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Orthopedics This Week

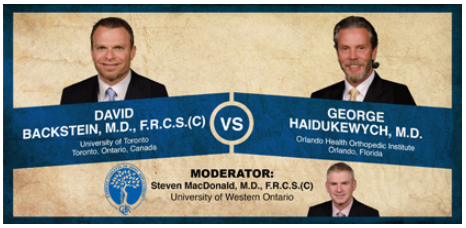
WEEK IN REVIEW

4 POD Defender Puts DOJ on Ropes >> The government's healthcare cop, the DOJ, says Reliance Medical violated the Anti-Kickback Statue of the False Claims Act. Rubbish, says Reliance's lawyer, Pat Hooper who beat the DOJ the last time they went after physician owned entities. He says the government's just coming back for a second bite of the apple. Read how he is defending his clients and PODs.

8 Harvard Developing Pants With "Muscles" That Walk! // One Hip Surgery Saves $160,000 in Future Medical Costs! // Don't Know Your Patient's Global Sagittal Angle? You Should >> Harvard's Wyss researcher details their remarkable Soft Exosuit invention. John Tongue, M.D. documents the lifetime societal cost savings of hip fracture surgery. A spine fellow in the NYU Langone laboratory discusses his discovery of the Global Sagittal Angle, which "unmasks" the link between spinal and lower limb alignment.

11 Dunbar, Berend Debate the All Poly Tibia >> "It's undeniable that the all poly tibia is cheaper," argues Mike Dunbar. "And there is no backside wear, more poly for the same tibial resection, better RSA data, and better survivorship." "I agree that all poly components are equal to well-designed monoblock designs," counters Mike Berend. "But caution… it's design and technique sensitive."

15 Backstein v. Haidukewych Over the Mega Prosthesis >> David Backstein has his favorite mega prosthesis system and he's not giving it up any time soon. "You have shorter length of stay, and there is no chance of malunion or non-union." George Haidukewych pulls the reins in, saying, "Mega prostheses have a limited role, namely, in situations where fixation is likely to fail. ORIF remains the gold standard for periprosthetic fractures."



BREAKING NEWS

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One **Stem Cell Fact** You Need to Know

Will **Jeff Binder** Follow **Blackstone** to China?

Recalls of Medical Devices **Down**

Mortality Rates Chopped in Half Due to…Data?

Physicians Targeted in **Fraudulent Tax Return Scam**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: It is time for investors to focus on the third quarter earnings. But we think institutional investors are really just trying to lock in the gains of 2014 and avoid mistakes heading into the end of the year. The U.S. economy is recovering and, as we can see from the steady strengthening of the U.S. dollar, it stands in sharp relief to the economies of Europe, Japan and China. In fact, the only real cloud is that ever rising dollar.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	11.52%	(1.01%)	Live by the M&A, die by the M&A? Integration can be a struggle. Sure. But those concerns are fully priced in SYK.
2	7	Symmetry Medical	6.55	9.04	Huge jump this week. The transformation of SMA is sparking the imagination of investors.
3	6	Integra LifeSciences	12.57	0.06	Cheapest equity in orthopedics based on PE, PEG and PSR. Why? 12% operating profit margins. But that can and will likely change.
4	2	Zimmer	29.12	1.88	Now the Biomet acquisition is baked into ZMH's price. And investors just kind of hang on for the next three months.
5	5	NuVasive	8.01	0.37	NUVA has been outperforming analyst's expectations routinely. Will they do it again this quarter? Analysts predict $0.25/share.
6	3	Medtronic	28.84	(0.03)	Analysts seem to be distracted by the shiny object of tax inversion. Next earnings report expected in November.
7	4	Globus Medical	29.68	5.71	Investors have been bidding GMED higher. Valuation now moderately expensive. But with these profit margins, still a top ten company.
8	8	Exactech	10.26	(1.91)	This is the 6th least expensive orthopedic equity. Investors in Exactech have enjoyed an 11% bump from its yearly low.
9	9	ConMed	10.51	(4.59)	New management in charge. Analysts taking a decidedly conservative approach to sales and earnings estimates as they get to know the new team.
10	10	Johnson & Johnson	26.58	3.76	Watch out for the dollar. A strong dollar changes the risk/reward for investors buying JNJ's dividend in this low interest rate environment.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	LDR Holding Corp.	LDRH	$31.52	$818	15.12%
2	Tornier N.V.	TRNX	$24.01	$1,174	11.93%
3	Alphatec Holdings	ATEC	$1.73	$169	9.49%
4	Symmetry Medical	SMA	$10.13	$380	9.04%
5	MiMedx Group	MDXG	$7.21	$762	6.19%
6	Globus Medical	GMED	$19.45	$1,835	5.71%
7	Wright Medical	WMGI	$31.00	$1,563	4.17%
8	Johnson & Johnson	JNJ	$107.10	$302,053	3.76%
9	Zimmer Holdings	ZMH	$101.66	$17,172	1.88%
10	CryoLife	CRY	$10.25	$286	0.59%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.14	$7	-61.25%
2	Aurora Spine	ASG	$1.57	$25	-22.42%
3	MicroPort Scientific	853	$0.48	$684	-20.89%
4	TiGenix	TIG.BR	$0.73	$118	-14.33%
5	K2M Group Holdings	KTWO	$13.26	$492	-10.28%
6	Orthofix	OFIX	$30.84	$569	-8.19%
7	ConMed	CNMD	$37.40	$1,023	-4.59%
8	Smith & Nephew	SNN	$84.03	$15,008	-3.68%
9	Bacterin Intl Holdings	BONE	$4.61	$31	-3.35%
10	Exactech	EXAC	$23.10	$318	-1.91%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$63.34	$62,043	16.28
2	Globus Medical	GMED	$19.45	$1,835	16.50
3	Zimmer Holdings	ZMH	$101.66	$17,172	18.23
4	Johnson & Johnson	JNJ	$107.10	$302,053	18.35
5	Exactech	EXAC	$23.10	$318	19.06

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$30.84	$569	257.28
2	NuVasive	NUVA	$35.16	$1,652	68.10
3	Symmetry Medical	SMA	$10.13	$380	52.29
4	CryoLife	CRY	$10.25	$286	30.79
5	Smith & Nephew	SNN	$84.03	$15,008	28.70

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$10.25	$286	1.03
2	Exactech	EXAC	$23.10	$318	1.06
3	Globus Medical	GMED	$19.45	$1,835	1.23
4	ConMed	CNMD	$37.40	$1,023	1.63
5	Zimmer Holdings	ZMH	$101.66	$17,172	2.13

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$30.84	$569	13.98
2	NuVasive	NUVA	$35.16	$1,652	5.57
3	Symmetry Medical	SMA	$10.13	$380	4.36
4	Smith & Nephew	SNN	$84.03	$15,008	2.84
5	Johnson & Johnson	JNJ	$107.10	$302,053	2.59

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	$0.14	$7	0.34
2	Alphatec Holdings	ATEC	$1.73	$169	0.82
3	Bacterin Intl Holdings	BONE	$4.61	$31	0.90
4	Symmetry Medical	SMA	$10.13	$380	0.95
5	RTI Biologics Inc	RTIX	$5.17	$294	1.21

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.73	$118	20.64
2	MiMedx Group	MDXG	$7.21	$762	9.62
3	LDR Holding Corp.	LDRH	$31.52	$818	7.33
4	Wright Medical	WMGI	$31.00	$1,563	5.81
5	Johnson & Johnson	JNJ	$107.10	$302,053	4.11

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

POD Defender Puts DOJ on Ropes

BY WALTER EISNER

The phone rang. The voice on the other end of the line said, "My name is Pat Hooper. I'm Reliance Medical's lawyer."

Patric Hooper/Hooper, Lundy & Bookman, PC

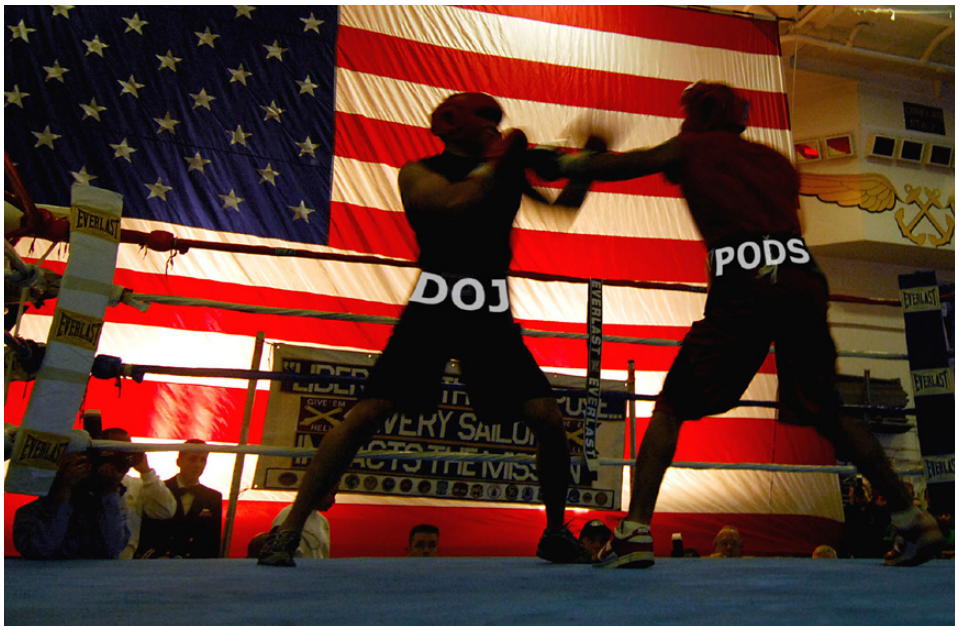
Reliance Medical Systems, LLC is the device manufacturer with physician owned distributor (POD) partners that was recently sued by the U.S. Department of Justice (DOJ) for allegedly engaging in illegal kickbacks.

