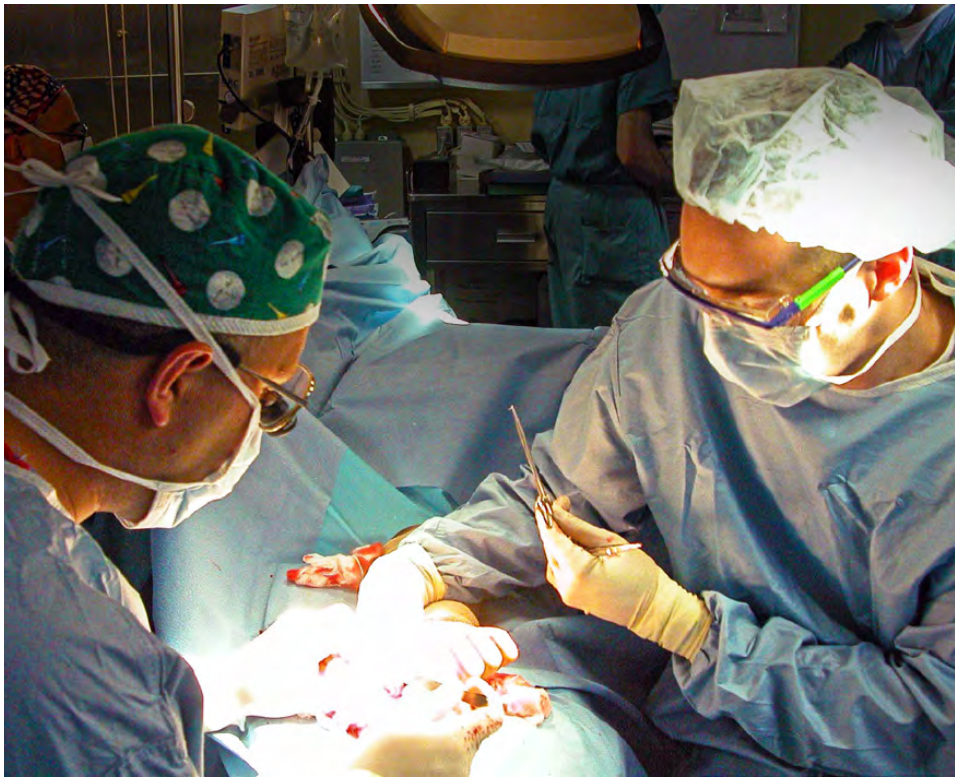
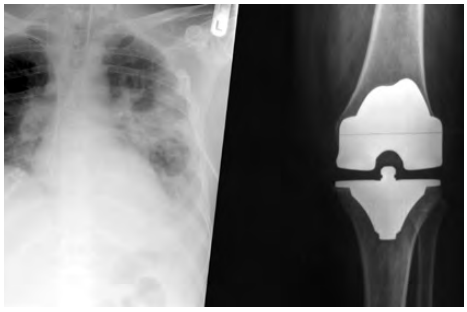
VOLUME 13, ISSUE 7 | MARCH 7, 2017

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: Crazy talk from the White House, North Korea missile launches and rising international concerns are fueling higher levels of volatility. Investable dollars is clearly flowing into safe havens. JNJ, MDT, SYK and cash machine GMED are all rising, while any company that is perceived to be a work in progress (CNMD, IART), is drifting to the sidelines. The perception of risk is rising and the price tag for risk—interest rates—is also following suit.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Medtronic	20.54%	7.71%	MDT's 3rd quarter report showed that sales and market share fundamentals are stronger than Wall Street expected.
2	3	Zimmer Biomet	23.86	(0.19)	ZBH announces a $0.24 per share cash dividend. AAOS is just a week away. Expecting to hear about several new products.
3	7	Globus Medical	29.72	6.80	Globus's yearend report showed that EBITDA % and Gross Margin % higher than such peers as ZBH, SYK and NUVA.
4	4	Integra LifeSciences	15.21	1.52	IART's story is going to be constant over the coming 12 months. Integration of its billion dollar acquisitions. How's it going?
5	2	Orthofix	9.02	0.11	Strong close to 2016 with overall sales up 4% but Extremity up 14% and Biostim up 6%. Should have an excellent AAOS.
6	6	Johnson & Johnson	27.98	10.05	Buyers have pushed JNJ's valuation to unusually high levels for steady JNJ. This looks like a flight to safety.
7	5	Stryker	22.69	5.75	Stryker is making MAKO one of the highlights of its AAOS program this year. Robotic assist for orthopedic surgery remains a lively debate topic.
8	9	Smith & Nephew	18.40	(0.10)	How is SNN's robotics business (Blue Belt) doing? Looking forward to finding out at AAOS.
9	10	Exactech	9.20	1.24	Exactech's extremity business is now more than $100 million/year. And rising at 15-18% annual rates. Undervalued!
10	8	Conmed	9.90	(6.17)	Conmed really couldn't afford to miss its Q4 estimates. One of the key valuation measures for CNMD is Price to Sales. Which is at a low 1.5x.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$4.58	$41	54.73%
2	Xtant Medical Hldgs	XTNT	$0.51	$9	35.07%
3	Pacira	PCRX	$50.45	$1,893	25.03%
4	RTI Biologics Inc	RTIX	$3.75	$219	17.19%
5	Wright Med Grp N.V	WMGI	$28.73	$2,977	13.96%
6	Johnson & Johnson	JNJ	$123.79	$335,885	10.05%
7	Nevro Corp	NVRO	$94.75	$2,765	8.17%
8	Medtronic	MDT	$81.86	$112,057	7.71%
9	NuVasive	NUVA	$75.66	$3,828	6.92%
10	Globus Medical	GMED	$28.10	$2,692	6.80%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	CryoLife	CRY	$16.25	$536	-14.92%
2	Lattice Biologics	LBL.V	$0.17	$12	-8.33%
3	ConMed	CNMD	$41.54	$1,156	-6.17%
4	SeaSpine Hldgs Corp	SPNE	$6.82	$79	-5.28%
5	MicroPort Scientific	853	$0.72	$1,039	-3.00%
6	Aurora Spine	ASG	$0.13	$4	-2.34%
7	Amedica Corp	AMDA	$0.39	$14	-1.52%
8	TiGenix	TIG.BR	$0.75	$186	-0.80%
9	Zimmer Biomet	ZBH	$118.28	$23,786	-0.19%
10	Smith & Nephew	SNN	$30.58	$13,378	-0.10%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Smith & Nephew	SNN	$30.58	$13,378	17.06
2	Globus Medical	GMED	$28.10	$2,692	19.37
3	Johnson & Johnson	JNJ	$123.79	$335,885	19.98
4	Medtronic	MDT	$81.86	$112,057	23.56
5	Exactech	EXAC	$24.50	$348	23.61

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$75.66	$3,828	95.36
2	MiMedx Group	MDXG	$8.35	$909	72.74
3	Orthofix	OFIX	$36.19	$649	51.55
4	CryoLife	CRY	$16.25	$536	42.02
5	Integra LifeSciences	IART	$42.73	$3,197	33.65

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$16.25	$536	1.40
2	Globus Medical	GMED	$28.10	$2,692	1.71
3	Exactech	EXAC	$24.50	$348	2.32
4	Stryker	SYK	$130.20	$48,549	2.48
5	Zimmer Biomet	ZBH	$118.28	$23,786	2.86

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$36.19	$649	8.06
2	NuVasive	NUVA	$75.66	$3,828	6.35
3	ConMed	CNMD	$41.54	$1,156	5.02
4	MiMedx Group	MDXG	$8.35	$909	4.85
5	Johnson & Johnson	JNJ	$123.79	$335,885	3.38

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Xtant Medical Hldgs	XTNT	$0.51	$9	0.15
2	Alphatec Holdings	ATEC	$4.58	$41	0.22
3	Aurora Spine	ASG	$0.13	$4	0.60
4	SeaSpine Hldgs Corp	SPNE	$6.82	$79	0.61
5	Amedica Corp	AMDA	$0.39	$14	0.73

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.75	$186	83.13
2	Nevro Corp	NVRO	$94.75	$2,765	12.10
3	Pacira	PCRX	$50.45	$1,893	6.85
4	Globus Medical	GMED	$28.10	$2,692	4.77
5	Johnson & Johnson	JNJ	$123.79	$335,885	4.67

