VOLUME 7, ISSUE 19 | JUNE 14, 2011

Orthopedics This Week

week in review

4 **Senate Looking at Physician Distribution Companies** ◆ A bipartisan group of U.S. Senators want the Office of Inspector General to investigate the growth of Physician-Owned Distributorships and let them know if federal legislation is needed to keep them legal and ethical. Some POD owners agree. Read what the Senators found in their own investigation.

8 **Final Norian Chapter Unfolds** ◆ Last week lawyers for four senior orthopedic executives asked for leniency before a U.S. District Judge as he considered how much (if any) jail time he would impose for their part in the 2003 Norian bone cement debacle. We know these guys and they are good people.

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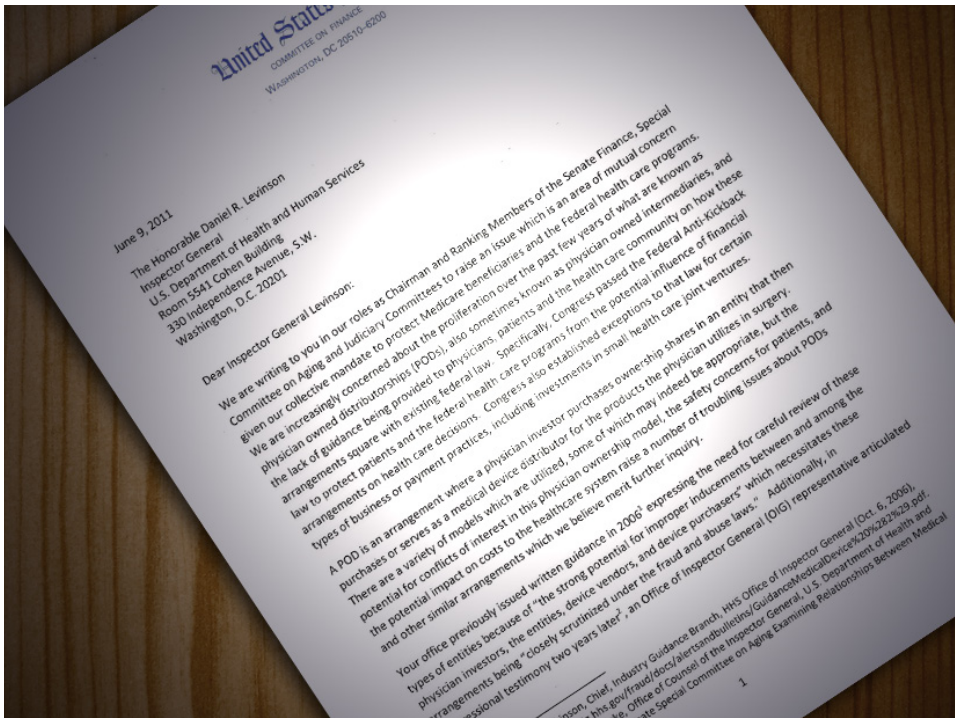

picture of success

25 **One Ortho Entrepreneur's China Venture, Part II** ◆ Whatever you do, don't give the first toast at a Chinese dinner if you're not the host. Peter Slate, CEO of Bonono Orthopedics, discusses why these things matter and how to operate in the Chinese business environment.

breaking news

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Stryker Pays Premium for Extremity Company

Medtronic Confirms Spine **Pink Slips** in Memphis

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Chocolate Milk Tops Gatorade, Really!

Huge Joint **Arthroplasty** Disparities

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For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Is the U.S. economy heading for a double dip recession? Stubbornly high unemployment is probably the single most powerful external influence affecting orthopedic implant demand. With CMS budget cutting and a generally tighter reimbursement environment, Wall Street ortho equity buyers have moved to the sidelines.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Orthofix	14.72%	8.82%	Lowest P/E to growth rate and a thoroughly diversified global ortho platform. Back to #1.
2	3	NuVasive	6.84	4.97	NUVA is down 12% in the last year yet sales for 2011 rising 12%—2,400 basis point gap between perception and reality.
3	5	Zimmer	27.75	(9.10)	Hit an air pocket this past week but ZMH remains the 3rd best value equity in ortho. Up two spots.
4	6	Johnson & Johnson	26.33	0.14	Synthes' Forteo deal with Eli Lilly reminds us that surgery and pharma are joined at the hip. Will soon join JNJ. It's called synergy.
5	1	Alphatec	-2.01	3.68	Looks like profit taking after a three-month run. Equity will probably mark time to AANS and NASS meetings this fall.
6	4	Stryker	25.23	(5.93)	Increased dividend 20% to $0.18 per share. That's the good news. Made an acquisition, no one got excited, that's the bad news.
7	8	Smith & Nephew	22.8	(5.91)	Wound healing becoming the new "hot" category. Can SNN get Wall Street to take notice?
8	NR	Kensey Nash	34.24	0.93	Buys troubled Norian from Synthes for $22 big ones. It's accretive. Estimates rise. Back on the Power Rankings.
9	10	Symmetry	8.08	(7.09)	Key to SMA is profit margin and rate of new product development. Both could rise due to recent reorganization.
10	NR	Wright Medical	8.76	(4.55)	Dead cat bounce or bargain hunting? More buyers than sellers for WMGI these days.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Orthovita	VITA	$3.83	$295	35.34%
2	MAKO Surgical	MAKO	$29.19	$1,196	12.83%
3	RTI Biologics Inc	RTIX	$2.83	$156	9.69%
4	Orthofix	OFIX	$39.87	$720	8.82%
5	NuVasive	NUVA	$33.60	$1,333	4.97%
6	Tornier N.V.	TRNX	$26.93	$1,051	4.79%
7	Alphatec Holdings	ATEC	$3.38	$301	3.68%
8	Synthes	SYST.VX	$174.95	$20,780	3.65%
9	Kensey Nash	KNSY	$23.80	$203	0.93%
10	Exactech	EXAC	$17.86	$234	0.22%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$1.44	$45	-18.75%
2	Bacterin Intl Holdings	BONE	$3.71	$141	-12.71%
3	Integra LifeSciences	IART	$45.61	$1,303	-11.66%
4	Medtronic	MDT	$38.02	$40,658	-9.58%
5	Zimmer Holdings	ZMH	$62.86	$12,067	-9.10%
6	ConMed	CNMD	$26.14	$740	-8.60%
7	Symmetry Medical	SMA	$8.91	$324	-7.09%
8	CryoLife	CRY	$5.35	$149	-5.98%
9	Stryker	SYK	$58.17	$22,570	-5.93%
10	Smith & Nephew	SNN	$53.19	$9,493	-5.91%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$38.02	$40,658	11.59
2	Kensey Nash	KNSY	$23.80	$203	13.52
3	Johnson & Johnson	JNJ	$66.09	$181,162	13.71
4	Zimmer Holdings	ZMH	$62.86	$12,067	13.88
5	CryoLife	CRY	$5.35	$149	14.46