When a writer gets a call from a lawyer, the news is usually not good.

This time, however, it was fascinating. After talking with Mr. Hooper, it is increasingly obvious to this writer that the government's case against Reliance is standing on very shaky legs indeed. It is in no way a slam dunk for the DOJ. At the end of the call, we could only reflect on the old adage, "Where one stands depends upon where one sits."

A Stand Off

Hooper, a former Deputy Attorney General in California and lead counsel in the seminal 1995 *Hanlester* case regarding physician ownership of labs, is taking the position that the Department of Justice's Office of Inspector General (OIG) is a cop trying to improperly stitch together entirely new public policy out of mere legal scraps that the courts and elected officials have addressed over the years, found to be confusing, **but legal.**



Wikimedia Commons and U.S. Navy photo by Mass Communication Specialist Seaman Apprentice Matthew Bookwalter

The Accusation

Hooper's clients, Adam Pike and Bret Barry are accused of violating the False Claims Act (FCA). The DOJ says they knowingly assisted hospitals and physicians to file false claims for Medicare reimbursement. It says claims filed by the hospitals and doctors were "tainted" by illegal kick-backs due to surgeon ownership in PODs set up by the defendants.

In response to the government's September 8, 2014 complaint, Hooper filed a motion to dismiss the case on September 19, 2014, arguing that case law, precedent and some inconvenient truths are fatal to the government's case.

The first inconvenient truth is that the DOJ, according to the motion, neglected to tell the court about the 1995 *Hanlester* case. Second, the government failed to inform the court of the 2006 California Attorney General's opinion and other findings that PODs are legal. Third, the hospitals did not file any false claims because the surgeries actually took place and would have occurred regardless of which devices were used. Fourth, the defendants paid the physician investors in accordance to the law. Fifth, his clients have no input into whether or not surgeries are necessary because they are not physicians and finally, the government failed to cite even one specific instance of any false claim and relied on broad and inconsistent allegations that all claims were false.

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

RELIANCE MEDICAL SYSTEMS, APEX MEDICAL [illegible] OGIES, LLC, KRONOS [illegible] OFFMAN; [illegible]

CASE NO. CV-14-6979 DDP PJWx

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS

Date: November 3, 2014
Time: 10:00 a.m.
Courtroom 3
Hon. Dean D. Pregerson

Trial Date: None Set

Reliance's Motion to Dismiss

Based on those issues, Hooper is asking the court to dismiss the government's complaint

Hanlester Precedent

Hanlester Network v. Shalala was a test case of a 1989 OIG Fraud Alert regarding "suspect" joint ventures. *Hanlester*, says Hooper in Reliance's filing, was the "first instance in which physicians self-referral joint ventures were challenged" under the Anti-Kickback Statute (AKS).

Doctors had invested in partnerships that operated clinical labs managed by SmithKline to which they referred patients. "As here, the general partners marketed the ownership interests in the laboratories to physicians who were most likely to use the laboratory services...and received distributions based on the percentage of their ownership in the partnership rather than on the number of tests referred."

In 1989, the OIG announced it was excluding the labs and founders from the Medicare program (Medicare Death Penalty) because "the payments were really kickbacks for referrals which violated the AKS." The OIG used their fraud alert as its "playbook" for litigating the case, says Hooper.

As in Reliance, the OIG alleged that encouraging physician owners to use the laboratories as much as possible, was unlawful.

Defining Unlawful Inducement

The Court of the Ninth Circuit saw it differently. According to Hooper, the court "concluded that *encouraging lim-*

ited partners to increase their use of the laboratories and the fact that the limited partners received 'substantial' distributions from the partnership laboratories, did not constitute unlawful inducement under the AKS." Hooper was the lead lawyer for the labs.

Hanlester resulted in the government having to prove that a defendant knew that the AKS prohibited offering or paying remuneration to induce referrals and to prove further that the defendant engaged in the prohibited conduct with the specific intent to disobey the AKS.

According to Reliance's motion, the "intent" issue was so "problematic" that DOJ obtained an amendment to the AKS in 2010 as part of the Affordable Care Act to eliminate the requirement imposed by *Hanlester* requiring proof of specific intent. Their motion notes that the DOJ has also omitted mention of *Hanlester* in any Advisory Opinions, Fraud Alerts and other guidances.

Relying on the California Attorney General

Also "conspicuously" absent from DOJ's complaint is any mention of the February 27, 2006 Opinion of the California Attorney General which specifically addressed the legality of POD under California's anti-kickback statutes. The opinion concluded that "*a physician may prescribe for a patient a medical device that is distributed by a company in which the physician has an ownership interest*," and "the company may solicit physician investors in the company."

Reliance and their healthcare business attorney relied on this opinion in conducting their business in California.

The Confusion of "Hatch"

It's not surprising, argues the Reliance motion, that due to the "stiff competition for the very large manufacturing companies," Congress was asked to look into PODs, producing the "Hatch Report" in 2011. The report noted that "*two major national laws firms have come down squarely on opposite sides of the issue*. It appears that hospitals and physicians, like medical device manufacturers, would benefit greatly from clear legal guidance regarding doing business with PODs," continued the report. Furthermore, the reports states that the "most consistent comment from individuals interviewed by the Committee was '*it is unclear to them if PODs are legal or illegal.*'"

A Second Bite of *Hanlester*

In response to the Hatch Report, the OIG issued their 2013 Special Fraud Alert. "The list bears a striking resemblance to the list of suspect criteria in the 1989 OIG Fraud Alert that culminated in the *Hanlester* proceeding... and to the allegations in the Complaint against Reliance," states Reliance's motion. Furthermore, the 2013 Fraud Alert post-dates the alleged false claims submitted between 2007 and 2012.

Ownership Disclosure

Reliance points out that an October 2013 OIG report about device utilization rates when PODs are involved, states that, "*Federal Law does not require physicians to disclose ownership in device companies to hospitals they practice in and does not require them even to disclose such ownership to their patients.*"

Malpractice Dressed Up as False Claims

In Reliance's motion addressing the issue of medical decisions made by surgeons, Hooper cites case law that says the FCA is not intended to "substitute as a federal remedy for medical practice actions."

The suit against Reliance and the related whistleblower action against a Reliance POD surgeon investor named Aria Sabit, M.D., "appear to be malpractice actions dressed up as FCA claims."

What Claim?

DOJ has the burden of each element of its FCA causes of action, says Hooper.

He says the government relies on "unreasonable presumptions" such as that PODs are "inherently suspect" to make their claim. The government "must state with particularity" false claims. Courts do not have to accept as "true" factual allegations that are, among other things, internally inconsistent to consider a motion to dismiss.

The government makes two contentions.

First, the Medicare claims submitted by the doctors and hospital were false because they were tainted by kickbacks and the defendants knowingly caused the presentation of claims even though certain surgeries were not medically necessary. The government only claims "certain" unidentified surgeries were not medically necessary.

Second, asks the Reliant motion, "How can it possibly be considered reasonable to assume defendants knew that certain surgeries performed by the four identified surgeons were unnecessary when the related whistleblower case only alleges that some claims for surgeries performed by Sabit were unnecessary?"

"Which is it?" asks the motion.

It's ALL "Fee for Service"

The defendants should be able to reasonably assume that the hospital's quality assessment committees, medical staffs, and utilization review commit-

tees would function as required under the controlling Medicare conditions of participation.

"Obviously, DOJ is asking the court to presume that doctors are motivated primarily by money and that their integrity may be purchased for the right price. Among the problems with this cynical and unsupported presumption, is that it could be applicable to any physician who is compensated for his services under a fee-for-service arrangement."

Prosecution Through the Press

Finally, the Reliance motion accuses the government of attempting to prosecute this case in the press.

For example, the DOJ issued CIDs (Civil Investigative Demands) on Reliance in January 2013. Months later the whistleblower suit against Sabit was filed. Reliance claims the whistleblowers had been feeding info to the feds since 2010.

CIDs are supposed to be confidential to protect against "unflattering publicity." Yet, states the Reliance motion, "highly inflammatory and disparaging (albeit) false allegations were leaked to the press in a *Wall Street Journal* article while the whistleblower lawsuit was still sealed."

This "strategy of trying the case in the press" continued on the day the DOJ filed their complaint against Reliance by issuing a press release alleging that Reliance paid Sabit for unnecessary surgeries.

What's on Trial? Fee for Service?

