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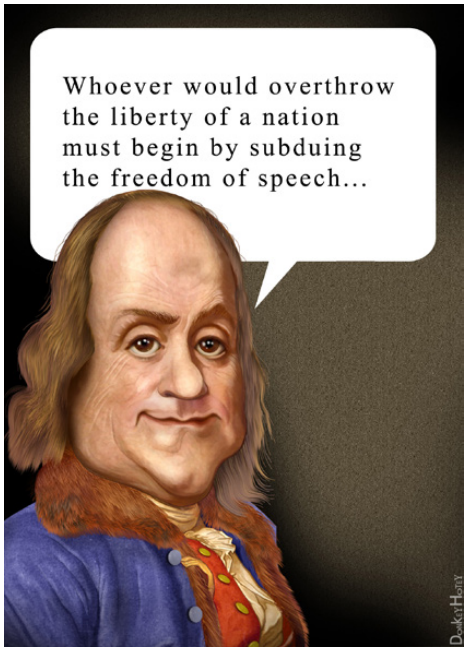
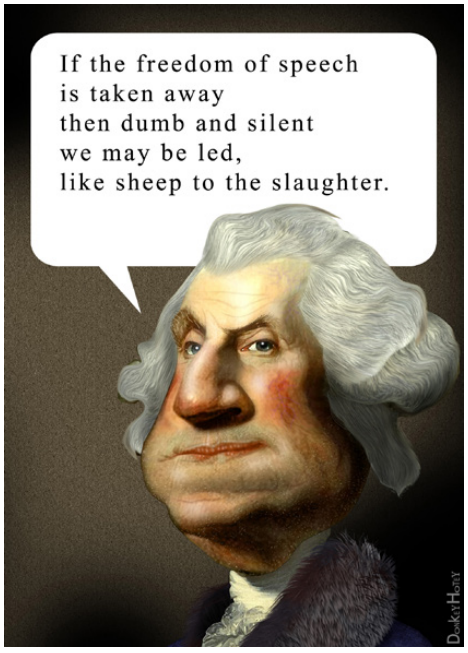
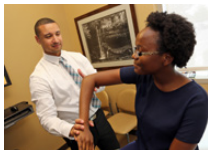
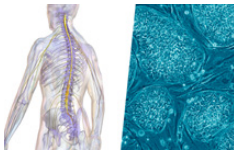
Orthopedics This Week

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: Three systemic problems created this past week's collapse of equity markets around the world: falling oil prices, an unavoidable recession in China and the fear that central banks have little dry powder left with which to prevent deflation. For investors in orthopedic stocks, it's back to fundamentals like cash flow and stability. Until oil stabilizes and China's recession has run its course, equities are only for the patient investor.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	0.84%	Outstanding cash flow, huge bank account and a product portfolio that is the most diverse of any orthopedic company.
2	2	Smith & Nephew	20.19	(2.53)	SNN has always had a slightly better growth profile in ortho than its more diversified recon competitors.
3	10	Johnson & Johnson	28.44	(4.61)	One of the mantras from market analysts over the past few days has been that healthcare is a haven in the storm. JNJ epitomizes that.
4	4	Xtant	(16.41)	8.82	One of the few bright spots is the former Bacterin, now Xtant Medical. Up a solid 8.8% in the last month.
5	3	Medtronic	27.92	(3.32)	The Covidien deal happened because of cheap debt. Trading debt for equity at this scale is one of the problems driving this market.
6	9	Orthofix	2.35	16.60	Another major bright spot. OFIX is on the rebound and investors with risk capital are getting positions established here.
7	8	Zimmer Biomet	30.35	(3.85)	In terms of valuation, ZBH is the second least expensive equity in ortho (after Exactech).
8	5	RTI Biologics	7.50	(1.63)	Strong quarterly sales and earnings are bringing new investors into RTIX.
9	7	Integra LifeSciences	13.74	(7.48)	Integra's international exposure (China, Brazil, in particular) helped in the past quarter but may not contribute much going forward.
10	6	Globus Medical	30.87	(5.81)	Cash flow is excellent, for sure, but investors are moving to more diversified ortho holders in this market.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$38.14	$719	16.60%
2	Bacterin Intl Holdings	BONE	$3.70	$43	8.82%
3	NuVasive	NUVA	$51.93	$2,541	4.72%
4	Stryker	SYK	$99.37	$37,419	0.84%
5	RTI Biologics Inc	RTIX	$6.62	$381	-1.63%
6	Smith & Nephew	SNN	$35.06	$15,681	-2.53%
7	Medtronic	MDT	$74.27	$105,032	-3.32%
8	Zimmer Biomet	ZBH	$104.36	$21,223	-3.85%
9	Johnson & Johnson	JNJ	$95.56	$264,616	-4.61%
10	ConMed	CNMD	$54.80	$1,518	-4.89%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$0.58	$58	-57.59%
2	Aurora Spine	ASG	$0.20	$4	-45.28%
3	MiMedx Group	MDXG	$9.16	$998	-27.93%
4	Wright Medical	WMGI	$23.05	$1,185	-12.12%
5	Tornier N.V.	TRNX	$22.33	$1,100	-12.02%
6	LDR Holding Corp.	LDRH	$40.39	$1,171	-11.68%
7	Exactech	EXAC	$18.17	$255	-10.58%
8	K2M Group Holdings	KTWO	$22.01	$910	-10.56%
9	CryoLife	CRY	$10.30	$305	-10.04%
10	MicroPort Scientific	853	$0.37	$522	-9.85%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Exactech	EXAC	$18.17	$255	16.22
2	Johnson & Johnson	JNJ	$95.56	$264,616	16.23
3	Zimmer Biomet	ZBH	$104.36	$21,223	18.97
4	Globus Medical	GMED	$25.63	$2,437	19.73
5	Stryker	SYK	$99.37	$37,419	22.08

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	$10.30	$305	86.12
2	NuVasive	NUVA	$51.93	$2,541	82.93
3	MiMedx Group	MDXG	$9.16	$998	61.07
4	RTI Biologics Inc	RTIX	$6.62	$381	38.31
5	Smith & Nephew	SNN	$35.06	$15,681	31.30

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$25.63	$2,437	1.61
2	Zimmer Biomet	ZBH	$104.36	$21,223	1.69
3	Exactech	EXAC	$18.17	$255	1.82
4	Smith & Nephew	SNN	$35.06	$15,681	2.03
5	ConMed	CNMD	$54.80	$1,518	2.18

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$51.93	$2,541	5.54
2	MiMedx Group	MDXG	$9.16	$998	4.07
3	Medtronic	MDT	$74.27	$105,032	3.37
4	Johnson & Johnson	JNJ	$95.56	$264,616	3.35
5	CryoLife	CRY	$10.30	$305	2.87

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.58	$58	0.28
2	Exactech	EXAC	$18.17	$255	1.03
3	Bacterin Intl Holdings	BONE	$3.70	$43	1.23
4	RTI Biologics Inc	RTIX	$6.62	$381	1.45
5	MicroPort Scientific	853	$0.37	$522	1.47

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.81	$130	20.68
2	MiMedx Group	MDXG	$9.16	$998	8.44
3	LDR Holding Corp.	LDRH	$40.39	$1,171	7.84
4	Medtronic	MDT	$74.27	$105,032	5.18
5	Globus Medical	GMED	$25.63	$2,437	5.14

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

Court Dump FDA's Off-Label Prohibition Authority

BY WALTER EISNER

Say goodbye to the FDA's off-label marketing prohibition as we know it. A federal judge put another nail into the off-label marketing coffin on August 7, 2015 when he said the FDA's rule prohibits free speech.

This was the second nail. The first nail came in 2012, when a drug sale rep's conviction of violating the misbranding rule was tossed out by a federal appeals court in the *Caronia* case for the same reason.

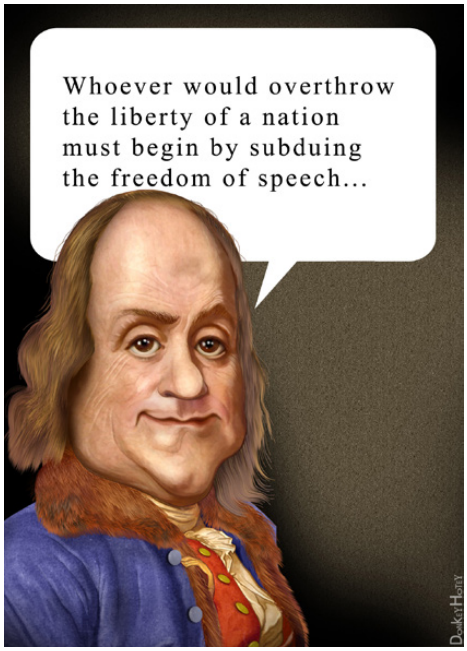
"Congress Shall Make No Law"

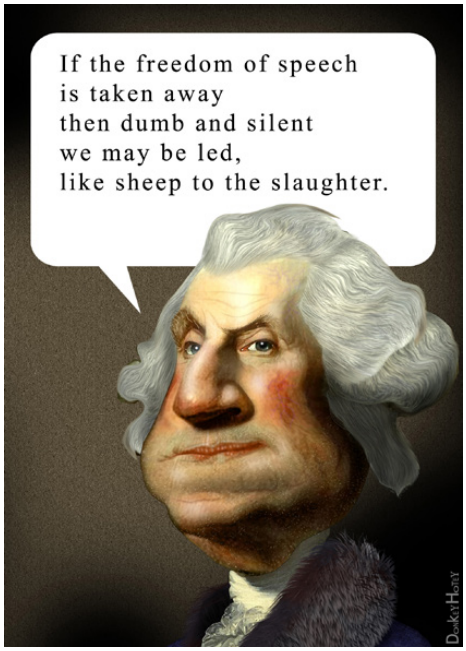
Here's what the Constitution says in the First Amendment about free speech: "Congress shall make no law…abridging the freedom of speech…." It's simple and elegant. No law. Period.

