CMI) in the U.S. The surgery was performed by Wayne Gersoff, M.D. in Denver, Colorado.

Rescission Battle

Readers may remember that Ivy Sports was an institutional investor in Regen Biologics when the FDA rescinded ReGen's approval of the company's

Collagen Meniscus Implant/Ivy Sports Medicine, LLC.

meniscus implant. That decision forced ReGen to declare bankruptcy, but Ivy Sports kept the product alive and continued with a suit against the FDA, arguing the rescission was unlawful and that the FDA should have followed the reclassification route if it wanted to reclassify the device.

A U.S. district court agreed with the FDA, but Ivy Sports appealed. Ivy Sports won the appeal on a 2-1 vote of the judges.

So the implant lives on and is finally reaching U.S. patients.

Collagen Meniscus Implant

The implant is a biocompatible scaffold made of highly purified collagen that

can be used to reinforce and repair a meniscus defect following partial meniscectomy or for irreparable meniscus tears. The implant has the general shape of the human meniscus and is trimmed by the surgeon to match the size of the meniscal defect. The implant is inserted via a minimally invasive procedure and sutured in place to the native meniscus.

Ivy Sports chairman and CEO Bob Pangia said he is seeing a shift in the medical community towards preserving the meniscus to prevent degenerative changes to the articular cartilage. "Approximately 20% of meniscal injuries result in a meniscus repair or meniscus transplantation, while 80% are treated via partial or total meniscectomies. Once a portion of the meniscus is removed, the articular cartilage can experience excessive stress which may lead to arthritic changes and the onset of osteoarthritis (OA). Due to the long-term degenerative nature of OA, patients may experience increased pain and reduced function. If the pain is too severe, patients may become candidates for a total knee replacement." He added that the availability of the CMI in the U.S., offers physicians another option when faced with the difficult decision to repair or resect the meniscus.

The CMI, says the company, is the only collagen scaffold for repair and reinforcement of the meniscus that has been cleared for sale in the U.S. The implant has over 20 years of clinical experience in more than 6,000 CMI cases worldwide and has been reported in 42 peer-reviewed publications.

The CMI was officially introduced to the U.S. market at the recently completed Arthroscopy Association of North America (AANA) Fall Course in Dallas Texas, on November 12-14, 2015.

Long live good ideas. — *WE*

LEGAL

OIG Warns Providers Over Information Blocking

Patient information can be a powerful competitive advantage between providers fighting over those patients. On October 6, 2015, the Office of Inspector General (OIG) issued a new alert to make sure providers don't abuse that information and run afoul of the Anti-Kickback Statute (AKS).

The government has spent billions of dollars to promote the adoption of "meaningful use" of health information technology and ensure the electronic exchange of patient information. The Department of Justice even included a safe harbor exemption under the AKS for electronic health record (EHR) for such adoption.

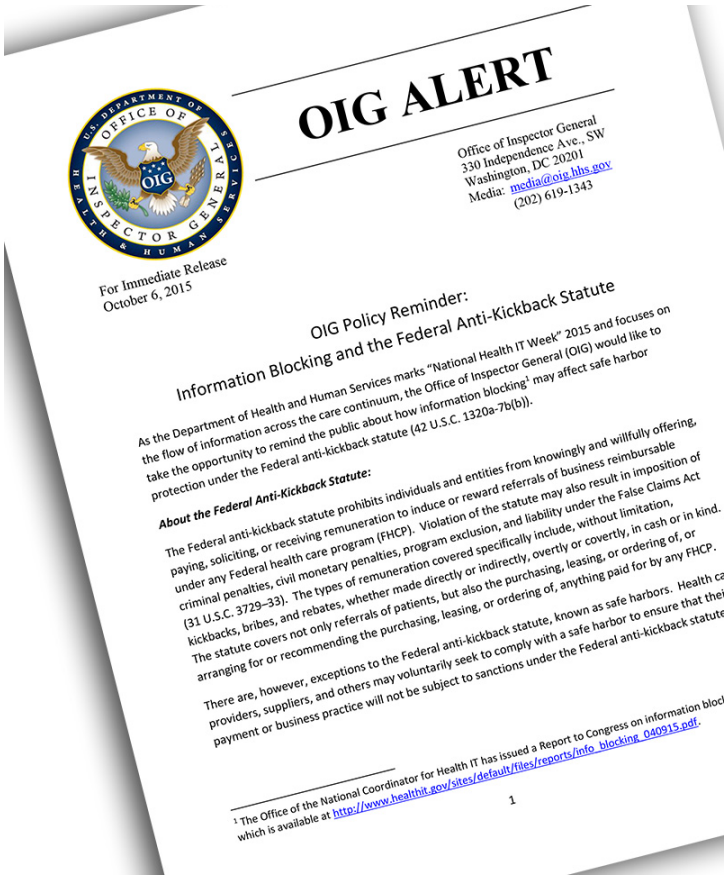
Electronic Health Record Safe Harbor

The EHR Safe Harbor, according to lawyers from McDermott Will & Emery, permits certain healthcare providers and other donors to pay up to 85% of the cost of EHR technology provided to a physician practice or other referral source if the arrangement meets all EHR Safe Harbor elements. The third element of that safe harbor requires that "The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services)."