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$33.60	$1,333	40.00
2	ArthroCare	ARTC	$32.33	$883	27.17
3	Synthes	SYST.VX	$174.95	$20,780	22.87
4	Wright Medical	WMGI	$14.68	$573	22.58
5	Exactech	EXAC	$17.86	$234	20.77

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$39.87	$720	0.91
2	Kensey Nash	KNSY	$23.80	$203	1.03
3	Exactech	EXAC	$17.86	$234	1.14
4	NuVasive	NUVA	$33.60	$1,333	1.20
5	Symmetry Medical	SMA	$8.91	$324	1.29

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Alphatec Holdings	ATEC	$3.38	$301	2.91
2	CryoLife	CRY	$5.35	$149	2.85
3	ConMed	CNMD	$26.14	$740	2.27
4	Johnson & Johnson	JNJ	$66.09	$181,162	2.07
5	ArthroCare	ARTC	$32.33	$883	1.69

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$8.91	$324	0.90
2	RTI Biologics Inc	RTIX	$2.83	$156	0.94
3	ConMed	CNMD	$26.14	$740	1.04
4	Wright Medical	WMGI	$14.68	$573	1.10
5	Exactech	EXAC	$17.86	$234	1.23

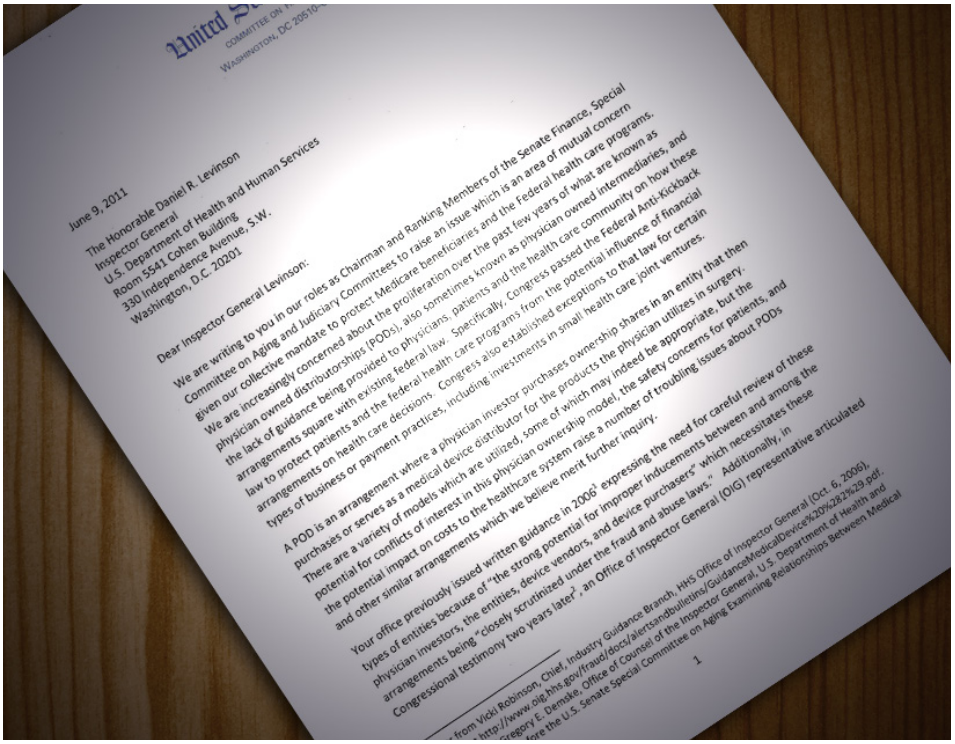
Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	MAKO Surgical	MAKO	$29.19	$1,196	26.99
2	TiGenix	TIG.BR	$1.44	$45	18.64
3	Bacterin Intl Holdings	BONE	$3.71	$141	7.56
4	Synthes	SYST.VX	$174.95	$20,780	5.64
5	Tornier N.V.	TRNX	$26.93	$1,051	4.62

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

Senate Looking at Physician Distribution Companies

By Walter Eisner



Levinson letter

On May 17, we reported that the U.S. Senate was looking into Physician-Owned Distributorships (PODs).

On June 9, a bipartisan group of Senators officially called for an investigation by the Office of Inspector General (OIG) into the structure of PODs and the, "lack of guidance being provided to physicians, patients and the health care community." Their call comes on the same day the American Association of Surgeon Distributors (AASD) announced the formation of their trade association.

POD Physicians Applaud

"I applaud the Senators' interest in obtaining regulatory clarity and necessary oversight for this model and look

John Steinmann D.O.

forward to the opportunity to meet with members of interested Senate committees to convey a balanced perspective on this model," said John Steinmann, D.O., widely regarded as one of the founders of the POD movement, in a statement to *OTW*.