If Reliance and Hooper have their way and this case goes to trial, they'll challenge the government on some facts such as how much money the defendants actually made or what percentage of Sabit's surgeries used Reliance implants. But mostly this will be about the level of participation we will allow physicians in the business of healthcare. This is a policy question that must be answered by elected representatives, not as Hooper sees it, by the cop of healthcare.

In this case, the legal questions are simple. Did Reliance knowingly help hospitals and doctors file false claims for Medicare reimbursement? Do they share a legal responsibility for the medical decisions made by a physician?

Reliance argues the case should be dismissed because the allegations do not constitute a plausible claim for relief and not sufficiently specific or particular about the claims at issue.

Hooper and his clients say they can't wait to let a jury decide. ♦

Harvard Developing Pants With "Muscles" That Walk! // One Hip Surgery Saves $160,000 in Future Medical Costs! // Don't Know Your Patient's Global Sagittal Angle? You Should

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

Harvard Developing Pants With "Muscles" That Walk! "Put on your smartest suit," means something different in this day and age. And according to the federal government, it is worth investing in. The Defense Advanced Research Projects Agency (DARPA) is entrusting $2.9 million so that the geniuses at The Wyss Institute for Biologically Inspired Engineering at Harvard University can create a biologically inspired "smart suit." Conor Walsh, Ph.D. is the founder of the Harvard Biodesign Lab and assistant professor of Mechanical and Biomedical Engineering at the School of Engineering and Applied Sciences at Harvard. He tells *OTW*, "Many of us engineers have worked on some form of rigid exoskeleton, some of which can enable paralyzed people to walk. Our new approach was to ask, 'What if people who have some mobility could move around better?' A traditional exoskeleton may not be suitable for these situations because they are relatively slow, heavy, and they can interfere with a person's natural motion."

"Our first proof of concept was a pair of pants with embedded webbing to which we attached artificial muscles. And while we showed that one could apply large enough forces to have a positive impact on mobility, the device wasn't portable. We then set to work on trying to make the device battery powered and, lighter. The key innovation was related to making the actual textile lighter; then we embedded actuators in the textile and generated forces that were in parallel with the underlying muscles. We applied the low-power microprocessors to the ankle and hip and they replicated the actions of the muscles. Then we used a variety of sensors to send signals to a microprocessor to detect how the wearer is moving (walking, crouched, etc.) so the user could apply the right amount of assistance."

"The Soft Exosuit is easily pulled on like a pair of pants and is meant to be worn under one's daily clothing. For those in the military, it means that they can walk longer distances without getting as fatigued. Wearing the Exosuit would also help reduce the risk of injury when carrying the typical heavy loads that soldiers have to contend with."

"This is a platform technology for a wide variety of people who suffer from immobility due to muscle weakness after neurological or orthopedic injury. For these patients the current care results in them being relegated to a bed for a long period of time or put in rigid braces, each of which can lead to further muscle atrophy. An exosuit could allow patients to get walking sooner because they are unloading soft tissue and tendons while they are in the process of repairing; the suit

Soft Exosuit / Source: Harvard Biodesign Lab

also provides combined assistance and rehabilitation. The medical possibilities are huge, from those who experience a stroke to patients with multiple sclerosis and cerebral palsy…essentially any case involving an abnormal gait pattern."

"Over the next year months we will be evaluating the Exosuit with the Army, putting prototypes on soldiers as they undergo a training course. The Army representatives will quantify the soldiers' performance and then we will go forward and optimize the system (perhaps making it even lighter or easier to put on and remove). Our ultimate goal is to have a system that is affordable for the millions of people who need assistance with mobility. In order to achieve that goal, the price of the Exosuit may need to cost less than the current rigid exoskeletons that sell for approximately $70,000."

One Hip Surgery Saves $160,000 in Future Medical Costs! While most talk of the cost of orthopedic surgery, few point out the societal benefits. John Tongue, M.D., former head of the American Academy of Orthopaedic Surgeons, thought it was time to do something about that. Along with colleagues Dr. Tongue, who practices at Cascade Orthopaedic Group in Oregon, worked with health economists to determine the lifetime societal benefit of hip fracture surgery. Dr. Tongue tells OTW, "Orthopedic surgeons are heavily criticized for the cost of procedures at a time when we are searching for value in healthcare. We know the projections and we understand that we as a nation cannot afford to sustain the present costs. Well educated people tell me that they are concerned about the cost of orthopedic care, but no one is aware of the societal benefits. We undertook five studies, one on total hip replacements, another on anterior cruciate ligament reconstruction, one of rotator cuff surgery, another on discectomy, and this latest one on hip fracture…all revealed a cost savings to society."

"Our new study, published in *Clinical Orthopaedics and Related Research*, clearly demonstrates that the societal benefits outweigh the direct costs of hip fracture surgery. We found that the average lifetime societal benefits exceeded the direct medical costs of hip fracture surgery by $65,000 to $68,000 per patient; the lifetime societal savings exceeded $16 billion for older patients in 2009. We estimated the lifetime

cost of a hip fracture to be $81,300, of which approximately 44% of the costs were associated with nursing facility expenses. On a per-patient basis, the lifetime societal savings of undergoing hip fracture surgery was estimated at $160,000."

"Our team conducted a literature review and analyzed Medicare claims data. We also worked with health economists who cross-correlated data sets, used economic models, added insights from a panel of clinical experts, and performed sensitivity analysis (a way of estimating whether or not the assumptions you made are in the ballpark). The results also projected that hip fracture surgery produced an average increase of 2.5 quality adjusted life years based on a patient's life expectancy and level of physical function for patients with intracapsular fractures, and 1.9 years for patients with extracapsular fractures."

"These studies on five different orthopedic conditions provide vital information that has heretofore not been estimated. And it is good news for orthopedic surgery in terms of maintaining access to musculoskeletal care for patients going forward. There are now other medical societies looking into doing similar studies with the same team of healthcare economists."

Don't Know Your Patient's Global Sagittal Angle? You Should Many people look for a new angle when searching for answers. Bassel Diebo, M.D. a spine research fellow in the spine lab at NYU Langone Medical Center, has found one. Dr. Diebo tells *OTW*, "In my quest to study the impact of spinal alignment on the musculoskeletal system, I was inspired by the work of Jean Dubousset about the 'conus of economy,' defined as the cone in which the body can stay balanced within a narrow range (polygon of sustentation) without energy expenditure. When I looked at the EOS imaging of a number of patients I noticed that we were missing an opportunity to capture information on what was happening with the lower body when it comes to spinal malalignment."

"If there is sagittal malalignment or deterioration in the sagittal plane then the body recruits compensatory mechanisms. This begins with the pelvis as it tilts backwards, and knee flexion is also recruited as a way to maintain erect posture. These mechanisms are energy draining, compromise walking and debilitate the quality of life."

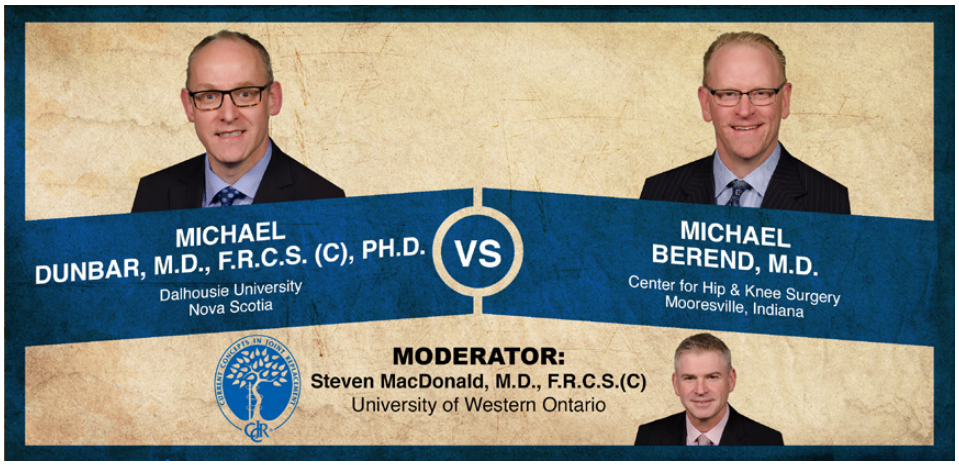
"The angle I developed, the Global Sagittal Angle, goes as a fan from the knee to C7 and from the knee to S1. This angle can give the surgeon an idea if the patient is standing in the conus of economy or has truncal inclination or forward alteration. In the lateral view the angle gets bigger when the patient tilts forward, retroverts the pelvis or flexes the knee. Clinically, this angle unmasks the compensatory mechanism in the lower limbs, and connects orthopedic fields (spine, hip and knee). Although a study on normative population remains to be done, but we hypothesize that the ideal postural alignment is a zero angle after treatment—that means there is no malalignment and no compensatory mechanism. I'm pleased that this work has received some recognition, and that I will have the opportunity to present it at the American Academy of Orthopaedic Surgeons annual meeting in Las Vegas, Nevada, 2015."

