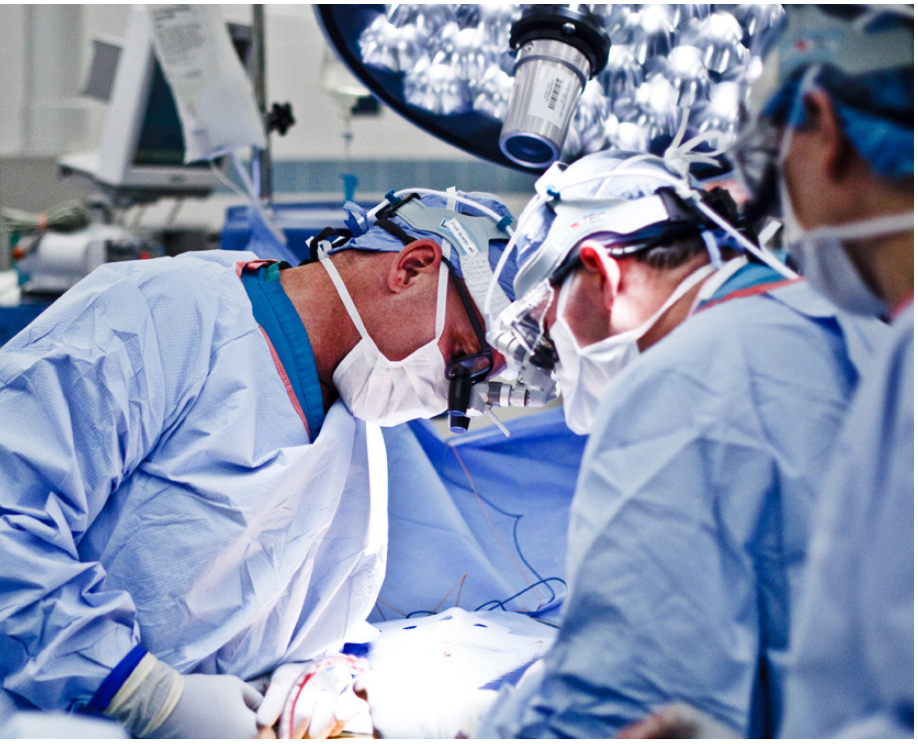
VOLUME 10, ISSUE 6 | FEBRUARY 25, 2014

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: Wow. These last two weeks have been a roller coaster ride for three high profile orthopedic firms—Alphatec, Orthofix and ConMed. Alphatec was hit with a $73 million adverse court ruling. ConMed attracted some of Wall Street's notorious vulture capitalists. And Orthofix still doesn't have any financials to report. Alphatec's value fell by a third. ConMed's rose by 10%. And Orthofix remains the dirt cheapest stock in ortho.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	15.71%	4.48%	Working at Stryker must be exhilarating these days. More strategic acquisitions were announced in February.
2	3	Smith & Nephew	20.25	6.99	Speaking of strategic...the purchase of ArthroCare gets kudos all around. But execution will be SNN's biggest question mark.
3	4	Zimmer	27.31	(1.05)	ZMH sticks to its knitting which, for 2014, means knees. This is the year of the knee and ZMH has it well covered.
4	7	ConMed	10.37	9.84	Love em or hate em. Fact is, those vultures on Wall Street can drive up equity prices. It's ConMed's turn.
5	6	Symmetry Medical	6.50	2.56	The whole issue at SMA is: Will 2014 be better than 2013? If so, then SMA is inexpensive. If not, then management has some 'splaining to do.
6	2	Globus Medical	28.29	1.68	Profit taking hit the spine guys this past week. Globus, with such strong earnings, was affected the least.
7	9	Johnson & Johnson	26.58	(2.97)	JNJ's DePuy/Synthes sells more orthopedic products than any other firm on the planet. Can this elephant learn to dance?
8	10	Integra LifeSciences	11.77	(1.33)	Expecting earnings this week and consensus of analysts is that IART will report small earnings increase on 4% sales growth.
9	5	NuVasive	6.30	(3.84)	Terrific presentation at last week's Stem Cell Summit in NYC. All public spine cos were hit with profit taking last week. Q4 results due in about 10 days.
10	8	Medtronic	28.84	(3.43)	AAOS is nearly here and it will be interesting to see how aggressive (or not) MDT spine will be in New Orleans.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	$3.84	$217	16.01%
2	ConMed	CNMD	$47.77	$1,319	9.84%
3	Smith & Nephew	SNN	$79.26	$14,154	6.99%
4	Tornier N.V.	TRNX	$20.27	$984	4.92%
5	Stryker	SYK	$82.10	$31,023	4.48%
6	Symmetry Medical	SMA	$10.00	$373	2.56%
7	Baxano Surgical Inc	BAXS	$1.27	$57	2.42%
8	ArthroCare	ARTC	$48.54	$1,668	1.72%
9	Globus Medical	GMED	$23.60	$2,201	1.68%
10	TiGenix	TIG.BR	$1.25	$201	1.36%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$1.50	$146	-36.44%
2	CryoLife	CRY	$9.79	$273	-16.32%
3	MiMedx Group	MDXG	$7.24	$749	-13.19%
4	Bacterin Intl Holdings	BONE	$0.59	$31	-9.58%
5	Orthofix	OFIX	$21.54	$419	-7.55%
6	Aurora Spine	ASG	$4.26	$66	-7.12%
7	NuVasive	NUVA	$36.78	$1,641	-3.84%
8	Medtronic	MDT	$57.12	$57,026	-3.43%
9	Johnson & Johnson	JNJ	$91.52	$258,901	-2.97%
10	Exactech	EXAC	$23.04	$312	-2.21%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$21.54	$419	8.65
2	Medtronic	MDT	$57.12	$57,026	15.38
3	CryoLife	CRY	$9.79	$273	16.20
4	Zimmer Holdings	ZMH	$95.40	$16,312	16.60
5	Johnson & Johnson	JNJ	$91.52	$258,901	16.71

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$36.78	$1,641	96.79
2	Symmetry Medical	SMA	$10.00	$373	75.30
3	ArthroCare	ARTC	$48.54	$1,668	32.06
4	Integra LifeSciences	IART	$47.37	$1,522	30.23
5	ConMed	CNMD	$47.77	$1,319	26.10

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$23.04	$312	1.07
2	Orthofix	OFIX	$21.54	$419	1.24
3	Globus Medical	GMED	$23.60	$2,201	1.40
4	Zimmer Holdings	ZMH	$95.40	$16,312	1.72
5	ConMed	CNMD	$47.77	$1,319	2.01

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$36.78	$1,641	7.87
2	Symmetry Medical	SMA	$10.00	$373	6.28
3	Integra LifeSciences	IART	$47.37	$1,522	5.50
4	CryoLife	CRY	$9.79	$273	4.05
5	Smith & Nephew	SNN	$79.26	$14,154	2.96

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.50	$146	0.75
2	Orthofix	OFIX	$21.54	$419	0.91
3	Bacterin Intl Holdings	BONE	$0.59	$31	0.93
4	Symmetry Medical	SMA	$10.00	$373	0.93
5	RTI Biologics Inc	RTIX	$3.84	$217	1.09

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.25	$201	49.11
2	MiMedx Group	MDXG	$7.24	$749	27.69
3	Globus Medical	GMED	$23.60	$2,201	5.70
4	ArthroCare	ARTC	$48.54	$1,668	4.41
5	Baxano Surgical Inc	BAXS	$1.27	$57	3.94

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

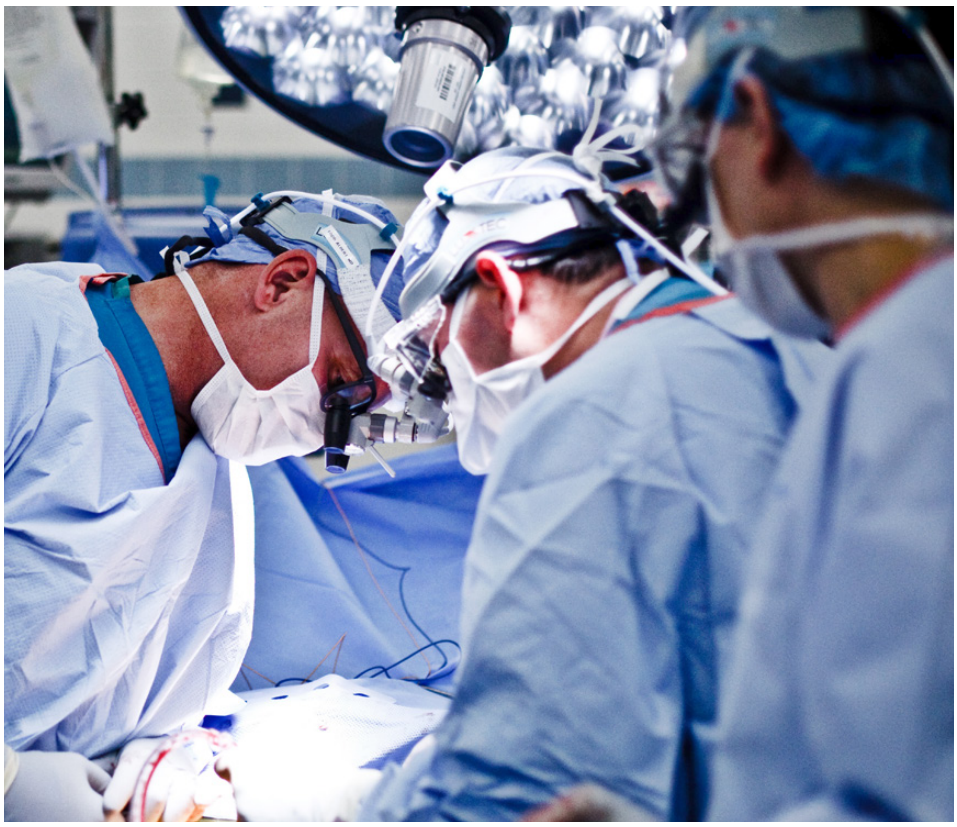
The Top 22 North American Knee Surgeons

BY OTW STAFF

When knee surgeons discuss their exemplary colleagues, these are the ones they are talking about. Behold, the super elite in the knee world!

Here is that list. We don't have "the market" on lists…this isn't the be-all and end-all list—but it is **a** *list of the most impressive knee surgeons in the country. This information was obtained via a telephone survey of thought leaders in the field. The information in quotes is what we heard about these surgeons.*

In alphabetical order, here are the top 22 knee surgeons in North America.



Andrew Huth and RRY Publications LLC

David Backstein, M.D., M.Ed, F.R.C.S.C. is an associate professor at the University of Toronto, the Head of the Division of Orthopaedic Surgery at Mount Sinai Hospital, and the Medical and Lead Chair at the Mount Sinai Centre for Musculoskeletal Disease. "He does a terrific job as head of the division. He is very talented when it comes to complex knee construction and revision; he has been instrumental in the development of the porous metal implants that we use for revision and guidance systems. He has distinguished himself as a great educator because he breaks complicated concepts down to the fundamentals."