Information Blocking

Why might a provider restrict use of, or even block certain patient information? To prevent a competitor from getting that information.

But the OIG got wise to that possibility and issued the alert warning providers that health information blocking



OIG ALERT

Office of Inspector General
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Washington, DC 20201
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For Immediate Release
October 6, 2015

OIG Policy Reminder:

Information Blocking and the Federal Anti-Kickback Statute

As the Department of Health and Human Services marks "National Health IT Week" 2015 and focuses on the flow of information across the care continuum, the Office of Inspector General (OIG) would like to take the opportunity to remind the public about how information blocking[1] may affect safe harbor protection under the Federal anti-kickback statute (42 U.S.C. 1320a-7b(b)).

About the Federal Anti-Kickback Statute:

The Federal anti-kickback statute prohibits individuals and entities from knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward referrals of business reimbursable under any Federal health care program (FHCP). Violation of the statute may also result in imposition of criminal penalties, civil monetary penalties, program exclusion, and liability under the False Claims Act (31 U.S.C. 3729–33). The types of remuneration covered specifically include, without limitation, kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, in cash or in kind. The statute covers not only referrals of patients, but also the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, anything paid for by any FHCP.

There are, however, exceptions to the Federal anti-kickback statute, known as safe harbors. Health ca providers, suppliers, and others may voluntarily seek to comply with a safe harbor to ensure that thei payment or business practice will not be subject to sanctions under the Federal anti-kickback statute

[1] The Office of the National Coordinator for Health IT has issued a Report to Congress on information block which is available at http://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.

1

Courtesy of HHS Office of Inspector General

can impact whether the AKS harbor remains safe.

When the OIG amended the EHR Safe Harbor in 2013, it stated in the preamble to the final rule, that "[D]onors must offer interoperable products and must not impede the interoperability of any electronic health record software they decide to offer...Agreements between a donor and a vendor that preclude or limit the ability of competitors to interface with the donated software would cause the donation to fail to meet the condition" of the safe harbor, and, "thus preclude protection under the electronic health records safe harbor."

The McDermott lawyers say the OIG alert cites several examples of information blocking that would threaten protection under the EHR Safe Harbor. "For example, if a provider limits the use or interoperability of software by agreeing with the potential referral source to prevent a competitor from interfacing with the software, the safe harbor requirements would not be satisfied. Likewise, if the software vendor agrees with a provider to charge high interface fees to outside providers or suppliers or to competitors, the safe harbor requirements may not be satisfied."

The lawyers advise providers that in order to avoid running afoul of the AKS (and resulting False Claims Act claims), when offering physician practices or other referral sources below-cost EHR technology, they should "take care to avoid health information access restrictions that unreasonably interfere with access to information for continuity of care or other appropriate purposes and, thereby, threaten EHR Safe Harbor protection."

To read the entire OIG document, click here: http://oig.hhs.gov/compliance/alerts/guidance/policy-reminder-100615.pdf — *WE*

BIOLOGICS

Orchid Acquires Cam Bioceramics in China

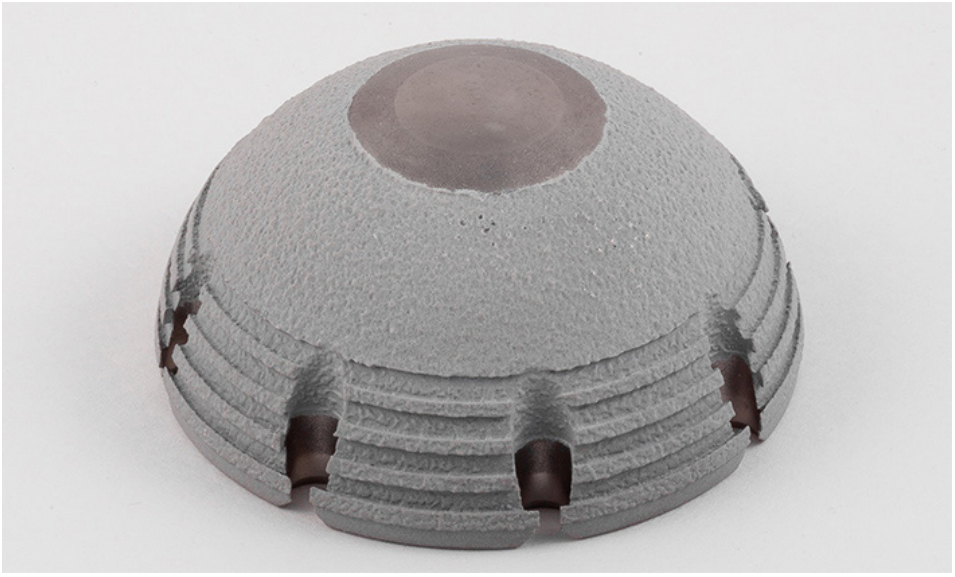
Orchid Orthopedic Solutions has signed an agreement to acquire the Cam Bioceramics coating facility and operations in Suzhou (Cam China), a company that provides hydroxylapatite (HA) plasma coatings in China. Cam Bioceramics, based in Leiden, the Netherlands, specializes in calcium phosphates; the company is Dutch-owned.