Steinmann says he also applauds the efforts of the AASD, "which has worked very hard to establish standards governing the ethical and legal operation of this model. Accreditation by AASD provides recognizable assurance of compliance, quality, and protection of patient interest, similar to accreditation for hospitals and surgery centers."

The AASD told *OTW* on June 9 that is also supports the Senators' action.

The POD Market

PODs have captured somewhere between 10-15% in the U.S. of the

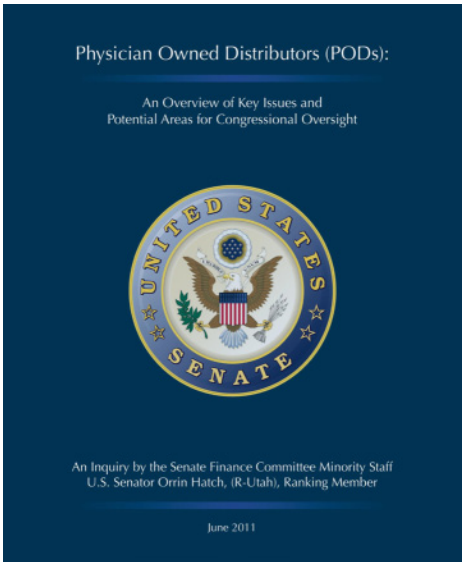
$9.6 billion spinal hardware market, according to Wells Fargo analyst Larry Biegelsen in a June 9 investor note.

A Senate Finance Committee analysis for Republican Senator Orrin Hatch, the Ranking Member of the committee, identified at least 20 states with multiple PODs that appear to be operational. Over 40-plus PODs have been identified in California alone. "In particular, there seems to be a marked increase in rural areas where the POD distributor model is being used very aggressively," said the analysis.

The request for the investigation was in the form of two letters to Donald Berwick, M.D., Administrator of the Centers for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services (HHS) Inspector General Dan Levinson, JD. The requests came after the Hatch analysis was released on June 9.

Hatch Analysis: Overutilization and Unnecessary Surgeries

The Hatch analysis claims to have identified several instances where the utilization for spine refusions or total joint surgeries spiked significantly in areas after the PODs were established.



United States Senate

Senators Charles Grassley, Orrin Hatch and Max Baucus/Hatch Senate Website

Hatch's analysis cites anecdotal evidence about unnecessary surgeries, including a surgeon who "provided examples to the Committee of elderly patients in a POD area who were receiving eight to 10 fusions in their back despite the serious health risks posed by these procedures." Hatch also noted patients who "died from multiple operations" and a more than 300% increase in spinal re-operation rates at one hospital following the creation of a POD in the area.

The letters requesting the investigation were signed by Democratic Senators Max Baucus, the Chairman of the Senate Finance Committee, Herb Kohl, Chairman of the Special Committee on Aging and Republican Senators Hatch, Bob Corker (Ranking Member of the Special Aging Committee), and Chuck Grassley (Ranking Members of the Judiciary Committee).

The Confusion Conundrum

The letter to Inspector General Levinson said, "There is much confusion in your office's stance on PODs as there is confusion in the health care community about how to arrange these in a legal manner. Until there is clarity, inappropriate versions of these entities could continue to proliferate, potentially driving up medical device costs to the Medicare and Medicaid programs putting patient safety at risk."

Lawyers for PODs say there is no confusion and the government has already chosen not to ban PODs.

On August 19, 2008, CMS, in 73 Fed. Reg. 48,727, wrote, "We are not adopting the position that physician-owned implant or other medical device companies [are entities to which physician may not refer if they have an ownership interest]").

"Accordingly," wrote Hooper Lundy attorney Charles Oppenheimer in a May 20, 2011 letter to *OTW* (after we called for more regulatory clarity on the subject), "PODs remain permissible under the Stark law, if properly structured and operated, so as to satisfy the indirect compensation arrangement exception." Oppenheim wrote the 2008 CMS statement was given in response to a comment from, "a 'large medical device manufacturer' effectively seeking to ban PODs under the federal physician self-referral statute (the 'Stark law')."

Oppenheim wrote the government has "chosen not to ban PODs, despite the efforts of [the law firm] Hogan Lovells, on behalf of the large medical device companies it represents, to shut down healthy competition from PODs, because these large device companies are threatened by the POD business model, which is saving hospitals millions of dollars compared to more traditional medical device distribution channels."

The OIG Letter

The Senators tell Levinson that it appears that over the last 18-24 months there has been a "substantial" growth of PODs.

"Curiously, this follows...a marked fifteen fold increase in the number of spinal fusion surgeries from 2002-2007." The Senators say further analysis is required to determine whether these developments are related.

In spite of POD attorney Oppenheim's assertion that there is no confusion about the government's position on PODs, the Senators say, "there is confusion...about how to arrange these in a legal manner." Until then, "inappropriate versions of these entities could continue to proliferate."

The Senators worry that the government's existing OIG guidance, "which is largely focused on physician-owned providers of ancillary healthcare services...is not adequate to protect against the risk of PODs abuse." As a result, the letter says some PODs are being structured "in very haphazard ways."

August 12 Deadline

The Senators want Inspector Levinson to report back to them by August 12 on the results of his inquiry looking into current POD structures and activities, along with recommendations for further action and whether or not the issue requires further legislation.

They are especially interested in an analysis of operational and legal issues.

POD Models

Some PODs, according to the letter, "appear to have appropriate frameworks," but there are, "far more which are operating in a manner that appears to be unethical and illegal...We are most concerned about allowing such activities to operate without additional guidance and oversight."

The Hatch analysis cites, as an example, "if a POD was not permitted to do business with its own investors, their partners, or affiliated hospitals, presumably they would be acting as a traditional distributor and not be able to profit from their usage or the usage of other physician investors. However, even this

structure would not prevent two separate PODs from using each other's products as a means to circumvent these rules."