John W. Barrington, M.D. is an orthopedic surgeon with the Texas Center for Joint Replacement in Plano and is director of the Joint Institute at Texas Health Presbyterian Hospital Plano. "Dr. Barrington is a well recognized hip and knee replacement surgeon. He has built on his group's strong clinical and research history, and has presented his work nationally on joint replacement anesthesia protocols and less invasive hip replacements. He is a destination provider in the Dallas area."

Keith R. Berend, M.D. is an orthopedic surgeon with Joint Implant Surgeons in Columbus, Ohio and a clinical assistant professor in the Department of Orthopaedics at The Ohio State University. He is co-developer of the Biomet Rapid Recovery Program. "Dr. Berend is a national leader in hip and knee replacement who has pioneered surgical techniques of anterior hip surgery and partial knee replacement. He has developed outpatient arthroplasty protocols and produced increased value through higher patient satisfaction and outcomes. He is a proven contributor in clinical research and teaching."

Michael E. Berend, M.D. is an orthopedic surgeon at the Center for Hip & Knee Surgery/St. Francis Health in Mooresville, Indiana. "He has done a tremendous amount of research and is a leader in partial knee replacement and also understands what factors correlate with long term success or failure of primary total knees."

Robert E. Booth, Jr., M.D. is the medical director of the Aria 3B Orthopaedic Institute in Philadelphia and a former president of The Knee Society. "He is a scholar-surgeon who has dedicated his academic career to the advancement of orthopedics and patient care."

Henry D. Clarke, M.D. is an associate professor of orthopedics at Mayo

Clinic in Arizona. "Dr. Clarke is a highly respected surgeon who is an active member of The Knee Society. He is well known for his research and commitment to the arthroplasty community on an international level."

Craig J. Della Valle, M.D. is an orthopedic surgeon at Midwest Orthopaedics at Rush and associate professor at Rush University Medical Center in Chicago. He is also director of the Adult Reconstructive Fellowship at Rush University Medical Center/Central DuPage Hospital. "He is not only a super surgeon, but he is a tremendous researcher who has done superb work on hip and knee reconstruction. He has taken issues such as infected and painful joint replacement and developed algorithms that advance the field."

Douglas A. Dennis, M.D. is an orthopedic surgeon with Colorado Joint Replacement in Denver and assistant clinical professor at the University of Colorado School of Medicine. He is a past president of The Knee Society and the American Association of Hip and Knee Surgeons (AAHKS). He is co-medical director of the Porter Center for Joint Replacement and director of Clinical Research, Rocky Mountain Musculoskeletal Research Laboratory. "He is a veteran in the field of knee reconstruction who has made an immense contribution to the literature and given his utmost dedication to education."

Michael Dunbar, M.D., Ph.D., F.R.C.S.C. is professor of surgery in the Division of Orthopaedics at Dalhousie University and director of Research for Orthopaedics at that institution. "He is an innovator who is helping to usher in a new way of thinking about total joint replacement. He challenges the norm, and continues to push for advancement and understanding of our field for the betterment of our patients."

Arlen D. Hanssen, M.D. is an orthopedic surgeon at Mayo Clinic in Minnesota. He is a past president of The Knee Society. "Dr. Hanssen is one of the most skilled knee surgeons and thought leaders in U.S. for complex knee replacement surgery. He has exceptional academic skills and his clear and logical thoughts and approach to complex knee issues makes him a standout in the U.S. knee arthroplasty community."

Aaron Hofmann, M.D. is the founder of the Hofmann Arthritis Institute in Utah and director of the new Center

for Precision Joint Replacement at Salt Lake Regional. Dr. Hoffman is also a clinical professor at the University of Utah School of Medicine. "He is a great innovator and scholar-surgeon who has invested immense energy in the education and training of many young surgeons."

Raymond H. Kim, M.D. is an orthopedic surgeon with Colorado Joint Replacement in Denver. "He is a well-respected orthopedic surgeon…a real rising star who does great total knee arthroplasty work. He has published extensively and has been course director at numerous orthopedic meetings."

Gwo-Chin Lee, M.D. is an assistant professor of orthopedic surgery at the University of Pennsylvania in Philadelphia and program director of the Adult Reconstruction fellowship at that institution. "Dr. Lee is a dedicated clinician, educator and researcher who has extensive experience in complex revision surgery and management of periprosthetic joint infections. He is unafraid of challenging the norms of knee surgery and continues to explore ways to improve outcomes in knee arthroplasty."

Adolph V. Lombardi, Jr., M.D., F.A.C.S. is president of Joint Implant Surgeons, Inc. in New Albany, Ohio, and a clinical assistant professor at The Ohio State University in both the Department of Orthopaedics and the Department of Biomedical Engineering. "He is a standout surgeon who continues to advance our field with his passion for research and patient care."

William J. Long, M.D., F.R.C.S.C. is an orthopedic surgeon at Insall Scott Kelly Institute for Orthopaedics and Sports Medicine; he is also a director and chief of research at that facility. "He is very involved in teaching and gets his audience involved in the Socratic method; in the OR he is excellent. His most important work is on the long term survival of total knee arthroplasty in young patients."

Jess H. Lonner, M.D. is an orthopedic surgeon with Main Line Health in Philadelphia. He is also associate professor of orthopedic surgery at Rothman Institute, Thomas Jefferson University Medical School. "He has earned the respect of his peers as an innovator in orthopedic surgery, particularly in the fields of robotic surgery and patellafemoral replacement. His contributions to improving patient care through research and education have been outstanding."

Steven J. MacDonald, M.D., F.R.C.S.C. is professor of orthopedic surgery at Western University, chief of orthopedics and chief of surgery, at London Health Sciences Centre, University Campus in London, Ontario. Dr. MacDonald is the current president of The Knee Society. "He is a superstar who has written quite a lot about patient satisfaction and how to manage patients who are less than satisfied with their total knee replacement. He is taking us to the next level in our field."

R. Michael Meneghini, M.D. is assistant clinical professor and director of Adult Lower Extremity Fellowship, Department of Orthopaedic Surgery, Indiana University School of Medicine. He is also adjunct professor in the Department of Mechanical and Biomechanical Engineering at the Rose-Hulman Institute of Technology. "He is a leader in the field of adult reconstruction who is actively involved in research and teaching and has published several landmark articles on hip and knee arthroplasty."

Javad Parvizi, M.D. is an orthopedic surgeon and director of clinical research at the Rothman Institute. "He is a leader in the field who is always willing to challenge the norms—especially when it comes to infection. He has made us come to a consensus on joint infection. He has a dynamic personality, is a tireless researcher, and trains many residents that speak very highly of him."

Christopher L. Peters, M.D. is a professor of orthopedic surgery operations at the University of Utah. "He is a talented surgeon who has done some great and impactful research on both patient specific instrumentation and revision total knees."

Giles R. Scuderi, M.D. is vice president of orthopedic services for the North Shore-LIJ Health System in New York. An attending orthopedic surgeon at Lenox Hill Hospital and Franklin Medical Center, Dr. Scuderi is also a past president of The Knee Society. Additionally, he is an assistant clinical professor of orthopedic surgery at Albert Einstein College of Medicine and one of the directors of the Insall Scott Kelly Institute for Orthopedics and Sports Medicine. "He has written numerous articles and continues to be a prominent figure in our sphere of influence. He is known for his work on redesigning The Knee Society scoring system, which has helped us thoroughly evaluate patients. He is very energetic, a great teacher, and a fabulous surgeon."

Brian D. Springer, M.D. is an orthopedic surgeon with OrthoCarolina, and is the fellowship director at OrthoCarolina Hip and Knee Center. "He is an excellent surgeon who is known for revision total knees. His clinical skills are exemplary, he achieves good outcomes, and his patients love him." ♦

MicroPort Orthopedics

Integrity In Motion™

Your **NEW** global partner, with 60 years of orthopedic excellence.

Quality
Our talented manufacturing team, built on 60 years of experience in Arlington, TN, remains focused on Quality

We're only as good as the last patient experience.
Our mission is to get patients back to a state of mobility that feels as natural as possible.

Innovation
Our investment in the future fuels our relentless pursuit of technology to keep us ahead of the market and you ahead of your patient's expectations.

Responsiveness
We are driven to provide you and all our customers around the world with the most responsive, reliable service in the industry.

Come visit us at Booth 665 at AAOS in New Orleans!

ortho.microport.com

Tony Castellvi, 61, Spine Surgeon and Research Luminary

BY ROBIN YOUNG

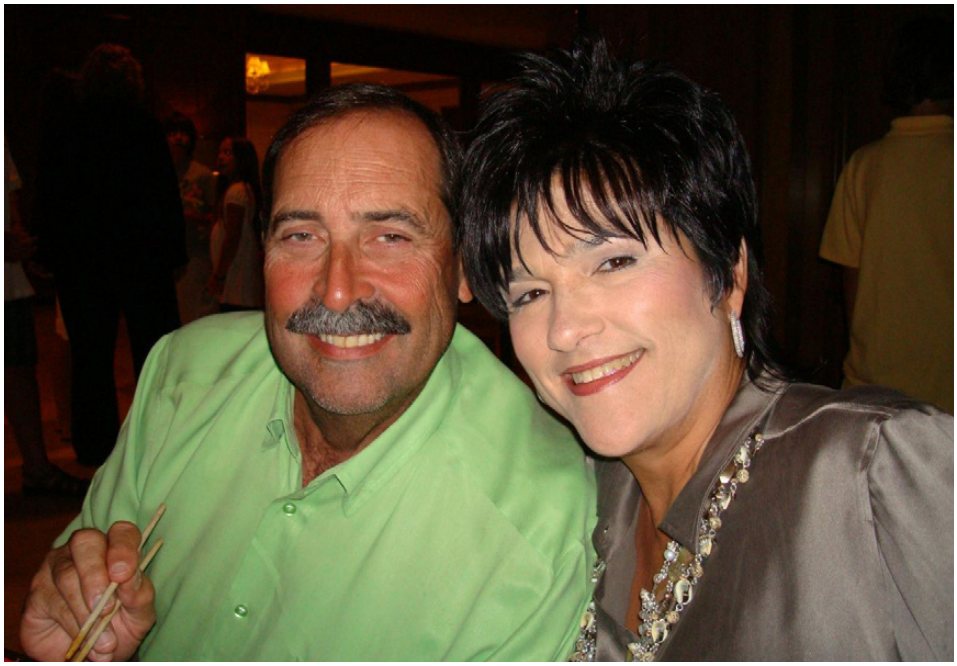
It is with a heavy heart that we pass along the news that one of the spine community's most beloved surgeons, Antonio (Tony) Castellvi, died suddenly this past Saturday morning. The cause of death, we understand, was a pulmonary embolism.

Dr. Castellvi is survived by his wife and best friend of 38 years, the wonderful Ramona, and their three children: Ramona Little, 36, Antonio "Cheech" Castellvi, 35, and Alejandro Castellvi, 30.

During the course of his career, Antonio E. Castellvi, M.D. played a very important role in expanding the understanding of motion preservation and became one of the leading experts in the field of preservation of motion. His research in this area led to numerous publications in both Spanish and English and podium presentations at more than 50 conferences and meetings nationally and internationally.