There is no exception for the FDA, yet the FDA abridges speech when it chills the right of device and drug makers by mandating that they can only speak about on-label information. On-label information the FDA has approved.

Courtesy of Amarin Pharma, Inc.

This second case began when four physicians, Jonathan Herbst, Eric Rishe, Peter Gottesfeld and Ralph Yung and a fish oil maker, Amarin Pharma, Inc. sued the FDA in federal court to secure their rights to provide and receive truthful information, even if that information wasn't on the FDA-approved label.





Wikimedia Commons, Flickr and DonkeyHotey

Paul A. Engelmayer, a U.S. district court judge in New York (and former *Wall Street Journal* reporter), agreed with the physicians and company.

In a 71-page opinion, Judge Engelmayer cited the 2012 *Caronia* decision by an appeals court which threw out the conviction of a drug rep, who had shared truthful, but off-label information with physicians. That court held that the FDA cannot "prohibit and criminalize truthful off-label promotion of FDA-approved drugs."

U.S. District Judge Paul A. Engelmayer/securitiesdocket.com

But the *Caronia* decision wasn't enough for the FDA. The agency argued that *Caronia* only applied to one special case and continued to threaten to make criminals of anyone else trying to push truthful off-label speech.

Amarin makes Vascepa, a tryglyceride-lowering drug (fish oil). The FDA approved it for one use, but physicians widely prescribed it for another use. Amarin wanted to make truthful statements to physicians about that off-label use. The FDA did not challenge the truthfulness of Amarin's off-label information. However, the FDA threatened to bring misbranding charges against the company if it distributed the information.

Amarin went to court and asked the federal judge to issue an injunction to

keep the FDA from making them criminals. The court granted their request.

FDA Safety and Effectiveness Authority History

A little history about the FDA's authority is helpful.

Prior to 1938 companies could market products without FDA approval. Then 100 people died after ingesting elixir sulfanilamide and Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA). Approval was needed for safety, but not effectiveness. This led to some manufacturers deliberately misleading the public and physicians about the effectiveness of their product. So Congress amended the FDCA in 1962 to require a demonstration of safety AND effectiveness and that the FDA must approve the product before it can be distributed.

Off-Label As Standard of Care

But the FDA doesn't regulate physicians and after a product is approved, physicians can use it any way they see fit. By 2001, approximately 21% of prescriptions were for off-label purposes. In some cases it became the norm. The therapeutic value of off-label use became widely recognized.

In 2009, the FDA acknowledged that off-label uses "may even constitute a medically recognized standard of care."

Misbranding, False Claims and Off-Label

The FDCA does not expressly prohibit the promotion of products for off-label use, but the FDA applies a "misbranding" criminal charge if someone promotes off-label. Punishment can result in a one year prison term and a $1,000 fine. If it's shown that you intended to mislead, then you can go prison for three years and face a $10,000 fine. Companies found guilty of off-label promotion also face civil and federal suits under the False Claims Act.

It's not an idle threat. In recent years federal prosecutors, according to the court, have "actively" pursued criminal misbranding charges against companies and sales reps. In 2012, GlaxoSmith-Kline pled guilty to misbranding and paid a $1 billion fine. The same year, Abbott Laboratories, Inc. paid a $500 million fine. In 2010 Allergan Inc. paid a $375 million fine.

When the manufacturers' "speech" is untrue or misleading, the FDA says the public's health in endangered. But generally speaking, the FDA says its goal in pursuing criminal charges is to encourage the use of the agency's approval process.

The FDA has allowed some off-label educational activity by manufacturers by issuing draft guidances on how manufacturers should respond to unsolicited requests for off-label information. The manufacturer should disseminate truthful and non-misleading information only to that person and tailored to answer only the requester's specific question.

Before *Caronia*, no one had challenged the FDA's application of the misbranding provision of truthful and non-misleading promotional statements.

FDA Challenges Begin

In the 1998 *Friedman* case, a public interest group challenged the FDA over the prohibition of distribution of textbook excerpts and article reprints from medical and journals. The court rejected the FDA's argument that those commercial communications were illegal. The FDA appealed. Perhaps fearing a loss, the agency pulled the appeal and adopted a much narrower construction of the guidance document.

Then in 2012 came *Caronia* and the appeals court said "that a manufacturer's speech promoting off-label use is constitutionally protected commercial speech, and that the First Amendment places limits on a misbranding prosecution to the extent it is based on the truthful promotion of FDA-approved drugs for off-label use."

But the FDA chose to read *Caronia* "narrowly" and said the decision preserved their right to bring misbranding actions.

In February 2014, the agency issued an updated draft guidance regarding the dissemination of scientific or medical journal articles under certain conditions. The guidance said that if a sales representative characterizes an article to suggest that a drug is safe or effective for an unapproved use, the agency may use such speech as evidence that the manufacturer intended to promote that use.

Then in June 2014, the agency agreed to conduct a comprehensive review and issue a new guidance within a year. That promised guidance had not been issued at the time of Amarin's lawsuit. On July 7, 2015, the agency declined to tell the court when the new guidance would be offered.

Amarin's Legal Challenge

Amarin sought FDA approval for two separate uses of Vascepa. The company received FDA approval on September 25, 2011 to market Vascepa for treating adult patients with triglyceride levels above 500 mg/dL of blood ("severe

hypertriglyceridemia," or "very high triglycerides"). The second request was for patients with triglyceride levels between 200 and 499 mg/dL of blood and who are already on statin therapy ("persistently high triglycerides").

The second request was the off-label use at issue in this case.

After failing to receive FDA approval for the second use and being threatened with misbranding prosecution, the company and the four physicians filed suit in May 7, 2015.

The physicians argued that they needed truthful and non-misleading information to make informed decisions about what's best for their patients. They argued that the FDA's current method for regulating the flow of off-label information "severely restricts" medical professionals' access to information from the source most knowledgeable about the product.

FDA Responds

In June 2015, the FDA tried to narrow the dispute of some of Amarin's communications by noting that "some fall within the scope" of existing allowed claims. The FDA tried to make Amarin's suit irrelevant by offering to define some conditions under which the company could communicate to physicians about some of the information in question.

The agency reiterated that it was reviewing its regulations over dissemination of information and a new guidance would be forthcoming.

Amarin could have declared victory and gone home at that point. But the company pressed on.

On June 23, 2015, the FDA opposed Amarin's request for preliminary relief. The agency told the court that if the company accepted its proposal, the controversy would be moot. If Amarin didn't agree to the agency's proposal to modify some statements, then Amarin's plan was a "frontal assault…on the entire approval framework."

On June 30, the company told the agency it wasn't interested in their proposal and the agency's threat to prosecute the company as an attempt to "refight old, lost battles."

On July 7, 2015, the court heard the arguments.

Judge's Ruling and Aftermath

The judge said the "Court's considered and firm view is that, under *Caronia*, the FDA may not bring such an action based on truthful promotional speech alone, consistent with the First Amendment. A fair reading of that decision refutes the FDA's view that the Second Circuit's ruling was limited to the facts of *Caronia*'s particular case."

Jude Engelmayer ruled that Amarin had established a "substantial likelihood of success on the merits on this point," and granted the injunction. He noted that misbranding is "unlike the crimes of jury tampering, blackmail, and insider trading to which the FDA has analogized, in which 'the speech is the act'."

So now what?

The decision "brings to a head over twenty years of wrangling between the industry and the FDA on the applicability of the First Amendment to FDA off-label marketing," John Kamp, executive director of the Coalition for Healthcare Communication told John Sullivan of *Policy and Medicine*. "Furthermore, it leaves little room for FDA to protect its existing enforcement scheme, and puts all that much more pressure on the agency to provide new policy guidance in the area."

The court's decision also "casts doubt on FDA's long standing rules enabling limited 'scientific exchange' with some professionals but banning the promotional communication by the sales force and media marketing," Kamp adds.

The case is the "first decision that clearly and unequivocally rebuffs the government's view that off-label promotion can be prosecuted even if it is truthful and non-misleading," Floyd Abrams, a partner at Cahill Gordon & Reindel and Amarin's counsel, said during a call with reporters after the ruling.

Warning to Manufacturers

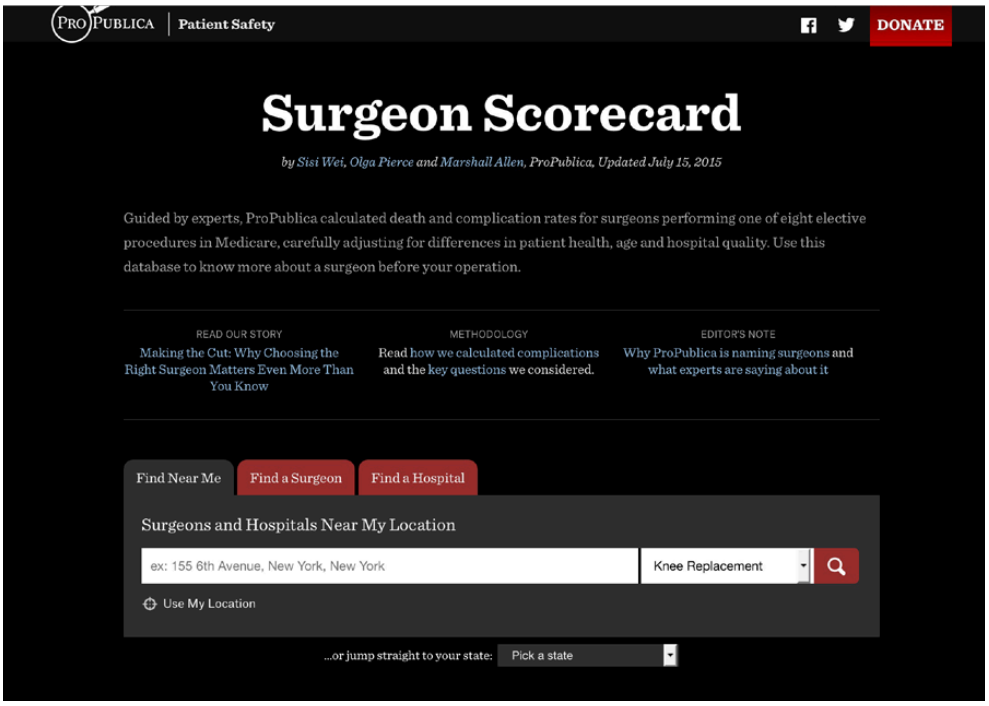
But before manufacturers turn their sales reps loose on physicians with truthful yet off-label information, consider that the judge said there were limitations and gave some advice to manufacturers when he said:

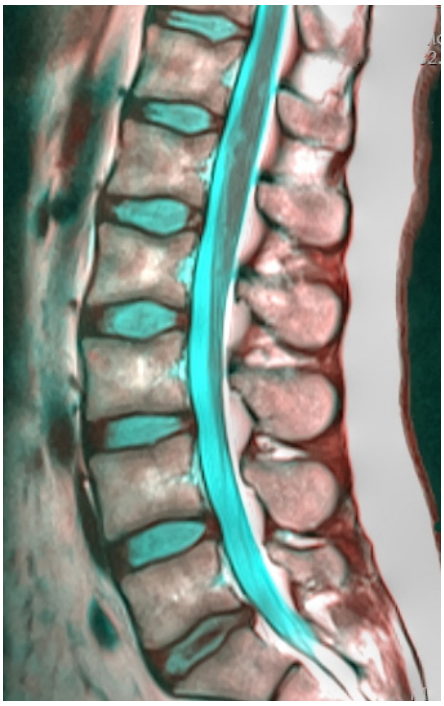
> "Although the FDA cannot require a manufacturer to choreograph its truthful promotional speech to conform to the agency's specifications, there is practical wisdom to much of the FDA's guidance, including that a manufacturer vet and script in advance its statements about a drug's off-label use. A manufacturer that leaves its sales force at liberty to converse unscripted with doctors about off-label use of an approved drug invites a misbranding action if false or misleading (e.g., one-sided or incomplete) representations result. *Caronia* leaves the FDA free to act against such lapses."

The FDA has 60 days after the ruling to appeal. ◆

Lumbar Spine Fusion (Posterior): Safest Hospitals, Safest Doctors, Ranked

BY ROBIN YOUNG





Surgeon Scorecard and MRI of Lumbar spine / Source: ProPublica.org, Wikimedia Commons and Nevit

ProPublica, an independent, non-profit newsroom that produces investigative journalism in the public interest, created a searchable web app which allows anyone to search the Medicare database for specific hospitals or doctors and then to see their complication rates per Centers for Medicare and Medicaid Services (CMS).

Additionally, the app ranks both the hospitals and physicians against their peers.

This data is okay, not great.

To being with, this is Medicare data. It excludes patients under 65 years old which, for spine surgery, is the bulk of the market.

Also, there are many confounding reasons for any particular complication rate. This data does not account for co-morbidities like obesity, diabetes, prior surgeries, heart disease and other diagnosis which are associated in the literature with higher rates of complications. Some physicians will not perform revision surgeries, so their complication rates will be lower.

This data should be treated as more interesting and entertaining than useful for actually selecting a care provider.

We know from our sister company PearlDiver Technologies, Inc. that the data coming from CMS has a lot of noise in it.

Here is how ProPublica described their methodology:

> *"Our analysis is based on billing data hospitals submitted to Medicare from 2009-2013. We analyzed 2.3 million procedures: hip and knee replacements, three types of spinal fusion, gallbladder removals, prostate removals and prostate resections. ProPublica's analysis accounted for factors such as patients' health and age. We focused only on elective cases because they typically involve healthier patients with the best odds of a smooth recovery."*

Sources: Centers for Medicare and Medicaid Services; ProPublica Analysis

Authors and researchers: Marshall Allen, Olga Pierce, Mike Tigas, Al Shaw, Lena Groeger, Annie Waldman, Ryann Grochowski Jones, Jonathan Stray, Cecilia Reyes, Tobin Asher, Mariana Barbosa.

"If you spot an error, please let us know at scorecard@propublica.org."

The ProPublica researchers found that the overall complication rates in the United States is low, ranging from 2% to 4%, depending on the type of surgery. Furthermore, ProPublica found 756 surgeons in the database who performed at least 50 operations yet did not record a single complication in the five years covered by the analysis. Another 1,423 surgeons had only one.

Bottom line, U.S. surgeons are excellent and overall have very low complication rates.

Of the ten largest metropolitan areas in the United States, here are the safest of the safest hospitals and surgeons. We

(See tables below and on page 10.)...

Metro Area	Hospitals With the Lowest Complication Rates and the Physician Associated With Each Hospital With the Lowest Complication Rate
10 San Jose, California	1. Stanford Hospital, Stanford (Noman Khan) 2. Dominican Hospital, Santa Cruz (Christopher Summa) 3. Valleycare Medical Center, Pleasanton (Kevin Booth) 4. Washington Hospital, Fremont (Desmond Erasmus) 5. Good Samaritan Hospital, Fremont (Edward Rustamzadeh
9 Dallas, Texas	1. Taylor University Medical Center, Dallas (Robert Viere) 2. Methodist Hospital for Surgery, Addison (Andrew Park*) 3. Baylor Medical Center at Uptown, Dallas (Craig Callewart*) 4. Medical Center of Lewisville, Lewisville (Brady Giesler) 5. Texas Health Presbyterian Hospital Flower Mound, Flower Mound (Brady Giesler)
8 San Diego, California	1. Grossmont Hospital, La Mesa (John Finkenberg) 2. Alvarado Hospital Medical Center (Choll Kim*) 3. Scripps Mercy Hospital, San Diego (Lance Alenau) 4. Sharp Memorial Hospital, San Diego (Richard Ostrup*) 5. Sharp Chula Vista Medical Center, Chula Vista (Lance Alenau)
7 San Antonio, Texas	1. South Texas Spine and Surgical Hospital, San Antonio (Gilbert Meadows) 2. Methodist Hospital, San Antonio (Tom Kingman) 3. Baptist Medical Center, San Antonio (Robert Johnson) 4. Innova Hospital San Antonio (Rafael Parra) 5. Christus Santa Rosa Hospital, (Gerardo Zavala*)
6 Phoenix, Arizona	1. Scottsdale Healthcare Thompson Peak Hospital, Scottsdale (Justin Field) 2. Scottsdale Healthcare Shea Medical Center, Scottsdale (William Stevens*) 3. Surgical Specialty Hospital of Phoenix, Phoenix (Daniel Lieberman*) 4. Oasis Hospital, Phoenix (Dennis Crandall*) 5. Banner Thunderbird Medical Center, Glendale (Jonathan Landsman)
5 Philadelphia, Pennsylvania	1. Pennsylvania Hospital of the University of Pa Health System, Philadelphia (Stephen Dante) 2. Jeanes Hospital, Philadelphia (Leonard Bruno) 3. Holy Redeemer Hospital and Medical Center, Meadowbrook (Gene Salkind*) 4. Phoenixville Hospital, Phoenixville (Sagi Kuznits) 5. Main Line Hospital Paoli, Paoli (Kenan Aksu*)
4 Houston, Texas	1. Houston Orthopedic and Spine Hospital, Bellaire (Stanley Jones) 2. Memorial Hermann Texas Medical Center, Houston (Vivek Kushwaha) 3. Methodist Sugar Land Hospital, Sugar Land (Jeffrey Wood) 4. Sugar Land Surgical Hospital LLP, Sugar Land (Mohammad Etminan) 5. Memorial Hermann Sugar Land Hospital, Sugar Land (Mohammad Etminan)

**Occasionally, the same physician is listed at different hospitals but with the same CMS data. When that occurs, we selected the physician with the next lowest complication rate and designated this person with an asterisk.*

3 Chicago, Illinois	1. Skokie Hospital, Skokie (Noam Stadlan) 2. Evanston Hospital, Evanston (Michael Kornblatt*) 3. Northwest Community Hospital, Arlington Heights (E. Quinn Regan) 4. Palos Community Hospital, Palos Heights (Richard Lim) 5. Advocate Christ Hospital & Medical Center, Oak Lawn (Anis Mekhail*)
2 Los Angeles, California	1. Cedars Sinai Medical Center, Los Angeles (Hyun Bae) 2. Saint John's Health Center, Santa Monica (Khawar Siddique*) 3. Huntington Memorial Hospital, Pasadena (Ben Pradhan) 4. Methodist Hospital of Southern Ca, Arcadia (Christopher Aho*) 5. Verdugo Hills Hospital, Glendale (Ben Pradhan)
1 New York City, New York	1. Hospital for Special Surgery, New York (Patrick O'Leary) 2. Englewood Hospital and Medical Center (Frank Moore) 3. Mount Sinai Hospital, New York (Mark Antonacci*) 4. Lenox Hill Hospital, New York (Mitchell Levine*) 5. Long Island Jewish Medical Center, New Hyde Park (Jeff Silber)

**Occasionally, the same physician is listed at different hospitals but with the same CMS data. When that occurs, we selected the physician with the next lowest complication rate and designated this person with an asterisk.*

listed the top five hospitals (as ranked by ProPublica from CMS data) in each metropolitan area plus the single surgeon at each hospital with the lowest complication rates.

Coming in future articles are the rankings for knee replacements, lumbar spine fusion anterior approach and cervical spine fusion.

The ProPublica app may be accessed at the following website: https://projects.propublica.org/surgeons/ ♦

Richard Hawkins, M.D. Receives AOSSM Sports Medicine Leadership Award // Geoffrey Westrich, M.D. Taking Helm at Eastern Orthopaedic Association // Study: 100% Union Rate for Calcaneal Osteotomies!