"Additionally, I am working on a prospective study where we are trying to assess the clinical outcome of spine treatment—operative or non-operative—by using more dynamic methods than what is traditionally used, such as the Fitbit. We give patients a Fitbit six weeks before surgery and thus we record their daily functionality. Then, after treatment (surgical or other), we give the Fitbit back to the patient for another six months of data to see if there is a benefit or not. Traditionally, we would give patients questionnaires in separate time points post-op and that's pretty much it. Using the Fitbit, along with our questionnaire, is a step forward towards a more patient centered approach and daily evaluation for the treatment outcome. Moreover, we will be giving patients the ability to specify what they want in terms of outcomes…to say, for example, 'My goal is that I can play with my grandchildren, and I want the treatment to accomplish this aspect' This is new." ♦

Dunbar, Berend Debate the All Poly Tibia

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

This week's Orthopaedic Crossfire® debate is "The All Poly Tibia: Cheaper and Better." For the proposition is Michael Dunbar, M.D., F.R.C.S. (C), Ph.D. of Dalhousie University in Nova Scotia. Against the proposition is Michael Berend, M.D. of the Center for Hip & Knee Surgery in Mooresville, Indiana. Moderating is Steven MacDonald, M.D., F.R.C.S. (C) of the University of Western Ontario.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Dunbar: "The all poly tibia is absolutely cheaper. Mike's partner and mentor wrote a paper in 1994 saying that they are about 30% cheaper (Ritter). Another study—from 2007—suggested that it's about $750 cheaper per case. Why? There has to be additional material, but also it's the machining and engineering that goes into modular tibias to make these things work."

"Residents may say, 'Why are you guys so uptight about the locking mechanism?' Well, this *was* a big deal in the past, and in the more recent past it's been an issue with certain prostheses where the locking mechanism has failed. It generated significant backside debris and it created large bone voids in multiple series of patients. All of the subsequent design and machining has driven up the cost of modular implants."

"A benefit of an all poly tibia is that because it does not have to mate to a metal component, for the same tibial resection you end up with more polyethylene. We know that if your poly is too thin and there is third body wear then you can get into runaway wear with significant complications."

"Mike may say that we should use metal backed modular tibias because they result in easy revisions. This is false, and there is lots of data to support this. In a series from Mayo by Rob Trousdale et al., they reported on 56 isolated tibial exchanges. They said, 'Isolated tibial insert exchange led to a surprisingly high rate of early failure. Tibial insert exchange as an isolated method of total knee revision should therefore be undertaken with caution even in circumstances for which the modular insert was designed and believed to be of greatest value.'"

"The reasons for early revisions are instability and infection, which poly exchange will likely not address. The reasons for late failure are aseptic loosening and poly wear. The only issue here is poly wear, and few surgeons are going to go back and exchange a polyethylene into a poor locking mechanism."

"So are they better? There is a meta analysis from 2011 (Cheng, Tao, *Acta Orthopaedica*) saying that statistically, there is no difference in any of these studies between metal backed and all poly tibias. But they did find significantly more lytic lines in the metal backed group. I believe this relates to the RSA (radiostereometric analysis) data."

"There are multiple RSA studies looking at these two constructs. A 2005 study from Hyldahl (*Acta Orthopaedica*) was a randomized controlled trial comparing 20 all poly and 20 metal backed. They found significant differences in the RSA migration patterns, with the metal backed being the worst and having the most subsidence over time. Why is that?"

"Another RSA study looked at 11 metal backed and 10 all poly and found the same problem with subsidence. The issue is that under asymmetrical load if you subside with a central keeled tibial component with a high modulus, then you're going to get liftoff on the other side. And when you have a monoblock all poly tibial component it's not going to lift off…it's going to deform instead

under that same asymmetrical load—and that may be protective. In fact, this is what they found in this data."

"Data from the Kaiser Permanente registry included 27,657 primary total knee arthroplasties (92% modular and 8% monoblocks). A hazard ratio less than 1.0 means that you have a favorable advantage (less likely to be revised). When they looked at all comers in the all poly group the hazard ratio was half (50% reduction in revision)."

"So, all poly tibias are cheaper and better—no backside wear, more poly for the same tibial resection, better RSA data, and better survivorship.

Dr. Berend: "The experience of your center and our publication of disastrous results with the all poly tibia with the AGC [anatomic graduated component] is either a poor reflection on us or on patient selection—or implant design. Proposed options for solving wear include improved locking mechanisms, a change in femoral material, using a mobile bearing type design, changing the poly formulation with cross linking or vitamin E."

"There are advantages of the all poly tibia; for one, it is non-modular. The data show that less than 5% of us are willing to put in a non-modular implant, so we need to consider training and surgeon comfort issues."

"Mayo Clinic has looked at just over 11,000 TKRs [total knee replacement], examining patient and implant factors. They concluded that the most effective design in the long term was a non-modular, metal backed tibial component with cemented fixation with all poly patellar resurfacing and retention of the PCL (posterior cruciate ligament)."

"We've used the one piece AGC for nearly 30 years, have published many times on the wear protection afforded by compression molded poly in a one piece design. Ritter found a 15 year survival rate of 99%. Our 10 year results with the all poly implant were not so favorable—68% survivorship in a series of 500 knees. The mechanism is the same, with failure of the medial tibial bone, resorption, remodeling in the tibia, and then eventual loosening."

"We have learned a lot about the bone response, and we've looked at an all poly tibia placed in varus. At midterm follow-up there was remodeling in the medial tibial plateau, eventual subsidence, and loosening requiring revision. We have compared metal backed to all poly implants. The strain—measured in the surface of the tibia—is anywhere from 40-500% higher with all poly implants. We think that correlates

with our finite element analysis studies, which show increased strain in the proximal tibia. We think that in patients with a higher mass and smaller tibial components that these combined factors can lead to early resorption and failure."

"We took the same data from Hans Hyldahl and we developed a model comparing the size of the tibial component and the patient's mass and developed a calculated stress equation. Looking at those with a small tibial component in a patient with high mass, in our series we had a 20% failure rate. So patient and implant factors led to higher failure than just looking at all poly alone."

"What if you could get a non-modular implant with metal backing to protect against tibial overload? We performed this in a cemented fashion with an implant that comes in one piece, but you can remove the poly if necessary. We had a less than 1% reoperation rate and at a mean follow-up of four years we had eight revisions, of which three were poly exchanges where the components were retained. There were four aseptic revisions where the poly was exchanged for recurrent hemarthrosis, flexion instability, and stiffness (two cases). It's an advantage of a one piece metal backed implant that you can change it if you want. I agree that poly exchange alone is very rare, but for specific indications I think not having to remove the tibial component is an advantage."

Moderator MacDonald: "Mike Dunbar, why has an all poly tibia fallen out of favor?"

Dr. Dunbar: "Historical data shows that it can be a problem. Surgeon comfort is an issue as well. They might say, 'I have everything done, I'm cemented, but not quite happy and I can always flip up that extra 2mm.' And there's not a lot of push now, but we will be pushed to consider this for cost reasons."

Moderator MacDonald: "Mike Berend, is there a role for an all poly tibia?"

Dr. Berend: "Yes. It's design sensitive and we need to reconsider how to train people. You can't change your mind once you've cemented it in, so you need to think about deciding your thickness earlier in the operation."

Moderator MacDonald: "To either one of you: is the cementing technique different?"

Dr. Dunbar: "No, not that I am aware of."

Moderator MacDonald: "You presented some RSA data. In our revision prac-

tices it's uncommon that we're revising a knee because the tibial component loosens."

Dr. Dunbar: "I feel the low modulus aspect is critical because you don't get the compression or asymmetric load differentiated into liftoff. Mike is showing it from the finite element view, saying that if you get this wrong or pick the wrong patient then it can be disastrous because there is a 350% increase in forces."

Moderator MacDonald: "So who do you use an all poly in now?"

Dr. Dunbar: "I don't use an all poly tibia."

Moderator MacDonald: "And the role for highly crosslinked poly, Mike Berend?"

Dr. Berend: "We have felt for more than 25 years that poly wear isn't an issue in total knees. So if you take a knee that's non-modular then that solves the wear problem. In our hands cross linking may have a role if you're using modular implants."

Moderator MacDonald: "Mike Dunbar, why don't you use an all poly tibia?"

Dr. Dunbar: "I do use monoblocks, but they're not all poly and they have a low modulus. I use those in people who have a very defined high varus thrust."

Moderator MacDonald: "Are there patients in whom you should avoid an all poly tibia?"

Dr. Berend: "The more significant deformity you have, and varus thrust, and when you know you have a higher margin for error for not placing the component well…or if you make a deeper tibial resection and you have a smaller footprint…those patients would cause me concern."