Dr. Castellvi was an honors graduate of the University of Zaragoza Medical School in Spain and completed his orthopedic residency at the University of South Florida, his spine fellowship at the University of Rochester.

Over the course of more than 30 years, Tony built a very successful practice focusing on cervical, lumbar or thoracolumbar problems, degenerative disease and deformity, scoliosis, reconstruction, spinal cord injury and motion preservation.



Dr. Castellvi with his wife, Ramona

Since 2005, Dr. Castellvi also served as course chair for Current Solutions in Spine Surgery in Hawks Cay, Florida—otherwise known as the "Duck Key Meeting." Tony's meeting was one of the highlights of the year for many researchers and practitioners. Additionally, he served as a board member of the International Society for the Advancement of Spine Surgery and is one of 10 members to review abstracts to determine which will be presented internationally.

Tony also found time to serve as an assistant professor at the University of South Florida and Director of Spine Fellowship at the Florida Orthopaedic Institute.

But what most of us who knew him will remember best is Tony, the man. He was bigger than life, full of passion for his patients, for the science, for his colleagues and above all for his family. The world is truly diminished with Tony gone.

The funeral Mass for Antonio E Castellvi will be Wednesday at 2pm at Christ the King. The wake will be Tuesday evening at 6pm at Christ the King Catholic Church at 821 S. Dale Mabry Hwy, Tampa 33609 with reception to follow.

Ever since word of Tony's passing began making the rounds, condolences and remembrances have been streaming in from everywhere.

Anyone who would like to give a gift in remembrance of the life of Antonio Castellvi is invited to donate to Christ the King Scholarship Fund (Elementary school) in Tampa Florida and to Tony's Foundation for Orthopaedic Research and Education (FORE).

Here are some of comments from his friends.

"Tony was a 'true innovator and thought leader in spine surgery and he always managed to do so with a smile on his face and a glad hand' My thoughts are with his family and friends." —*Tom Errico*

"When I think of Tony, I think of someone larger than life; he really loved life more than just about anyone I know. He was never shy with his opinion and never afraid to challenge conventional thought. I always thought of Tony as a clinician scientist—meaning he always thought about the patient and his/her outcome from a pragmatic view, yet he grounded everything he did in data and evidence. One thing I always loved about Tony is that you always knew where you stood with him. The spine community lost a real asset on Saturday. Thanks." — *Marc V.*

"Trained by Lou Goldstein and Don Chan. Tony's key paper was on transitional vertebra which was published in *Spine* 1984. He really enjoyed innovative spine technology." — *avid Polly*

"Tony's life was taken suddenly this past Saturday. He will be sorely missed not only as a leader in spine surgery but also as an innovator. His wonderful Duck Key meeting is one of the current great and one of my favorite spine meetings. His friendship, warm smile and laugh will remain in my memory forever. Our prayers and thoughts go out to his wife Ramona and his beautiful family." — *Richard D Guyer, MD; President, Texas Back Institute*

"This is Terrible news!!!!!! Colleagues were drawn to Tony by his kindness and outgoing warm personality. In addition to his commitment to his patients, Tony was an innovator, involved in the development and study of a number of novel spinal technologies. He was however truly in his element during his annual course in the Keys when he was leading clinical case discussions; challenging us to think critically and at the same time applying his ample common sense to solving clinical challenges. The spine world has lost a loyal friend, teacher, strong patient advocate and an outside of the box problem-solver." — *Frank M. Phillips, MD; Professor, Orthopaedic Surgery; Spine Fellowship Co-Director; Rush University Medical Center, Chicago IL*

"I am saddened to hear of Tony's passing. He made many important contributions to the spine surgery world, particularly in assessing new operative techniques for the treatment of common spinal disorders. His loss will be felt." — *Chris Bono*

"Tony was a wonderful husband, father, friend, physician, educator, inventor and perhaps most of all—a pleasure to spend time with. There was never a boring moment when with him. His laugh was contagious as was his enthusiasm for life with a focus on family, science and fishing. Tony will be sorely missed." — *Stephen Hochschuler*

"Tony was the type of surgeon who was passionate about his belief that motion preservation is a goal for spine procedures when feasible. More importantly,

he demonstrated his focus on this issue by including and not dismissing others who may have alternative methods to achieve this same goal. I have personally benefitted by Tony's friendship and his courses at Duck Key where education, recreation and camaraderie made this one of the most popular courses worldwide. Tony will be sorely missed by all of us." —*Tony Yeung*

"Tony is a gentle man who loved his family and his work. He is also a thrill seeker. He is both very private about himself but very open and generous to his friends. His achievement of establishing a yearly spine meeting in the Keys of Florida that attracted open dialogue on the progress of Spine Care and Surgery based on Sound Scientific grounds has become a must attend for many of us. His generous dedication of time and energy for ISASS will be much missed, but his example has already prompted many of his colleagues and friends to carry on. He will be missed by many of us, who has only fond memories of him."— *Hansen Yuan*

"The spine field has suffered another great loss today; Tony was a true leader, a great teacher and wonderful doctor for his patients. He will be sorely missed but he leaves the spine field richer due to his lifetime of work."— *Eric Muehlbauer, Executive Director, North American Spine Society*

"Dr. Castellvi was a charming, stimulating, and a great person to be around. There are those who take energy from us in interaction and those that give us energy and inspiration. Tony gave in abundance and will be sorely missed by all."—*Alex Lukianov, Chairman and CEO, NuVasive, Inc.*

"My son became a patient of Dr. Castellvi in Dec. /January 2013-14. As a former Surgical Technician in the Tampa Bay area I knew of his surgical expertise and was very relieved to know my son was in good 'hands.' From myself and family, we extend with much sadness, our deepest, sincere sympathy to his family. With much respect.
—*April Strouse & Family*

"My condolences go out to the Castellvi family. I had the great pleasure of working with him several years ago when I was a regional sales manager at a spine company. My thoughts and prayers are with all of you." —*John Conti*

"I don´t believe it…from Spain, all the spine surgeons are…I don´t know what is the appropriate word in English…Personally, Tony showed me a new view of medical decisions… His enthusiasm in his work and his family showed me a new perspective…His big smile and passion will forever be missed…

My family heart condolences go to his family… My little son…Juan, knew him 6 months later and doesn´t understand what's happened. He remembered him with a big smile and a respected friend of me. I´m sorry for my English." —*Dr. Rafael Ramos, Spine Service, University of Valladolid, Spain*

"I rarely read the newspaper but to pick it up on this rare occasion and be hit with this awful, awful loss is devastating to all of us who knew and loved 'Nuno'. My heart and tearful condolences go to his family and those who were lucky enough to cross his path. Sincere prayers." —*George Alvarez*

"Dr. Castellvi just performed spinal fusion on me a month ago. I could not have found a more brilliant physician and kinder gentleman than he. I feel lost without him in the follow up care I might need, but I feel even greater

sorrow in losing what felt like a true friend." —*Jeffrey Baker*

"My heart, too, is heavy with the loss of Tony. Even though I only had the pleasure of his presence a few times and at Cheech's wedding, Dr. Castellvi was beautiful in my eyes. Ramona, Jorge and the rest of your beautiful family, please know that this was God's will. Trust that his wonderful life on earth will continue through you." —*Cynthia (Billys) Olson*

"From all of us at Aurora Spine – We are deeply saddened by the death and loss of our friend Dr. Castellvi. His smile & passion will forever be missed." —*Trent Northcutt and Team Aurora*

"I have never met a finer gentleman than Dr. Castellvi. He allowed me to walk again on Sept. 9, 2013. I am proud of my 10"scar down my back, and will wear it with pride!" —*Mary Canedy*

"So sad to hear of the passing of such a great figure in our industry. Dr. Castellvi was always the quintessential gentleman to everyone he dealt with, regardless of their station in life. I knew Tony over the years as someone with whom I periodically worked as a distributor and rep. He always greeted me with his contagious ear to ear grin along with his full attention and respect. All of us in the industry will miss him as a great surgeon but even more importantly, as a great friend!" —*John I. Maynard*

"I have known Tony and his brothers Willie and Jochi since we were kids. We vacationed together with our families. Our children grew up together. Aside from all of his great accomplishments in spine surgery, his even greater accomplishment was that of a Father, Husband and friend. There will always be a void in my heart. I love you and miss you, my Brother. May God smile on you forever !!!!!" —*Luis Crespo, M.D.*

"Dr. Castellvi saved my life June 8, 2013." —*Frederico Pollicina*

"Dr. Castellvi was a perfect example of what a great spine surgeon should be. He achieved a good balance in life succeeding in all aspects of and prioritizing family, friends and patients. He was unique and will be missed." —*Frederico P. Girardi, M.D.* ♦

OTW has been asked to provide the following links for donations/condolences/remembrances, etc.

1. *Dr. Castellvi's obituary: http://bcmacdill.tributes.com/our_obituaries/Antonio-E.-Castellvi-99629899*
2. *In lieu of flowers, donations can be made as follows: FORE (Foundation for Orthopaedic Research & Education) Click on the link: http://foreonline.org/Ways%20To%20Give* **OR** *Christ the King Church on behalf of Tony Castellvi http://www.ctk-tampa.org/*

Court Rules Autologous Stem Cells Are Drugs—Final Ruling?

BY WALTER EISNER

A "Mixture" processed from a patient's own mesenchymal stem cells (MSCs), placed in a solution to culture and then combined with an antibiotic doxycycline and injected back into the patient, is a drug and therefore subject to FDA regulation.

But scientifically, that is a very difficult position to support. Which begs the question: Does bad science make good law?


United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT
Argued October 21, 2013
Decided February 4, 2014
No. 12-5254
UNITED STATES OF AMERICA,
APPELLEE
v.

U.S. District Court of Appeals

On February 4, 2014 the U.S. District Court of Appeals for the District of Columbia in the case of United States of America v. Regenerative Sciences, LLC ruled that Dr. Chris Centeno was indeed making a "Mixture" of autologous MSCs and that is a "drug" and therefore subject to FDA regulation.

Chris Centeno, M.D.

RRY Publications LLC

Chris Centeno, M.D. and his partners at Regenerative Sciences argued long and hard that their process did NOT create a "Mixture" but rather simply expanded the patient's own cells and was, therefore, the practice of medicine and regulated by individual state medical boards. Not the FDA.

In point of fact, Dr. Centeno had fully complied with the FDA ruling several years ago and was pursuing this very expensive litigation simply for the principal of the matter. His practice is unaffected by either the FDA's previous ruling or this court's ruling.

In view of what is scientifically correct and best for his patients, Centeno made the decision to use an antibiotic (doxycycline) during the culturing of the patient's own cells.

Most doctors' office in the U.S. have items that are combined with other items (mixtures) for injection that have travelled from another state to that doctor's office.

So, in Centeno's view, the principle at stake here is whether the FDA can regulate such common medical activities—especially if they are based on the physician's own medical and scientific training and judgment. The D.C. court may well have opened the door wide to just such micro-regulation.

FDA Warning and Physician Challenge

At a huge cost in time and dollars, Dr. Centeno fought his battle all the way up to the D.C. Circuit. He is not a wealthy man and this appeals court ruling may

be the last stop of a journey that started in 2008 when the FDA sent a Warning Letter to Regenerative.