According to the November 19, 2015 news release: "The acquisition of Cam China strongly commits Orchid to the market in Asia. We will continue to expand our manufacturing platform and coating capabilities in China to support the growing demand from our global and local customers," said Christopher Norbye, Orchid's China-based international executive vice president.

"We are convinced that Orchid is the perfect company to continue the development of the operations and relationships we have built over the last four years in China and I am confident the team in China will have great opportunities to grow the business together with Orchid going forward," added Gerard Kok, the founder and owner of Cam Bioceramics.

Norbye told *OTW,* "Adding the Cam China coating facility supports our long-term strategy to have full value stream services on three continents: North America, Europe and Asia. We are continuing to look at businesses that will support this strategy and be a good fit to our Orchid culture. The timing is something that cannot always be controlled, but when the right opportunity comes, it makes sense to execute."

Asked about their plans in China over the next one to two years, he noted, "We will ensure success by supporting this facility with the Orchid global coating expertise and offer our customers world class service and quality from China. We will also continue to invest in people, equipment and processes to further grow our capabilities in China." — *EH*



Courtesy of Orchid Orthopedic Solutions

India Launches First Stem Cell Medication

India's first stem cell drug, called Stempeucel, is expected by its supplier to be on the market by the end of this year. Stempeucel is made from stem cells in the bone marrow and is manufactured by Stempeutics Research, a firm owned, in part, by Cipla Ltd. The drug is intended to treat Buerger's Disease, a rare condition marked by a reduced blood flow to the limbs. About a million people in India are affected by this ailment.

"We are waiting for the conditional approval from the Drug Controller General of India (DCGI). Once the approval is in place, we are planning to launch the product in the Indian market", said B.N. Manohar, Stempeutics managing director and chief executive officer.

Courtesy of Stempeutics Research

According to Shine Jacob, writing for the publication *Live Mint*, the company is set to start phase III trials in the U.S. and Europe to prove the drug's efficacy and determine its dosage. Stempeutics' aim is to launch the product in Europe by 2018. It plans to seek permissions from the European regulator European Medicines Agency (EMA) to conduct a trial on 200 patients in Europe.

The EMA has already granted Stempeucel an orphan drug designation which means that no other drug is available for that disease and it is an unmet medical need. This development is expected, by its producers, to fast track its clearances. The company can get a 10-year market exclusivity if awarded an orphan drug status and clears trials. Out of the 18 countries in which Stempeutics has applied for patents, seven countries—the U.S., Australia, New Zealand, China, Japan, Singapore and South Africa—have granted the drug patents.

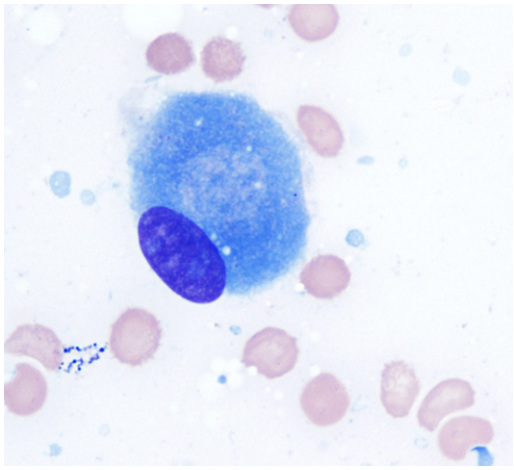
About 200,000 people are estimated to suffer from Buerger's Disease in the U.S. and Europe combined. Currently, only painkillers are used to treat the condition, in which the patient's blood vessels become inflamed, and blocked with blood clots. Manohar said, "Currently, there is no drug available in the world for this treatment. Stempeucel's second phase clinical trial was the largest one in the world for Buerger's Disease." According to Manohar, about 90 patients involved in this trial across 11 hospitals saw pain reduction, increased blood flow and ulcer reduction.

According to the company, it is also set to start phase II trials in India for using Stempeucel for diabetic foot ulcers. Since the drug has already passed safety trials for Buerger's Disease, it can directly start Phase II trials for diabetic foot ulcer. — *BY*

Researchers Turn Mesenchymal Stem Cells Into Osteoblasts

Researchers at the University of North Carolina (UNC) School of Medicine are on to something significant. They have found a way to get mesenchymal stem cells to become not the customary fat cells but osteoblasts—bone cells. The researchers used cytochalasin D, a naturally occurring substance found in mold, to alter gene expression in the nuclei of mesenchymal stem cells. To the researcher's astonishment, this forced them to become bone cells.