Moderator MacDonald: "Thank you gentlemen." ♦

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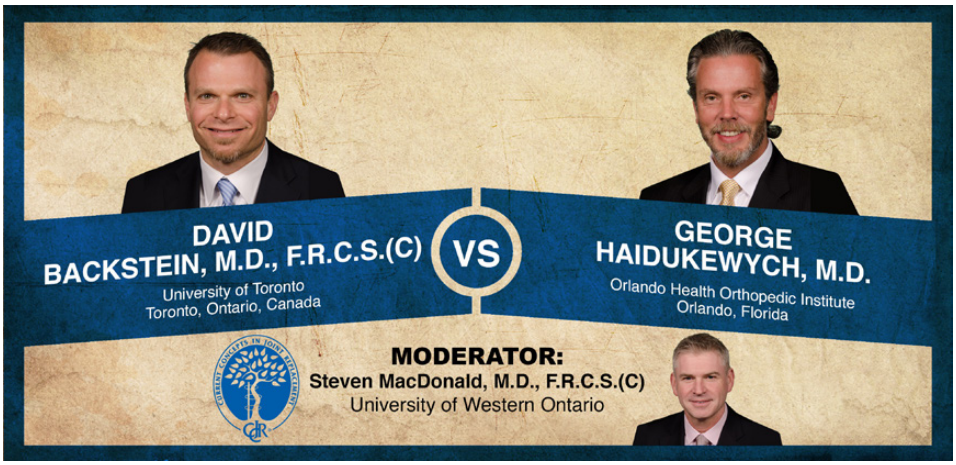
Backstein v. Haidukewych Over the Mega Prosthesis

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



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "Mega Prostheses for Well Fixed TKA Femoral Fx's." For the proposition is David Backstein, M.D., F.R.C.S.(C) of the University of Toronto. Against the proposition is George Haidukewych, M.D. of Orlando Health Orthopedic Institute. Moderating is Steven MacDonald, M.D., F.R.C.S.(C) of the University of Western Ontario.

Dr. Backstein: "Some of the literature says that 0.3%-2.5% of total knee replacements [TKA] end up with a periprosthetic fracture (Fuji 2006, Dennis 2001). Patients are almost always elderly, and they often have poor tolerance for immobilization. Open reduction internal fixation (ORIF) almost certainly leads to a period of protective weight bearing, long hospital admissions, rehab, etc."

"In a typical distal femoral periprosthetic fracture there is poor bone quality, comminution, and it is in close proximity to the implant—and with that I couldn't get any sort of fixation with a plate. Often, I see cases where patients have had an attempt at ORIF which has failed."

"In surgery for a periprosthetic fracture you first remove the polyethylene. Then you remove the distal femur, carefully and slowly coming around the medial side with a cautery. You then get retraction, protecting the posterior structures, and having someone pull on the femur. Be especially careful not to get into the neurovascular structures. We're usually doing this operation within days of the fracture so things are easily mobilized off the back of the femur."

"We then come around on the lateral side and keep doing that until we get the whole distal femur out, releasing all the collateral ligaments. We remove the tibial side with a reciprocating saw, and then the rest of the operation flows similarly to a revision knee replacement. You remove the baseplate, freshen the tibial cut, ream the tibia, size the baseplate and pin it, then quickly finish preparation of the femur. Next, we freshen up the distal femoral cut. I measure preoperatively how long a spike we have and therefore how much distal femur I'm going to have to replace."

"There aren't a lot of landmarks for rotation, so I use patellar tracking. The system I use has the ability to modify rotation—even once you cement it in the implant. Because most of these patients are elderly, I go fully cemented and fill up the canals with cement. I mark my rotation either with a pen or with a scratch from a saw."

"So for these types of fractures we should use immediate mobilization. They end up having a short length of stay, there is no chance of malunion or non-union as you have with ORIF."

Dr. Haidukewych: "Mega prostheses do have a role in the treatment of fractures above well fixed knees. However, it's a limited role, namely, in situations where fixation is likely to fail. ORIF remains the gold standard. There are no published, prospective randomized studies comparing ORIF to mega prostheses for these fractures."

"Periprosthetic fractures almost always occur at the flange of the distal femoral component. And the prosthesis is almost always well fixed and has been functioning well, so I think we should save the knee whenever possible."

"The goals are to maximize distal fixation, get the fracture to heal, and correct alignment. The challenges are poor bone quality, short distal segments, and obstacles to distal fixation by parts of the femoral component. There are two trends, one of which is submuscular locked plating. The other is retrograde nailing with multi-planar, angle

stable locking screws. Nails are tissue-friendly and mechanically sound, but you need good notch access and you need to pay attention in order to avoid malalignment."

"Most modern total knees have good notch access for retrograde nailing. I typically do the surgery through an arthrotomy and pass the nail under direct vision so I don't damage the component. And with modern nails you can get multi-planar, locked screws. The argument about weight bearing is a moot point; I let patients bear full weight and start range of motion (ROM) immediately."

"As for plating, they offer coronal plane stability, and you can get almost ridiculously distal fragments with plates. With multiple points of fixation you can cheat the plate until you get extremely distal—even shooting around the lugs. If you leave everything alone, are biologically friendly, and bridge the metaphysis, it will heal. With modern variable angle implants and polyaxial implants you can target the most distal segments and still get predictable healing in cases where in the past we probably would have done a distal femoral replacement."

"You must be good with a C-arm and you must be vigilant to avoid malalignment in two planes. I like to prep both legs so I can get a perfect lateral without disturbing the limb that I'm operating on. The bump can help avoid the typical hyperextension. You slide the submuscular plate under the vastus, correct the length and rotation, check it multiple times with the C-arm, then put the screws in, leaving the metaphysis alone."

"The last five years of studies show union rates of 88-100%; nails are doing somewhat better than plates. Mega prosthesis: On the positive side, there is full weight bearing, no fracture to heal, and early ROM. The downsides are that they are incredibly expensive, complications are high, it requires expertise, and there are extensor mechanism problems. If ORIF fails you can do a mega prosthesis. What do you do if a mega prosthesis fails?"

"Recent studies show the following complication rates: 63% patellar (Schwab, 2006), 50% overall (Falker, 2013), 45% overall (Mortazavi, 2011), 17% overall (Chen, 2013), 16% overall (Berend, 2009). Mortazavi said it best: '…due to the relatively high rate of complications, this procedure should be reserved for patients where alternative treatments are not possible.'"

"I do a mega prosthesis as a last resort, such as with severe distal osteolysis or multiple segments for a nonunion. ORIF remains the gold standard."

Moderator MacDonald: "David, do you send some cases to your trauma colleagues?"

Dr. Backstein: "If there is enough bone and I can make an attempt at fixing it then I will fix it. But that's not the real controversy. It's what to do with the real distal ones. As for the real proximal ones I agree 100% with George—those should be fixed."

Moderator MacDonald: "George, is David crazy doing these mega prostheses so early? When do you decide to do it?"

Dr. Haidukewych: "If I'm not sure, I get a CT and look at that distal fragment to see if there is severe osteolysis that hasn't been treated. If I'm unsure, I will do a midline incision, and approach it through a lateral subvastus approach. I'll look at the quality of that distal bone, and I can either nail or plate it through that incision. If it's like wet tissue paper then I can excise the femur and do the entire case through the lateral subvastus, pushing the tibia up and out. But that's rare; usually we know ahead of time and I'll fix it and they heal. To Dave's comment about the really distal ones, there is one study on that, published last year by Collinge. They looked at the cases where the fracture was completely distal to the femoral flange; union rates were in the high 80s. So even those ridiculously short fragments with locked plating… you can get those to heal."

Moderator MacDonald: "Would you both concede that almost universally these implants are well-fixed? It's a bone stock issue not a fixation issue."

Dr. Haidukewych: "Correct."

Dr. Backstein: "Yes. To the cost issue, we've done a cost analysis and if a patient stays in the hospital for an extra two or three days then the cost issue is completely neutralized."

Moderator MacDonald: "So how do you set femoral rotation? There are no landmarks."

Dr. Backstein: "People mention the rough line, but there is not a true landmark. I put my trials in where the patella seems to want to be. And I modify the rotation with the trials until I get the patella tracking nicely. I mark that rotation and that's where I cement it."

Moderator MacDonald: "What are the key things?"

Dr. Backstein: "Getting the rotation and length…it's easy to underestimate the length and then end up with a hyperextended knee. People think this is a big operation and the knee is going to get stiff. I think it's the opposite. If you removed every ligament and all soft tissue is gone, the tendency is for looseness and hyperextension. So I make sure that at the end of the operation it's achieving full extension without any hyperextension."

Moderator MacDonald: "I agree with George. When these cases go smooth they are great. But if there is a complication they are a disaster."

Dr. Haidukewych: "Especially infection. We need a study to follow these for a year to look at readmissions, failure of fixation, and the double-digit complication rates. The reoperation rate in some of the more modern series on the distal femoral replacement for this diagnosis was very high. It's almost a double-digit infection rate in some series, so we need to look at the whole one to two year encounter rather than worrying about one or two days in the hospital."

Dr. Backstein: "I agree. We have unpublished data on about 30 cases over the past two years and we don't have anywhere near a double-digit complication rate. I don't think this is something that everybody should be doing."

Moderator MacDonald: "How do you avoid the thing going into valgus?

Dr. Haidukewych: "Valgus and hyperextension. When you lock it with that distal locking bolt you must really pay attention with the C-arm that it doesn't drift."

Moderator MacDonald: "Thank you gentlemen."♦

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COMPANY

Will Jeff Binder Follow Blackstone to China?

Is Biomet, Inc., CEO Jeff Binder going to China?

Xinrong Best Medical Instrument Co.