The analysis also notes there are many different structural twists on POD models and the following are some of the many examples of the variations on the POD models identified by the Committee:

- Every physician investor receives a percentage of the money that their surgeries generate for the POD;
- Each physician investor is compensated equally, irrespective of his or her individual usage;
- An individual physician investor's usage is carved out from the profits he or she receives, but receives profit from the other physician investors' usage;
- The POD's product use is limited to procedures that are not federally reimbursable;
- The POD is organized to sell devices designed by the physician investors;
- The POD includes a shell, or second corporation/entity (i.e., a construction company), which is used to facilitate payment to the physician investors so as to avoid direct payment from the POD that is selling the products to its physician investors; and
- PODs that span multiple states such that physician investors from each state only profit from physician investor usage in the other state.

The letter includes over 30 specific questions that asked about the background of PODs, legal and investment issues.

Self Compliance and Standards

Steinmann said he and his colleagues have reviewed Hatch's analysis and subsequent letters to CMS and HHS and are confident they have addressed each of the issues identified by the Senators.

Steinmann concluded, "Despite the large orthopedic companies' fierce and well-funded opposition, our distributors have created millions in annual savings that could not have been obtained by the hospitals without this model, achieving this result with FDA cleared, quality medical devices from U.S. manufacturers and without a shred of evidence of inappropriate utilization. Our model embodies exactly what the U.S. government is asking of physicians in healthcare reform—which is to align with hospitals and innovate means to reduce healthcare costs while preserving quality and safety.

"Our compliance program along with the Standards set forth by the AASD should go a long way in providing government protection against abuse while preserving what has proven to be the most effective method to control costs associated with medical devices."

Senator Hatch says his analysis of the financial incentives created by PODs, show a "dangerous precedent [that] can lead to serious overutilization and force unnecessary, invasive procedures for patients. This arrangement demands further scrutiny and should be investigated."

We'd like to introduce Dr. Steinmann to Senator Hatch when the doctor comes to Washington. Sounds like they agree to the need for POD clarity. ◆

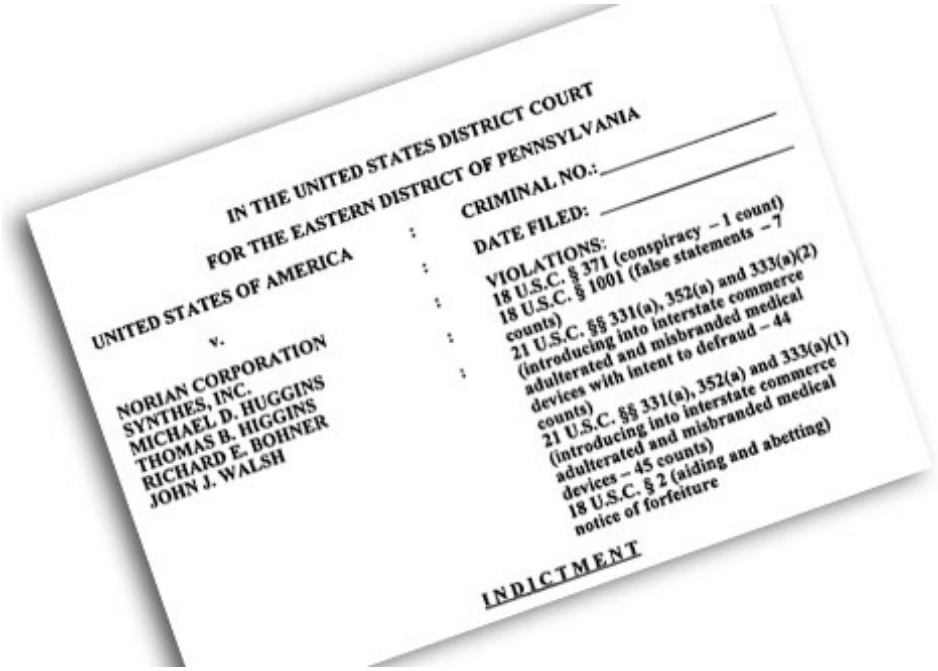
Click here to read the Levinson letter.

Final Norian Chapter Unfolds

By Robin Young and Walter Eisner

Last week lawyers for four senior orthopedic executives asked for leniency before U.S. District Judge Legrome D. Davis as he considered how much (if any) jail time he would impose for their part in the 2003 Norian bone cement debacle.

The four former Synthes executives are Mike Huggins (former President of Synthes North America and, later, President of Synthes Spine), Richard Bohner (former Vice President of Operations for Synthes Spine), John Walsh (former Director of Regulatory and Clinical Affairs of Synthes Spine) and Tom Higgins (former President of Synthes Spine and later Synthes Vice President of Global Strategy).


IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
UNITED STATES OF AMERICA : CRIMINAL NO.:
: DATE FILED:
v. :
NORIAN CORPORATION :
SYNTHES, INC.
MICHAEL D. HUGGINS
THOMAS B. HIGGINS
RICHARD E. BOHNER
JOHN J. WALSH
VIOLATIONS:
18 U.S.C. § 371 (conspiracy – 1 count)
18 U.S.C. § 1001 (false statements – 7 counts)
21 U.S.C. §§ 331(a), 352(a) and 333(a)(2) (introducing into interstate commerce adulterated and misbranded medical devices with intent to defraud – 44 counts)
21 U.S.C. §§ 331(a), 352(a) and 333(a)(1) (introducing into interstate commerce adulterated and misbranded medical devices – 45 counts)
18 U.S.C. § 2 (aiding and abetting)
notice of forfeiture
INDICTMENT

Synthes

All four pled guilty in mid-2009 to misdemeanor count #97 (shipping adulterated and misbranded Norian XP in interstate commerce) which carries a penalty of up to one year in prison and a $100,000 fine.