"This was not what we expected. This was not what we were trying to do in the lab. But what we've found could become an amazing way to jump-start local bone formation," said Janet Rubin, M.D., senior author of the paper and professor of medicine at the UNC School of Medicine. She added, "And the bone forms quickly. The data and images are so clear; you don't have to be a bone biologist to



Wikimedia Commons and Gabriel Cabonetti

see what cytochalasin D does in one week in a mouse." By injecting a small amount of cytochalasin D into the bone marrow of mice the researchers had caused bone to form.

As reported by the journal *BioScience Technology* the protein called actin, forms fibers that span the cytoplasm of cells to create the cell's cytoskeleton. Osteoblasts have more cytoskeleton than do adipocytes (fat cells). Buer Sen, M.D., first author of the research published in the journal *Stem Cells* and research associate in Rubin's lab, used cytochalasin D to break up the actin cytoskeleton. This should have destroyed the cell's ability to become bone cells, he noted. Instead, Sen found that actin was trafficked into the nuclei of the stem cells, where it had the surprising effect of inducing the cells to become osteoblasts.

Rubin's first reaction to Sen's discovery was disbelief. "This must be wrong. It goes against everything in the literature." Sen replied, "I've rerun the experiments. This is what happens."

Rubin's team expanded the experiments and found that when actin enters and stays in the nucleus, it enhances gene expression in a way that causes the cell to become an osteoblast. — *BY*

ALLOB Awarded Orphan Drug Designation

Bone Therapeutics' allogeneic bone cell therapy product called ALLOB has received Orphan Drug Designation (ODD) from the European Medicines Agency (EMA) as well as from the U.S. Food and Drug administration(FDA), The product is used in the treatment of the genetic bone disorder osteogenesis imperfecta—more commonly known as brittle bone disease.

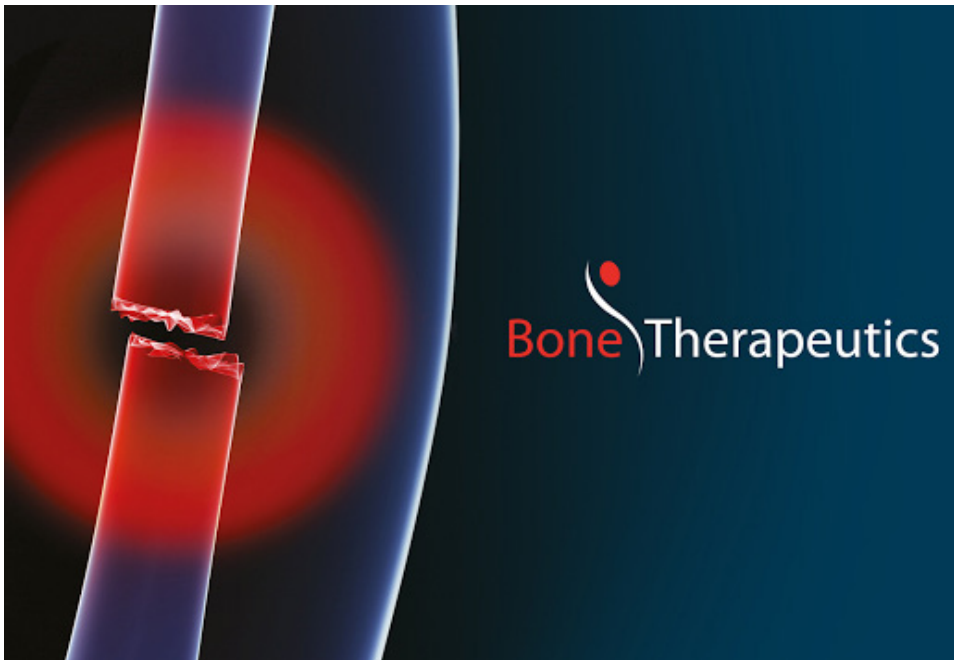
The press release states:"Osteogenesis imperfecta is a rare genetic disorder that causes bone fragility, fractures and deformities. The estimated prevalence for Europe and the U.S. is 0.64 cases per 10,000 inhabitants." Treatments for the disability are limited. They include surgery and the use of bisphosphonates—strategies that are often associated with severe complications. At present here are no long-term solutions.

According to the press release, this orphan drug designation "opens up the possibility for Bone Therapeutics to further develop its allogeneic bone cell therapy product, ALLOB, for the treatment of osteogenesis imperfecta." Since the underlying cause of the disorder is genetic, the allogeneic origin of the ALLOB cells could be a significant benefit.

Bone-forming cells can be administered systemically or locally at the site of fractures in order to improve structural integrity of the bone matrix by replacing the defective bone cells. The possibility exists that ALLOB could increase bone strength, decrease the risk of new fractures and accelerate fracture repair in these patients.

By obtaining orphan drug designation, Bone Therapeutics will benefit from market exclusivity in Europe for ten years and for seven years in the U.S. It has been almost ten years since the FDA granted an orphan drug designation in the field of osteogenesis imperfecta.