Blackstone Group LP, the lead Wall Street banker in the Biomet, Inc. private equity ownership group, announced on September 23, 2014 that it was acquiring an "unspecified" stake in China's Xinrong Best Medical Instrument Co. Xinrong is a Chinese-based developer of orthopedic implants with trauma, spine and joint applications. Published reports quoting insiders say the deal is for $100 million.

With Zimmer Holdings, Inc.'s $13 billion offer to buy Biomet from Blackstone's group, the company has cash to expand into China's orthopedic market. When Zimmer and Biomet merge, the number of CEO chairs will presumably decrease to one. Binder is young and likely to seek high level challenges.

New CEO

Xinrong, founded in 2000, is one of the last independent medical devices companies in China and was reportedly interested in Blackstone's ability to attract top-level managers. A team is apparently already assembled, including a new chief executive officer from a leading global orthopedic company. Blackstone will also help Xinrong with its marketing and sales efforts.

The Chinese company is also looking to draw experience from Blackstone's other portfolio companies in the sector, according to published reports. Apparently, Blackstone was not the only suitor, nor did it have the highest bid. The trump card was Blackstone's management stable.

Competitive Pricing

Xinrong is planning to target hospitals and other care organizations in tier-2 and tier-3 Chinese cities. Furthermore, the company is aiming to be more competitive on implant pricing than foreign competitors. China's government reimburses about 70% of a patient's costs, but 30% out-of-pocket is still beyond many of China's patients.

According to Boston Consulting Group, where Binder spent five years, China's orthopedic implant market will grow from $1.3 billion in 2013 to $4.1 billion in 2020, driven by an ageing population, increasing disease, improving treatment rate and growing affordability.

"With China's ageing population and increasing disposable income, the market growth for orthopedic implants is significant," said Blackstone senior managing director Yi Luo in a statement. Luo is based in Shanghai and led the deal.

Binder should be used to air travel. When he took over as CEO of Biomet, he reportedly commuted by company jet from his home in Austin, Texas, to Warsaw, Indiana, on a weekly basis. He has an advanced degree in public affairs from the Woodrow Wilson School at Princeton University. — *WE*

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Recalls of Medical Devices Down

In what is good news for the medical device industry, a recall consultancy firm's study reports that the medical device industry has experienced its lowest number of medical device recalls since 2012.

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There were 275 recalls of devices from 148 different companies, according to the 15-page report prepared by Stericycle. The report was based on data obtained from several government agencies including the U.S. Food and Drug Administration.

According to the report, more than half of the recalls, 57%, took place within the United States and just one other country. Twenty-eight percent of the companies involved in recalls this past quarter—which ended June 30—had two or more products recalled. Seven percent of the companies involved had five or more recalls.

An analysis reported earlier this year from the FDA and cited in the news release noted that device recalls over the past decade have more than doubled, with software-related recalls being the most common type of product or device recall. — *BY*

LEGAL

Physicians Targeted in Fraudulent Tax Return Scam

Medical societies are reporting that physicians who are waiting until October 15, 2014 to file their 2013 tax returns are being targeted at higher-than-normal rates of a tax fraud scheme involving phony tax returns.

In June the Texas Medical Association reported that more than 100 of their members notified the association someone had stolen their Social Security numbers and attempted to claim their tax refunds. Victims also include physician assistants, advanced practice registered nurses, dentists, podiatrists, and pharmacists. According to the medical societies of North Carolina, New Hampshire, Vermont, Connecticut, and Michigan, more than 100 health care professionals in each state were victims of this year's tax refund fraud scheme.

The scam involves someone other than the physician filing tax returns using his or her Social Security number.

Data Security Breach?

Brian Krebs, former *Washington Post* reporter and author of *KrebsOnSecurity.com*, reports that the data breach could have occurred at a national organization that certifies or provides credentials to physicians. He notes the scheme comes on the heels of the Centers for Medicare & Medicaid Services' (CMS') release of payment information for 880,000 health care professionals nationwide.

The release included the national provider identifier (NPI) number of each physician. However, Krebs points out, NPI numbers have long been available through CMS, and the payment information CMS made public did not include physicians' Social Security numbers.

Fraudulent Tax Returns

Krebs added that the thieves steal or purchase Social Security numbers and other data on consumers, and then electronically file fraudulent tax returns claiming a large refund. The thieves instruct the IRS to send the refund to a bank account that is tied to a prepaid debit card, which the fraudster can then use to withdraw cash at an ATM. The fraudulent returns took place shortly after the April 15, 2014 tax deadline and the thieves beat physicians to the IRS with returns. The IRS then rejected returns submitted at the later date by the physician.

Take Precautions

Even if you haven't been victimized, the Secret Service recommends all physi-

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cians visit *www.experian.com/fraud* and place yourself on a 90-day credit fraud alert. This could potentially slow or halt further attempted identity theft activities. While not every physician is at risk of identity theft, this is a suggested precautionary measure.

The American Medical Association offers suggestions for physicians affected by the scam:

- File a paper return, and attach a Form 14039 Identity Theft Affidavit to explain what happened.
- Attach copies of the 5071C letter and any other notices from the IRS to your tax return. If you have not received notice from the IRS, but believe your personal information may have been used fraudulently; call the IRS Identity Protection Specialized Unit at (800) 908-4490.

The North Carolina Medical Society (NCMS) suggests contacting the following agencies if you learn your Social Security number has been used fraudulently:

- File a complaint with the Federal Trade Commission (FTC) on its website.
- File a local police report.
- Call the Social Security Administration's (SSA's) fraud hotline at (800) 269-0271 to report fraudulent use of your Social Security number or use the SSA website.
- Consult the U.S. Department of Justice website for additional information on fraud and identity theft.

The IRS is required to bear the loss of fraudulent returns. Physicians are urged to file their returns early next year and beat the thieves to the punch. — *WE*

Big Pharma and Devices: Sunshine Act Not Ready

Implementation of the Sunshine Act through the CMS (Centers for Medicare and Medicaid Services) Open Payments program goes into effect on September 30, 2014.

The heads of Big Pharma, biotechnology and medical devices aren't happy about that and want CMS to stop publishing physician payment information until industry has a chance to suggest and secure changes before going public.

On September 18, 2014, the heads of AdvaMed (Advanced Medical Technology Association), BIO (Biotechnology Industry Organization) and PhRMA (Pharmaceutical Research and Manufacturers of America), wrote CMS Administrator Marilynn Tavenner to complain that they have not had an opportunity to meet with CMS to assure that patients don't get the impression that all payments to physicians are "suspect."

No Opportunity to Review

"Unfortunately, with only less than two weeks before the public website is to go live, we have not been given an opportunity to review how CMS intends to present this crucial contextual information or to consult with CMS on its content. We are hopeful that this situation can be addressed before the first expected release of Sunshine data September 30."

Specifically, the trade group bosses write that for implementation of the Sunshine Act to be successful and for the data to be meaningful to patients and the public, "the CMS Open Payments program public website must provide clear background information and context regarding such industry relationships. Such background ensures the reported data is helpful in patient decision-making. Further, providing context for reported payments and other transfers of value is critical to ensuring patients do not form mistaken impressions that all payments to physicians are suspect."

Confused Submissions

In addition, they are concerned that CMS is going to withhold as much as

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one-third of the data that was submitted by industry. They say that based on reviews by their members of the removed data, it appears they all followed the rules. "It is not clear why this volume of data is being withheld. We are hopeful that this issue can be resolved expeditiously so that the data that is made available to the public is accurate, useful and complete."

The launch of the Open Payments database was delayed when a Louisville, Kentucky, electrophysiologist named David E. Mann, M.D., complained that payments were being attributed to him even though they were made to another physician with the same name. In the process of reviewing that complaint, the agency found "intermingled data," where physicians were being linked to medical license numbers or national provider identification numbers that were not theirs.

The agency then said it was returning about one-third of submitted records to the manufacturers and [group purchasing organizations] because of intermingled data, and will include these records in the next reporting cycle. Those records won't be posted until June 2015. CMS said there too many errors and might even level fines if further mistakes are made.

Changes Sought

The heads of the trade groups said they support and are committed to the goals of the Sunshine Act, but they want a chance to chime in and secure changes before it all goes public.

The sun is supposed to shine on physician payments on September 30, but the skies are not all clear yet. — *WE*

BIOLOGICS

One Stem Cell Fact You Need to Know

Everyone who works with stem cells knows that human pluripotent stem cells can become any of the 220 cells in the body. Undifferentiated cells are influenced by the chemicals in the lab dish in which they are grown. By using different chemicals, researchers can direct the cells to become whatever kind of cells they want.

Terry Devitt, writing for *University of Wisconsin News,* reports that something other than the chemicals in the petri dish affects cell differentiation. The hardness of the surfaces on which stem cells are grown also exerts a profound influence on the cells' fate.

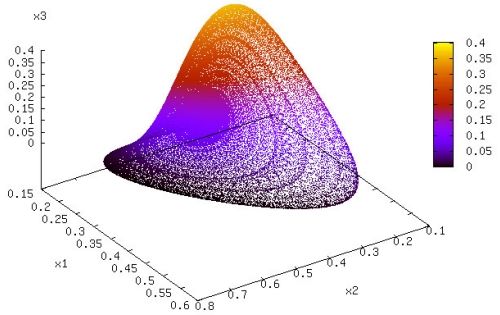
"Investigators use soluble growth factors to get the cells to differentiate," explained Laura Kiessling, Ph.D., a UW-Madison professor of chemistry and biochemistry and stem cell expert. She and her associates grow stem cells in plastic dishes coasted with a gel that may contain as many as 1,800 different proteins. She says that, whether or not the gel contains proteins, the cells are always working at becoming something—but in seemingly random ways.