What Went Wrong?

Synthes acquired Norian Corporation in July 1999. Norian at the time was a Cupertino, California-based start-up company founded by Stanford professor Brent Constance. His invention was an injectable, resorbable, calcium phosphate bone cement.

About the same time four miles north of Norian's offices another company, Kyphon Inc., was revving up to enter the market for vertebral compression fracture (VCF) repair with a unique delivery system for bone cement in the spine. In 1999 the dominant bone cement was acrylic polymethylmethacrylate (PMMA)—which was being used off-label in the spine fairly routinely.

Between 1999 and 2001, Kyphon's sales grew from $261,000 to $36,073,000. Kyphon's biggest risk was that its business relied on PMMA cement,which was not *at the time* approved for use in the spine (by April 2004, the FDA had cleared a PMMA for use in vertebral bodies). Furthermore PMMA is exothermic and does not remodel to bone.

Could an injectable calcium phosphate, like Norian, solve the PMMA problem for Kyphoplasty procedures?

Adapting Norian SRS for Vertebroplasty

In the spring of 2000, say prosecutors, Synthes Spine's product development team interviewed orthopedic surgeons and others who used PMMA off-label to treat VCFs. How can Synthes improve on PMMA with its new injectable calcium phosphate? One idea was to incorporate radiopaque barium sulfate into the calcium phosphate to make it easier to see on X-rays. This new formulation was called Norian XR.

Norian XR was cleared for sale by the FDA in 2002 as a medical device to treat bone voids or defects in the skeletal system. Synthes marketed Norian XR from 2002 to 2004, selling only around 200 units and booking total net sales of approximately $400,000.

In the meantime, Kyphon's annual sales into the VCF market rocketed to $213 million.

Unfortunately for Synthes Spine, the marketing clearance granted by the

FDA stated that Norian XR was not intended for use in the spine.

Finding the Path to the VCF Market

The prosecutors argued that the company recognized early on that there were two possible ways to get Norian XR into the VCF market. One was to ask the FDA to approve XR for use in VCR treatment and go after an investigational device exemption (IDE) to test the safety and efficacy of XR. Or, two, Synthes could arrange for surgeons to try Norian XR in VCF procedures through a limited so-called "test market," during which Synthes could evaluate the safety and efficacy of the product.

The federal prosecutors argued that this second path was illegal and that the Synthes executives knew it.

By late summer 2002, said the prosecutors, Synthes had approached certain spine surgeons and asked them to use Norian SRS in VCF procedures as part of an initial Synthes "test market."

An email sent by a Synthes regulatory employees on or about August 23, 2000, to several of the indicted execs said, "[a]s everyone is well aware, I hope, we do not have a spine indication for Norian SRS at this time." The email went on: "recently reviewed a vertebroplasty 'Test Market' forecast for Norian SRS and equipment sent from the spine PD…Regulatory is unaware that this is even being considered. We cannot promote the use of SRS for unapproved indications, and this is especially true for use in the spine, where the FDA has previously made it clear to Norian that any intra-spinal use would require additional approval…We are aware that the spine PD group has been considering developing a delivery system which could be used for vertebroplasty with any substance and which would therefore only be able to be used or promoted for use with autograft or allograft at this time. Such instruments would be Class I – Exempt. However, any suggestion on our part that the instrument could be used with SRS would be considered promotion of an unapproved use of SRS."

Synthes

The "Test Market" Campaign

Despite these warnings, said the indictment, the company conducted two XR "Test Market Kick-Off" surgeon meetings, and one surgeon forum from August 2003 through mid-January 2004, training approximately 52 spine surgeons to use Norian XR to treat VCFs.

Huggins, Higgins and Bohner attended the first surgeon meeting on August 15 and 16, 2003, held in San Diego with spine surgeons selected by Synthes. Lectures and PowerPoint presentations were presented by Synthes executives and attending surgeons regarding the use of Norian XR in vertebroplasty to treat VCFs. A lab was held during which the surgeons injected Norian XR into the vertebral bodies of cadavers.

A second training meeting was held in Charlotte, North Carolina, on September 19 and 20, 2003.

Patient Deaths

Sometime around June 2002 clinical investigators at the University of Washington informed Synthes and some of the defendants that they had found that the calcium contained in Norian SRS had a unique interaction with blood, providing both a surface on which clots could form and a chemical stimulus to clot formation. The pilot studies further showed dramatic clotting of a pig's lung veins following injection of a small amount of SRS.

Six months later, December 19, 2002, the FDA cleared Norian XR as a general bone void filler with a label stating that XR was intended to fill only bony voids that were "not intrinsic to the stability of the bony structure" in the extremities, spine and pelvis, and further warning that XR was "not intended for treatment of vertebral compression fractures."

One month later, January 13, 2003, a spine surgeon used SRS that had been back-table mixed with barium sulfate in a surgery using Synthes's Cavity Creation instruments on a patient who became immediately hypotensive and died on the operat-

ing table. The doctor could not rule out the barium plus Norian SRS as a cause of death.

Nine months after the first patient death, on September 19, 2003, another spine surgeon used Norian XR with the Synthes Cavity Creation instrument. The patient in this case also suffered a hypotensive episode and died. In this case the doctor noted a cement leak and believed that it was the cause of the episode and could not rule out Norian XR as a cause of the death.

Throughout this period there were intensive meetings, emails and discussions at Synthes about the causes and responses to the patient deaths. Prosecutors alleged that Synthes and the defendants considered, but ultimately rejected, the idea of recalling or removing XR from the market.

Three months after the second death, on January 22, 2004, another spine surgeon used Norian XR to treat a VCF and, again, a hypotensive event occurred leading to a pulmonary embolism. This patient also died and, again, the doctor could not rule out Norian XR as a cause of death.