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

Richard Hawkins, M.D. Named "Mr. Sports Medicine" by AOSSM The American Orthopaedic Society for Sports Medicine (AOSSM) has named Richard Hawkins, M.D., founding partner of the famed Steadman Hawkins Clinic, as this year's recipient of the Robert E. Leach Sports Medicine Leadership award. Dr. Hawkins told *OTW*, "It is significant honor to receive the Robert E. Leach Sports Medicine Leadership award (Mr. Sports Medicine). It is particularly gratifying especially because I knew Bob Leach. He was an exceptional surgeon and gentlemen who made major academic contributions to our field."

Dr. Richard Hawkins with Dr. Robert E. Leach

Dr. Hawkins, now a program director for the Steadman Hawkins Clinic of the Carolinas Fellowship Program, added, "I did my undergraduate training at our local university in London. During that time I did a knee fellowship with Dr. Jack Kennedy and in 1975 I did a cervical spine and shoulder fellowship under Drs. Bill Fielding and Charlie Neer. When I returned to practice in London, my shoulder practice grew exponentially."

"I grew up in London, Ontario, Canada, and I did my training there, including fellowships in knee, shoulder, and spine. I practiced there for many years, during which time I developed my interest in the health of the shoulder. Then in 1990 the opportunity to go to Vail, Colorado, presented itself. Dr. Richard Steadman and I subsequently established the Steadman Hawkins Clinic, and we have had the pleasure of treating numerous high level athletes. In 2008 I accepted an offer to establish the Steadman Hawkins Clinic of the Carolinas in Greenville, South Carolina."

"I wouldn't be a doctor if it weren't for athletics. Having played a variety of sports, including semi-pro football, it has given me an understanding of the physical and psychological aspects of working with athletes."

"I am proud to have trained approximately 200 doctors from all over the world as sports medicine physicians. They appreciate our research-oriented perspective, as well as the fact that we take that knowledge and apply the related principles to patient care. I'd like my legacy to be that of teaching and mentoring young surgeons and families. Part of what we do is teaching life lessons, and to be a good teacher you must be a good learner. I learn from everyone around me and I love being a student of life. I'm fortunate to have tremendous relationships with my patients; whether it's the kid from down the street or a professional athlete, I revel in caring for my patients. More importantly, a commitment to family comes first."

Geoffrey Westrich, M.D. New President of Eastern Orthopaedic Association Geoffrey Westrich, M.D., an acclaimed orthopedic surgeon and researcher, has been named president

of the Eastern Orthopaedic Association (EOA). Dr. Westrich, director of Research, Adult Reconstruction and Joint Replacement at Hospital for Special Surgery, told *OTW*, "It's a thrill to be given the chance to lead such a tremendous organization. Years ago I was honored with the EOA resident award, then once I went into practice I became involved in several EOA committees; I have served on the board of directors for 15 years."

Dr. Westrich, who dedicates his practice to treating hip and knee patients, notes, "The EOA encompasses 13 Eastern U.S. states—all the way down to Puerto Rico. Our purpose is to promote and foster the advancement of the art and science of orthopedic surgery. The organization has a nice balance of academic and private practice orthopedic surgeons, meaning that we get a meaningful cross fertilization of experience and ideas."

"As president, I will continue to foster educational programs via an academic liaison who is on the board of directors. And we will ask state representatives to reach out to various orthopedic surgeons in their respective areas in order to determine if there are more individuals who might be a good fit for the EOA."

Not only does Dr. Westrich hold a medical degree from Tufts University School of Medicine, but he obtained a Bachelors degree from Tufts School of Engineering. He was then invited to join Eta Kappa Nu, a prominent engineering honors society. Dr. Westrich completed his orthopedic surgery residency at New York Hospital-Weill Cornell Medical Center, followed by a hip and knee fellowship at Hospital for Special Surgery and an additional fellowship in hip, knee, and trauma in Bern, Switzerland.

100% Union Rate for Calcaneal Osteotomies! A new jig for use with calcaneal osteotomies just may be the future, says Gregory Guyton, M.D. of Union Memorial Hospital in Baltimore. Dr. Guyton and his colleagues have performed 60 calcaneal osteotomies through a minimal incision and have achieved a 100% union rate. Dr. Guyton tells *OTW*, "We set out to see if using a jig and a burr would be a safe, effective option for performing calcaneal osteotomies. We used calcaneal oste-

otomy as an initial approach to create a paradigm for learning how to do these surgeries with a jig and a very minimal 5-8mm incision. We are taking a minimally invasive surgery (MIS) concept and adding an element of predictability and reliability that will hopefully give surgeons new perspective and more treatment options."

"We have created a jig to put in the side of the heel to guide the burr through the sweeping motion required to cut the calcaneus. Doing this procedure without a jig—i.e., freehand—is valid, but it is less predictable as far as deciding how to create the osteotomy angle and how to orient the osteotomy. Recent research has helped define a specific location of the starting point for calcaneal osteotomy in order to avoid neurovascular injury. Specifically, the safe zone is defined by drawing a line between the plantar fascia and the posterosuperior prominence of the calcaneous and projecting the line 10mm forward…doing this avoids the sural nerve and its branches with percutaneous incisions."

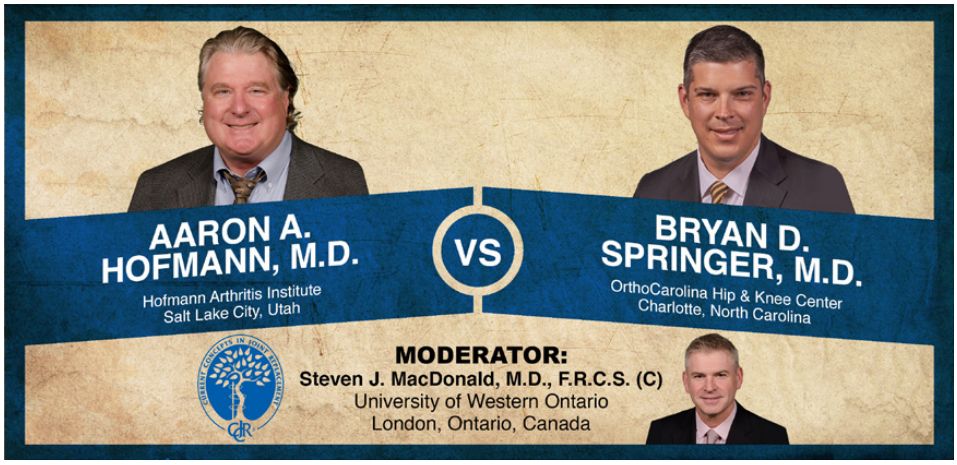
"It was a bit surprising to see in our study that there was less of a tendency to injure the smaller, lateral calcaneal nerves by using a burr as opposed to using a larger incision and a saw. This was probably because the larger incision stretches the nerves where as the small burr incision tends to avoid these small branches altogether."

"To date we have performed approximately 60 calcaneal osteotomies with a 100% union rate, no significant infections, and no issues regarding the tibial nerve or the sural nerve. So we now know that this is a safe and effective procedure. A reduction in pain and morbidity compared to the open technique remains difficult to validate, however, because we have always done this in conjunction with other open procedures elsewhere in the foot. Once we further develop the technique and have the opportunity to potentially extend minimally invasive concepts to other parts of the flatfoot correction, we hope to see further reductions in patient morbidity and pain." ♦

Measured Resection Trumps Gap Balancing in TKA

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 16th Annual Current Concepts in Joint Replacement® (CCJR) – Spring meeting, which took place in Las Vegas this past May. This week's topic is "Measured Resection Trumps Gap Balancing in TKA." For the proposition is Aaron A. Hofmann, M.D. from the Hofmann Arthritis Institute in Salt Lake City. Bryan D. Springer, M.D. with OrthoCarolina Hip & Knee Center in Charlotte is in opposition. Moderating is Steven J. MacDonald, M.D., F.R.C.S.(C) from the University of Western Ontario.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Hofmann: I'm going to be talking about measured resection being the simple way to do knee replacement. It's the way I've done knee replacement for the last 30 years and I think it's the least complicated way to do that, so let me just take you through how that's done and the reasoning behind it.

There are lots of different names for this measured resection technique, the new name is kinematic, perhaps. That takes it to the extreme. Or the anatomic alignment, basically trying to get your knee balanced. A classic resection basically puts the tibia perpendicular to the long axis and then you spend the rest of the operation trying to balance around that. That's my bias. Or you can take an anatomic philosophy and go parallel to the tibia and few degrees of varus and make your rectangular resection in extension and flexion. I think we all agree that's our goal—to have a rectangular resection, in flexion, extension—and I do it by following the patient's anatomy.

The difference, I think, with gap balancing, perhaps, and measured resection really comes from the tibial side. So if you make a perpendicular cut, you're going to remove bone lateral and medial and that really means that you're going to have to spend a lot more time balancing. If you take that same knee and cut parallel with two or three degrees of varus on the tibia, you're balancing act is almost nothing.

Let me take you through a typical case. A medial sleeve is prepared…we have a mantra for this…medial meniscus, medial sleeve, medial osteophytes and we remove that soft tissue, but basically this is the only releasing we're doing on a varus knee…just releasing that medial sleeve. On the lateral side, basically the lateral meniscus, the lateral sleeve, and lateral osteophytes are removed. If we look at the distal femur, you're really taking an even resection on the medial and lateral side of the distal femur.

With this measured resection technique, we're referencing the posterior condyles…on a varus knee you automatically externally rotate a little bit because there is a little cartilage missing medially…I draw in Whiteside's line to make sure the rotation parallels that. And maybe lateralize the jig just a little bit, but basically following the patient's anatomy within a degree.