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

12 Leading North American Hand Surgeons

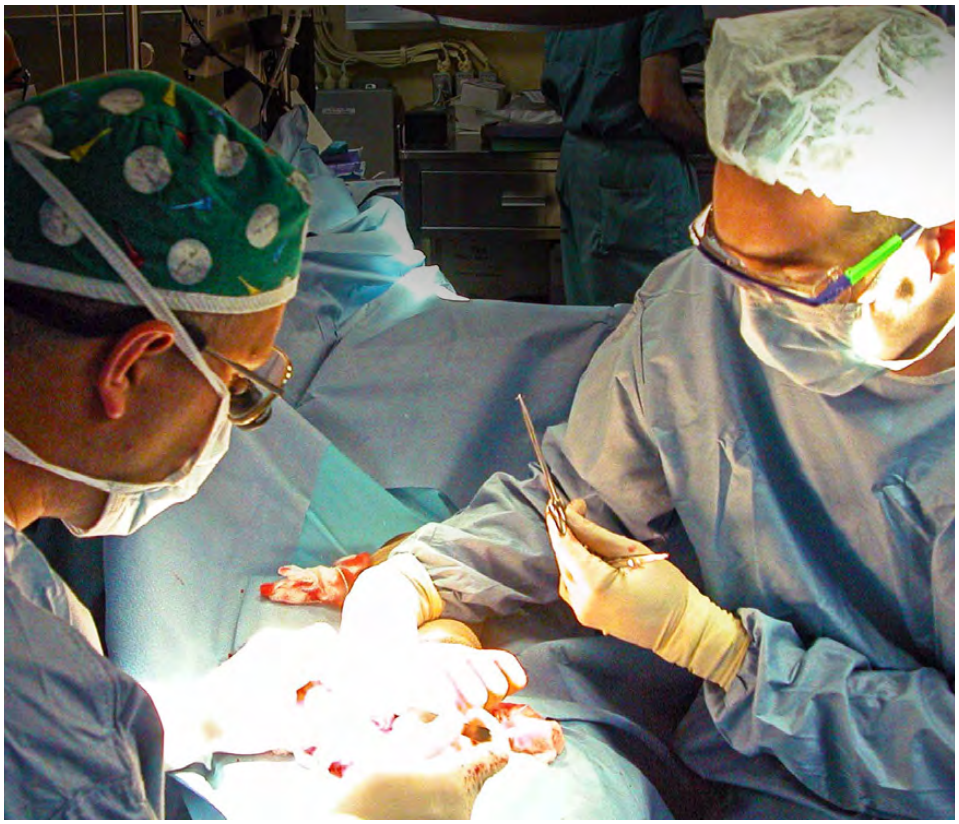
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

According to their colleagues, these are the leading orthopedic hand surgeons in North America. Whether handling the wrist, elbow, or hand, these surgeons have impressed their professional colleagues with their dedication and expertise.

This list is not be-all and end-all list—and many equally dedicated and remarkable physicians practice in every corner of North America. It is **a** list of the physicians who were mentioned by the thought leaders in this field. *No one at OTW offers candidates to this list nor can influence who is recommended to this list.*

The information in quotes below come from the colleagues of the physicians on this list and illustrate why they made this list.

In alphabetical order, then, here are 12 of the finest orthopedic hand surgeons in North America.



Wikimedia Commons and U.S. Navy

Julie E. Adams, M.D. is an orthopedic surgeon at Mayo Clinic in Rochester, Minnesota. She is a former president of the Minnesota Orthopedic Society. "She has a finely-tuned sense of how to do a thorough assessment of the patient's condition. Her talents extend to many problems of the hand and wrist. She has participated in the establishment of American Academy of Orthopaedic [AAOS] Surgeons guidelines regarding carpal tunnel syndrome."

Mark S. Cohen, M.D. is a professor, and director of the Section of Hand and Elbow Surgery at Rush University Medical Center in Chicago; he is also the director of Orthopaedic Education. "He is a leader in problems about the wrist who has influenced colleagues throughout the world with his understanding about the complex kinematics of the wrist, surgical options for treatment of various conditions, and his contributions are considered standard of care for numerous conditions about the wrist as well as elbow."

Jeffrey A. Greenberg, M.D. is an orthopedic surgeon at the Indiana Hand to Shoulder Center in Indianapolis. "He is a leader in the field of upper extremity. Known regional, national, and international for his excellence in teaching, patient care, and research. Jeff is also an international ambassador with trips to Guatemala to care for those without access to hand surgery."

James P. Higgins, M.D. is chief of The Curtis National Hand Center at MedStar Union Memorial Hospital. "He is a leader in the field of upper extremity, primarily microvascular surgery. He directs a large group of hand surgeons at Union Memorial Hospital. He is known regionally, nationally, and internationally for his excellence in teaching, patient care, and research in free osteochondral grafts."

Neil F. Jones, M.D. is an orthopedic surgeon at the University of Califor-

nia, Irvine. He is a past president of the American Society of Surgery of the Hand. "Dr. Jones is a recognized international expert in complex reconstructive problems of the pediatric hand. He is an outstanding technical surgeon and has a wide experience in the use of microsurgical techniques in successfully restoring function to the most deformed traumatic or congenital anomalous pediatric hand deformity. Dr. Jones has brought a lasting improvement not only to patients' hands but their lives as well as their loved ones."

Jesse B. Jupiter, M.D. is a hand and upper extremity orthopedic surgeon at Massachusetts General Hospital, and the Hansjorg Wyss AO Professor of Orthopedic Surgery at Harvard Medical School. He is a former president of the American Association for Hand Surgery and the American Shoulder and Elbow Surgeons. "Dr. Jupiter is a well-established leader in upper extremity orthopedics. Given his dedication to teaching, not only at Harvard and Mass General, he has been a global ambassador for the specialty and for the AAOS. He is one of the most worldwide recognized names in orthopedics. His contributions span all levels of the upper extremity from developing novel treatment techniques, inventing fixation devices, to the microsurgical reconstruction of severe elbow and humeral soft tissue and bony defects."

Graham King, M.D. is a professor in the Department of Surgery at Western University and the chief of surgery at St. Joseph's Health Centre in Ontario, Canada. He is a former president of the Canadian Orthopaedic Research Society. "Dr. King is probably the world's expert on disorders of the elbow. He has completed premier research on the elbow (and the wrist) in his unique motion analysis laboratory for many years. He is a prolific author, and he lectures around the world. He has made countless contributions to the upper extremity literature, most with profound clinical implications."

Scott H. Kozin, M.D. is the chief of staff for Shriners Hospitals for Children and a clinical professor for the department of orthopedic surgery at Temple University School of Medicine. He is a past president of the American Society for Surgery of the Hand and past president of the American Association of Hand Surgery. "Dr. Kozin is one of the premier upper extremity experts for children and adolescents in the World. He has written and lectured extensively in areas ranging from congenital deformity to brachial plexus nerve reconstruction. He recently helped organize and perform the first bilateral arm transplant in a child."

Don Lalonde, M.D. is a professor in the Division of Plastic and Reconstructive Surgery at Dalhousie University in Halifax, Nova Scotia. "He has revolutionized hand surgery by popularizing the game changer of 'wide awake hand surgery.' He has counteracted the myth that epinephrine should be avoided in hand surgery and has espoused use of local anesthesia with epinephrine to improve patient outcomes, decrease surgical risk and cost and improve surgical access to hand procedures. Not only is he a skilled hand surgeon, but also he is a humble and generous man who shares his expertise freely with others."

John D. Lubahn, M.D. is an orthopedic surgeon at the University of Pittsburgh Medical Center, as well as with Hand, Microsurgery and Reconstructive Orthopaedics, in Erie, Pennsylvania. He is a former president of the Eastern Orthopaedic Association, the American Foundation for Surgery of the Hand, and the Academic Orthopaedic Society. "Dr. Lubahn is the consummate hand surgeon. He is the orthopedic and hand chairman at Hamot Hospital System in Erie. Known internationally for his developmental role in endoscopic cubital tunnel release, his contributions have ranged from wrist arthritis to Dupuytren's contracture. He has advanced pediatric hand care as a leader in the Shriner hospital system. He was named one of the top hand surgeons by *US News and World Report*."

A. Lee Osterman, M.D. is an orthopedic surgeon at The Philadelphia Hand Center, and a full professor of Hand and Orthopaedic Surgery at Thomas Jefferson University. He is a past president of the American Association for Hand Surgery (AAHS) and a past president of the Eastern Orthopedic Association. "He is internationally known for his great contributions in education and surgery. Dr. Osterman has trained a generation of hand surgeons and is known for his excellence in patient care and tireless efforts on behalf of his patients and his trainees. He has developed innovations in wrist arthroscopy and in management of the troublesome Essex Lopresti lesion."