The FDA charged that Regenerative's procedure violated 21 CFR 1271.1—FDA's human cell, tissue and tissue-based products (HCT/P) regulation—by running afoul of its "minimal manipulation" provisions and because the resulting stem cells were not "intended for homologous use only." Of course, it was a bit of a head scratcher to say that using a patient's own cells was not homologous use. But, given that interpretation, the procedure did not qualify as an HCT/P product and was therefore a drug.

The physicians of Regenerative disagreed and filed a lawsuit against the FDA in 2010 challenging the characterization of its Regenexx procedure. A July 2012 decision by the U.S. District Court sided with the FDA's interpretation of the regulations.

Centeno's Battle

Dr. Centeno and his partners appealed that decision.

"Since 2008, we have been challenging the FDA on whether a physician creating autologous, more than minimally manipulated cells (>MM) for his or her own patients was creating a drug or practicing medicine. This has always been an uphill battle, but one we felt was worth it as physicians do things everyday which should be regulated by FDA (if they weren't physicians). For example, if you mix drug A and B, technically you need an IND (Investigational New Drug Application) for a combination product. If you alter an existing surgical tool, you would need an IDE (Investigational Device Exemption)," Dr. Centeno told *OTW*.

He added, "Despite all of our efforts, the D.C. Circuit ruled that your little medical practice can be regulated like a Pfizer drug factory if you use more than minimally manipulated autologous cells. While we're not happy about their ruling, we fully accept that this is the law now that has been vetted by the courts and will do our best to follow it to the letter."

Centeno made it clear that not much changes for his practice as a result of this ruling since they haven't used >MM cells since 2010, the moment FDA took a formal position that the cells were a drug.

"This doesn't impact PRP (platelet-rich plasma) or BMC (bone marrow cells) right now, as these fall squarely into the <MM rubric. However, if you're creating adipose SVF (stromal vascular fraction) by using any method (ultrasound, collagenase, trypsin, etc.) that dissociates cells from tissue, it does apply. The D.C. Circuit opinion means that the novel theories about why many physicians believe their use of SVF isn't FDA regulated no longer hold water," said Centeno.

The Decision

Specifically, said the court, two statutes were violated, the Federal Food, Drug & Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., and the Public Health Service Act (PHSA), 42 U.S.C. § 201. The Regenexx "Mixture" did not satisfy the requirements of those laws and was therefore deemed "adulterated" or "misbranded."

"The text of those statutes forecloses" the argument that the Mixture is not subject to regulation said the court.

Defining Drugs and Biological Products

The FDCA defines a "drug" as any "article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body."

The PHSA defines "biological product" in similarly broad terms as any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative...or analogous product... applicable to the prevention, treatment, or cure of a disease or condition of human beings."

"Both of these wide-ranging definitions clearly apply to the Mixture, an article derived mainly from human tissue and intended to treat orthopedic diseases and to affect musculoskeletal function. Indeed, appellants do not actually dispute that the plain language of the statutes compels this conclusion," wrote the court.

The court said Regenerative was urging it to construe the FDCA "in light of purported federalism concerns." But, said the court, that lacked merit and Regenerative's arguments boiled down to the following syllogism: "the FDCA was not intended to infringe on states' traditional role in regulating the practice of

medicine; the Procedure fits Colorado's statutory definition of the 'practice of medicine'; therefore, the FDA's regulation of the Procedure exceeds the FDA's authority under the FDCA. This syllogism is flawed twice over."

Practice of Medicine v Regulating Drugs

First, said the court, Regenerative's legal argument "misapprehends what this case is about," by attempting to characterize this case as an effort by the FDA to "restrict the use of an autologous stem cell procedure." However, said the court, the focus of the FDA's regulation is the Mixture. "The FDA does not claim that the procedures used to administer the Mixture are unsafe; it claims that the Mixture itself is unsafe. Appellants' arguments about the practice-of-medicine exemption are therefore wide of the mark."

Second, the court added that Regenerative is, "wrong to suggest that the scope of the FDCA depends on state-by-state definitions of the 'practice of medicine.'"

"While the FDCA was not intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians." Regenerative's legal construction of the FDCA, added the court, by contrast, "would allow states to gut the FDCA's regulation of doctors, and thereby create an enormous gap in the FDCA's coverage, by classifying the distribution of drugs by doctors as the practice of medicine. Such a construction is not tenable."

Equally untenable, said the court, is Regenerative's contention that because the procedure occurs entirely within the state of Colorado, the Mixture lacks a sufficient connection to interstate commerce to permit federal regulation under the Commerce Clause.

Citing precedents dealing with the growing of marijuana and wheat for personal consumption, the court said the Mixture does "undoubtedly have effects on interstate markets for orthopedic care, [and] actually includes an article shipped in interstate commerce, namely, doxycycline."

"We therefore hold that, by virtue of its use of doxycycline, the Mixture is within the scope of drugs—and, by extension, biological products."

Failing the Minimal Manipulation Test

The court dismissed Regenerative's arguments that the Mixture is exempt from the FDCA's manufacturing and labeling requirements even if it is otherwise subject to federal regulation.

The FDA promulgated regulations to ensure the safety of [HCT/Ps] used for

therapeutic purposes in 2001. Those regulations define HCT/Ps, as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."

"HCT/Ps may qualify as drugs or biological products, and when they do, the FDA generally regulates them accordingly." However, noted the court, there is an exemption from regulation for any HCT/P that is no more than "minimally manipulated."

"Minimal manipulation" of cells means "processing that does not alter the relevant biological characteristics."

Regenerative claimed the exemption applied to the Mixture, while the FDA said culturing MSCs alters the genes and proteins they express.

To be fair, that notion that culturing MSCs alters genes and proteins is also scientifically difficult to support. Indeed, at *OTW*'s annual New York Stem Cell Summit, literally dozens of papers are presented annually which directly contradict the FDA's position.

Issues of Fact

The court gave Regenerative credit for creating a "genuine issues of fact" by submitting expert affidavits arguing that the government's views are based on scientific studies that do not apply to Regenerative's culturing process.

But, why let facts get in the way of an intended ruling. According to the court, Regenerative gave no response to other reasons offered by the government. "For example, appellants admit that the culturing process is designed to 'determine the growth and biological characteristics of the resulting cell population.'"

And in some cases, said the court, Regenerative added substances to the cell culture that "affect the differentiation of bone marrow cells."

"These concessions are fatal to appellants' attempt to claim refuge."

The court also claimed that Regenerative conceded that culturing MSCs affects their characteristics and offered no evidence that those effects constitute only minimal manipulation. Said the court; "they fail to carry that burden as a matter of law."

Compounding

Regenerative argued that the Mixture is exempt from the FDCA's manufacturing and labeling requirements because it is a compounded drug.

"A compounded drug must be produced using certain types of 'bulk drug substances,' one of which is 'bulk drug substances...that...are components of drugs approved by the [government]. Appellants assert that the Mixture meets this definition because cultured MSCs are a component of the FDA-approved drug Carticel."

But even if that were the case, the court said it would not be enough to meet the law. "To qualify as a 'bulk drug substance,' an item must be 'represented for use in a drug, and appellants point to no evidence in the record even suggesting that MSCs are held out for use in Carticel. Appellants therefore fail to establish that the Mixture is exempt from the FDCA's manufacturing and labeling requirements."

Adulterated or Not?

The FDCA provides that a drug "shall be deemed to be adulterated...if... the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice."

The court concluded, "It is undisputed that appellants' facilities, methods, and controls for processing the Mixture violated federal manufacturing standards in numerous respects. Therefore, the Mixture is per se adulterated, regardless of any other safety protocols appellants happen to use."

Civics Lesson

Is this the end of a very expensive civics lesson for Dr. Centeno? The court's ruling is still open to interpretation but initial word coming from the Centeno team is that they will not appeal any further. If this is the end of the legal fight, then perhaps it becomes a civics lesson. The courts, after all, only interpret the law, not make it. The court was very clear that they were not interested in making law in this case and that if a remedy exists, it lies with lawmakers in Congress. ♦

OP-1® IMPLANT from Olympus Biotech.

Still the first to market.
Still a safe and truly biologic solution.
Still the only BMP approved for long bone nonunions.

IMPORTANT SAFETY INFORMATION

HUMANITARIAN DEVICE

OP-1 IMPLANT is authorized by Federal law for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. The effectiveness of this device for this use has not been demonstrated.

Brief summary of contraindications and warnings:

- OP-1 IMPLANT is contraindicated in patients who (1) are pregnant (2) have or have had a malignancy (3) are skeletally immature (4) are pregnant or want to become pregnant within 2 years of treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.
- The use of OP-1 IMPLANT may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.
- There are no adequate well controlled studies of OP-1 IMPLANT in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

Please see the package insert for the complete indication, contraindications, warnings, precautions, adverse events and other important medical information.

Caution: Federal law restricts this device to sale by or on the order of a physician.

OLYMPUS®
Your Vision, Our Future

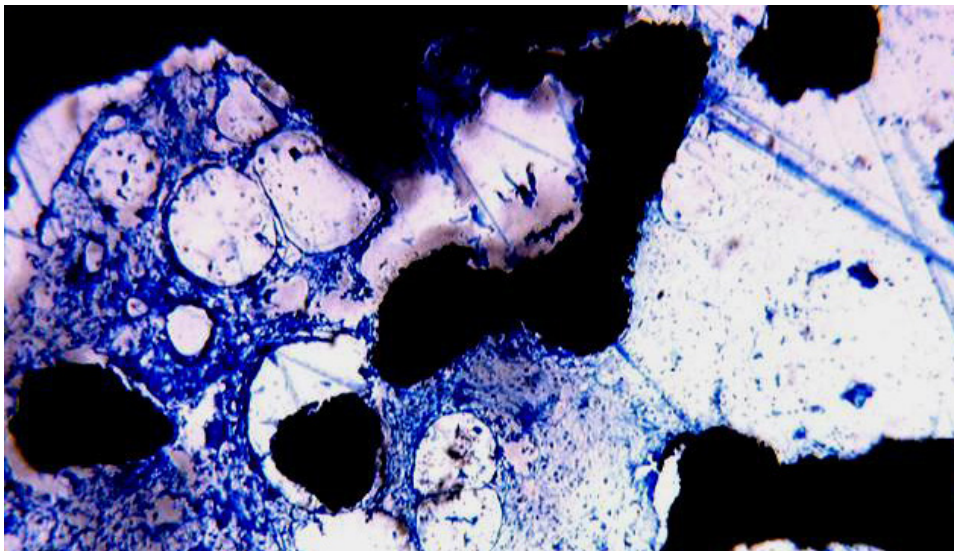
OLYMPUS BIOTECH CORPORATION
35 South Street, Hopkinton, MA 01748, USA
866-476-2663
www.olympusbiotech.com
PRB-056-13

OLYMPUS BIOTECH
Leading Regenerative Medicine

New Study: 95% Meniscal Allograft Survival Rate! // ACDF Non-Fusion Rate Higher Than Expected // Are Antibiotic-Containing Balls the Future of Infection Prevention?