Company CEO Enrico Bastianelli said: "We are delighted to have received orphan drug designation for ALLOB. Currently, we have not initiated clinical trials in this field. However, the orphan drug designation gives us the opportunity to further enhance our product portfolio in the future and develop a more effective treatment that, contrary to the available treatments, targets the cause of the disease." — *BY*



Courtesy of Bone Therapeutics

LARGE JOINTS

No Link Found Between Infection and Type of Anesthesia

Is there a relationship between the type of anesthesia used to perform a joint replacement surgery and the incidence of surgical site infections (SSI)?

According to a new study titled "The Impact of Anesthetic Management on Surgical Site Infections in Patients Undergoing Total Knee or Total Hip Arthroplasty" published in the November 15, 2015 issue of the journal *Anesthesia & Analgesia* the answer is 'no'. And its conclusion appears to debunk earlier research that purported to find a link between the type of anesthesia used in joint replacements and a risk of surgical site infection.

Wikimedia Commons and David Dorward; Ph.D. National Institute of Allergy and Infectious Diseases

Surgical site infection is one of the most challenging and costly complications associated with total joint arthroplasty. The primary of the case-controlled trial was to compare the risk of SSI within a year of surgery for patients undergoing primary total knee arthroplasty (TKA) or total hip arthroplasty (THA) and revision TKA or THA under general anesthesia versus neuraxial anesthesia.

The researcher's secondary aim was to determine which patient, anesthetic, and surgical variables influence the risk of SSI. The researchers hypothesized that patients who undergo neuraxial anesthesia may have a lesser risk of SSI compared with those who had a general anesthetic. The researchers were Sandra L. Kopp. M.D.; Elie F. Berbari, M.D.; Douglas R. Osmon, M.D., MPH; Darrell R. Schroeder, M.S.; James R. Hebl, M.D.; Terese T. Horlocker, M.D. and Arlen D. Hanssen, M.D.

The seven researchers conducted a retrospective, case-control study of patients undergoing primary or revision TKA and THA between January 1, 1998, and December 31, 2008, who subsequently were diagnosed with an SSI. The cases were matched 1:2 with controls based on type of joint replacement (TKA ver-

sus THA), type of procedure (primary, bilateral, revision), sex, date of surgery (within 1 year), ASA physical status (I and II versus III, IV, and V), and operative time (<3 vs >3 hours).

They found 202 SSIs during the 11-year study period. Of the infections identified, 115 (57%) occurred within the first 30 days and 87 (43%) occurred between 31 and 365 days. From both univariate and multivariable analyses, the authors found no significant association between the use of central neuraxial anesthesia and the postoperative infection (univariate odds ratio [OR] = 0.92; 95% confidence interval [CI], 0.63–1.34; $P = 0.651$; multivariable OR = 1.10; 95% CI, 0.72–1.69; $P = 0.664$).

The use of peripheral nerve block was also NOT found to influence the risk of postoperative infection (univariate OR = 1.41; 95% CI, 0.84–2.37; $P = 0.193$; multivariable OR = 1.35; 95% CI, 0.75–2.44; $P = 0.312$). The factors that were found to be associated with postoperative infection in multivariable analysis included current smoking (OR = 5.10; 95% CI, 2.30–11.33) and higher body mass index (BMI) (OR = 2.68; 95% CI, 1.42–5.06 for BMI ≥ 35 kg/m^2 compared with those with BMI < 25 kg/m^2).

The authors concluded that there was no difference in the incidence of SSI in patients undergoing total joint arthroplasty under general versus neuraxial anesthesia. They further wrote that the use of peripheral nerve blocks does not influence the incidence of SSI. More meaningful to SSI risk was higher rate of BMI and smoking—both of which were found to significantly increase the incidence of SSI in patients undergoing lower extremity total joint arthroplasty.

The conclusions of this study are in contrast to other, recent studies using large databases which concluded that the use of neuraxial compared with general anesthesia was associated with a decreased incidence of SSI in patients undergoing total joint arthroplasty. — *BY*

Is Medicare Hip/Knee Replacement Data Flawed?