FDA Inspection

The FDA was watching and conducted an unannounced inspection at the Norian plant in West Chester, Pennsylvania, from May 11 through June 18, 2004. At the close of the inspection, the FDA's investigator issued a "483" report saying, among other things, that Synthes did not submit an IDE application to the FDA prior to initiating the Norian XR "test market" and that Synthes had shipped Norian in interstate commerce for the purpose of use in vertebroplasty or kyphoplasty to treat fractures of the vertebrae, an indication for which Norian XR had not been cleared or approved by the FDA.

Synthes

Guilty Pleas and Sentencing

The U.S. Attorney's office also initiated an investigation and brought indictments against Synthes and these four senior executives in June 2009. Before summer ended that year, the defendants had entered guilty pleas.

Sentences will be handed out in the coming days or weeks. Jail time is possible. Synthes corporate paid a $23.5 million fine and was ordered to divest Norian—which they did earlier this year to Kensey Nash for $22 million.

Lessons

Every aspect of this story is tragic. What if...If only...What were we thinking?

Punishment started in 2003 for these former Synthes executives and has been continuing if not increasing ever since. Sentencing could, in some sense, be anti-climatic.

"For 'tis not in mere death that men die most." – Elizabeth Barrett Browning

There are lessons in this story for us all. Bottom line, despite withering competitive pressures and as much as we may tug and fight with the FDA, every company and executive must abide by the letter and spirit of the FDA's rules. Which, of course, we all know. But in middle of the battle, it can be easy to forget.

To do otherwise is to risk falling into the abyss. ◆

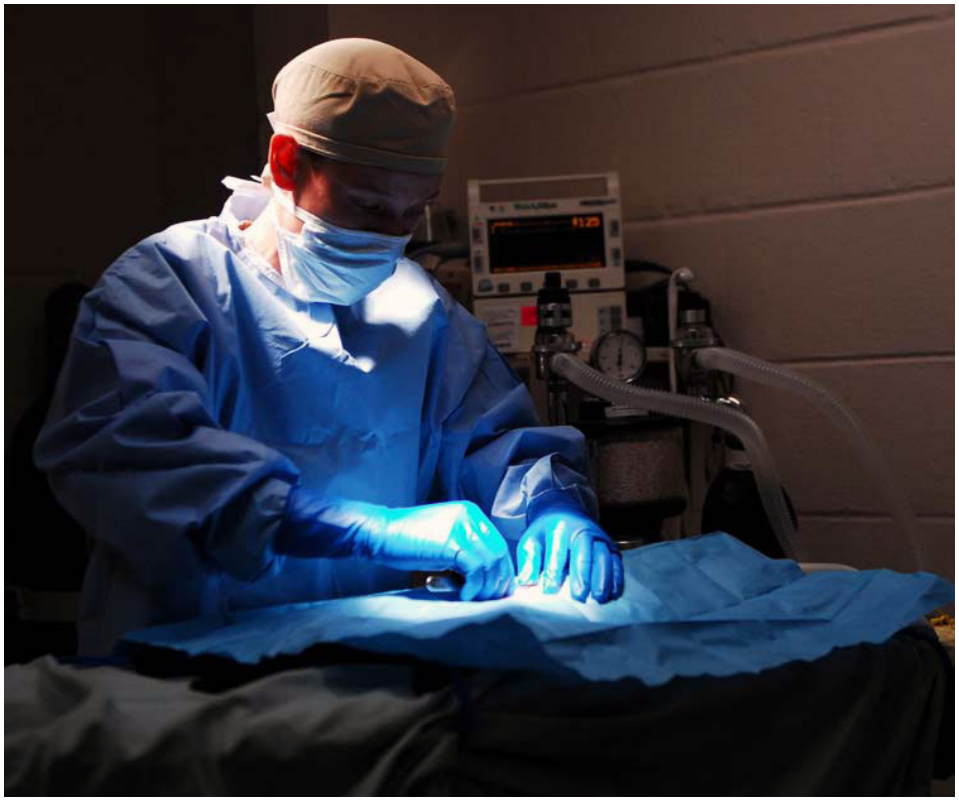
The Benefits of an Orthopedic Trauma Room

By Elizabeth Hofheinz, M.P.H., M.Ed.

"My craniotomy trumps your closed fracture!"

Well, you won't hear those *exact* words, but the fact is that there are many such behind-the-scenes issues that can cause tension between hospital staff—especially if your institution does not have a dedicated orthopedic trauma room.

Dr. Philip Wolinsky is a traumatologist with the University of California at Davis Medical Center who set out on a mission: do a literature review and establish the benefits of having an orthopedic trauma room. The goal was to provide concrete information, both for surgeons whose hospitals may be debating the merits of their existing trauma room, and for those who want to convince their hospitals to add one. Dr. Wolinsky presented his findings at an instructional course lecture at the 2011 meeting of the American Academy of Orthopaedic Surgeons.



Michael Baltz/Wikimedia Commons

He notes, "Trauma rooms have changed the way orthopedic trauma surgeons practice. In the past, an emergency case such as a craniotomy could get into to the OR quickly and the elective cases were scheduled when they could be. But what to do about the patient with a broken tibia? It doesn't have to be done post haste, but it can't wait six weeks… those cases were traditionally hard to get on the OR schedule. Yes, they could be done in the middle of the night or during the day; but for the latter option you would have to bump other elective cases or cancel clinic, neither of which are good options for the surgeon or patient. As a result of this and other deterrents, trauma was not a popular career choice for orthopedists."