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

New Study: 95% Meniscal Allograft Survival Rate! Failure is far from a given for those who undergo meniscal allograft transplantation (MAT). In what is the largest series in the literature, Brian Cole, M.D. and colleagues have just this week published information indicating positive results for those undergoing meniscal allograft transplantation. Dr. Cole, Professor in the Departments of Orthopaedic Surgery and Anatomy & Cell Biology at Rush University Medical Center, told *OTW*, "We looked at 200 patients who underwent MAT, 172 of whom were evaluated at 59 months with a minimum two year follow-up. Sixty-percent of these patients had a combined MAT with a concomitant articular cartilage procedure such as an osteochondral allograft. Our goal was to determine the indications for a second surgery after a meniscal transplant, as well as what would be likely to happen if people required a second surgery. Thirty-two percent required a second operation (due to scar tissue and/or persistent symptoms)."



Courtesy of the University of Texas Health Science Center

"There was a 95% allograft survival rate at five years; even those who had to undergo a second surgery fared well with an 88% survival rate (however they were at a slight increased risk of failure). This news helps us as far as educating people in this complicated patient group. These are typically individuals who have undergone multiple operations; our study helps us to better understand what the future looks like for these patients. We can now say to patients, 'Even if you undergo a meniscal allograft transplant—with or without a subsequent arthroscopic surgery—it doesn't mean it is going to fail."

ACDF Non-Fusion Rate Higher Than Expected That bone is fused, right? Look again, says Dan Riew, M.D. Dr. Riew is the Mildred B. Simon Professor of Orthopedic Surgery, Professor of Neurological Surgery, and the Chief of the Cervical Spine Service for Washington University Orthopedics and Director of the Orthopedic Cervical Spine Institute. He told *OTW*, "While non-unions following ACDFs are rare, because of the sheer volume of such procedures done in the U.S., many patients return post-operatively, saying that they are still experiencing pain. 'Impossible,' says the surgeon. You are fused.' But the surgeon is not looking carefully enough."

"Along with my colleague, Dr. K.S. Song, I recently published a paper on this topic, where we found that in order to properly diagnose a fusion on a CT scan following arthrodesis with a cage, you must look for bridging bone formation **outside** of the cage. If you just look inside, you will often see what appears to be bridging bone in patients who are not fused. This is the largest study in the literature with intra-operative confirmation of fusion status and conclusively shows that 'bridging bone' inside the cage is an unreliable sign of fusion. Doctors should learn how to diagnosis this because it is so easy to surgically fix non-unions and patients are so happy afterwards."

Revolutionary, Infection-Fighting Balls Little balls packed with antibiotics just might be the wave of the future for infection prevention, say research-

ers from the University of Texas Health Science Center at Houston (UT Health). Terry Clyburn, M.D., and Catherine Ambrose, Ph.D., have found that by coating porous metal implants with antibiotic-containing microspheres they could prevent infections in grossly contaminated wounds in a rabbit model. Dr. Ambrose told *OTW*, "Orthopaedic infections lead to extra surgeries and weeks or even months of antibiotic treatment. In addition, antibiotics that are taken systemically do not penetrate well into infected bone, and thus high doses of antibiotics are required, which can have serious side effects. Local delivery of antibiotics directly to the infected bone tissue is optimal, but when we started this research the methods for local delivery were limited. We wanted a local delivery system that was biodegradable and could deliver near linear doses of the antibiotic for the required length of time (at least six weeks). We anticipated that this type of drug delivery system would reduce the number of surgeries, decrease medical costs, and improve the effectiveness of antibiotics. Delivering the antibiotic in this way successfully prevented infection in 100% of the cases studied, resulting in an increase in implant integration."

Dr. Clyburn noted, "We sought to develop a means to deliver effective doses of antibiotics to the local tissues for a more effective duration, while not interfering with soft tissue or bone healing and without requirement of further surgery to remove the delivery agent."

Dr. Ambrose commented, "We were surprised to learn that a relative simple system worked well for this application. Our microspheres are actually only made from a few ingredients, and all of the ingredients are already approved by the FDA for use in humans. In addition, we discovered that if we create microspheres of the right size, then healthy bone would grow right around them to heal the patient's wound."

"The most unpredictable result," said Dr. Clyburn, "was that even when we directly contaminated a metal implant with Staph Aureus, that the antibiotic microspheres protected 100% of these implants from infection and allowed excellent ingrowth of bone into the implant. We certainly hope that we can show a similar result in protecting human implants from such infections!"

Dr. Ambrose stated, "Our work is unique as we have optimized the size and composition of the microspheres to cure bone infections and to allow the microspheres to be used around total joint replacements."

"Several researchers have sought solutions to this challenging issue," added Dr. Clyburn. "Most researchers have worked on applying a coating of antibiotics or bactericidal agents to implants which release over a very short duration. We feel that a more prolonged period of protection may be more beneficial."

"Getting approval from the FDA for investigation in human trials is the next step," says Dr. Ambrose. "Although each individual ingredient in the microspheres is already FDA-approved, the combine product still must undergo investigation."

Dr. Clyburn added, "We are exploring possibilities overseas where such studies are more easily performed."

Simon Lee, M.D. Presented With Award Simon, Lee, M.D. of Midwest Orthopaedics at Rush has been presented with the Community Leadership Award by the Chicago Health Executives Forum (CHEF) for his work with "Soles4Souls." Award recipients have worked to bridge the gap in the fragmentation of health care and delivery of services and have promoted education as a measure to strengthen communities.

In 2007, Dr. Lee helped to establish the Chicago-area chapter of Soles4Souls, a Nashville-based charity founded by a fellow foot and ankle specialist, that collects donated shoes from the warehouses of footwear companies to distribute to people in need. Every year since 2007, Dr. Lee has organized Chicago's annual year-end event called "Our Hearts to Your Soles," providing medical foot screenings for Chicago-area homeless men and women at the Franciscan House of Mary and Joseph on Chicago's west side.

Employees from Midwest Orthopaedics at Rush, as well as orthopedic surgery residents and medical students from Rush University, work under the supervision of Dr. Lee and his colleagues to examine and treat the feet of the overnight clients. This program provides homeless Chicagoans with relief for cold, wet, uncomfortable feet as well as a new pair of shoes and socks. It also educates the medical students and residents about the issues faced by the homeless and how they as medical professionals can help.

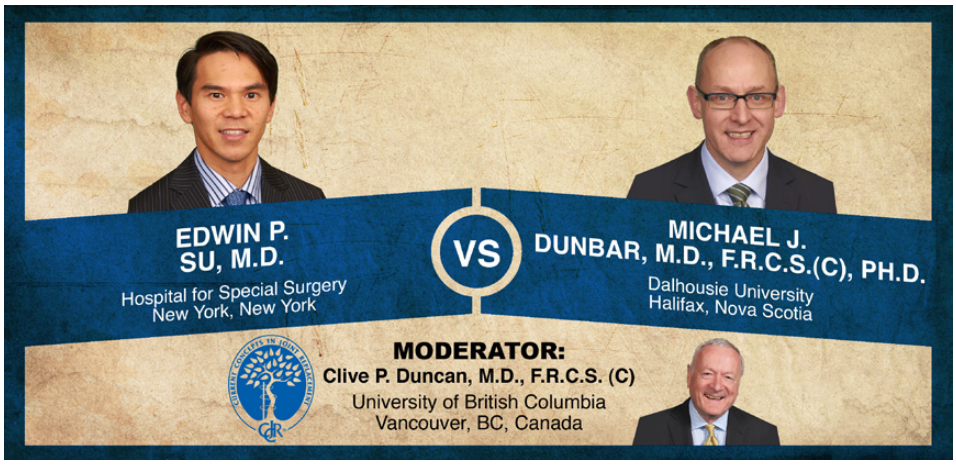
George Kalliolias, M.D., Ph.D. Awarded Sontag Fellowship George Kalliolias, M.D., Ph.D., a physician-scientist in the Division of Rheumatology at Hospital for Special Surgery, will be honored with this year's coveted Sontag Fellowship in recognition of his advancement of promising research in rheumatoid arthritis. Dr. Kalliolias was chosen as this year's Fellow from a class of 15 researchers who will be receiving grants from the Arthritis National Research Foundation (ANRF), in partnership with The Sontag Foundation.

Dr. Kalliolias' research is focused on inhibiting the joint destruction that is caused by inflammation in rheumatoid arthritis. Specifically, he is investigating the role of joint fibroblasts, important but little-studied players that represent a new and exciting potential therapeutic target for rheumatoid arthritis. ♦

Su Takes on Dunbar Over Surface Replacement

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

"Surface replacement provides several advantages over THR, including bone preservation, greater stability, and a higher activity level," says Edwin Su. Michael Dunbar disagrees, saying, "Resurfacing is more invasive, has worse outcomes, produces metal ions and pseudotumors, is hard to revise, and does not provide better function."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "Surface Replacement Arthroplasty: A Viable Option." For the proposition is Edwin P. Su, M.D. from Hospital for Special Surgery (HSS); against the proposition is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax, Nova Scotia. Moderating is Clive P. Duncan, M.D., F.R.C.S.(C) of the University of British Columbia.

Dr. Su: "A total hip replacement (THR) is one of the most successful operations ever devised, so we must have clear evidence as to why we might want to change that. The problem with THR is wear and osteolysis. If you look at the Swedish Registry—stratified by patient age—you see in young patients that at 10 years there is a dramatic decrease in the survival of these implants…with almost a 40% revision rate by 20 years."

"We also know that dislocation is an issue, and dislocation as a reason for revision is increasing. I think that is because patients are more active and younger. The challenge is doing a THR in young, active patients; their increased activity may lead to an earlier need for revision."

"The benefits of hip resurfacing are bone preservation, joint stability, better reproduction of natural anatomy, and it loads the bone more physiologically. And it may lead to a higher activity level for our patients. It is indisputable that hip resurfacing preserves femoral bone. We did a cadaver study to look at both the acetabular and femoral sides. One of the arguments against resurfacing is that it takes more bone from the acetabulum. But we found that this isn't true with modern implants. It also leads to a more stable joint."

"We know that in our patients dislocation can be an issue. Some surgeons were going toward large diameter metal-on-metal THR to solve that problem, but it's no longer being used in the U.S. So how to achieve stability in a patient that needs it? It is a more physiologic loading of bone. In a total hip it receives load from the top, it's transmitted through the stem, and is converted into hoop stresses. But a hip resurfacing would load the bone from the top into the femoral neck as it should be. And what will happen if you continually load a THR you can get breakage. With a hip resurfacing that's not possible."

"I think it also leads to a better restoration of normal hip mechanics. And some interesting data was presented at the International Society for Technology in Arthroplasty in 2012 by Haddad showing that the activity level in a group of patients randomized to either THR or hip resurfacing was higher in the latter group. Hip resurfacing in certain subgroups are performing well in national joint registries. If you examine the revision rate of hip resurfacing you see that females have a higher revision rate, almost double, than males. Let's look at the data by age stratification. For hip resurfacings in men under the age of 65, the 10 year results were a 6% revision rate for resurfacing; for THR—same age group—at 10 years it was 8% for males and females. The hip resurfacing group has a lower revision rate in this age population in males in Australia."