David S. Zelouf, M.D. is an orthopedic surgeon at The Philadelphia Hand Center, and an assistant professor in orthopedic surgery at Thomas Jefferson University. "He is a leader in the field of hand surgery. He is widely recognized as a talented teacher and for his excellence in patient care. Dave is an exceptional surgeon able to impart his knowledge and expertise to fellows in training." ♦

ChoiceSpine's Gutsy Purchase of Exactech Spine

BY ROBIN YOUNG

On January 31, 2017 ChoiceSpine, LP and Exactech, Inc. issued a joint announcement that $20 million Exactech spine (annual sales) had been sold to Knoxville, Tennessee-based ChoiceSpine. The main reaction throughout the spine industry was… ChoiceSpine? Who's ChoiceSpine?

ChoiceSpine is the Knoxville, Tennessee, spine company founded by Marty Altshuler and Rick Henson. And if anyone was surprised, then they probably hadn't been paying attention.

About six years ago Rick and Marty bought the once $40 million Orthotec spine portfolio and made the leap from Knoxville-based spinal implant distributor to full-fledged developer, manufacturer and distributor of spinal implants with an expanding patent estate and business all over the U.S. and seven other countries.

Indeed, this announcement by ChoiceSpine and Exactech can be traced to a 2005 phone call.

Lost a Line, Found a Mission

"In 2005 we got a phone call and a fax saying we didn't have distribution rights any longer for one of our major product lines here in Knoxville, Tennessee," recalls ChoiceSpine co-founder Rick Henson. "We had to make a strategic decision. Either we had to pick up another line and be a distributor for another line or do something different."

And doing something different was what Rick and Marty did. They bought Orthotec. "What we did is that we decided that we were going to buy Orthotec's intellectual property rights and distribution rights for the United States and seven other countries. Thus Choice Spine. That is what started in 2006."

Courtesy of ChoiceSpine

As Marty remembers the transition: "We went quickly from being a distributor to being a designer, manufacturer and marketer of spinal implants across the U.S. That was a pretty daunting task but we had a great partnership working together as owners and were blessed in the Team we assembled in a short time to accomplish our strategic goal and mission."

But the biggest issue for Rick and Marty was the perception that they were a small, regional distributor. Not a national, to say nothing of international, supplier.

"When we got started we were looked at as a regional company based in the South. As we started to grow into the Northeast, Midwest and West Coast we had to get across that barrier that we were just a regional company," recalls Marty.

Necessity, being the mother of invention, also pushed the young company into product development. "In 2010 we started a rapid development process and this year we will have 90% of what a surgeon typically uses on an everyday basis." Says Rick, "This year, 2016, we'll have the best development year in ChoiceSpine's history. This year alone we're coming out with a posterior cervical system, an MIS system and also a zero profile system."

Exactech's Spine and Biologics Business

Exactech had one of its best years ever in 2016. Sales rose an estimated 4.50% (the final numbers were released February 21) from $242 million last year to an estimated $253 million in 2016. For 2017 Wall Street's analysts are forecasting that Exactech's growth rate will rise to about 6.0%.

Best of all, Exactech's market value soared 38% over the last 12 months to today's $354 million.

But spine and biologics were not contributors to that sales growth. Extremity, hip and knee implant and instrumentation sales really carried Exactech's growth in 2016. Extremity product sales now comprise 37% of Exactech's total annual sales and grew a very strong 16% in 2016. Hip and knee implant sales were also up slightly in 2016.

But spine and biologics, which were down about 9% at the nine month mark, will almost certainly be down for the full year as well.

The following table shows how Exactech's spine and biologics business has struggled since the acquisitions of Altiva and Vertiflex's assets in 2008 and 2009.

While Exactech's spine business was struggling from 2008-2016, ChoiceSpine's was growing. As Rick Henson explained: "We have now grown out of two facilities and are looking at even larger office locations. At the end of 2009, 2010 we had about 75% of our bag complete. We had a brand new cervical plate. We had a brand new pedicle screw system. We had cervical interbodies. We had lumbar interbodies. Pretty much 75% of what a typical spine surgeon is using on a daily basis."

The Purchase

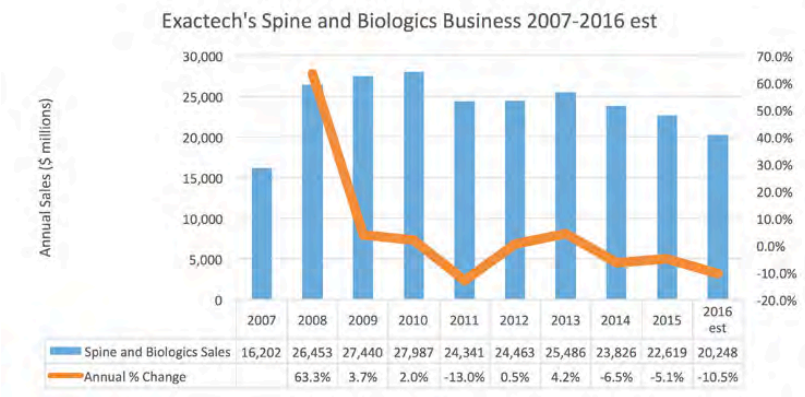
The orthopedic industry, generally, is in the middle of an M&A boom. We count 23 deals in the last 24 months (see table at the end of this article). And we probably missed a couple or more.

For Exactech, this was the right deal at the right time.

Said Exactech CEO David Petty, "For nearly a decade, Exactech has driven innovations in spinal surgery and we are pleased to have made meaningful contributions to patient care. We are confident the transfer of these products to ChoiceSpine will provide a continued focus on improving patient care for that population. This divestiture will allow us to sharpen our focus on investments in the core extremities and large joint segments of our business."

For ChoiceSpine, this purchase expands their sales bag considerably. The metal/polymer implants purchased from Exactech include:

- Proliant® Pedicle Screw System. This is a dual lead thread screw



Source: SEC filings and RRY Publications LLC

system which allows for faster insertion and incorporates the patented Tightlok® thread pattern which reduces screw pull out and facilitates fusion. EZ Set tulip head which allows surgeons to more easily position and set the tulip head in any position for rod insertion.

- Gibralt® Posterior cervical thoracic spine system that features top-loading polyaxial screws with an EZ Set tulip head and Tightlok thread technology. The system includes hooks, offset connectors and rod-to-rod connectors which can be constructed into a multitude of configurations based on individual patient anatomy.

- Gibralt® Occipital Plate, a comprehensive solution for posterior stabilization and fusion of the cervical and thoracic spine. Gibralt works in conjunction with Proliant and HydraLok pedicle screw systems for a full spine solution.

- Octane® Straight PEEK Interbody Spacer System that provides two different implant options to accommodate a traditional straight spacer insertion or a less invasive insert-and-rotate technique. Octane is made from PEEK-Optima® polymer with radiographic markers and comes in multiple footprints: Bilateral posterior approach using 24mm spacers, or unilateral posterior approach using 28mm and 32mm spacers. The addition of plasma sprayed titanium coating options in cervical and lumbar is an extra option to just PEEK-only users.

- Octane® M, a new design of interbody fusion implant which allows atraumatic entry to its final position between two vertebral bodies.

- Acapella® Cervical Spacer system with integrated anchors that features single-step implantation with an integrated locking mechanism that complements ChoiceSpine's current Tomcat standalone cervical that is a screw-based system.

- Ambassador™ Anterior Cervical Plate System with narrow plate profile and cam-design locking mechanism and multiple size options.

ChoiceSpine's Martin Altshuler said about the Exactech product line: "The additional technologies that Exactech has access to, combined with our expanding portfolio, allows us to further solidify our company as a premier, full-line spinal fusion provider in the U.S., with further growth

opportunities in select international markets."

Rick Henson, added: "We're now in a position to dive deeper into our growth strategy by adding and introducing new distribution and surgeon users to our current and future technologies that we plan to launch over the next few months."

Looking ahead

There is little question that this transaction vaults ChoiceSpine into a new level in the spine industry. In addition to the products acquired from Exactech, the ChoiceSpine guys are working on a full line of biologic implants as well. For that Marty told *OTW*; "Stay Tuned."