Kiessling, noting that cells appeared to react to the surfaces near to them, decided to find out if the quality of a surface mattered to a stem cell. According to DeVitt, her group created gels of different hardness to mimic muscle, liver and brain tissues. They also wanted to find out if the surface alone, without any added proteins or chemicals, would influence cell fate decisions and have an effect on differentiation.

The results, Kiessling reported, showed that a soft, brain tissue-like surface, independent of any soluble factors, was catalyst enough to direct cells to become neurons, the large elaborate cells that make up the central nervous system. "We didn't change anything but switch from a hard surface to a soft surface," Kiessling says. "They all started looking like neurons. It was stunning to me that the surface had such a profound effect."

Devitt reported that the Wisconsin researchers believe that the mechanical properties of a surface are influencing a protein called YAP. YAP is found in the cytoplasm and the nucleus of a cell, and when it is in the nucleus, YAP regulates gene expression. According to the study results, YAP is excluded from the nucleus on the soft gels, and its depletion there helps drive the stem cells onto a brain cell developmental pathway.

Kiessling's group's finding, that the simple mechanical properties of a surface can play a major role in helping stem cells decide what to be, may—in her opinion—inform the methods used for producing large quantities of cells for therapeutic use. — *BY*



This is an artistic representation of how stem cells react to different bio-mechanical stresses./Wikimedia Commons and Magnus Manske

Getting Physicians Comfortable Prescribing Marijuana

An Israeli Company, Syqe Medical, has developed a hand-held device that delivers a controlled dose of cannabis. According to Emily Wasserman, writing for *Fierce Medical*, the palm-sized inhaler requires a fraction of the cannabis usually prescribed monthly for pain. The inhaler works by vaporizing tiny granules of cannabis in doses as small as 1 mg which allows physicians to tailor the dosage to the needs of each patient. This also puts the drug in a form that is difficult to sell on the black market.

Wasserman quoted Elon Eisenberg, director of the Pain Relief Unit at Haifa's Rambam Hospital, as saying the inhaler added "a much needed treatment in the limited armamentarium of effective therapies for the management of chronic pain."

Syqe Medical's CEO Perry Davidson told the *Wall Street Journal* that the company hopes to enter the U.S. market which he believes will reach $10 billion in the next five years. "We see it as a challenge," Davidson said. "If we can unlock it…we believe that we can finally bring cannabis in as a mainstream drug, and have physicians be comfortable using it." — *BY*

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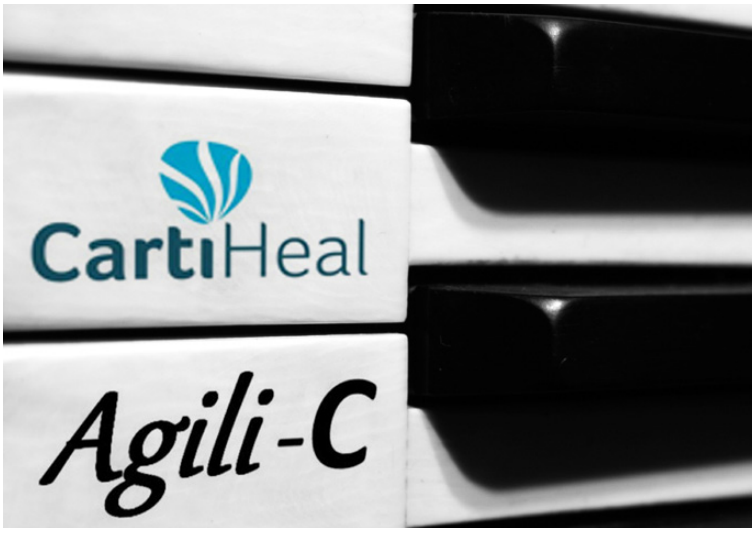
Israeli Firm Earns US Patents

CartiHeal, Ltd. has been awarded four patents, three by the U.S. Patent Office and one by Japan's, for its cell-free, off-the-shelf cartilage regeneration technology for patients with injuries to the articular surface of joints. CartiHeal is a privately held medical device company headquartered in Kfar Saba, Israel.

The patents describe the use of coral scaffolds, called the Agili-C Implant, for the treatment of cartilage and bone defects, osteoarthritis and assorted joint disorders. According to the company's release, the implant demonstrated clinical safety and effectiveness in a series of clinical trials, by enhancing regeneration of true hyaline cartilage and subchondral bone.



Courtesy of CartiHeal, Ltd. and RRY Publications

"These four patents strengthen CartiHeal's IP portfolio, and position the company at the forefront of innovative technologies in the field of cartilage regeneration," reports Nir Altschuler, founder and CEO of CartiHeal. "Cartilage regeneration represents one of medicine's most challenging unmet needs. We are proud to say that CartiHeal and its breakthrough technology are able to meet this challenge."

The company claims that its Agili-C implant promotes regeneration of hyaline cartilage and its subchondral bone, simultaneously without the use of cells, growth factors or other exogenous agents. Industry representatives voted Agili-C one of the top 10 most exciting Israeli medical-device and pharmaceutical developments to watch for in 2014. — *BY*

LARGE JOINTS

Large Joint Innovation Much, Much Trickier Than Expected

Newer is not always better where joint replacements are concerned. In some cases, the latest design on the market may be inferior. When Art Sedrakyan, M.D., Ph.D., of Weill Cornell Medical College in New York City, and colleagues examined hip replacements with modular femoral necks, a new device technology, they found that the cumulative rates of revision surgery at 5 and 10 years were 7.4% and 10.8%, compared with rates of 3.7% and 6.4% for conventional prostheses with non-modular necks.

Medical writers such as Nancy Walsh, of *MedPage Today* and Louise Prime of *On Medica* are claiming that innovations to devices used in joint replacement have been introduced without convincing evidence that they are any better than existing implants.

Prime wrote, "None of five innovative hip or knee replacement devices improved functional or patient-reported outcomes compared with older-established devices. In fact, outcomes were worse in some cases."

The study she referred to was Sedrakyan's. He and his colleagues searched the literature for comparative studies, gathered data from the national registries of England and Wales and, located 42 studies reporting on 23 cohorts. Their conclusion was that new technologies were being entered into the market without quality evidence of any benefit over existing, well-proven and safe alternatives.

They wrote, "Widespread and ongoing dissemination of these technologies cannot be justified from an evidence-based perspective. Existing devices may be safer to use in total hip or knee replacement."

Among their recommendation was that that registry enrollment should be mandatory and that device regulation should be overhauled. — *BY*

Courtesy of H. John Cooper, M.D.; Robert M. Urban, Ph.D.; Richard L. Wixson, M.D.; R. Michael Meneghini, M.D.; Joshua J. Jacobs, M.D. and J Bone Joint Surgery Am, 2013 May 15:95(10):865-872.

ACL Surgery Cuts Elite Performers' Ranks

The good news is that most athletes who undergo anterior cruciate ligament (ACL) reconstruction surgery return to some form of sport. The bad news is that only 55% will return to competitive level sports, according to Kathryn Doyle, writing in *Reuters Health* about a study conducted in Australia.

Wikimedia Commons and Brandon Wiggins

Ph.D. student Clare L. Ardern of the School of Allied Health in the Faculty of Health Sciences at La Trobe University in Bundoora, Australia, reviewed 69 articles on ACL surgery and return to play published between April 2010 and November 2013. The papers covered 7,556 patients, 81% of whom returned to some sport after their injury. However, only 65% were able to return to their pre-injury level. And fewer were able to be competitive in their sport.

The researchers found that younger players and men were more likely to get back into their sport than were older players and women. Also elite level sportsmen were about six times more likely to fight their way back to a competitive level than were non-elite athletes.

Doyle quoted the lead author Ardern as saying, "I think we used to presume that everyone returned to their sport after surgery, especially since one of the main reasons why people have surgery is because they want to return to sport. But clearly these results show that this is not the case."