"This data can help us select patients who will have the greatest success with resurfacing, namely, men under 65 with primary osteoarthritis and a large femoral head size."

Dr. Dunbar: "In the UK from 2004 to'06 almost half of all patients under the age of 55 received a resurfacing, and it was almost a third in Australia. This was not the case in the Scandinavian countries. And I would implore this great nation to avoid this mistake."

"The primary thrust is that resurfacing is meant for the young male. We should drill down and look at the same slides in an opposite manner to see where this evidence comes from. The major advantage is survivorship. Is that true? In the Australian registry we find data on 12,000 patients; yes, it's the older patients that have a higher risk factor. But all-comers included, resurfacing has a worse outcome than primary THR. If you break that out, females come out a disadvantage, so perhaps at best young males are equivalent to a well done total hip. But there's no advantage in the literature for resurfacing over THR."

"The data from England and Wales is more profound, and discriminates itself better in terms of the fact that resurfacing is significantly worse than all other constructs in the UK. Even in the U.S. with early reports of the Durom there are high failure rates for resurfacing at five years. So this has not been a panacea to increase our survivorship."

"One of the reasons that survivorship is reduced is because of the generation of metal ions. It's a fact that if you use a metal-metal resurfacing you are more likely to produce metal ions. In a paper we did looking at an early series of resurfacing, we saw significantly elevated metal ions. What was more concerning was that those ions remained elevated after two years. We've been told in the past that with the bedding in these ions will abate, but this was not our experience. And we know that these ions can cause pseudotumors. A well done report on 129 patients from the Netherlands showed that 28% of patients at five years had some evidence of pseudotumor with MRI imaging."

"When you do use resurfacing, because of these metal ions, you get into difficult conversations with your patients, and difficult management treatment algorithms. If there is pain, you need to follow metal ions; you must collect serum and urine and that can be difficult to collect and interpret. If they're elevated and the patient is symptomatic you likely need cross sectional imaging, which is difficult to obtain because of the metal artifact. And you may need to revise the patient because of these high metal ions. Why would you want these headaches for something that's not going to give you a big advantage?"

"Another reason why we promote resurfacing is that it is less invasive

than THA. I believe this is false. In my experience this was THE most invasive procedure we had to do because you could not remove the femoral neck and head to get access to the acetabulum. It's a massive dissection because these are often young, fit males with large muscles. Some suggest that this has led to neck fracture. Also associated with this is the very unusual phenomenon of neck narrowing."

"With respect to preservation of the bone stock there's no question that you don't violate the femoral canal. But what's the evidence about the outcome of preserving this bone stock? Looking at the Australian Registry we see 397 cases of resurfacing that went on to failure and then were revised, what were the outcomes of those procedures? The revised cases—despite the preserved bone stock in the femur—did significantly worse than a primary THA."

"Some say large head can improve function, but where is the evidence? In a Charnley award winning paper (Lavigne, et al.) of head to head, randomized comparison of large head metal-metal total hip to resurfacing, there was no advantage to the resurfacing over the THR in terms of restoring biomechanics, gait, etc."

"If you think about it, yes, there is a larger femoral head with a resurfacing that may give you an advantage, it's not the femoral head by itself that's the issue…it's the ratio of the head to the neck. In some cases you have an advantage using a total hip with respect to ROM because the clearance is greater."

Moderator Duncan: "Ed?"

Dr. Su: "There are concerns with resurfacing with regard to the metal-metal bearing. It requires increased monitoring, timely discussions with your patients, and an understanding on their part that they will have elevation in their metal ion levels for their entire lives. But some of the data you presented from the registries…those were the population at large and they didn't stratify into the best patient scenarios. So that's where we can benefit from the registries, i.e., tailor our indications for the patients who are going to do the best."

Dr. Dunbar: "We do have to be very careful in interpreting the registry data because it can homogenize the data. But it does look at an entire nation's experience. To your point that it reduces the dislocation rate, I think that perhaps dislocation rate shouldn't be an issue in that if you do a high enough volume with the right approach and appropriate surgical technique, then dislocation is not a big issue. Instead, we've chased our tail trying to reduce dislocation rate by changing the implants. We're finding out that if we have a group of low volume surgeons using an implant that's supposed to be forgiving it actually turns out to be unforgiving because mal-positioning on a metal-metal resurfacing is what causes the runaway metal ions. The difference is that you're an expert on this technique; I don't do as many. We need to discuss the entire surgical audience who might take these on."

Moderator Duncan: "Mike, under what circumstances will you agree to do a surface replacement?"

Dr. Dunbar: "Someone who had had some sort of fixation previously within the femoral canal…or someone with a profound level of offset that you may feel you can't reconstitute with a typical or even an advanced implant. In that case I'd send them to a high volume resurfacing surgeon."

Moderator Duncan: "Ed, what is in the future in terms of technological and training advances that may allow us to revisit this with more enthusiasm (because it has waned in North America)?"

Dr. Su: "The challenge is to remove the metal from the equation, as well as remove the production of cobalt and chromium. In the past we've used metal-poly, however we didn't have highly crosslinked poly so they were subject to massive osteolysis. There are other material possibilities."

Moderator Duncan: "Tell us about your follow-up surveillance of these patients."

Dr. Su: "Those with a metal-metal resurfacing return annually; those with metal-poly hips return every five years. So those in the former category get annual X-rays and I monitor their metal levels at 1,3,5,7, 10 years. If it's above a certain level then I will get cross sectional imaging to look at the soft tissues."

Moderator Duncan: "So the femoral side fails. Are you going to leave the acetabular component alone and go with a metal-metal revision or revise both sides of the joint?"

Dr. Su: "In the past I've removed both components and revised the acetabulum. There is a dual mobility option… an off label option where we can use that large poly head to articulate with and save the socket."

Moderator Duncan: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Spring Meeting, May 18 - 21 in Las Vegas, Nevada.

COMPANY

Spine Market Up, Medtronic Loses Share

Medtronic, Inc.'s reported spine revenue was flat, on a constant currency basis, during the last quarter. Total spine sales were $744 million.

Core spine was also flat. A company announcement on February 18, 2014, said that if declining balloon kyphoplasty sales were excluded, core spine sales grew in the low single-digits. BMB (Infuse) revenue declined by 1%, as the business is seeing signs of sequential stability in underlying demand and faced a favorable comparison due to a supply constraint in the prior year period.

New Launches Expected

Management told analysts that the company expects to launch their next generation Prestige LP artificial cervical disc in the U.S. in summer 2014 and enhance their interbody and cervical plate offerings with a series of launches in the next fiscal year.

Losing Market Share

The company estimates the global and U.S. spine markets continued to show signs of stability.

Glenn Novarro of RBC Capital Markets, LLC, estimates that Medtronic lost 80 basis points of U.S. core spine market share, compared to a 50 basis point share loss in the last quarter.

Medtronic Spine 3Q14	Sales ($ in millions)	% Change*
Total Sales	**$744.0**	**flat**
Core Spinal	$631.0	flat
Biologics	$113.0	down 1%

Source: Medtronic, Inc.
** constant currency*

Spine Market Growing

Novarro said worldwide spine market growth appeared to be up approximately 3% during the quarter on a constant currency basis. "We believe the underlying health of the worldwide spine market was slightly improved on a sequential basis, owing to slightly better underlying U.S. spine market trends." He estimates that the U.S. spine market was up about 2% during the quarter, while international spine market growth was in the mid-to-upper-single-digits. He says NuVasive, Inc. was one of the largest U.S. share gainers in the quarter while DePuy/Synthes and Medtronic continued to cede market share.

After the Medtronic results, Novarro says he continues to see evidence pointing to a stable to slightly improving U.S. spine market. "However, part of the improvement in [fourth quarter] U.S. spine trends could have been due to a pull-forward of procedures to [the second half of 2013] from 2014, owing to Obamacare concerns. We saw this dynamic occur in other orthopedic markets like hips/knees. Accordingly, we will continue to look for evidence of a more sustainable uptick in U.S. spine market growth in 2014."

Medtronic, Inc.

—WE (February 20, 2014)

Stryker Buys Two Companies in February

Over the course of two days in February (18th and 19th), Stryker Corporation announced agreements to acquire Berchtold Holding, AG, and Pivot Medical, Inc. for the company's MedSurg and Neurotechnology division.

Berchtold, a privately held business in Germany and the U.S., sells surgical infrastructure equipment. The purchase price is $172 million. Pivot, is a Sunnyvale, California, privately held company that sells products for hip arthroscopy. No purchase price was provided for the Pivot acquisition in the press announcement.

According to the company release, Berchtold has been selling healthcare equipment for over 90 years and had sales of approximately $125 million in 2013. Their product portfolio includes surgical tables, equipment booms, and surgical lighting systems geared towards maximizing efficiency and safety in operating rooms and ICUs (intensive care units). Stryker said combining Berchtold's solutions with their own endoscopy operating room equipment portfolio "will create a comprehensive, quality-focused offering equipped to satisfy a wide range of customer needs around the globe."

The Berchtold acquisition is expected to close in the second quarter of 2014.

Pivot was founded in 2007 with a focus on hip arthroscopy procedures treating femoroacetabular impingement syndrome (FAI). Pivot has a platform of instruments and implants to access and restore mobility to the hip with minimal incisions.

Hip arthroscopy, according to Stryker, is the fastest growing procedure in sports medicine resulting from improved procedural solutions and growing demand for less invasive solutions.

Timothy Scannell, Stryker's group president, MedSurg and Neurotechnology, said the acquisition will allow Stryker to combine Pivot's "innovative platforms in hip arthroscopy with Stryker's knee and shoulder sports medicine solutions, and full line of arthroscopy visualization and tissue resection devices."

That acquisition is expected to close in the first quarter of 2014.

—WE (February 20, 2014)

Logos of courtesy of Stryker, Pivot Medical and Berchtold

Globus: 2013 Wrap Up and New Acquisition

Globus Medical, Inc. has announced preliminary sales results for 2013. The company anticipates fourth quarter 2013 sales of $115.2 million, a 14.6% increase over fourth quarter 2012. Full year 2013 estimated sales increased 12.6% over the prior year to $434.5 million, exceeding the company's previous guidance of $432 million. The company expects 2014 sales to be in the range of $480 million-$486 million.

Globus Medical, Inc.

Commented David Paul, Chairman and CEO of Globus, in the January 14, 2014 news release: "2013 was an outstanding year of execution, delivering innovative new products, and expanding our sales force, while delivering strong financial results. Our business remains robust, and our fourth quarter and full year performance in 2013 is a testament to the consistent and focused execution of our strategy. We believe we will continue to grow our business at rates significantly above the industry by innovating in rapid response to the needs of our customers and patients and growing our sales footprint on a worldwide basis."

The company is also announcing the acquisition of Excelsius Surgical, LLC, a company that is developing a next

generation surgical robotic positioning platform for spine, brain and therapeutic markets. The Excelsius Surgical system is a robotic surgical aid for navigating and facilitating surgical access, implant sizing, positioning and placement, and is designed to enable surgeons to perform procedures more quickly and with greater accuracy, safety and reproducibility than is currently available in the marketplace today.