This was an exceedingly strategic move for Rick and Marty. At this rate, ChoiceSpine will be the ***choice*** for more and more spine surgeons. ♦

RECENT ORTHOPEDIC COMPANY ACQUISITIONS

Date	Acquired Company	Purchaser
Feb-17	Codman	Integra Life Sciences
Feb-17	Exactech Spine	ChoiceSpine
Oct-16	RespondWell	Zimmer Biomet
Jul-16	Alphatec's International Business	Globus Medical
Jun-16	Biotronic Neuronetwork	NuVasive
Jun-16	LDR	Zimmer Biomet
Jun-16	Medtech	Zimmer Biomet
May-16	Biomedical Enterprises	DePuy Synthes
May-16	Stanmore	Stryker
Apr-16	Cayenne Medical	Zimmer Biomet
Apr-16	Safewire	Stryker
Apr-16	Sage Products	Stryker
Jan-16	BST-Cargel	Smith and Nephew
Jan-16	Ellipse	NuVasive
Oct-15	Blue Belt Technologies	Smith & Nephew
Jul-15	X-Spine Systems	Bacterin
Jun-15	Biomet	Zimmer
Jun-15	DeOST LLC	Smith & Nephew
May-15	S2 Interactive	Smith & Nephew
Feb-15	Branch Medical Group	Globus Medical
Feb-15	Olive Medical	DePuy Synthes

Source: RRY Publications LLC

stryker

Tritanium® PL

Posterior Lumbar Cage

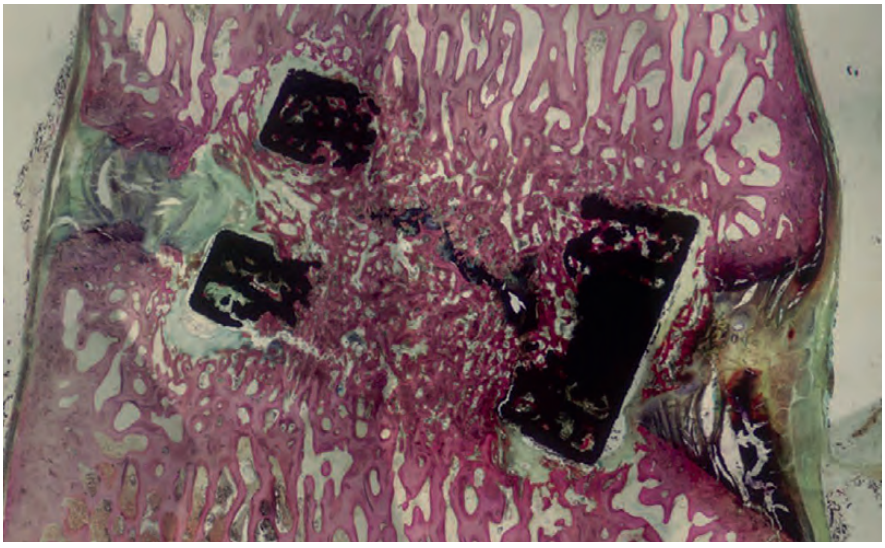
Featuring Tritanium In-Growth Technology:[1]

Inspired by biology
Enabled by technology

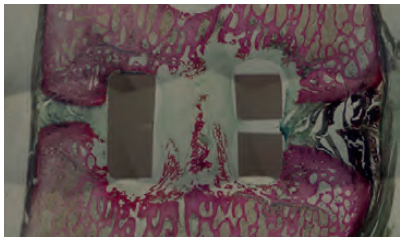
Built to fuse™

8 weeks post-op in an ovine model[2]

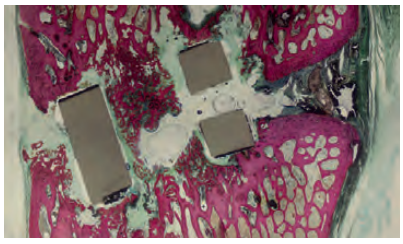
Tritanium PL Cage



PEEK cage



Ti Plasma Sprayed PEEK Cage



Sagittal view. Correlation to human clinical outcomes has not been established.

Experience exciting new innovations at the AAOS Annual Meeting – Booth #3133 – including a 3D virtual reality tour of Tritanium In-Growth Technology.[1]

For more information, please visit www.stryker.com/builttofuse/

References:
1. Tritanium technology claim support PROJ43909.
2. Pre-clinical study final report, SRL 15-02 / Stryker -02-15.

"Built to fuse" relates to the Tritanium PL Cage's indication as an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. See Tritanium PL Cage IFU QIN4427TRIIBD and 510(k) 152304 for full detail.

Available through Stryker's Spine Division | 2 Pearl Court | Allendale, NJ 07401-1677 | Tel. 201 749 8000

2nd Settlement in Glucosamine Chondroitin Lawsuit

BY JESSICA MEHTA

On February 1, 2017, federal District Judge James B. Zagel of the Northern District of Illinois approved a preliminary settlement to resolve pending lawsuits against The Nature's Bounty Co. (NBTY), their subsidiary group Rexall Sundown, Inc., and numerous retailers including Target Corp., Costco Wholesale Inc., and CVS Pharmacy Inc.

Putative class action lawsuits filed by six named plaintiffs (Nick Pearson, Francisco Padilla, Cecilia Linares, Augustina Blanco, Abel Gonzales, and Richard Jennings) claimed on behalf of themselves and 30,245 class action lawsuit members that a plethora of glucosamine supplements and joint health supplements exaggerated the claimed benefits.

The brands and supplements specifically listed in the court documents include Osteo Bi-Flex Triple Strength, Flex-a-Min Triple Strength, Kirkland Glucosamine Chondroiton, and CVS Triple Strength Glucosamine Chondroiton with MSM (methylsulfonylmethane). However, should the settlement move forward, several dozen related brands and supplements will be affected. The plaintiffs are represented by Bonnett, Fairbourn, Friedman & Balint, P.C., Boodell & Domanskis, LLC, and Denlea & Carton LLP. This settlement agreement was filed April 10, 2015.

This is the second proposed settlement.

History in the Making

Rexall is the manufacturer of various glucosamine joint health supplements which are sold under many names including the popular Osteo Bi-Flex.

Photo creation by RRY Publications, LLC

The manufacturer also creates a number of private-label brands of chondroitin joint health and glucosamine supplements for big name retailers named in the lawsuit.

The original putative class action lawsuits were filed June 14, 2011 in Illinois. Later, California and Massachusetts were part of the suit. The plaintiffs claimed that NBTY made exaggerated statements regarding cartilage repair and rebuilding that were misleading and/or false. Since the claims were made in three states, they fall under a myriad of consumer protection laws which aren't connected to physical injuries or safety.

The first agreement required Rexall to pay a total of $5.36 million. This included $1.93 million to the class counsel, $1.5 million in administrative fees and notices, $865,284 to the class members, $179,676 in attorney fees, and $30,000 to the six plaintiffs. It also included a likely "*cy-près*" payment of $1.13 million to the Orthopedic Research and Education Foundation (OREF). *Cy-près* is relatively popular in class action lawsuits in the U.S. and literally translates to "so close." Although it originated in England, it's often a means of providing extra class action lawsuit settlement funds to non-profit organizations.

The Seventh Circuit Court called the first agreement a "selfish deal between class counsel and the defendant" and that it "disserves the class." Plus, the appeals court balked at the claim and notice forms, saying that the original award of $3 per bottle with a maximum of four bottles per household, or $5 per bottle with a 10 bottle maximum with proof of purchase, was too conservative. The new settlement requires no proof of purchase.

Circuit Judge Richard Posner penned the opinion which reversed the judgement on November 19, 2014 as part of a three-judge collaboration.

> "Class counsel shed crocodile tears over Rexall's misrepresentations,

describing them as 'demonstrably false,' 'consumer fraud,' 'false representations,' and so on, and pointed out that most of the consumers of Rexall's glucosamine pills are elderly, bought the product in containers the labels of which recite the misrepresentations—and number some 12 million. Yet only one-fourth of one percent of these fraud victims will receive even modest compensation, and for a limited period the labels will be changed, in trivial respects unlikely to influence or inform consumers. And for conferring these meager benefits class counsel should receive almost $2 million?"

Round Two (And Prepping for a Possible Round Three)

NBTY has maintained through both settlement proposals that the allegations aren't true. However, as detailed in the new, second memorandum filed by plaintiffs on May 14, 2015, the defendants agreed to remove key statements on scores of brands and products. This memo was seeking preliminary approval of the second settlement.

As part of the new agreement, the group of defendants will stop stating that certain brands and supplements help to repair and/or build cartilage. Specifically, according to court documents, Rexall is barred from using the phrases "fixing, mending, reconditioning, rehabilitating, increasing, developing, building, repairing, rebuilding, renewing, regrowing, adding, regenerating, or rejuvenating cartilage" as detailed in the plaintiff's memorandum. Rexall is also prohibited from "other claims regarding the effect of the covered products on cartilage … or other types of structure/function claims, such as claims that the covered products support, protect, or promote joint comfort, mobility, or health."