We come to the tibia, there is a difference there. If we're sacrificing the PCL [posterior cruciate ligament], we want to go just a little bit flatter. The newer designs actually have 3 degrees built into the polyethylene to compensate for the flexion gap being a little bigger than the extension gap—cutting the tibia a few degrees flatter solves that.

If we look from the proximal tibia, you can sight the block. There's an even resection medial and lateral. Again, I'm only following the patient's anatomy to within about 2 degrees of varus. I'm not a whack-o that's going 5 or 6 degrees of varus, but I am following the patient's anatomy, so I'm looking to get an even resection medial and lateral.

Tibial sizing is done in standard ways, slightly lateralizing the tibial component and then basically a flatter tibial trial is something I've used for over

20 years. It's like an articulating block spacer. You can check your flexion extension gap using flat spacers. Don't forget about the patella that also should be a measured resection. I medialize it. I mark the medial sagittal ridge and I try to get back to that same thickness and simply remove the lateral facet of the patella.

I do take an intraoperative fluoroscopic x-ray on all patients and I document the interfaces at the time of surgery, not in the recovery room where basically you get 2 obliques.

My varus knees have slight varus on the short film, long axis looks like the mechanical axis is going through the medial compartment. It's a perpendicular cut on the tibia, not a varus cut, for valgus legs, again using measured resection. And it's a very efficient technique. Our average tourniquet time is 35 minutes. I think the proof of the pudding is basically the longevity of the components—98% survival.

Dr. Springer: I think our goals of total knee replacement are aligned regardless of the technique that we use. We're trying to restore the mechanical axis, we're trying to get symmetric ligament balance and a knee that moves through a range of motion, and there's certainly debate and controversy about what surgical technique best achieves this. Where I think we differ, however, gap balancing takes a step-wise approach to the knee, balancing the extension gap and then the flexion gap. The main difference centers on how we rotate the femoral component. I think in my mind, using bony landmarks, can lead to inaccuracy in your ability to accurately find them at the time of surgery.

We take a step-wise approach to the knee. We cut the distal femur. We cut the proximal tibia. And then the knee is balanced in extension. Our goal then is to create a rectangle—so to go from asymmetry in extension, to a nice symmetric rectangular extension gap with appropriate tension on the ligaments.

What you have to realize, however, is that those releases that you do in extension **do** have an effect on the femoral component when you go into flexion. And depending on the amount of release that you have to do, a large medial release leads to instability on the medial side in flexion. You have to appropriately adjust your femoral rotation to accommodate for that and bony landmarks simply just don't do that.

Then we balance the knee in flexion. This can be done in a variety of ways.

You can use lamina spreaders. You can use a tensioner which allows you to set it at 90 degrees of flexion. Place tension on that knee in flexion. Match my balanced extension gap. Pin the block. And then be able to look at the 4-in-1 one cutting block in reference to my tibia as well as to the symmetry of the tension on the ligaments in flexion before I make my cuts and make any adjustments as needed.

Fixed bony landmarks, however, really suffer from the inability of the surgeon to accurately and reproducibly find them at the time of surgery. And I think this leads to substantial variation in the rotation and the sizing of the femoral component.

Let's look at those bony landmarks in a little more detail. The upper transepicondylar axis—your ability to accurately find it within 3 degrees is only about 75% of the time. The AP axis, or Whiteside line, 32% range of error in the surgeon's ability to accurately locate it. And 3 degrees off your posterior condyles, again inaccurate about 40%-45% of the time. And as it turns out, it make sense. Again, bony landmarks at best, 70% of the time are able to create a nice rectangular flexion gap.

What about gap balancing versus measured resection and its ability to accurately find those landmarks? Tom Fehring, 100 consecutive posterior stabilized knees comparing the two techniques. Rotational errors greater than 3 degrees were present in almost half when bony landmarks were used to determine femoral component rotation.

Doug Dennis and Ray Kim looked at femoral component liftoff in flexion using fluoroscopic studies… gap balancing had a significantly lower incidence of condylar liftoff greater than 1mm when those patients went into deep flexion. And more recently, Stephen Kreuzer looked at 31 total knees using navigation, looking at all the bony landmarks compared to a gap balance technique, looking at post-operative CT scans to assess the femoral component rotation, and there were significant differences in the lack of the ability of the bony landmarks to accurately balance the knee in flexion.

So in conclusion, I think our goals are the same and I think we're aligned regardless of the technique that is used. But I think our ability to accurately find these landmarks is very limited and in

my hands a gap balancing technique reliably reproduces a more balanced knee.

Moderator MacDonald: Thank you Brian, very nicely defended. I've not seen a clinical paper to show a difference. Not the biomechanics or the lift-off things, but actually clinically does it make a difference to the patient clinically. Aaron what do you think?

Dr. Hofmann: I'd say no. I think I'm really talking about how simple the operation can be and how you can make it transferrable to everybody in the world essentially. And to make a speedy, efficient operation. I think the fallacy in the papers that were being quoted by Dr. Springer…measured resection is not measured resection medial and lateral on the tibia. If you make a perpendicular cut on the tibia… and that's what I do and that's what the classic guys never do 'cause you want a perpendicular axis on your tibia…but if you do that you've already started out with screwed up anatomy. I think if you follow the patient's varus anatomy on the proximal tibia, if it's there…and it's there on a varus knee, it's not there in a valgus knee…then the rest of the balance is easy. I'm sure I'm doing the same thing doing my flexion extension balancing…basically I'm using flat insert trials to do that, so it's not that I'm not balancing the knee or fine tuning, or tweaking it, but I'm doing it a different way.

Dr. Springer: I think in reality there's a lot more overlap here than what we think there is between these two techniques. We all want to look at the gap balancers over here and the measured resectors over here, and I think we tend to congregate in the middle a little bit more depending on how you look at the operation as a whole. For example, my distal femoral cut and my proximal tibia cut are essentially measured resection techniques. And my balancing in flexion is based on tension on the ligaments as opposed to bony landmarks. I think there is a big overlap there.

Moderator MacDonald: Well, gentlemen, thank you for a wonderful debate. Thank you very much. ♦

Please visit www.CCJR.com to register for the 2015 CCJR Winter Meeting, December 9 - 12 in Orlando, Florida.

COMPANY

SeaSpine Sets Sail With Intervertebral Body Fusion Device

SeaSpine Holdings Corporation has announced the launch of its Ventura NanoMetalene transforaminal intervertebral body fusion device. The product is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD).

According to the August 10, 2015 news release, "NanoMetalene is an ultra-thin layer of commercially pure titanium molecularly bonded to a PEEK-OPTIMA implant. It is applied in a proprietary high-energy, low-temperature surface process and encompasses the entire implant, including the center graft window…With convex surfaces and multiple footprints, surgeons can create a secure anatomical fit, and Ventura NanoMetalene's large graft aperture for autogenous bone graft assists in fusion. Ventura NanoMetalene is optimal for either open or minimally transforaminal lumbar intervertebral fusion (TLIF) procedures."

"We collaborated with our surgeon partners to create an implant that utilizes existing instrumentation and addresses today's increasingly complex spinal surgery requirements," said SeaSpine CEO Keith Valentine. "NanoMetalene technology is a great bridge product in our portfolio because it offers the benefits of hardware with biologic-driven features that support bone growth. Its success to-date supports our plan to develop additional implants leveraging NanoMetalene technology in the future."

Colin Smith, company vice president of Marketing and Product Development, told *OTW,* "The biggest challenge was identifying the right technology that allowed us to bond commercially pure titanium to PEEK while retaining the benefits of PEEK (such as favorable post-operative imaging and modulus of elasticity) and adding the recognized biologic properties of a nano-topography titanium surface." — *EH*

SeaSpine Holdings Corportion

LEGAL

New Harvard Study: Drug Approval FAST-ER Than Devices

Pity the poor medical device manufacturer. The Food and Drug Administration (FDA) sets them on a longer road to device approval than it does the makers of blockbuster drugs. According to Fink Densford, reporting on a recent Harvard Business School study, new medical devices on average take 34% longer to get approval from the FDA than do drugs.

Wikipedia Commons and Stefan-XP

The lead investigator was Ariel Stern. He and his colleagues examined 30 years of FDA data (1977-2007) and compared the processing time for new drugs against that used to evaluate high risk medical devices. They found that new medical devices, on average, took 34% longer to get FDA approval than did new drugs.

Examples of pioneering devices examined in the study were pacemakers, coronary stents, implantable cardioverter defibrillators, tracheal and bronchial

tubes, prosthetic limbs, and intraocular implants.

Stern wrote in his working paper *Innovation under Regulatory Uncertainty: Evidence from Medical Technology* that the average time required for devices to get approval is 7.2 months longer than pioneering drugs. He conservatively estimated the cost of the additional delay at $6.7 million "This comes on top of the estimated average of $94 million to bring a new high-risk device to market," he said.

These costs of delay represent a particular burden for smaller companies. Delays can represent a large part of their research and development costs, which, Stern says, "prohibits pioneering development by smaller firms in the medical device field."

The comparison between the tasks taken on by small medical device companies as compared to small drug firms is striking. Small device firms work on follow-up applications where they submit from 14% to 21% of all new device FDA applications. Small drug firms, however, made up 36% to 54% of new drug supplications and only 11% to 46% of drug follow-on applications

Stern says that some of the reason for the delay on medical devices can be blamed on the fact that drug testing at the FDA has been streamlined for drugs but not for devices. Stern further explained that the FDA categorizes devices by their function, not their underlying technology. "That kind of labeling can lead to excessive testing on devices that have already been approved by the agency for other uses," Stern is quoted by Densford as saying. — *BY*

Clinical Evidence Gathering Shifting to Post-Approval

The U.S. relies on gathering clinical data to show a device is safe and effective before the FDA will grant approval. But that's changing, according to a new study.