"We are very excited by the strategic fit and potential of Excelsius Surgical. Our product development efforts focus on products designed to minimize tissue disruption, blood loss and surgical complications, and we believe that the use of advanced technology solutions, such as the Excelsius Surgical system, will enable surgeons to consistently achieve better surgical outcomes," said David Paul in the January 8, 2014 news release. "Recent trends in the adoption of navigation technology as well as advancements in imaging only serve to reinforce our belief that technology will play an increasingly greater role in surgery in the future. We believe that this acquisition positions Globus to be a leader in this important area."

The Excelsius Surgical robotic positioning system is being designed to integrate intra-operative digital imaging with a sophisticated robotic surgical assistant that maintains anatomical positioning during the surgery with sub-millimeter accuracy. The technology was developed in conjunction with Dignity Health's Barrow Neurological Institute at St. Joseph's Hospital and Medical Center in Phoenix, Arizona. Co-founders Neil R. Crawford, Ph.D., Associate Professor of Spinal Biomechanics at Barrow, and Nicholas Theodore, M.D., neurosurgeon and Chief of Spine Surgery at Barrow, led the development of the technology.

—EH (February 12, 2014)

FDA Denies FzioMed PMA

"We regret to inform you that your PMA (premarket approval) application is denied."

With those words on October 21, 2013, the FDA notified John Krelle, the president and CEO of FzioMed, Inc. that his company's Oxiplex Gel product will not be allowed in the U.S. The agency posted the letter on their website on February 10, 2014.

Regulatory Gauntlet

FzioMed filed their PMA application in August 2007. The agency's orthopedic panel met in July 2008 and voted to recommend against approval. The FDA then issued "not approval" letters in September 2008 and once again in January 2010. In October 2011, the company requested supervisory review by the Office of the Center Director of the not approvable decision. A letter issued on October 9, 2012, by William Maisel, M.D., on behalf of the Office of the Center Director, upheld the not approvable decision.

The company then chose to exercise the option to consider the October 9, 2012 decision letter to be a denial of approval of the PMA and requested an administrative review by filing a petition for reconsideration on November 5, 2012. On November 4, 2013, the company announced that FDA Commissioner Margaret Hamburg, M.D. approved their petition for an independent review of their PMA and a special Medical Devices Dispute Resolution Panel was convened. Then came the letter of denial.

According to the company, no jurisdiction other than the U.S. has ever denied an application for approval of Oxiplex, which has been available outside the U.S. for more than a decade. It is approved in 70 countries including the 28 member states of the European Union, The Russian Federation, Canada, and Mexico, as well as on the Continents of Africa, Australia, South America and Asia.

FzioMed, Inc and RRY Publications LLC

Letter of Denial

The letter of denial identified the reasons for denying the PMA and identified the measures necessary to make the PMA approvable. "In summary," stated the letter, "you have not provided a reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling."

The agency said additional confirmatory clinical evidence of device performance is needed to establish a reasonable assurance of the effectiveness of the device. The letter noted that the company's U.S. pivotal study failed to show a statistically significant and clinically significant difference in the overall treatment effect for Oxiplex.

The letter also noted that the FDA's orthopedic panel raised questions related to the safety of the device in the intrathecal space as well as the effect of the device on osteoid activity and local cytokine release. "You stated at the panel meeting that there are primate data and other ongoing studies that would address these concerns. However, to date, you have not provided these data to FDA for review," continued the letter.

FDA Requirements

The agency offered advice to the company when submitting further evidence in the form of additional clinical data that show a statistically and clinically significant treatment effect in the relevant patient population.

"The data may be from one multiple-arm study or from two separate studies, and should use a primary effectiveness endpoint of mean reduction from baseline pain to 6 month post-operative residual pain using a validated pain scale. To provide evidence of a reasonable assurance of effectiveness to support both or either indications, the study(ies) should demonstrate in the relevant patient population a statistically and clinically significant result of at least a 10% difference in the primary effectiveness endpoint, in favor of Oxiplex, when the mean difference between the groups is divided by the treatment effect in the control group. This assumes at least a 50% reduction in baseline to 6-month residual pain in the control group. Other primary effectiveness measures may also be acceptable. If you plan to leverage any prior clinical data, we encourage an assessment of the final device formulations to ensure comparability across important specifications."

According to the company, Oxiplex was studied in two U.S. FDA-approved Investigational Device Exemption (IDE) clinical trials, as well as two foreign confirmatory clinical studies in subjects undergoing spine surgery. The IDE pivotal study, which required more than five years to complete, found that subjects having both leg pain and severe preoperative back pain experienced a greater reduction in leg pain when treated with Oxiplex compared to undergoing surgery alone.

"The extensive body of peer-reviewed published literature on Oxiplex, as well as extensive commercial experience outside the U.S. in more than 340,000 surgeries, provides additional evidence of the safety and effectiveness of the device for use in conjunction with spine surgery," stated a company press release last November.

—WE (February 10, 2014)

LEGAL

AdvaMed Claims 165,000 Jobs Lost to Device Tax

The Advanced Medical Technology Association (AdvaMed) says the 2.3% medical device excise tax implemented on January 1, 2013, has cost America as many as 165,000 jobs.

Morguefile and RRY Publications LLC

The association conducted an electronic survey of all its members between November 14 and December 9, 2013. Approximately 15% (38 companies) responded. Those companies, according to a February 18, 2014 press release, account for approximately 40% of the domestic device sales revenues. Respondents were almost evenly divided between large and small companies, with 45% having sales below $100 million and the remainder with sales above this amount.

Of the responding companies 40% were currently not operating at a profit.

According to the report, the tax has led to direct employment reductions of approximately 14,000 industry workers and foregone hiring of 19,000 workers. Then adding in the indirect jobs tied to each industry job, the total climbs to the 165,000 job loss estimate.

The report also found that almost one-third of respondents said they had reduced R&D as a result of the tax. Almost 10% of respondents said they had relocated manufacturing outside of the U.S. or expanded manufacturing abroad because of the tax.

In terms of investment dollars, three-quarters of respondents said they had taken one or more of the following actions in response to the tax:

- Deferred or cancelled capital investments
- Deferred or cancelled plans to open new facilities
- Reduced investment in start-up companies
- Found it more difficult to raise capital (among start-up companies)
- Reduced or deferred increases in employee compensation.

"Medical technology provides tremendous value to patients and the U.S. health care system," said David Dvorak, president and CEO of Zimmer, Inc., and Board chairman of AdvaMed. "Americans deserve policies that encourage strong investment in medical devices in order to make advances that will help improve even more lives."

MassDevice reported on February 18, that the results paralleled some findings from a recent Emergo Group survey that similarly reported lowered R&D spending and job losses in 2013 as a result of the medical device tax. "The Emergo survey, however, also found that fewer medtech executives reported negative effects overall than had been expected. An increasing percentage reported that the tax had no impact on their company in 2013."

"Overall, the impact of the [medical device excise tax] is being felt by industry, but the impact seems to be less severe than depicted by the media and industry organizations," according to Emergo.

"Contrary to the claims of some of the proponents of this tax, companies are simply not able to pass the tax on and are not anticipating a windfall from expanded coverage," AdvaMed President & CEO Stephen Ubl said in a conference call with reporters.

Finding $30 Billion

Repealing the tax has been a challenge for AdvaMed because repealing the $30 billion in anticipated tax revenues must be made up somewhere else.

When asked about that issue during the call with reporters, *MassDevice* reported that Dvorak said the association was ambivalent about the funding source for repeal. "This is a new year and potential pay-fors are yet to be identified. We, frankly, believe that it's a matter that policy-makers ought to take on."

Former President Bill Clinton reportedly reiterated the importance of finding a pay-for, telling an audience last month that efforts to repeal the medical device tax must come with a strategy to make up the lost funds.

"You've got medical device people, they hate the tax," Clinton said during January's Patient Safety, Science & Technology Summit. "If you want to get rid of it you've got to say how you'd replace it."

The political will to repeal the tax is there as a large bipartisan group of lawmakers has signed up to sponsor such legislation. However, no one is volunteering to take cuts.

—*WE (February 19, 2014)*

Major and Sweeping Changes Planned for FDA

Like the British navy sailing to the Falkland Islands, the Food and Drug Administration (FDA) has been signaling that big changes are afoot in 2014 in how the agency will be reorganized.

In late 2013, the agency announced it would need to "realign" its programs to keep up with "unparalleled challenges" posed by advances in science, globalization and product complexity.

On February 4, 2014, *Regulatory Focus* writer Alexander Gaffney reported that FDA Commissioner Margaret Hamburg, M.D. has unveiled major and sweeping changes to the agency which will see the agency's many divisions reorganize in an attempt to "become more specialized and able to address increasing scientific and regulatory complexity."

He reports that in a memo to all heads of FDA's regulatory centers, Hamburg said that recommendations made by an internal "Program Alignment Group" (PAG) are being used to "chart a course for modifying Agency functions and processes to improve communications and collaboration and to clarify roles, responsibilities and decision rights across all agencies."

Commodity-Based and Vertically-Integrated

Hamburg said the PAG had unanimously recommended that the agency's regulatory and compliance activities "be organized around distinct commodity-based and vertically-integrated regulatory programs." In other words, paraphrased Gaffney, there should be agency-wide alignment around pharmaceutical quality, medical devices, biological products, bioresearch monitoring and food/feed products.

"These programs should have governance and budgets that ensure that resources are allocated and devoted to strategies, priorities and goals and that FDA speaks with one voice on policies and operations related to any given commodity," Hamburg explained.

All regulatory centers have until October 2014, to come up with an implementation plan.

Rise of ORA

Hamburg said that the Office of Regulatory Affairs (ORA) will be more fully aligned with centers, but at the same time will not lose operational, organizational or fiscal resources.

According to Gaffney, Hamburg noted PAG's endorsement of more specialized resources, saying that some medical devices have become so complex that it may require sub-specialists in one specific area just to be able to carry out effective oversight of a single manufacturer. This will require advanced training resources and new methods of management within ORA, she said.

Each center now develops its own annual work plan. But now, says Hamburg, the centers and ORA will share responsibility for "monitoring adherence to the work plan on a regular basis and will engage in regular communication and coordination to ensure that the work plan is accomplished."

More Specialization and ORA University

Compliance officers will also need to specialize in some regards, Hamburg said. "The goal should be to have a cadre of compliance officers across the Agency who have a similar level of technical expertise as the specialized investigators and who can work more closely with Center experts on complex scientific, manufacturing or other regulatory challenges," Hamburg wrote.

As such, training will be crucial to the endeavor, Hamburg continued. ORA will be coordinating with the various regulatory centers to come up with collaborative training plans, which will be administered through the "ORA University" training platform.

FDA Headquarters/FDA

Performance-Based Metrics

With respect to compliance, Gaffney wrote that Hamburg said the PAG had agreed that each center should be charged with constructing a new program-based work planning regime to base compliance activities on risk factors, public health outcomes, past inspectional history and operational experience. Those activities would then be tracked with performance-based metrics "clearly demonstrating public health and compliance outcomes," she said.