Dr. Wolinsky, a reviewer for the *Journal of Orthopaedic Trauma*, says, "Now that trauma rooms are growing in number things are quite different. For example, if you look at the number of applicants to trauma fellowships, they have skyrocketed over the last three or four years. Trauma has become a popular career path, to a large extent because adding a trauma room provides numerous work benefits—not to mention that it is easier on one's home life. When I first started as a resident there were young surgeons covering trauma just so they could get their practices up and running. In effect, they were using trauma coverage as a bridge and then once they became established as, say, a sports medicine specialist, they would say, 'I'm not getting up in the middle of the night anymore for cases that aren't real emergencies. No more trauma call for me.' Then you get into the problem where the hospital is routinely left with inexperienced surgeons because the veterans are opting out. Obviously, that is not ideal for patients."

Back to those semi urgent cases. Dr. Wolinsky states, "If you have a patient with a broken tibia, but you do not have a trauma room then the person has to stay in the hospital until you can get

"No one wins when you're doing a case at 3am with a team that can't find the equipment and isn't up to speed on the implants."

U.S. Navy photo by Mass Communication Specialist 2nd Class Chad A. Bascom/Wikimedia Commons

OR time. Let's say I am a sports medicine specialist who has to cover call—and my week is already scheduled with office hours, elective cases, etc. If someone with a tibia fracture comes in you can't do it the next day because the elective time is booked. You can try to do it after hours but that is when the hospital is less staffed…*and* you are competing with appendectomies, neurosurgery cases, etc. And guess whose non-urgent tibia fracture is way down on the list?"

"That surgery is either going to carry over to the next day or the hospital is going to call you at 3am and you have to do the procedure then. You shake your head and say, 'Hey, I'm only going in to do this surgery at 3am because it's convenient for the hospital. I'm not at my best and that isn't the best for the patient.' It's a spiral…and you don't have to look far to see why trauma call isn't popular."

Dr. Wolinsky, who says he would "never ever" work at a hospital that didn't have a dedicated orthopedic trauma room, details, "Hospitals claim that trauma care doesn't generate income, but a 2008 *Journal of Orthopaedic Trauma* study conducted by Heather Vallier, M.D. on a level one trauma center demonstrated that in fact trauma was generating income for the hospital."

Beyond this talking point, there are the very real issues of staffing and equipment that arise when there is no orthopedic trauma room. "Ideally, you would have surgeons and nurses who are interested in and accustomed to these cases. And the knowledge level/experience of the staff is important as well…you really need people who know how to locate equipment and which piece goes where. This is especially important now that cases are getting more complicated and the equipment is often more involved."

Elaborating, Dr. Wolinsky notes, "No one wins when you're doing a case at 3am with a team that can't find the equipment and isn't up to speed on the implants. What usually happens is that the equipment is taken away at the end of the day to be cleaned. And the night staff, individuals who cover *all* specialties, may not know how to find what you need in Central Supply…your case just got longer."

So what else can trauma surgeons point to when talking to reluctant hospital administrators? Dr. Wolinsky: "A 2006 study by Timothy Bhattacharyya, M.D. showed that the addition of an ortho-

"If I choose to operate in the middle of the night it's not clear if that is any better for that patient's outcome. But I do know that if I do it in the middle of the night I will be fatigued the next day and by 3 or 4pm I am burning out my daily reserve of energy. If I look at this issue philosophically I think, 'Maybe I am helping one person in the middle of the night, but I'm probably not helping people much the next day."

pedic trauma room resulted in fewer elective cases being bumped, a 72% reduction in hip fractures done after 5pm, and resulted in decreased operative time and a reduction in complication rates."

Which brings us to what definitely makes (anyone) sit up straight…liability issues. "Trauma patients are often young men who engage in risky behaviors, and whose situation may involve drugs or alcohol. Compared to the elective surgical population, these folks are often times underinsured or uninsured. And while it has not been documented that these patients are more likely to file a lawsuit, the fact is that surgeons worry about litigation. This is yet another reason to have a dedicated room where you can get these patients treated expeditiously and with a knowledgeable staff."

"Mr. Jones is in room 12." No, he's not… and he never was. Dr. Wolinsky delves into the details: "Booking patients into an OR can be mayhem at times. With a 'regular' OR, the surgeon has a set day/time by which he or she must book a patient. If they don't then the time slot is given away; the idea with a trauma room is that the time is more flexible. Without a trauma room a patient may come into the ER at 4am on a Monday, but our OR time gets released at 6am (meaning that you only have until 6am Monday to book cases for that day). There have been times when people booked fictitious patients into a room in order to hold it open—and then put real people in later. With a dedicated orthopedic trauma room, however, there is no danger of this. Your day will change based on what comes in the door…you have the flexibility to keep changing the cases."

Dr. Wolinsky's article, which has just been accepted for publication by the *Journal of Orthopaedic Trauma*, is balanced. He notes, "There are potential disadvantages to having a trauma room. One issue is that it may be easy to put *all* cases off until the following morning; this is especially the situation when you have a clinical problem that is unresolved in the literature. For example, we do not know definitively if an open fracture needs to go to the OR immediately. Is it the timing of the debridement or the quality that makes a difference as far as getting an infection…is 2am better than 7am? It can be tempting to say, 'Well, I probably don't need to do anything in middle of the night."

Taking a global perspective, Dr. Wolinsky says, "If someone with a low grade open fracture comes in at 2am you can either operate in the middle of the night or first thing at 7:30am. If I choose to operate in the middle of the night it's not clear if that is any better for that patient's outcome. But I do know that if I do it in the middle of the night I will be fatigued the next day and by 3 or 4pm I am burning out my daily reserve of energy. If I look at this issue philosophically I think, 'Maybe I am helping one person in the middle of the night, but I'm probably not helping people much the next day.' If I keep doing this I will reach the point where I say, 'It's not worth it.' And if all trauma surgeons were to do that we as a country would have a serious problem."