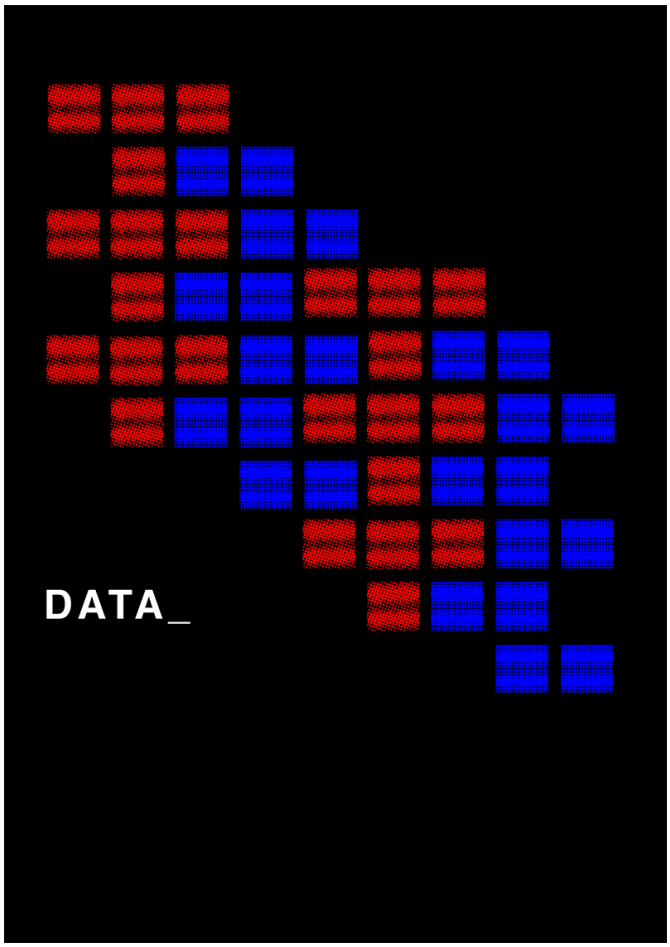
A new study from AARP (formerly the American Association for Retired Persons) raises troubling questions about Medicare's Hip/Knee Replacement data.

Medicare recently reported that readmission rates for hip/knee replacement patients were falling—specifically that readmission rate within 30 days after hip replacement in 2009 was 42 per 1,000 patients. By 2013, those rates had fallen to 34 per 1,000 patients. For knee surgeries, the 2009 readmission rate was 45 per 1,000 patients, and that rate fell to 34 per 1,000. In 2013, nearly 450,000 people got new knees or hips. Medicare spent $6.6 billion for their surgeries and treatment.

A new study from AARP, however, questioned the Medicare numbers. Lead author, Leigh Pervis, director of health services at the AARP Public Policy Institute, noted that the drop in readmission rates was only for patients on Medicare. For younger patients, those too young to be on Medicare but undergoing the same surgery, the study turned out differently. According to Pervis, for folks under 65, there was very little change in the rate of readmission.

Pervis found that for hip surgery, readmission rates dropped 38% for Medicare patients but just 3% for patients between the ages of 50 and 64. For knee surgery, the decline among the older group was 36%, compared with 12% among the younger group.

Bob Rosenblatt, writing for *Next Avenue* about the AARP study suggests that the rates of readmissions in Medicare are not what they seem to be because hospitals



Wikimedia commons and Eandertonallen

are putting more and more patients on "observation status." Observation status means that when a patients returns to the hospital, that he or she is put in a bed and treated but is not counted as an official admission.

This is happening because hospitals have been reducing readmissions among the Medicare population ever since the federal government began levying financial penalties for readmissions. Between 2011 and 2014 hospitals have paid $420 million in fines for readmissions, according to a *Kaiser Health News* report quoted by Rosenblatt.

Another source of the problem is difficulty with the surgery itself. The implant sites can become infected or doctors may not install the implants properly. The AARP study said: "It is notable that device complications were responsible for a large share of hospital readmissions following a hip or knee replacement. In fact, "the share of hospital readmissions linked to device complications actually increased between 2009 and 2013 among the 65- to 84-year-old age group."

The study went on to state that "medical experts have consistently expressed concerns that the U.S. Food and Drug Administration does not adequately regulate the safety and effectiveness of medical devices like artificial joints. The results of our analysis should serve as a warning to supporters of recent efforts to further reduce such oversight."

The study is titled "Impact of the Medicare Hospital Readmission Reduction Program on Hospital Readmissions Following Joint Replacement Surgery". — *BY*

EXTREMITIES

NovaBone Gets USP-TO Patent for Bone Regeneration Kit

Florida-based NovaBone Products, LLC has received a patent for its—as stated in the November 12, 2015 news release—"kit for a minimally invasive delivery of a composition for regenerating bone at or near the site of a bony defect."

"This patent is for an effectively designed and highly demanded delivery system that will include the use of porous and non-porous glass, as well as various particle sizes," said Greg Pomrink, vice president, Research and Development. "This patent demonstrates NovaBone Products' expertise in formulating collagen and bioactive glass devices that support surgeon's needs."

"We are using innovation, along with an aggressive research and development strategy to create devices that will facilitate surgeries while producing enhanced outcomes," said Art Wotiz, president, in the new release. "The new patents protect our technology and provide our company with the platform to continue to explore devices that will benefit the medical community and patients."

Wotiz told *OTW*, "This allowance brings the total of new patents for our collagen/bioactive glass platform to five. Taken together, our portfolio broadly protects for use of these composites when the amount of bioactive glass is 80% or greater. The allowance includes our MIS delivery system, the favored product of many surgeons."