Harlan Krumholz, M.D., the Yale University professor who was hired by Medtronic plc to review all the Infuse data, has just co-authored a study that found that "the generation of clinical evidence to understand device safety and effectiveness is shifting from predominantly premarket [PMA] to continual study throughout the total product life cycle."

That's how the Europeans do it. They get devices out to patients faster, but require more post-approval data through device registries and other means.

Krumholz, along with post graduate student Vinay Rathi and others said that their study shows that many high-risk therapeutic devices get FDA approval with only one study proving their safety and efficacy before going to market.

The researchers looked at all clinical studies of high-risk therapeutic devices receiving initial market approval via the PMA pathway in 2010 and 2011 identified through *ClinicalTrials.gov* and publicly available FDA documents as of October 2014.

Here's what they found.

- Eight high-risk therapeutic devices received initial marketing approval via the PMA pathway. They also identified 286 clinical studies of these devices: 82 (28.7%) premarket and 204 (71.3%) postmarket, among which there were 52 (18.2%) nonpivotal premarket studies, 30 (10.5%) pivotal premarket studies, 33 (11.5%) FDA-

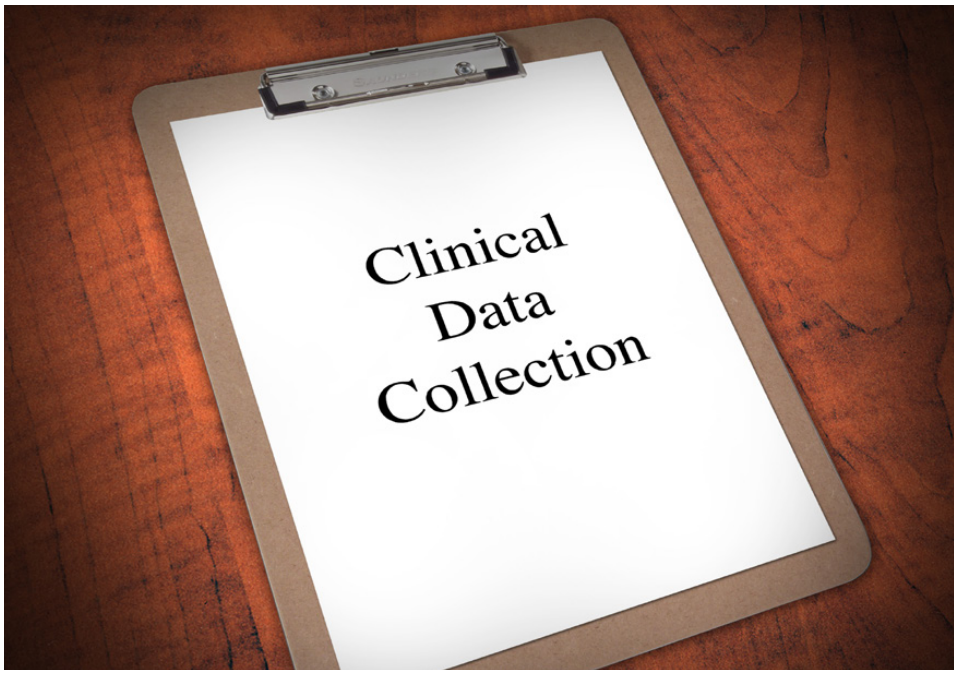


Photo creation by RRY Publications, LLC

required PAS (post-approval studies), and 171 (59.8%) manufacturer/investigator-initiated postmarket studies.

- Six of 33 (18.2%) PAS and 20 of 171 (11.7%) manufacturer/investigator-initiated postmarket studies were reported as completed.
- No postmarket studies were identified for 5 (17.9%) devices; 3 or fewer were identified for 13 (46.4%) devices overall.
- Median enrollment was 65 patients (interquartile range [IQR], 25-111), 241 patients (IQR, 147-415), 222 patients (IQR, 119-640), and 250 patients (IQR, 60-800) for nonpivotal premarket, pivotal, FDA-required PAS, and manufacturer/investigator-initiated postmarket studies, respectively.
- Approximately half of all studies used no comparator (pivotal: 13/30 [43.3%]; completed postmarket: 16/26 [61.5%]; ongoing postmarket: 70/153 [45.8%]). Median duration of primary effectiveness end point follow-up was 3.0 months (IQR, 3.0-12.0), 9.0 months (IQR, 0.3-12.0), and 12.0 months (IQR, 7.0-24.0) for pivotal, completed postmarket, and ongoing postmarket studies, respectively.

They concluded that among high-risk therapeutic devices approved via the FDA PMA pathway, "total product life cycle evidence generation varied in both the number and quality of premarket and postmarket studies, with approximately 13% of initiated postmarket studies completed between 3 and 5 years after FDA approval." — *WE*

BIOLOGICS

Fibrin Not Necessary for Fracture Healing?!

Vanderbilt researchers are shaking things up in the world of fracture care. The scientists have discovered that contrary to popular belief, fibrin is not required for fracture healing. Instead, fibrin breakdown must happen in order to have healthy fracture repair.

"Many of the current pharmaceutical protocols are based on using fibrin to promote fracture healing," said Jonathan Schoenecker, M.D., Ph.D., assistant professor of Orthopaedic Surgery and Rehabilitation, in the August 11, 2015 news release. "In certain instances it may help, but we've shown for sure that you don't need it. Bone biology does not require fibrin to heal a fracture."

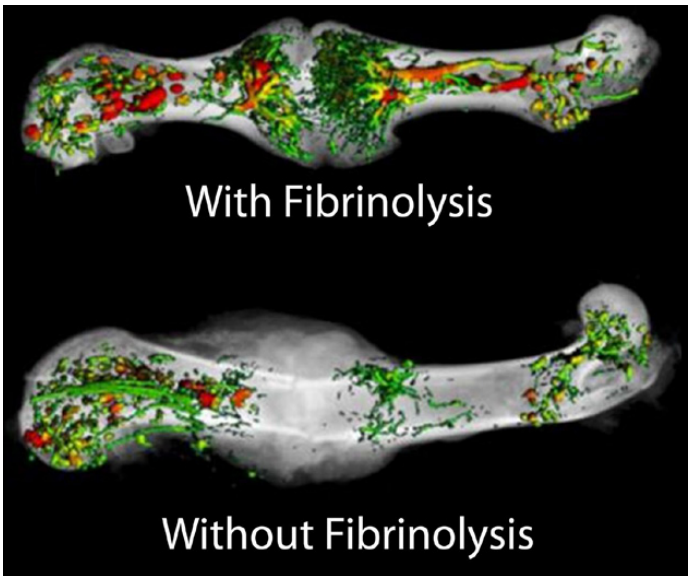
It was previously thought that fibrin promoted repair by providing a scaffold for the initial phase of new bone formation. But the Vanderbilt team found that fracture repair was normal in mice missing the fibrin precursor fibrinogen.

"Fibrin puts a cog in the machine and you don't get the anastomosis (vessel reconnection)," Schoenecker said.

The findings may explain why obesity, diabetes, smoking and advanced age impair fracture repair. They are all associated with impaired fibrin clearance, he explained. The investigators also found that mice unable to clear fibrin formed bone in muscle (heterotopic ossification).

Dr. Schoenecker told *OTW*, "Now that we have identified that the removal of fibrin is essential to heal fractures any pharmacologic with the capacity [to] reduce the amount of fibrin deposited in a fracture or promote its removal may function to enhance fracture healing. The big trick to developing these pharmaceuticals for orthopaedics is to optimize their ability to improve fracture healing without compromising fibrin's principle role—to stop a patient from bleeding. Currently, we are in preclinical animal trials with promising results."

"In order to figure out how fibrin blocks fracture healing, we had to first figure out exactly how a fractured bone re-establishes its blood supply. To do so we started from the published models on this topic and took a big leap forward by developing a new technique allow for visualization of new bone and blood vessels at the same time. From this data



Jonathan Schoenecker/Vanderbilt University Medical Center

we proposed an entirely new model of the process of fracture revascularization. Most importantly, we learned that fractures heal by first shunting blood flow from the inside of the bone to outside the bone. Then blood vessels grow outside the bone and connect to each other from opposite ends. This new model emphasizes the importance of the anatomic location of these newly developing vessels providing insight into how a device, such as an intramedullary nail on the inside of the bone or a plate on the outside of the bone, would impede or help this vascular process. From this information we are working on devices that stabilize the fracture, but do not get in the way of this essential process. Together, our findings strongly suggest the optimal treatment for fracture healing is a device that does not disrupt revascularization of a fracture and pharmacologics that limit or promote fibrin in the fracture bed." — *EH*

LARGE JOINTS

Dakota Doc Says Walking Prevents Hip Fractures

Richard P. Holm, M.D., reminded readers of the *Rapid City Journal* that prior to the development of a surgical repair for hip fracture, treatment involved six weeks of traction and bed rest. The death rate was 80% from blood clots or pneumonia. Doctors pinned bones together with ivory pins until a German doctor, during World War II, began using metal rods to stabilize bone fragments.

Wikimedia Commons and Gary Knight

Once hip pinning became popular, patients found that they could stand up and start walking within days of surgery, dramatically reducing the death rate following hip fracture. Holm wrote that presently, in about a third of the cases, the surgical repair of a fractured hip involves a new artificial ball and socket to replace the fractured hip. Pinning still works in most cases, he wrote, and is quicker, easier, cheaper, and sometimes safer than the more invasive total hip replacement surgery.

The risk of death from a hip fracture is now about 10% at one month, according to Holm, and rises to 40% at one year. In 2011 hip fractures resulted in about 30% of all U.S. hospitalizations, costing about $5 billion dollars and an untold amount of suffering.