Defendants are now required, in the second settlement, to pay out a total of $9 million with $7.5 million earmarked for cash awards to the 30,245 class action members and $5,000 each in incentive awards to class representatives and attorneys' fees. An additional $1.5 million will be set aside for administrative fees and costs of notice. The memorandum notes that it's unlikely there will be any leftover monies for any *cy-près* payment to the Orthopedic Research and Education Foundation in the new settlement.

The settlement includes 15 million households, and plaintiffs have reported that about 74% of the class will be reached through the notice. In the first settlement agreement, 76% of the class was slated to be reached. Notices will be sent via direct mail to 4.8 – 5.55 million households along with "robust publication notice" according to court documents.

Each member of the class action lawsuit will be eligible for $8 per bottle with a maximum of $104 per household (totaling 13 bottles). This second agreement was mediated by a now-retired United States District Court Judge, Wayne R. Andersen.

According to Judge Zagel, the new agreement "appears to be a fair, reasonable, and adequate settlement for the litigation, and is in the best interests of the class in light of the factual, legal, practical, and procedural considerations raised by the litigation." Judge Zagel's decision was revealed in a Securities and Exchange Commission filing. The fairness of the settlement hearing is scheduled June 30, 2017 and the deadline for filing claims is September 28, 2017.

Big Names, Big Claims

Should the cases move to trial, the attorneys for the plaintiffs stated in the memorandum that "The efficacy of the products has been the subject of scientific and medical debate over the last decade, and while Plaintiffs believe that the weight of the scientific evidence is in their favor, as with any other trial there is the risk that a jury would side with the Defendants."

This second agreement is in hopes of appeasing the issues raised by Judge Posner and the Seventh Circuit. In addition to the new $104 maximum instead of the original $50, the process for claims is now easier. The addition of new prohibitive statements on the various brands and supplements is also new to the second settlement. However, Rexall's potential total liability isn't dictated by how many claims are filed.

According to the plaintiff's attorneys, "The only way that Rexall may again be allowed to make these claims is if it becomes aware of the scientific support for any of the prohibited representations and obtains permission from the court, after notice to the class counsel, that it may again make the prohibited representations."

The Orthopedic Research and Education Foundation: "So Close," Yet So Far

Few unfamiliar with class action lawsuits (or charitable law in England) are familiar with the "*cy-près*" doctrine. It was born in the English Courts of Equity and the law of charitable trusts. Although it literally translates at "so close," it's usually meant as "as near as possible" when used in court systems. Today in the United States, it's almost exclusively found in class action lawsuit settlements.

Originally, it was designed for use when the goal of the settlement was impossible, illegal, or impractical. *Cy-près* lets

the court amend certain terms to make it "as near as possible" to the original intention of the "testator" (plaintiff in U.S. courts).

The most famous *cy-près* case in the U.S. was in the 1867 case of Jackson vs. Phillips. When he was living, Francis Jackson bequeathed $1,049 (about $29,000 in 2017) to a trustee's fund to "create a public sentiment that will put an end to Negro slavery in this country." Jackson himself died in 1861 when slavery was still legal. However, by 1865, the Thirteenth Amendment abolished it. Jackson's family tried to dissolve his trust—otherwise, his bequest would be lost to them in the name of charity and his wishes. The court rejected the Jackson family attempts to dissolve the trust, saying it should be used *cy-près* "to promote the education, support, and interests of the freedmen, lately slaves, in those states in which slavery had been so abolished."

In an effort to find the next best use of funds for this particular class action lawsuit, the Orthopedic Research and Education Foundation was selected. After all, the brands and supplements included in the lawsuit were to treat orthopedic issues. *Cy-près* payouts are practical, but always a last resort in class action lawsuits. In this case, with the new settlement, the 30,000+ class members are facing a much higher payout, which the court deems a more appropriate use of the potential funds.

OREF's mission is to "improve lives by supporting excellence in orthopedic research." As a non-profit, "OREF is dedicated to being the leader in supporting research that improves function, eliminates pain, and restores mobility, and is the premier orthopedic organization funding research across all specialties." OREF is also the top grant making resource for new investigators and for established clinicians who may not secure funding elsewhere due to their area of research. In 61 years, OREF has funded over $143 million including $2.5 million in research grants and $97,000 to support research programs in 2015 (the most recent report available). While the $1.3 million in *cy-près* from the settlement would have made an impressive impact on OREF's giving capacity, it's clear that this organization is well rooted and capable of continuing its operation when a miss is as good as a mile. ♦

Pneumonia After TJA; NYU & Bundled Payments; Direct Anterior and Revisions

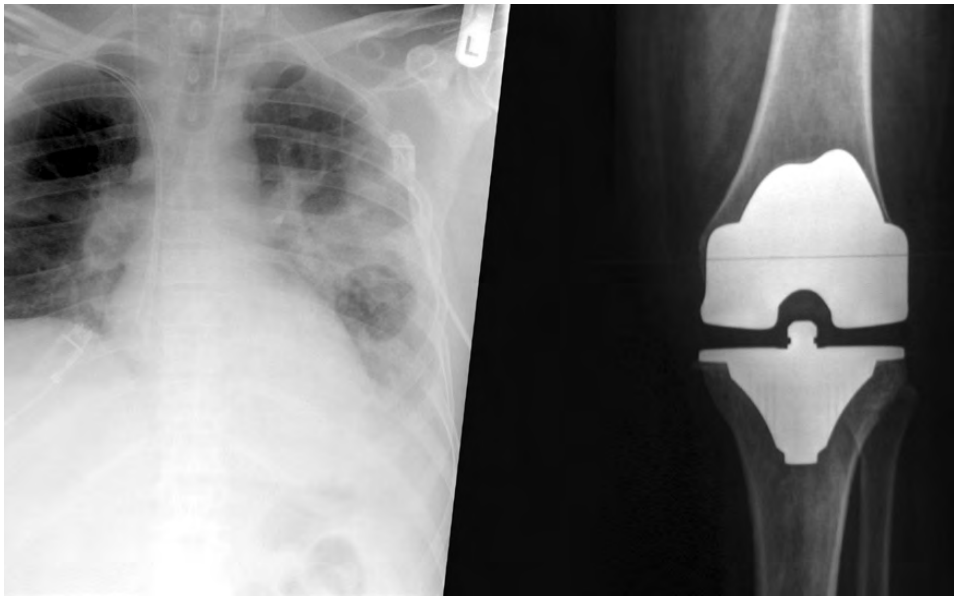
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Pneumonia After TJA: 1 in 25 Die! You don't hear much about pneumonia after total joint arthroplasty (TJA). To change that, researchers from Rush University Medical Center set out to get some specifics. Using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database, the team, which included Craig Della Valle, M.D., conducted a retrospective cohort study of patients undergoing TJA. In total, 66,493 patients underwent THA and 104,707 underwent TKA.

Daniel Bohl, M.D. is an orthopedic resident at Rush University, and participated in the research. He commented to *OTW*, "Hip and knee replacement have become impressively successful procedures, but they can rarely still be complicated by devastating medical events. We know a lot about many of these events (for example, blood clots that can form during or shortly following surgery). However, we know much less about others. Pneumonia is one of these events that certainly occurs but hasn't received much attention."

"We were surprised at how great an impact this complication can have on patients. That is, 4 of 5 patients who developed this complication were readmitted to the hospital, and 1 in 25 die."

"The strongest risk factors for pneumonia are COPD [chronic obstructive pulmonary disease], diabetes mellitus requiring insulin, and age ≥ 80 years. Given the serious implications of this pulmonary complication, evidence-based pneumonia prevention programs should be considered for patients with these risk factors. Such interventions include oral hygiene with chlorhexidine, sitting upright for meals, elevation of the head of the bed to at least 30 degrees, aggressive incentive spirometry, and early ambulation."



Wikimedia Commons, Christaras A and fpjacquot

BCPI: The NYU Langone Experience The Bundled Payments for Care Improvement Initiative (BPCI)…the merger of physician/patient/hospitals interests, shared risks…all with the maintenance of quality. Researchers with the Department of Orthopaedic Surgery at New York University Langone Medical Center (NYULMC) in New York City decided to examine the BPCI, looking at issues such as risk stratification, size of institution, and the development of infrastructure. NYULMC is a large, urban, tertiary, academic medical center.