"Our collagen/bioactive glass platform is critically important to NovaBone Products as we now have something for every clinician's preference. We are already seeing rapid growth of sales, and we expect this momentum to accelerate as we get more hospital approvals." — *EH*

NovaBone Products, LLC

Bariatric Surgery Reduces Psoriatic Arthritis Symptoms!

NYU Langone Medical Center researchers have found that psoriatic arthritis and psoriasis symptoms were significantly lessened in patients who underwent bariatric (weight loss) surgery. The study was led by Soumya Reddy, M.D., an assistant professor of medicine in the division of rheumatology at NYU Langone, and co-director of NYU Langone's Psoriatic Arthritis Center.

According to the November 7, 2015 news release, Dr. Reddy and her colleagues reviewed the medical charts of 9,073 weight-loss surgery patients who were treated between 2002 and 2013 at NYU Langone's Weight Management Program. "They identified 86 patients who had psoriasis before their operation, 21 of whom were also diagnosed with psoriatic arthritis, and compared their symptoms before and after undergoing bariatric surgery. Patients were on average monitored for more than six years, with an average excess weight loss of 46.2% body weight."

The researchers found that 62% of patients with psoriatic arthritis and 55% of patients with psoriasis reported improvements in their disease.

Dr. Reddy commented to *OTW*, "We undertook this study because of the increasing evidence of the association of obesity and psoriasis and psoriatic arthritis (PsA) and recent studies showing obesity may be a risk factor for the development of PsA. Several case reports and a two smaller case series have reported an improvement in psoriasis after bariatric surgery but no studies have evaluated PsA after bariatric surgery. We were not surprised to see improvement in psoriasis and psoriatic arthritis after bariatric surgery but we were surprised to see that improvement was associated with more severe disease and older age at diagnosis."

"It is important to be aware of the association of both obesity and PsA in pso-

NYU Langone MEDICAL CENTER

Soumya Reddy, M.D., New York University Langone Medical Center

riasis patients who may be presenting to the orthopedist for management of joint issues given treatment of these conditions may alter management. We have planned a prospective study evaluating psoriasis and PsA before and after bariatric surgery using objective physician derived measures such as PASI scores and joint counts. We also plan to evaluate for changes in inflammatory markers, adipokines, cytokines, and micro biome post surgery."

"It's important to have conversations with our patients with psoriatic diseases about healthy choices for weight management in overweight and obese individuals since there is growing evidence that excess weight may impact disease severity and response to medications. At the NYU psoriatic arthritis center we take a multidisciplinary approach to patients with referral to a nutritionist when appropriate." — *EH*

PEOPLE

In Memoriam: John Samuel Gould, M.D.

He was an accomplished orthopedic surgeon, a leader, and he had a passion for writing. John Samuel Gould, M.D., Professor Emeritus at The University of Alabama at Birmingham (UAB) School of Medicine passed away on September 29, 2015.

Dr. Gould was preceded in death by his parents, Dr. Nathaniel and Edith Marion Gould. He leaves his wife and loving companion of 50 years, Sheryl, and their four children: Elisabeth Rachel Fowler (Michael) of Birmingham; Katherine Rebecca Mathews (Joe Bill) of Sylva, North Carolina; Carolyn Virginia Burton (David) of Atlanta, Georgia; and John William Nathaniel Gould (Alexandra) of Franklin, Tennessee; and seven grandchildren: Frances Claire Fowler, Abigail Hartford Fowler, Benjamin Luther Mathews, Timothy Samuel Gould, Charlotte Rose Gould, August Nathaniel Burton, and Halsey Thomas Burton.

John Samuel Gould, M.D., Courtesy The Birmingham News

A private burial was held on October 1 at Southern Heritage Cemetery in Pelham, Alabama. A celebration of Dr. Gould's life took place November 14, 2015 in Birmingham.

John Gould was born in St. Johnsbury, Vermont, on May 10, 1939. He graduated from Harvard University in Cambridge, Massachusetts, and in 1964 from the University of Vermont Medical School in Burlington.

Dr. Gould began his general surgery internship at Boston City Hospital that year, and met and married his wife, Sheryl Hartford, in 1965. At the completion of his internship and one more year of general surgery, Dr. Gould joined the U.S. Navy and was stationed in San Diego, California.

During the first year of his two-year assignment he served as medical officer aboard the guided missile cruiser USS Canberra, which was deployed to Vietnam. After his time in the Navy, Dr. Gould began a residency in orthopedic surgery at the University of Pittsburgh. He then joined his father in private practice in Brockton, Massachusetts, for three years, after which time he decided to specialize in orthopedic hand surgery, and began a fellowship at Duke University in Durham, North Carolina.

Dr. Gould was selected to be full Professor of Surgery at University of Alabama Birmingham (UAB) in 1982. He remained chief of the Hand Section until 1986. He was then recruited to be Chief of The Department of Orthopaedic Surgery at the Medical College of Wisconsin.