Holm says that 90% of hip fractures happen as a result of falling. And

people fall because of inactivity and poor physical conditioning. He tells his clients that "inactivity is the most important risk factor for hip fracture. Although advanced age, poor eyesight, blood pressure medicines, soft bones, neurological and cardiac conditions are also risk factors, the big danger comes from a lifetime of inactivity." He tells his patients, "unless you want to end up on a cold linoleum floor someday (as did one of his patients) get out and get walking." — *BY*

Scale Predicts Joint Surgery Complication Risk

Which patients are at risk for complications following hip or knee replacement surgery? Two studies at the University of Pennsylvania Perelman School of Medicine have identified ways to identify candidates who are at risk for complications following replacement surgery.

"There is a need to better identify and predict post-operative complications so we can intervene and provide timely follow-up care," said Gwo-Chin Lee, M.D., assistant professor of Orthopaedic Surgery and senior investigator for both of the studies. "Total hip and knee replacements are very common, but they also can pose significant health risks to certain patients, especially older adults."

In one study, Lee's team examined the results of 1,012 patients who underwent total hip or knee replacements over a 10-month period. Seventy patients developed serious complications. Most were cardiopulmonary problems.

Of those 70 patients, 11 suffered setbacks within 24 hours and 59 developed problems more than 24 hours later. If the 59 patients had undergone same-day or short-stay surgery, they would have developed the complications at home and been placed at even greater risk.

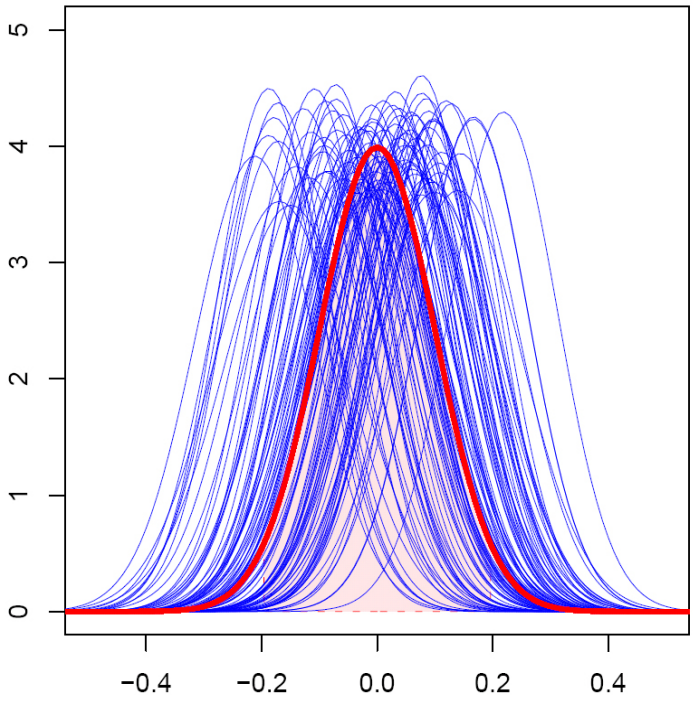
As a result of the findings, the researchers developed a scale that will allow orthopedic surgeons to determine if a patient is a candidate for same-day or short-stay procedures, or if that person should be admitted for traditional-duration surgery and recovery.

Patients who have at least one risk factor, such as chronic obstructive pulmonary disease (COPD), congestive heart failure, coronary artery disease, or cirrhosis, should not be considered for either outpatient or overnight-stay total knee or hip replacement.

In a second study, Lee and Maxwell Courtney, M.D., studied the records of 738 patients who had undergone the same types of hip or knee replacement surgery. They found that those who had to be admitted to intensive care or critical care after the procedures had a history of COPD, congestive heart failure, coronary artery disease, chronic kidney disease, needed medications to raise their blood pressure during the procedure, or they lost more than 1,000 milliliters of blood during surgery.

Based on their findings Lee and Courtney developed the Penn Arthroplasty Risk Score (PARS) to predict which patients would require intensive or critical care after either surgery. "Under the previous model, one in four patients were preemptively admitted to the ICU," said Lee. "However, we found that only 22% of the patients ultimately required such stepped-up intervention. By incorporating certain factors into the model, such as significant blood loss and the need to raise the patient's blood pressure, we have refined the selection criteria for post-surgery admission to the ICU."

Officials at the hospital believe that use of the PARS tool will result in fewer patients being routinely admitted to intensive care and critical care units after joint replacement surgery, which will result in lower costs without compromising patient safety. It will also ensure that scarce critical care beds are available for those who need them most. — *BY*



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EXTREMITIES

FDA Clears Tyber Medical's Wedge System

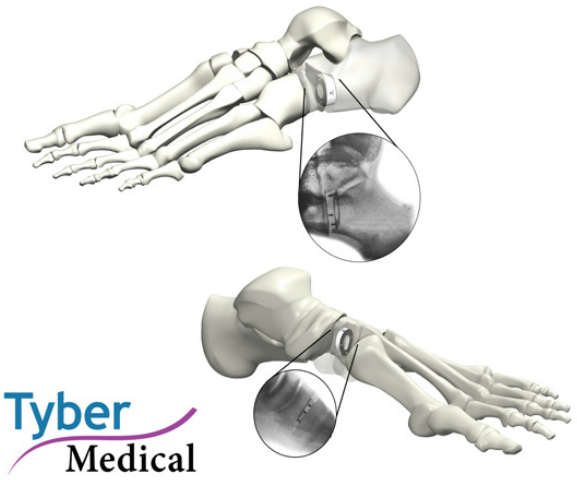
Tyber Medical, LLC, a private labeler Original Equipment Manufacturer (OEM), of Morristown, New Jersey, received 510(k) clearance from the FDA for its TyWedge Opening Osteotomy Wedge System. The item is a titanium plasma sprayed PEEK wedge implant specifically indicated for fusion.

According t the company's press release, the TyWedge system features the radiolucent properties of PEEK with a titanium plasma spray coating, as well as an optimized tooth profile for initial stability. This is reported to allow for angular corrections in the foot.

The TyWedge System is optimized for bone graft (autograft or allograft) containment, has radiographic markers for intraoperative visualization and instrumentation for precise implant placement. The TyWedge comes in two configurations with a total of 15 footprints, the Evans TyWedge with nine foot prints and the Cotton TyWedge with six foot prints.

"The TyWedge system marries the radiolucency of PEEK-Optima with the osseointegration properties of titanium allowing for direct visualization of the healing process," said Selene G. Parekh, M.D., Associate Professor, Department of Orthopedic Surgery, Duke University.

Chris Faresich, TyWedge Team Leader, said, "This FDA clearance is an important milestone for Tyber Medical where a superior wedge design allows for fusion with the use of allograft or autograft for an optimal flat foot opening osteotomy correction." — *BY*



Courtesy of Tyber Medical

SPORTS MEDICINE

Florida Hospital Initiates Sports Medicine Program With Local Schools

Florida Hospital is truly looking out for the local community. The institution is launching a sports medicine program with local schools that will involve a wide spectrum of services for children and adults. Patients will benefit from injury prevention and sports performance programs, as well as post injury services like outpatient rehab, noninvasive treatments and surgery.

"This is just one example of Florida Hospital's commitment to improve the health and wellness of the Tampa Bay community. We are proud to partner with local schools as well as the Pasco County School District for athletic training to serve and help keep youth athletes safe," said Mike Schultz, Florida Hospital West Florida Region President and CEO, in the August 17, 2015 news release.

As indicated in the news release, "Florida Hospital recently partnered with the Pasco County School District to provide full time athletic trainers in all 13 high schools across the country at no cost to the schools. The trainers are on the school campus every day and attend practices as well as home athletic games for a variety of sports."

"We are very excited to partner with a recognized health leader like Florida Hospital," says Amy Lipovetsky, Athletic Director for the Pasco County School District. "They are really raising the level of care for our student athletes."

Jonathan W. Phillips, M.D. , Florida Hospital Wesley Chapel

"Ideally, we want to help these young athletes prevent injuries. But if they do get hurt, our trainers are there to help them connect with the appropriate medical care," said Barbara J. Morris, DHSc, ATC, CSCS, ROT. Dr. Morris is Director of the Sports Medicine & Performance program, a program whereby medical professionals can help identify and correct dysfunctional movement that impede maximum sports performance and increases the risk of acute and overuse injuries.

Dr. Morris told *OTW*, "In an effort to provide cutting edge technology to our community we chose Head Rehab whose foundation is based on solid neuroscience combined with virtual reality technology which evaluates multiple areas of brain function; spatial memory, balance, reaction time. This science/technology is a good fit with our Sports Medicine and Performance program where we provide sports medicine services to 15 area high schools who provide a variety of sporting options to the student body."

"The equipment is easy to use, testing time is minimum and due to the technology student athletes are motivated to participate. The balance component, which addresses vestibular issues, is essential in determining return to play status."

"Our mark of success will be retrospectively looking at the diagnosed concussions for the academic year and assessing the successful return not only to play but to learning." —*EH*

UPMC LEMIEUX Sports Complex Creating Sports Magic in Pittsburgh

Were *you* one of the 7,000 people touring the new first-of-a-kind sports facility in Pittsburgh this weekend? The remarkable UPMC LEMIEUX Sports Complex—meant for training and treatment—has just opened its doors to welcome athletes of all ages and skill levels. The new facility, which boasts 50 sports medicine experts on site, uses science-based medicine to not only help prevent injury, but predict it.

The 185,000 square foot complex is a sophisticated mix of a practice facility for the Pittsburgh Penguins, and an outpatient treatment center for the University of Pittsburgh Medical Center (UPMC). With 24 dedicated orthopedic exam rooms, as well as MRI and X-ray equipment, the UPMC LEMIEUX Sports Complex is redefining what is possible under one roof.

There are two full size hockey rinks and a sports performance space where athletes can focus on developing their talents and optimizing performance. In addition, athletes can undergo physical and aquatic therapy onsite. High level sports medicine research is being performed the UPMC LEMIEUX Sports Complex, with physician-researchers asking the most pertinent questions related to injury and repair. There is truly something for everyone, with ice skating available to the public, and a Pittsburgh Penguins' elite program for young athletes.