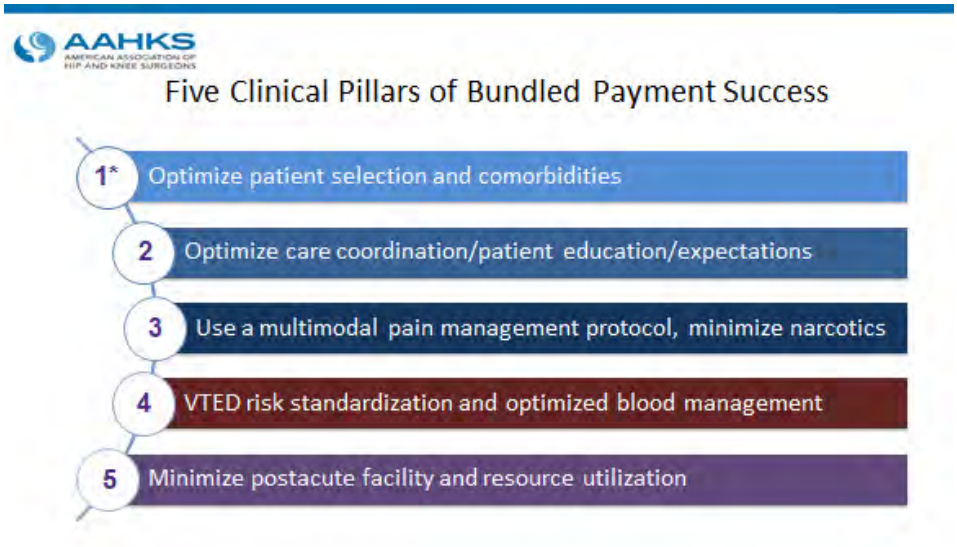
Richard Iorio, M.D. is chief of Adult Reconstructive Surgery at NYU Langone. He told *OTW*, "We entered BPCI Model 2 in January 2013 with the hope of controlling the hospital and episode cost of Medicare patients undergoing total joint arthroplasty (TJA) as we were losing money in those cases. In a 90-day episode of care, 40% of the cost is in the post-acute phase. By controlling the after acute care hospital costs, there is an opportunity to save money and beat the target price. We went from 75% of patients going to post-acute facilities to 25% over four years. Additionally, clean data and transparent data exchange between hospitals and docs leads to better alignment and gainsharing reinforces these alignment arrows."

"Comorbidities are a significant issue when it comes to BPCI as very sick patients could potentially be denied

access to care. At our institution, 74% of TJA patients had musculoskeletal comorbidities, 60% had hypertension, and the list goes on. Any comorbidity increases the risk of surgical complications, thus we developed a surgeon-directed risk factor stratification and modification program to delay surgery and optimize health status in the highest risk patients. This included individuals who were morbidly obese, those with uncontrolled diabetes and poor nutrition, and smokers, to name a few."

"Our conclusion was that there are five pillars of clinical bundled payment success. Then there is the data. It must be real-time, transparent, believable, and accurate. Otherwise, the foundation of the hospital-physician relationship is cracked and will not support continued cooperation. Lastly, gainsharing and physician/hospital alignment are critical. Involved, committed physicians must be an integral part of any bundled payment initiative. As for alignment, we have found that if you can get everyone on the same page in the areas of clinical management, technology, and clinician behavior, then it will likely result in good management of an entire episode of care."

"Yes, this is a huge organizational challenge, involving a large infrastruc-



Source: American Association of Hip and Knee Surgeons

ture commitment and many full-time employees. Robert Grossman, M.D., dean of NYU Langone Medical Center, and Joe Zuckerman, M.D., the chair of Orthopedics, were visionary, and saw BPCI as a great opportunity to decrease cost, improve quality and bring more value to our patients."

Direct Anterior Approach and Early Femoral Failure of Cementless THA

Research involving the Indiana University School of Medicine, The Rothman Institute at Thomas Jefferson University, and OrthoCarolina Hip and Knee Center has studied 478 consecutive early revision THAs to examine the inherent risks in the direct anterior approach (DAA) for total hip arthroplasty (THA).

The article, entitled "Direct Anterior Approach: Risk Factor for Early Femoral Failure of Cementless Total Hip Arthroplasty" was published in the January edition of *The Journal of Bone and Joint Surgery*. The authors wrote, "Analysis of the revisions due to early femoral failure showed them to be more common in patients who had undergone the direct anterior approach (57/112; 50.9%) than in those treated with the direct lateral (39/112; 34.8%) or the posterior (16/112; 14.3%) approach (p = 0.001). In multivariate regression analysis controlling for age, sex, laterality, Dorr bone type, body mass index (BMI) at revision, bilateral procedure (yes/no), and femoral stem type, the direct anterior approach remained a significant predictor of early femoral failure (p = 0.007). Most early revisions due to instability were associated with the posterior (19/40; 47.5%) or direct anterior (15/40; 37.5%) approach (p = 0.001 for the comparison with the direct lateral approach [6/40; 15.0%])."

Michael Meneghini, M.D. is an orthopedic surgeon at the Indiana University School of Medicine. He commented to *OTW*, "Many scientific inquiries begin with an observed clinical phenomenon that spurs the interest to validate and learn more. In this case, through our network of high volume revision centers, we noticed an increase in cementless femoral component loosening as the cause of early hip revisions. Previously, before the rapid adoption of the DAA, this etiology of failure was relatively uncommon. Further, having been trained on and performed the DAA personally, the technical challenge inherent with this approach is obtaining adequate femoral exposure to insert the femoral component safely. Therefore, we undertook this study to

see if there was a correlation between surgical approach and early femoral component failure and our hypothesis was supported."

"The main point of this article is that no surgical approach is perfect and there are risks inherent with each surgical approach, largely due to the anatomical considerations. Whereas the posterior approach has a greater risk of dislocation, the DAA has a greater risk of early femoral component failure. We are hopeful this will provide objective data regarding potential risks associated with a surgical approach that has been rapidly adopted by the orthopedic community and directly marketed to patients by the orthopedic device industry and surgeons."

Thomas K. Fehring, M.D. is an orthopedic surgeon with the OrthoCarolina Hip and Knee Center and a co-author on the research. He told *OTW,* "This study clarifies the potential risks and early failures seen in total hips using a variety of surgical approaches, one of which is the innovative anterior approach. These findings raise the question of how new technology should be introduced into orthopedic practice, especially when marketing outpaces the peer review process."

"Orthopedic surgeons should respond thoughtfully to innovative techniques, implants, or approaches. However, we must be vigilant in evaluating innovative solutions, making sure they are responsible innovations with lasting benefit to patients and not merely marketing innovations with no staying power. As arbitrators of orthopedic innovation, we alone can help our patients distinguish hype from hope."

"When new technology is introduced and there is not evidence-based data available, surgeons must decide whether adoption is worth the risk. This becomes more difficult when marketing efforts stimulate patients' demands and expectations in the exam room before evidence-based studies, such as this, are available. Clearly, good results can be obtained regardless of approach however the strengths and weaknesses of each must be understood. Future studies on this subject will help further clarify whether deviation from a successful operation via a time-honored approach is worth the risk." ♦

COMPANY

Medacta: New Medical Director; 140% Sales Growth!

S. Raymond Golish, M.D., Ph.D., M.B.A., a veteran clinician-scientist, has been named as the new Medical Director of the Medacta USA Spine Division. The company is also announcing enormous growth, with its Spine Division experiencing more than 140% sales growth in 2016. According to the February 1, 2017 news release, this division "now boasts five consecutive quarters of 24% quarter-over-quarter growth. Last year, the Division increased its customer base by 105% and added more than 40 new field agents selling its products in the U.S."

"Dr. Golish is a fellowship-trained spinal surgeon, medical device and data

S. Raymond Golish, M.D., Ph.D., M.B.A. / Courtesy of Jupiter Medical Center

scientist, and experienced healthcare administrator and executive. He currently acts as Medical Director of Spinal Surgery and of Clinical Trials at Jupiter Medical Center (Jupiter, Florida) and is a practicing spinal surgeon at Florida Spine Center in Palm Beach, Florida. He serves as Chairman of the American Academy of Orthopaedic Surgeons (AAOS) Biomedical Engineering Committee and Chairman and Director of the Board for the Research Committee of the North American Spine Foundation. From 2012 to 2016, he was a voting member on the U.S. Food and Drug Administration's Orthopaedic and Rehabilitation Devices Panel. Dr. Golish received his Ph.D. and M.D. from the University of California, Los Angeles in 2002 and 2004, respectively. He completed his spinal surgery fellowship at Stanford University in 2010 and received his M.B.A. from Duke University in 2013."