During his time in Milwaukee he began to change his focus from hand surgery to surgery of the foot and ankle and instituted a fellowship for orthopedic foot and ankle surgery at the Medical College. He headed that orthopedic program for 10 years before deciding to return to the warmer winters in Birmingham to join Alabama Sports Medicine and Orthopaedic Center until 2004. Dr. Gould then joined Orthopaedic Specialists of Alabama at Baptist Montclair Hospital.

In 2006 he rejoined UAB, this time as Chief of the Foot and Ankle Section of the Orthopaedic Division. There he treated hand and foot and ankle patients, with a special interest in nerve problems and total joint replacement for arthritic ankles. He was awarded the title Professor Emeritus of the UAB School of Medicine by the Board of Trustees on November 7, 2014.

At various times in his career Dr. Gould was selected to serve as president of the American Orthopaedic Foot and Ankle Society, of the Clinical Orthopaedic Society, of the Mid-America Orthopaedic Association and of the Alabama Orthopaedic Society.

Following his death, his friend wrote of Dr. Gould, "Writing was one of his greatest passions, and he had a true gift for it. He was Editor in Chief of the journal, *Microsurgery* (1986-1996), the *American Journal of Orthopaedics* (1996-2006), Foot and Ankle Editor for *Orthopaedic Knowledge Online Journal*, and authored four professional books: 'The Foot Book' Williams and Wilkins, 1988; 'Operative Foot Surgery' W.B. Saunders, 1994; 'My First Love: The Art, The Practice, and The Ethics of Medicine' Seacoast Publishers, 2004; and 'The Handbook of Foot and Ankle Surgery: An Intellectual Approach to Complex Problems' Jaypee Bros. 2013. He also self-published 'The Medical College of Wisconsin: The Gould Years,' where he described his ten years as chief of that department."

Rob Crabtree, administrative director of the UAB Division of Orthopedic Surgery, said of Dr. Gould, "My fondest memory of him is how loyal he was to the organizations wherever he worked. I affectionately nicknamed him 'The Professor' when we were still in private practice, never knowing we would have the opportunity to work in academic medicine together at a later date. I can recall numerous counseling and mentoring sessions that he conducted with his own fellowship trainees, younger new-to-the-practice surgeons, and most importantly, his ability to communicate with senior management partners/directors and administration. One of my highest honors was the Sunday evening he called me and asked me to co-author a book chapter with him about an administrative process. He was a communicative and wise champion."

"A specific example would be he actually kept a scorecard of our faculty at UAB on who attended resident interviews and resident graduation activities. As a seasoned leader who could have allowed others to assume more duties, he instead chose to lead by example, stressing the importance of the educational and research processes and initiatives in academic medicine. Even after progressing into his later years, he still attracted the Grand Rounds speakers overseeing that process and often sat down with me to go through the 'faculty roster' anytime we had an event because he believed in the highest of expectations of commitment."

"The orthopaedic community is aware of his passion for orthopaedics and his unsurpassed ability as a teacher and researcher/writer; however, having been very close to him, he had a tremendous love for his family and was a huge sports fan. He loved his alma mater of Harvard University and often

updated me of their football scores from the prior weekend. He also supported the University of Alabama (constantly ribbing me as an Auburn University graduate!!) and loved tailgating with friends. He followed traditional teams supporting the Boston Red Sox having grown up in the Northeast (I was so happy for him when the Sox won the Series in 2004 after a century drought) and also the Green Bay Packers in the NFL (having served as a Department Chairman in Wisconsin). He also was well-versed in national politics and would often share his views with me in his office during what we called our 'fireside chats.'"

Joseph Sherrill, M.D. had the pleasure of knowing Dr. Gould for many years. He said of his longtime friend, "I have had the privilege to have known, to have been mentored by, and to been an associate of Dr. Gould. John came to Birmingham in 1975 after finishing a fellowship in hand surgery with Dr. Leonard Goldner, who was a true pioneer in hand surgery."

"I began my orthopedic residency in 1977 where I was fortunate to be mentored by John for three months each year followed by a fellowship in hand surgery. Over a four-year period we spent a considerable period of time working together. John's greatest asset or love or strength was teaching. And this was perfect for me as my love was also to learn everything possible about caring for hand conditions."

"John was gifted with a brilliant intellect and ability to organize and train a team of physicians (residents, fellows, nurses) to provide quality care. Over 40 years John has trained a very large number of hand and later foot surgeons. I suspect most of his fellows and residents would attest to his teaching or mentoring skills and would place or rank him number one in this skill set. After completion of my hand fellowship I went into private practice with my father. John offered me a position to join staff at UAB in hand surgery but understood my need to work with my dad also having on orthopedic father."

"During his time in Birmingham until 1986 we continued our friendship thru our common love of hand surgery. When John returned to Birmingham in 1986 we finally became partners at Alabama Sports Medicine. I feel John's legacy as regards orthopedics, as well as hand and foot surgery, lies in his ability to teach and I know that his knowledge, surgical judgment and skill survives him and will be continued and will be passed on to the next generation by his numerous fellows and associates." — *EH*

Orthopedics This Week | RRY Publications LLC

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