Ardern told *Reuters Health* in an email message, "Some people may have changed the sport they played, but we were not able to measure this in our study." — *BY*

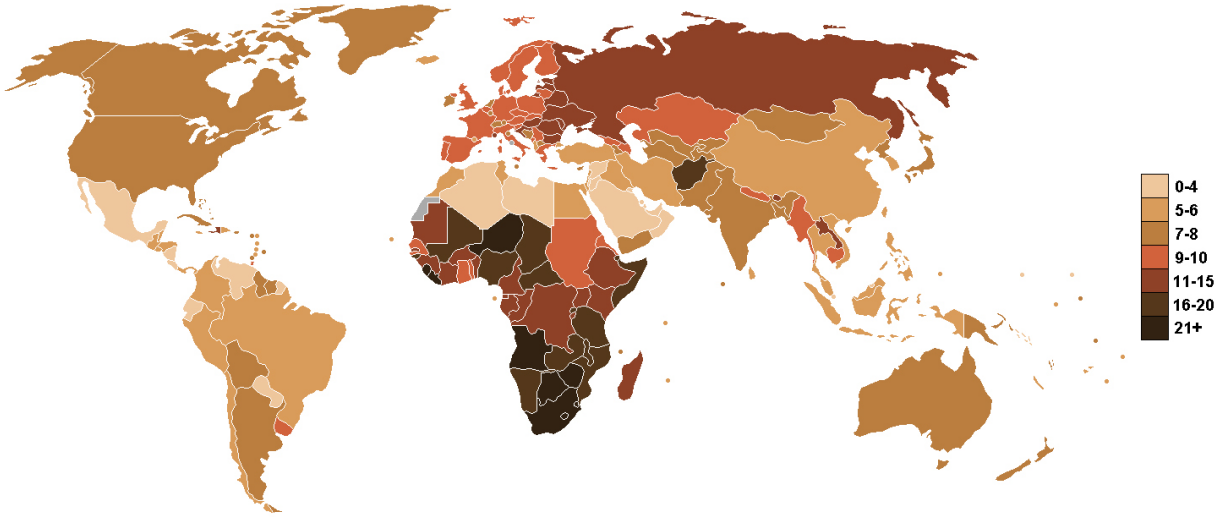
Mortality Rates Chopped in Half Due to…Data?

Because they have a national registry, researchers in the UK have learned that mortality after hip and knee replacement surgery in England, Wales and Northern Ireland has dropped by half in the eight years since 2003. Zasia Kmietowjcz, writing for the *British Medical Journal* (*BMJ*), reports that 90-day mortality rates after hip replacements fell from 0.56% in 2003 to 0.29% in 2011. The 45-day mortality rates after knee replacement fell from 0.37% to 0.2% over the same period.

The 10-year revision rates for hip and knee replacements are now less than 5%. Rates vary according to age, with younger patients more likely to need to have an implant replaced. The National Joint Registry holds data on more than 1.6 million cases of joint replacement, which it has been collecting since 2003. Doctors replaced 2205,686 hips, knees and shoulders in 2013.

The UK also has a National Hip Fracture Database which reveals the care given to 64,938 hip fracture patients in England, Wales and Northern Ireland. It found that the average 30-day mortality in 2013 was 8.05%, down from 8.1% in 2011-12. That amounted to 300 fewer people dying within 30 days of fracturing their hip.

Martyn Porter, MB ChB FRCS(Ed) FRCS Ed(Orth), the registry's medical director, said, "Whilst standards in British orthopaedics are high, I must encourage my colleagues to scrutinize and engage with National Joint Registry data on a regular basis to evaluate where additional benefits for patients can be maximized." — *BY*



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Canadian Health Authority Tells Ortho Docs "Slow Down"

For the second consecutive year the Winnipeg (Canada) Regional Health Authority (WHRA) has told orthopedic surgeons at Concordia Hospital to slow down the number of hip and knee replacements they are performing to stay within budget. The Concordia team, which operates in a state-of-the-art facility that opened in 2009, is once again on schedule to exceed its target.

In the fall of 2013 Concordia Hospital's surgical team found itself about to perform 1,650 hip and knee replacements by March 31 when its fiscal year ends. The problem was that the hospital was budgeted to carry out only 1,500, according to Larry Kusch, writing for the *Winnipeg Free Press*. The hospital leadership pleaded to be allowed to do more and the WRHA funded another 71. The hospital ended up performing 1,611 joint replacement surgeries.

This year the regulators authorized the hospital's surgical team to do 1,460 joint replacements—the normal 1,500 minus the 40 over-budgeted surgeries it did the previous year. Concordia is now on a pace to reach 1,668 in the current fiscal year. "The region is watching our numbers very closely, and we are already ahead of ourselves," a hospital source told Kusch.

When, in 2013, the hospital informed the regional health authority that it would exceed the revised target, officials had a choice of cancelling surgeries or forging ahead. The authority agreed not to cancel the procedures and instead charged the additional 40 to the new budget year.

When the number of surgeries this year began to track substantially higher than budgeted, Brock Wright, M.D., senior vice-president and chief medical officer of the Winnipeg Regional Health Authority, met with Concordia's leadership to discuss the situation. The region then gave the go-ahead to raise the target to 1,500 replacements.

One of the factors the region is weighing, according to Kusch, is the impact of a new trend to perform full hip replacements—instead of partial ones—in the case of fractures. Not every patient needs a full joint replacement under these circumstances, Wright noted, but some do. The WRHA wants to ensure the change in practice is medically warranted and wants to study the impact on its budgets. Wright said he understands there is a high demand for hip and knee replacements, but one program can not dramatically exceed its budget at the expense of other health services. — *BY*

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EXTREMITIES

Proception Medical – Ortho Innovations Incubator

Proception Medical, LLC is a medical device developer and incubator which, according to its founder, licenses commercially viable inventions from surgeon inventors, helps develop them, obtains the necessary commercialization approvals and then takes them through a limited launch. Proception has recently entered into exclusive agreements with two physician inventors for the development of their medical devices that are intended for the orthopedic extremity market.

proception™ medical
Bridging the gap

Proception Medical, LLC

Greg Kowalczyk, company principal and co-founder, said, ""Proception Medical is focusing on several therapeutic areas, but the orthopaedic extremity market, which is currently valued at $1.3 billion in the U.S. and is growing 10% per year, is a terrific target area for our first product entries. These first two products have tremendous clinical potential and together have the ability to improve the standard of care for over 832,000 procedures annually in the U.S." The procedures estimate is from iData Research.

Company officials plan to attend the annual meetings in Chicago of both the International Federation of Foot and Ankle Societies (IFFAS) and the American Orthopaedic Foot and Ankle Society (AOFAS) at the Hyatt Regency in late September. Kowalczyk reported that company management will be present at the society meetings assessing new invention opportunities and participating in strategic discussions with potential out-licensing commercialization partners. — *BY*

SPINE

LDR On a Roll With Surgeon Training

In order to maximize positive clinical outcomes, LDR pursues its surgeon education programs with the utmost planning and care. Their regional and national educational programs, which nearly 1,000 surgeons have attended in just the last 12 months, are ensuring that the nuances of the company's key products are clear to surgeons.

The company offers didactic training, peer-to-peer training, cadaver based training, surgeon visitation programs, and product specific instructional courses. LDR has run training courses in more than 20 states over the past year and periodically sponsors informational sessions concurrent with industry trade shows such as the North American Spine Society.

Wikimedia Commons and Mass Communication Specialist 3rd Class Matthew Jackson

Regarding LDR's professional medical education courses, Christophe Lavigne, CEO of LDR, told *OTW*, "LDR's most common surgeon training experience is cadaveric based, which is managed by the company's Professional Medical Education team. These courses include comprehensive didactic content along with a lab session of roughly equal length where attendees can take advantage of a proctor-led cadaveric surgical technique training experience."

Elaborating on the LDR peer-to-peer programs, he added, "The need and logistics for peer-to-peer training, where one surgeon is trained by an expert user, is confirmed and facilitated by LDR's Professional Medical Education team. The trainings involve a thorough didactic overview of the product technology, surgical technique, clinical data, on-label indications, etc. This is often followed by a comprehensive hands-on session with the instrumentation."

And finally, commenting on the surgeon visitation programs, Lavigne mentioned, "Physicians' requests for training are submitted through an online portal and are then vetted and managed by LDR's Professional Medical Education team. The team also identifies visitation sites. Selection criteria is based on the site team's technical experience, interest in and willingness to teach, and availability. A typical visitation includes a surgery observation along with additional meetings to discuss technical details, the surgical technique, indications and contra-indications, and also individual case reviews." — *EH*

PEOPLE

Jeffrey Mjaanes, M.D. Added to USA Men's Rugby Medical Team

Jeffrey Mjaanes, M.D. and Midwest Orthopaedics at Rush

Rugby enthusiasts can rest easy knowing that a new experienced sports medicine specialist will be helping to care for their favorite big league players. Jeffrey Mjaanes, M.D., a head physician for the DePaul University Blue Demons and a team physician for the United States Soccer Federation, has been added to the medical team for the USA Men's Rugby team, the USA Eagles. Dr. Mjaanes is an orthopedic surgeon at Midwest Orthopaedics at Rush.

When the USA Eagles take on the New Zealand All Blacks team at their Saturday, November 1, 2014 game at Soldier Field, it's Dr. Mjaanes who will be on site as the official physician. Dr. Mjaanes will attend team practices and then travel with the team to Romania for a week.

According to the September 24, 2014 news release, "Dr. Mjaanes previously worked with the team in February during training camps in Atlanta, Georgia, and Fort Lauderdale, Florida. His role was to help prepare them for the Rugby World Cup Qualifier held in Montevideo, Uruguay, where they tied 27-27. The team then returned to Georgia and beat Uruguay 32-13, advancing to compete in the World Cup in 2015."

Dr. Mjaanes told *OTW*, "Ever since covering my first rugby match, I have been captivated by the sport. I am excited to be working with such a great group of athletes as they make their way to the World Cup." — *EH*

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