"With his diverse experience as a surgeon, medical data scientist and expert in U.S. regulatory affairs, Dr. Golish will be an important addition to the Medacta spine team as it continues to introduce methodical, thoughtful and evidence-based innovations," said Francesco Siccardi, executive vice president of Medacta International. "His steadfast dedication to patient safety and the role that medical device innovation can play in improving life aligns well with our ideals at Medacta, and we are thrilled to have him on board as we look to meet our ambitious growth targets in the year ahead."

"Medacta's key differentiator is its unique corporate culture, which focuses on excellence in patient care, quality, evidence and innovation in a way that moves the field forward while keeping safety paramount," said Dr. Golish. "It's an exciting time for Medacta as a whole, but especially for its Spine Division, which experienced transformative growth in 2016 and is poised to meet or even exceed upon the bold growth targets set for 2017."

Asked about this growth, Medacta USA U.S. Vice President of Sales, Spine Division David Sponsel told *OTW,* "I attribute our Spine Division growth to three primary factors: the addition of more sales leaders, product managers, and sales professionals to our team; three new product launches; and our world-class learning centers, where we trained over 60 surgeons in 2016."

"Over the next 6-12 months, we plan to continue building upon our sales leadership and product management teams, while adding 40+ direct and independent sales agents. We're also maintaining a strong focus on supporting and strengthening our surgeon consultants and educators so we can help our current and prospective surgeon partners achieve clinical excellence when using Medacta products." — *EH*

NuVasive Posts 25.9% Fourth Quarter Sales Increase

NuVasive, Inc. announced on Thursday, February 9, 2017 that sales for the fourth quarter ended December 31, 2106 rose 25.9% (excluding currency and acquisitions) or 25.5% on a constant currency basis. Sales for the quarter were $271.1 million, which is up from $215.3 million reported in the fourth quarter of 2015.

NuVasive (NUVA), which is headquartered in San Diego, California, is a leading medical device company focused on spine surgery. For the full year of 2016, sales were $962.1 million, up from $811.1 million in 2015. The following table shows the sales details for 2016.

Glenn Novarro, an analyst with RBC Capital Markets, LLC, said in his report, "We raise our price target to $76 from $73. We continue to believe that NUVA offers medtech investors a unique combination of strong revenue growth, meaningful operating margin leverage, and significant earnings and cash flow growth, unmatched by its mid cap peers."

NUVASIVE Speed of Innovation

Courtesy of NuVasive

Gregory T. Lucier, chairman and chief executive officer of NuVasive, said in a release, "NuVasive delivered record fourth quarter results and exceeded expectations for the full year 2016. By all measures, the Company had a tremendous year executing against our market-share taking initiatives, delivering strong revenue growth, including a return to 20% year-over-year growth in our core International markets."

NuVasive, Inc.			
$ in millions	2015 Sales	2016 Sales	% Change
TOTAL	$811.1	$962.1	6.17%

Source: NuVasive, Inc. company documents

Lucier added, "In 2017, we are committed to driving further market expansion, especially in the spine deformity area, while significantly increasing our in-sourced manufacturing capabilities." — *TR*

LEGAL

FDA Approves Abuse-Deterrent Opioid

The FDA has approved a new extended-release opioid with abuse-deterrent properties.

This is important for orthopedics. For instance, patients with long-lasting, chronic back pain, particularly after multiple surgeries, are sometimes prescribed opioid or narcotic medications. In fact, one study cited by *WebMD,* showed that as many as 70% of back pain patients receive opioids. These drugs act on pain receptors in the brain and nerve cells to alleviate pain.

The Centers for Disease Control and Prevention estimates that 78 Americans die every day from an opioid overdose.

New Drug Application Approval

On January 9, 2017, the FDA approved the NDA (New Drug Application) for Egalet Corporation's Arymo ER (morphine sulfate extended-release tablets). The drug is approved to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment

Pexels

and for which alternative treatment options are inadequate. Arymo ER is formulated to give it physicochemical properties expected to make abuse by injection difficult. However, abuse by the intravenous, intranasal, and oral routes is still possible.

Reducing Risk and Abuse

According to the company's FDA application, Arymo ER tablets are "extremely hard, resistant to particle size reduction (PSR), and inhibit attempts at chemical extraction of the active pharmaceutical ingredient (API). In addition, the technology results in a viscous hydrogel on contact with liquid, making the product very difficult to draw into a syringe."

"These features are intended to address the risk of accidental misuse (e.g., chewing) in patients with chronic pain as well as intentional abuse via alternate routes of administration (i.e., manipulated oral, intranasal, intravenous)."

Egalet plans to launch Arymo ER, approved in three dosage strengths: 15 mg, 30 mg and 60 mg, in the U.S. in the first quarter of 2017.

More to Come

The same FDA advisory panel that recommended Egalet's drug also recommended the FDA approve a long-acting opioid made by Teva Pharmaceutical Industries Ltd, Vantrela ER.

It also recommended approval of a long-acting, abuse-deterrent opioid made by Pfizer Inc,, Troxyca ER, although it had reservations about the drug's ability to curb all forms of abuse.

To read more about the drug from the company, click here. — *WE*

12 Doctors Walk Into a Bad Investment…

Twelve South Dakota doctors practicing at the Center for Neurosciences, Orthopedic & Spine (CNOS) in Dakota Dunes filed a lawsuit against four hospital administrators for allegedly defrauding them of several million

Flickr, www.ccPixs.com, and Chris Potter

dollars. The doctors included orthopedic surgeons and neurosurgeons. As investors in Progressive Acute Care (PAC), the doctors claim the administrators purposefully presented the four hospitals as a healthy investment, allegedly covering up key details that ultimately led the hospital group to bankruptcy. In 2009, Progressive Acute Care owned three hospitals in rural Louisiana including Winn Parish Medical Center (Winnfield), Avoyelles Hospital (Marksville), and Oakdale Community Hospital (Oakdale) with plans to purchase Dauterive Hospital (New Iberia).

The lawsuit, filed in early 2017, claims that the doctors owned 40 percent of preferred equity. They were introduced to Progressive Acute Care by former CNOS CEO and former COO of PAC Mike Hurlburt. According to the lawsuit, Hurlburt teamed up with three other PAC members in 2012 to devise a plan to purchase a fourth Louisiana hospital, Dauterive Hospital. He allegedly "told the physicians that a return of three-to-four times their investment was assured, and that he was expecting a return of ten times their investment" according to court documents.

"Buy" the Numbers

Already with $8 million invested in the three other PAC hospitals, the doctors invested $3 million more to buy the fourth hospital. An additional $10 million in debt was also accrued so PAC could make the final purchase. However, the doctors claim that the figures Hurlburt gave for Dauterive were falsified. PAC declared bankruptcy in 2016, and during that filing a memo allegedly surfaced which shows PAC purposefully falsified the profitability quotient of Dauterive. PAC's 2016 bankruptcy fillings claim their total liabilities are $10 – 50 million, and total asset value is between $1 – 10 million (final figures will be available as the bankruptcy claim moves forward).

The doctors' lawsuit claims that, "What the physicians did not know was that each of these representations was based on fraudulently manipulated data or was highly misleading based on the omission of material facts." According to the doctors, the hospital administrators deliberately didn't disclose their internal audits which revealed a number of "deficiencies" within their financial department. The total equity investment in PAC is estimated at $8 million according to the lawsuit—all of which is now "worthless." This is inclusive of the $3 million in Series B Preferred Units spent to help purchase Dauterive.

As of February 17, 2017, the hospital administrators have not responded to the complaint. — *JM*

New FDA "Intended Use" Labeling Rule Causes Industry Convulsions

The FDA issued a final rule regarding intended use labeling on January 9, 2017 that sent device and drug makers into convulsions.

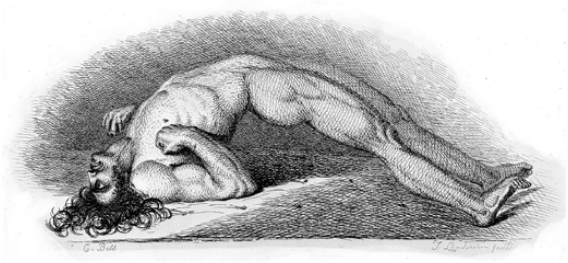
The final rule requires manufacturers to "provide…adequate labeling"…if the "totality of the evidence" establishes that a manufacturer objectively intends that a device [or drug] introduced into interstate commerce by the manufacturer is to be used for "conditions, purposes, or uses other than ones for which it has been approved, cleared, granted marketing authorization, or is exempt from premarket notification requirements."

When the FDA proposed to revise this rule in 2015, the agency removed the famous "knowledge" sentence which said that if a manufacturer "knows, or has knowledge of facts" that would give him notice, that a drug or device is to be used for uses other than the ones for which he offers it, then he must provide adequate labeling.