Watch the UPMC video here: http://insideupmc.upmc.com

Vonda Wright, M.D., an orthopedic surgeon with the University of Pittsburgh, is medical director of the UPMC LEMIEUX Sports Complex. Dr. Wright commented to *OTW*, "The UPMC Lemieux Sports Complex is the first of its kind partnership between elite sports medicine and elite hockey. We are working to build better athletes of all ages and skill levels and optimize human performance for the playing field and the game of life by unifying our tradition of delivering the best in sports medicine with elite hockey with world class sports performance and innovative research."

Freddie H. Fu, M.D. is chairman of the Department of Orthopaedic Surgery at the University of Pittsburgh. He told *OTW*, "UPMC never stops trying to take the best care of the patients with the best doctors." — *EH*

SPINE

New Stem Cell Therapy for Spinal Cord Injuries

Researchers at Rush University Medical Center are delving into a new therapy using stem cells to treat spinal cord injuries that occur within the first 14 to 30 days of injury. There is only one of center in the U.S. that is studying this new treatment. According to the August 13, 2015 news release, "The therapy uses a population of cells derived from human embryonic stem cells containing progenitor cells that support nerve cells and can potentially make poorly functioning nerves function better."

"There are currently no therapies which successfully reverse the damage seen in the more than 12,000 individuals who suffer a spinal cord injury each year in the United States alone," says Richard G. Fessler, M.D., professor of neurological surgery at Rush University Medical Center, in the August 13, 2015 news release. Dr. Fessler is principal investigator for the Phase 1 clinical trial involving AST-OPC1 (oligodendrocyte progenitor cells).

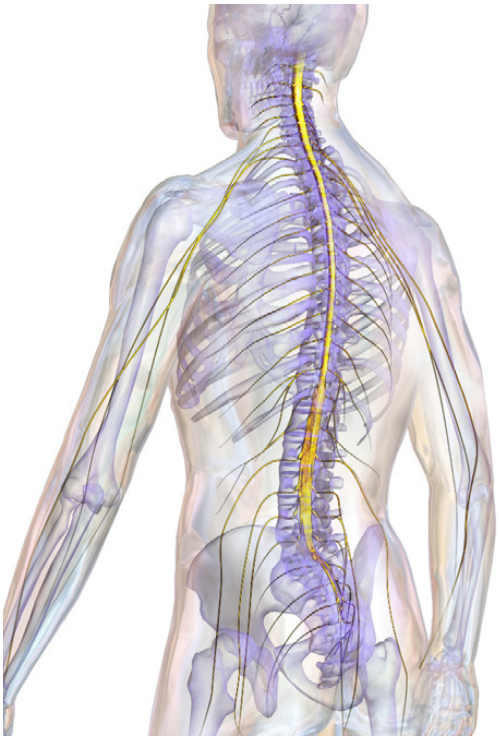
Enrollment is underway, and patients can expect a clinical trial that involves escalating doses of the special cells (AST-OPC1) for individuals with a complete cervical spinal cord injury. "These individuals have essentially lost all sensation and movement below their injury site with severe paralysis of the upper and lower limbs."

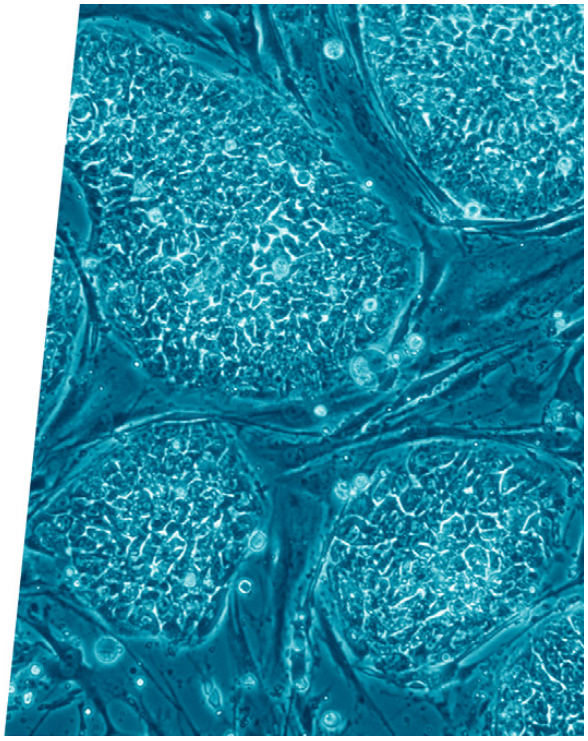
"In the future, this treatment may be used for peripheral nerve injury or other conditions which affect the spinal cord, such as MS [multiple sclerosis] or ALS [amyotrophic lateral sclerosis or Lou Gehrig disease]," said Dr. Fessler.

"For this therapy to work, the cord has to be in continuity and not severed. The study seeks male and female patients ages 18 to 65 who recently experienced a complete cervical spinal cord injury at the neck that resulted in tetraplegia, the partial or total paralysis of arms, legs and torso. Patients must be able to start screening within 25 days of their injury, and participate in an elective surgical procedure to inject AST-OPC1 14 to 30 days following injury. Participants also must be able to provide consent and commit to a long-term follow-up study."

Asked about the importance of the 14-30 day timeframe, Dr. Fessler told *OTW,* "Abundant data from animal research has suggested that transplantation close to the time of injury yields superior results to delayed transplantation. The 14 to 30 day window enables the patient to be stabilized from his injury, and provides enough time for evaluation of tests for inclusion/exclusion in the study."

"Two major events will occur over the next 6-12 months. First, each of the patients receiving a transplant will be followed closely to assess the results. Second, this study utilizes three cohorts of patients who will receive escalating doses of the stem cells. Over the next 6-12 months, therefore, as we move from one cohort to the next, the doses injected will be increased." — *EH*





Spinal cord and embryonic stem cells/Wikimedia Commons, Bruce Blaus and Nissim Benvenisty

Theragen LLC Acquires Electrical Stimulation Company

Theragen LLC, a privately owned medical device company located in Leesburg, Virginia, has acquired Neurotech North America, a manufacturer of non-invasive stimulation products used in orthopedics and for spine applications. The purchase includes commercial rights to Neurotech assets throughout the world including in Japan, Korea, Germany, Switzerland and Austria.

Prior to its sale to Theragen, Neurotech NA was a wholly owned subsidiary of BioMedical Research, Inc. and operated within the electrical stimulation sector. Its primary products include Kneehab XP, cleared for quadriceps strengthening; and Neurotech Recovery Back, a transcutaneous electrical nerve stimulation and neuromuscular electrical nerve stimulation technology cleared for the lower back.

"Neurotech's products are proven and possess an exceptional safety record," said Gary Grenter, president and CEO of Theragen. "After focusing the past 18 months on our R&D efforts, we are excited about entering the non-invasive therapeutics industry with these excellent products." Grenter declined to disclose the purchase price.

Theragen Chairman of the Board Kimball Chen said, "Theragen's mission is to develop non-invasive therapeutic solutions using electrical, mechanical and other forms of energy that will provide relief for sufferers both prior to and post surgical intervention. This acquisition demonstrates our commitment to this mission as we incorporate Neurotech's world-class technology, research and development into our portfolio."

Chen went on to comment, "I am pleased to be working again with Gary Grenter and J. Chris McAuliffe. This leadership team saw great success together at Biolectron and today's acquisition marks the first of many significant achievements to come for Theragen LLC." — *BY*

Courtesy of Theragen LLC and Neurotech NA

PEOPLE

Sam Akhavan, M.D. to Accompany U.S. Rugby Team to World Cup (England)

When the U.S. Rugby Team is making its way across the United Kingdom, Sam Akhavan, M.D. will be there. An orthopedic surgeon and sports medicine specialist with Allegheny Health Network and a team physician for USA Rugby, Dr. Akhavan has been officially selected to accompany the national team to the 2015 Rugby World Cup in England.

"It's an honor to be chosen by the team to care for these elite athletes as they face the toughest competition of their careers," Dr. Akhavan said in the August 18, 2015 news release. "Internationally, the Rugby World Cup is the third most watched sporting event after the FIFA World Cup and Olympics. It's exciting to be part of an event that connects so many people across the globe."

Sam Akhavan, M.D.

As indicated in the news release, "The Rugby World Cup will take place in eleven cities across England and Cardiff from September 18 through October 31. The United States will play its first bout versus Samoa on Sunday, September 20. Dr. Akhavan will accompany the team to several important matches leading up to its World Cup campaign and then will travel to England for a number of the final matches of the World Cup."

The fact that rugby players don't wear protective gear leaves them open to a wide range of injuries. As team physician, Dr. Akhavan will treat overuse injuries, traumatic injuries, sprained ligaments and strained tendons, and knee and shoulder injuries.

Dr. Akhavan directs both the Orthopaedic Sports Medicine Fellowship and Orthopaedic Research program at Allegheny General Hospital where he also serves as Associate Program Director for the Orthopaedic Residency and is an active member of the teaching staff.

Dr. Akhavan told *OTW*, "The most concerning injury that we deal with in rugby outside of the typical ligament tears (ACL, etc.) and shoulder dislocations/separations is head injuries. Concussions are something that World Rugby and USA Rugby have really been on the forefront in addressing. We have incorporated temporary substitution rules to allow time to evaluate players (the head injury assessment) as well use instant replay and spotters to ensure we minimize head injuries in the athlete."

"Rugby is one of the fastest growing sports in the United States. The rugby community is extremely tight knit and a dedicated athletic population. The pace and intensity of the game is very similar to American football but is essentially non-stop during both halves. Rugby medical coverage provides one of the most exciting and fast paced game coverage experiences and I would recommend it for anyone who loves covering sports." — *EH*

Craig Boyd and Wikimedia Commons

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