Hamburg said ORA will slowly evolve from a geographically-based model to one based on program or function. While this will call for commodity-specific offices and management, it will also require a separate plan, to be completed by June 2014.

Regulatory staffs and journalists love this stuff. Job security.

—*WE (February 13, 2014)*

Court Chills Reliance POD Alert Challenge

Chill out, dude, and don't bleed until you're shot!

That's in essence what a federal court in California told Reliance Medical Systems, LLC, on February 5, 2014, as it dismissed the company's constitutional challenge to the U.S. Department of Health and Human Services' Office of Inspector General's (OIG) March 26, 2013 Special Fraud Alert (Alert) on physician-owned distributors (PODs).

Reliance, which used to be involved in PODs, argued that the Alert "chilled" their right to speak to physicians about ownership in PODs. Reliance filed suit against the OIG on October 8, 2013, alleging that the Alert violated the First Amendment right of speech, due process rights under the Fifth and Fourteenth Amendments, and the Administrative Procedures Act.

But the Court didn't address those issues, simply saying that Reliance didn't have standing to challenge the Alert because they had not been harmed.

Specifically, the Court said the Alert had not been enforced in any way against Reliance. Thomas Bulleit and Peter Holman, of the law firm of Ropes and Gray LLP, said the Court made much of the fact that Reliance was not, at the time of the lawsuit, a POD, and, as such, could not conceivably have suffered any injury.

"Additionally, and perhaps most significantly, the Court rejected Reliance's argument that the [Alert] 'chilled' speech regarding formation of a POD, noting that all criminal statutes, by their very nature, may have a 'chilling effect' on personal behavior, but that such effect—which is merely part of an agency's authority to regulate economic conduct—does not amount to an actionable claim."

The lawyers say the case leaves unanswered how a court would rule if someone could demonstrate an injury-in-fact. For example, if an existing POD could show that the OIG imposed penalties pursuant to the Alert. "However, courts typically grant significant deference to administrative agencies in their interpretation of laws they are charged with administering, and thus the [Alert] is likely to be viewed simply an exercise of OIG's authority to interpret and implementing regulations. Thus, any injury to a POD in an enforcement action would be due to its alleged violation of the Anti-Kickback Statute, as interpreted by the applicable agency, and the [Alert] itself could not be the cause of the injury."

—*WE (February 12, 2014)*

Wikimedia Commons

LARGE JOINTS

One-Bill Joint Surgery Growing

Is the practice of charging one inclusive payment for surgical services, sometimes called "bundled payments," the future of joint replacement surgery? Executives at Blue Cross Blue Shield of North Carolina (BCBSNC) and the surgeons at Triangle Orthopaedic Associates (TOA) believe that it is.

Instead of billing separately for the surgeon, hospital, physical therapist, anesthesiologist and others, the two organizations, since 2012, have cooperated to provide for one-bill replacement surgery for knees. And on November 1, 2013, they began offering the same flat fee bundled terms for hip replacements. The surgeries are performed at North Carolina Specialty Hospital in Durham.

BCBSNC spokespersons Elaine Daniels and Lew Borman told *OTW* that insurers are moving away from the traditional fee for service reimbursement model to one that involves paying for a service. Both said they saw this system as the wave of the future in funding joint replacement. Daniels said that when they began paying a flat fee for knee replacements, they "expected to see positive results with this. Instead", she said, "the results have been transformative."

Among the positive results seen in knee replacement surgery were average cost savings of more than 22%, outcomes better than national benchmarks, a reduction in avoidable complications as compared to other total knee replacements performed in North Carolina and a patient satisfaction rating of 97%.

Wikimedia Commons

"The cost of a hip replacement surgery and follow-up care in North Carolina can range from $22,000 to $52,000, and the prices of many surgeries aren't always available to patients when surgeries are scheduled," said Brad Wilson, BCBSNC president and CEO. "This lack of transparency drives up health care costs more than $100 billion in the U.S. each year. Our new agreement with TOA takes the guesswork out of paying for hip replacement surgeries. The one-time payment will be 10-20% less than the average cost of hip replacements in North Carolina."

Under the agreement between BCBSNC and TOA, customers will pay TOA a one-time fixed rate for hip replacement surgeries rather than receive multiple bills. Officials of both firms say that this approach, also known as coordinated care, improves efficiency, reduces unnecessary paperwork and ultimately lowers health care costs.

The agreement between BCBSNC and TOA covers all appointments and care occurring during the inpatient stay, including the total hip replacement surgery and care related to any complications and all related post-operative care for 90 days after surgery, including physical therapy and follow-up care received at TOA.

"We know this approach to care works from the results we're already seeing from our knee replacement agreement," said Thomas A. Dimmig, M.D., president of Triangle Orthopaedic Associates. "We are pleased to work with BCBSNC again to bring another high quality, lower-cost orthopedic surgery option to BCBSNC customers."

Blue Cross and Blue Shield of North Carolina delivers health care products, services and information to more than 3.74 million members, including approximately 1 million served on behalf of other Blue Plans. The company was recognized as one of the World's Most Ethical Companies by Ethisphere Institute in 2012 and 2013. The company is an independent licensee of the Blue Cross and Blue Shield Association.

—BY (February 13, 2014)

EXTREMITIES

Shoulder Replacements Gain on Knees, Hips

Hip and knee replacement surgery has gotten most of the attention in recent years. But total shoulder replacement is coming into its own. Maureen Salamon, *HealthDay* reporter, writes that Mayo Clinic researchers have found that 93% of arthritis patients who underwent a total shoulder replacement needed no further surgery on their joints a decade later. Both sides of these patients' shoulder joints were replaced. For patients who had a partial shoulder replacement the success rate a decade later was 88%.

The study author, John Sperling M.D., an orthopedic surgeon at the Rochester, Minnesota clinic published his findings in the *Journal of Shoulder and Elbow Surgery*. He told Salmon, "We were most happy to see the consistency of pain relief and improvement of function among patients. Shoulder replacement has come a long way over the past 20 to 25 years. It's a one-hour surgery that requires one night in the hospital, and patients have a 90% chance of achieving excellent pain relief."

The comparison between the numbers seeking knee and hip replacements and shoulder joint replacements is striking, given that all three joint surgeries are driven by the same problem—pain and a loss of function caused by rheumatoid arthritis. About 53,000 Americans underwent shoulder replacement surgery in 2011 compared to more than 900,000 who had hip or knee replacements.

Sperling said that the surgery calls for a 4 to 6 inch incision in the upper shoulder region to allow for the removal of the diseased joint and its replacement with a plastic or metal joint. He said that it is a one-hour surgery that requires only one night in the hospital.

Wikimedia Commons and Leonardo DaVinci

Salamon quotes Anthony Romeo, M.D., a professor of orthopedics and director of shoulder and elbow surgery at Rush University Medical Center in Chicago, who said that Sperling's study provides "tremendous insight" into the results of shoulder replacement, a treatment that, he said, costs about $30,000.

"Shoulder replacement has really found its place on par with hip replacement and knee replacement," Romeo said." I hear very frequently of patients saying they're nervous about having a shoulder replacement because they've either never heard of it or it's so rare they're wondering how it can be a good option. I try to reassure my patients that this operation is as effective as hip or knee replacement. Shoulder replacement has moved to become a very predictable, reliable operation."

—BY (February 11, 2014)

REIMBURSEMENT

ACO's Big Savings as CMS Expands Bundled Payments

Medicare saved more than $380 million in 2012 through Medicare Accountable Care Organization (ACO) initiatives, Pioneer ACOs, Physician Group Practice demonstrations, and expanded participation in the Bundled Payments for Care Improvement Initiative.

Center for Healthcare Quality and Payment Reform

The Centers for Medicare & Medicaid Services (CMS) announced the savings on January 30, 2014, in an interim financial report. On the same day, the agency also announced a big expansion of Bundled Payments Initiative.

Health and Human Services Secretary Kathleen Sebelius said the findings demonstrate that "organizations of various sizes and structures across the country are working with their physicians and engaging with patients to better coordinate and deliver high quality care while reducing expenditure growth."

Medicare Shared Savings Program

The results for the Medicare Shared Savings Program ACOs show that, in their

first 12 months, nearly half (54 out of 114) of the ACOs that started program operations in 2012 already had lower expenditures than projected. Of the 54 ACOs that exceeded their benchmarks in the first 12 months, 29 generated shared savings totaling more than $126 million.

In addition, these ACOs generated a total of $128 million in net savings for the Medicare Trust Funds. ACOs share with Medicare any savings generated from lowering the growth in health care costs while meeting standards for high quality care.

Kenneth Wilkins, M.D., president of Coastal Carolina Health Care said their experience has shown that ACOs can increase quality while lowering costs. "As a result of the programs we've initiated, our patients have experienced better access to their primary care physician, higher quality measures, and fewer trips to the hospital." John Chessare, M.D., president and CEO of the Greater Baltimore Center Healthcare System said the Shared Savings Program is a "tangible reminder of the historic transformation taking place in our health care system."

Pioneer ACOs

An independent preliminary evaluation of the Pioneer ACO Model—the ACO model designed for more experienced organizations prepared to take on greater financial risk—also released data which shows Pioneer ACOs generated gross savings of $147 million in their first. Results showed that of the 23 Pioneer ACOs, 9 had significantly lower spending growth relative to Medicare fee for service while exceeding quality reporting requirements. These savings far exceed findings from a previous analysis conducted by CMS, which used a different methodology.

Barbara Walters, M.D., executive medical director for accountable care, with the Dartmouth-Hitchcock ACO, said she was encouraged by these results. "Our strategies of using patient outreach and education and regular follow up for targeted chronic disease programs are allowing us to anticipate patient needs before their health problems become worse."

Physician Group Practice Demonstration

CMS also released results for the Physician Group Practice Demonstration initiatives, which offered incentive payments for delivering high-quality, coordinated health care that generates Medicare savings. Those results confirmed, according to CMS, overall savings over the 5 year experience with 7 out of 10 physician group practices earning shared savings payments for improving the quality and cost efficiency totaling $108 million over the course of the Demonstration.

Big Bundled Payments Expansion

In addition to announcing the ACO cost savings, CMS also announced that 232 acute care hospitals, skilled nursing homes, physician group practices, long-term care hospitals, and home health agencies have entered into agreements to participate in the Bundled Payments for Care Improvement Initiative. Bundling payment for services that patients receive across a single episode of care, such as heart bypass surgery or a hip replacement, is one way to encourage doctors, hospitals and other health care providers to work together to better coordinate care for patients, both when they are in the hospital and after they are discharged.

The agency says this is the largest and most ambitious test ever of a bundled payment model in Medicare or any other payer in the U.S. Through this initiative, made possible by the Affordable Care Act, CMS will test how bundled payments for clinical episodes can result in more coordinated care for beneficiaries and lower costs for Medicare.

Final performance year-one results will be released later this year.

—WE (February 11, 2014)

Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

WRITERS

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Senior Writer
bgwy@msn.com

ADVERTISING

Tom Bishow
Vice President of Sales
tom@ryortho.com

PRODUCTION

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web, & Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
www.ryortho.com