In the agency's own citation from a case settled with pharma company Allergan, FDA said it would no longer "regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on that firm's knowledge that such product was being prescribed or used by doctors for such use."

Jeffrey Shapiro writes on Hymen, Phelps & McNamara, PC's *fdalawblog* that, "Shockingly, [the final rule] does not delete the 'knowledge' sentence as expected. On the contrary, it 'amends' the sentence to create an entirely new sentence that FDA had not mentioned in original proposal. Now the sentence incorporates a brand new 'totality of the evidence' standard.

"It appears that FDA has now written itself a blank check to find whatever intent it wishes to find, using an unconstrained calculus as to what the 'totality of the evidence' shows. Worse, the manufacturer's knowledge can be part of this evidentiary mix, thus negating the long overdue proposal to



Patient in a convulsion / Wikimedia Commons and Wellcome Images

eliminate 'knowledge' as an element of intended use."

Industry Petition

The Medical Information Working Group (MIWG), the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) immediately petitioned the FDA following this "unexpected decision" to revise the definitions of "intended use" for drugs and medical devices.

The industry groups call for this final rule to be stayed indefinitely and reconsidered because FDA failed to give fair notice or a meaningful opportunity to comment on this major shift.

If you want to sign the petition, click here.

The new rule is due to go into effect on March 21, 2017. — *WE*

EXTREMITIES

No Flowers, No Candy, No Card—No Dice

This lawsuit over a wrist injury is unlike any we have ever seen. And, appropriately, it is between two attorneys. After reading this we think it couldn't happen to two more deserving legal beagles.

Attorneys George Vallario and Peter Lindley are in the ultimate shakedown after a children's birthday party in Boca Raton, Florida. Vallario claims that Lindley's handshake injured him. Vallario says Lindley caused him "extreme pain," mental anguish, and now wants redress by way of a $15,000 lawsuit.

Flickr and www.flazingo.com/creativecommons

Vallario told the *Florida Record* that the handshake had such "ferocity, force, strength and violence" that he "yelped in extreme pain" and said, "Holy cow! Pete, what's wrong with you, man?" Lindley denies the allegations, saying handshakes are how "gentlemen have greeted each other for centuries." The birthday blunder occurred Saturday, February 8, 2014, and Vallario says he's been in pain for the past two years. "When I'm at church, I have to use my left hand to

pass the basket," he says. He also reports he can't open toothpaste caps.

Getting Handsy

Perhaps Vallario is new to such a greeting custom? No—Vallario says he's no stranger to handshakes. "I once had a nightclub in New York and I would shake 200 people's hands a night. That's what you did when you had a club. And nobody ever shook my hand so violently or forcefully as did Peter."

By Monday following the shaky situation, Vallario was at an orthopedic surgeon's office. He was treated three times per week for six months.

Admittedly, Vallario says he *does* have arthritis. However, when he told Lindley about his medical issue immediately after the handshake, Lindley's reply was, "So does my mother." Mom jokes appear to have no age boundaries. "I don't know why he's so strong," says Vallario. "He may have started a new workout regimen."

Two days after the handshake went haywire, Vallario texted Lindley. "No flowers? No candy? No card?" he asked. Lindley had no reply.

"All he had to do was something nice, but he wouldn't, so I did sue," Vallario says.

Lindley eventually offered Vallario a $500 out of court settlement, but was rejected. Lindley has made few comments on the lawsuit, outside of, "It's kind of ridiculous, actually." He's expected to testify that Vallario never shouted out in pain.

The case is set to go to court in mid-May. Vallario originally wanted to ask for $200,000 in damages. However, had Lindley apologized right away, "that would have been the end of it." — *JM*

SPORTS MEDICINE

New Study: We're Measuring Exercise all Wrong

Ten people running 10 meters are actually exercising in 10 different ways. According to an important new

Wikimedia Commons and Cellule Communications

study, we're measuring exercise activity all wrong.

Cain C.T. Clark of the Applied Sports Technology, Exercise and Medicine (A-STEM) Research Centre and of the Engineering Behavior Analytics in Sport and Exercise (E-Base) Research group of Swansea University in Swansea, Wales and colleagues reported in the March 2017 issue of *Sports Medicine* that while there are some reliable methods of measuring physical activity, more refinement is needed to better understand the fundamental differences in how we exercise.

The researchers reviewed studies published between January 2010 and December 2014 that looked at emerging analytical techniques of physical activity and included technique accuracy. Out of 50 articles reviews, 11 met eligibility criteria.

From their analysis, they concluded that "despite the diverse nature and the range in accuracy associated with some of the analytic techniques, the rapid development of analytics has demonstrated that more sensitive information about physical activity may be attained. However, further refinement of these techniques is needed."

Clark, who is now a junior lecturer at Hartpury University Centre in the United Kingdom told *OTW*, current techniques tend to focus on overall activity, but not the fundamental differences in activity.

"Think of it this way…If I have 10 people run 10 metres, they have all done the same amount of activity, right? I would assert no, each of those individuals would have covered those 10 metres in different ways, for some it would have been easy, for some it would have been hard, some would have used more *energy*, some would have less. So, there are far deeper, more fundamental issues than just *how much overall*."

Clark added that the future research should focus on the lack of depth in analyzing physical activity data.

"We know how much activity people do, we know why they do or don't, what we don't know is, fundamentally, *how* people are active, and how *different* we are at performing the same activity (i.e., gait, movement quality, motor control). If we have more detail on how people move, we may be able to tailor and tweak interventions and initiatives to be more palatable and appropriate for everyone. This is the key, ensuring and promoting sustainable physical activity." — TR

PEOPLE

Nikhil N. Verma, M.D. New Head Team Physician for Chicago White Sox

Nikhil Verma, M.D., a sports medicine physician with Midwest Orthopaedics at Rush (MOR) in Chicago, has been named head team physician for the Chicago White Sox. As noted in the February 22, 2017 news release, Dr. Verma, director of the Division of Sports Medicine for the Department of Orthopedic Surgery at Rush University Medical Center, performs more than 600 surgical procedures annually.

"Dr. Verma will take over the reins for Charles Bush-Joseph, M.D., who was head team physician since 2003 and is stepping down to assume the roles as incoming president of the American Orthopaedic Society for Sports Medicine, AOSSM, and board member of Rush Health."

Nikhil N. Verma, M.D. / Courtesy of Midwest Orthopaedics at Rush

"Like Dr. Bush-Joseph, Dr. Verma has a great reputation in the sports medicine industry," said Herm Schneider, Head Athletic Trainer for the Chicago White Sox, in the February 22, 2017 news release. "In addition to his strong background in research and academics, his clinical practice focuses on providing quality orthopedic care for athletes. These skills, complemented by his calm, caring demeanor make him a strong leader of our medical team."

Dr. Verma is also fellowship director for Sports Medicine and professor and Director of Clinical Research, Sports Medicine Section, Rush University Medical Center. He told *OTW*, "Fortunately we have enjoyed a mutually productive and longstanding relationship with the White Sox since 2003. During that time Dr. Bush- Joseph has developed a strong professional relationship with both management and players built on trust and professionalism. Over the last two to three years I have spent an increasing amount of time working with the team in preparation for this role and therefore expect a seamless transition."

"As a sports medicine physician, one of the goals of our career is to provide medical care to professional athletes, to provide them with the support they need to enjoy a productive and lasting career in athletics. I look forward to this opportunity and the challenges of managing the professional athlete." — *EH*

Mike English New President of Innovasis

Mike English has taken the helm at Innovasis, Inc., makers of spine and cranial implants based in Salt Lake City, Utah. English, who joined the company in 2014, most recently served as its Executive Vice President.

"I'm honored to have the opportunity to lead this extraordinary team. Our positive cash position and strong revenue growth will allow us to continue investing in innovation and talent," said English in the February 17, 2017 news release.

"He brings over 20 years of executive leadership experience in medical device and spine including Johnson & Johnson and NuVasive," says the news release. "Innovasis posted significant growth in 2016 while introducing the Excella-MIS system and the PX HA PLIF cage to the market. They are positioned to launch several new products in 2017 and plan to continue building their executive team."

Mike English told *OTW*, "We are focused on hiring key personnel to support our rapid growth. Recruiting new talent is paramount to our continued success."

Asked about his 6-12 month goals, English noted, "Preparing the company to move into a new facility that will accommodate our growing organization, improve synergy with our manufacturing unit, and create a world-class training environment for our physicians and distributors." — *EH*

Mike English / Courtesy of Innovasis, Inc.

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