Imagining himself in a patient's gown instead of a white coat, Dr. Wolinsky says, "There are a lot of people who come in at midnight with problems that we know can wait until 7am. If you were the patient, wouldn't you want the guy operating on you to be the one who has had a good night's sleep, and where the nurses are prepared and all of the right equipment is in place? I would want the 7am surgeon." ◆

company

Medtronic Confirms Spine Pink Slips in Memphis

Medtronic made it official on June 6 when the company informed the State of Tennessee that it had laid off 82 employees in Memphis in late April and early May.

The company announced earlier in the year that it was planning to eliminate 2,000 positions worldwide. The company eventually eliminated 1,700 positions. The 82 jobs in Memphis are at the company's struggling Spine and Biologics division. The company reported a 2% drop in revenues during the last quarter, driven by a 9% decline in Kyphon revenue.

According to a company spokesperson reported in the *Memphis Commercial Appeal*, Medtronic employs approximately 1,500 people in Memphis and has no plans for additional layoffs.

The spokesperson said the reduction was not completely done through layoffs. Some were through a "combination of cost-saving measures, expense controls and voluntary programs," like an early retirement program and voluntary severance program.

He said the company was doing this because Medtronic continues to experience softening in some of its core markets, including the spine market. The company believes those markets are growing at 3% to 4% , down significantly from the single, high-digit growth the company saw a few years ago and had to adjust their infrastructure to meet current growth expectations.

—WE (June 10, 2011)

Photo manipulation by RRY Publications LLC/Medtronic and morgueFile.com

Stryker Pays Premium for Extremity Company

It's been a busy 2011 for Stryker Corporation.

On June 6, the company announced an agreement to acquire France-based extremity product developer, Memometal Technologies S.A. for $150 million in cash, with up to an additional $12 million in milestone payments.

This comes on the heels of acquisitions of Boston Scientific's neurovascular business and Orthovita. The company also sold its OP-1 business and played musical chairs with ortho chief Mike Mogul leaving the company and Kevin Lobo taking over, first, the neuro/spine business and then getting put into Mogul's vacated chair. The company also reorganized itself into three divisions: Orthopedics, Neuro/Spine and Medical Surgical.

Memometal's Nitinol

Memometal develops, manufactures and markets products for extremity indications based on a proprietary

Stryker Corporation and Memometal Technologies

method for preparing and manufacturing a shape memory metal alloy. The company's products include devices for the foot and ankle as well as the hand and wrist market. With sales in 2010 of roughly $30 million, the company says Memometal's, "differentiated, comprehensive and proprietary product portfolio" will allow Stryker to gain broader access into the fast growing extremities market.

Nitinol is an alloy of nickel and titanium and is frequently used in medical devices. Mizuho Securities analyst Mike Matson wrote that Nitinol exhibits the properties of shape memory (it can return to its original shape after deformation upon reaching a specific temperature) and superelasticity (elasticity 10-30x normal metal). Matson added, "In addition to enhancing Stryker's extremities offering, we think that Stryker should be able to apply Memometal's Nitinol expertise across its other orthopedic implant product lines (particularly in trauma and spine) and potentially even in areas of its MedSurg businesses."

Matson noted that Stryker is paying 5.0-5.4x 2010 sales for Memometal, which is above the average 3.1x sales paid for orthopedic acquisitions. "While Stryker is paying a premium for Memometal, we think it is justified by Memometal's Nitinol capabilities and the extremities market's mid-teens growth rate," wrote Matson.

—WE (June 6, 2011)

biologics

Treated Stem Cells Heal Fractures

An estimated 600,000 people in North America have problems healing a fractured bone, according to Anna Spagnoli, M.D., an associate professor of pediatrics and biomedical engineering at the University of North Carolina at Chapel Hill. That number is significant to Spagnoli because she is the principal investigator in a promising study using stem cells to heal broken bones that, because of osteoporosis or other causes, fail to repair.

Bones that do not heal within the normal timeframe are called "non-union fractures." Mice that lack the ability to heal their broken bones are called "knockout" mice. Spagnoli and her colleagues extracted stem cells from the bone marrow of knockout mice. After engineering the stem cells to express IGF-I (IGF-1 is a hormone similar in molecular structure to insulin. It plays an important role in childhood bone growth and development. A synthetic analog of IGF-1, mecasermin is used for the treatment of bone growth failure in adults) they transplanted the treated cells back into the mice which had fractures of the long bone of the leg.

Using computer tomography scanning, the researchers discovered that the treated mice had better fracture healing than did control mice that had been either left untreated or treated only with stem cells. They found that the stem cells enriched with IGF-I became bone cells and helped the cells in the broken bones to repair the fracture, speeding the healing. Compared with controls left to heal on their own, treated mice had more bone bridging the fracture gap, and that new bone was three to four times stronger.

According to Spagnoli, "We found that stem cells empowered with IGF-I restored the formation of new bone in

Fracture right clavicle/mexican 2000/Wikimedia Commons

a mouse lacking the ability to repair broken bones. This is the first evidence that stem cell therapy can address a deficiency of fracture repair."

"This success in an animal model of fracture non-union," Spagnoli said, "is a crucial step toward developing a stem cell-based treatment for patients with fracture non-unions." The results are especially significant for "children with osteogenesis imperfecta, or brittle bone disease, and in elderly adults with osteoporosis, because their fragile bones can easily and repeatedly break, and bone graft surgical treatment is often not successful or feasible"

Spagnoli envisions "a clinical use of combined mesenchymal stem cells and IGF-I similar to the approach employed in bone marrow transplant, in which stem cell therapy is combined with growth factors to restore blood cells," she said. "I think this treatment will be feasible to start testing in patients in a few years."

IGF-I is approved for treatment of children with a deficiency of this hormone, causing growth failure. The National Institutes of Health supported the study through a NIDDK-NIH R01 grant.

—BY (June 8, 2011)

Stem Cell Bandage for Knees?

Regulators from MHRA (the Medicine Healthcare and Regulatory Agency which is the governmental agency in the United Kingdom responsible for standards of safety, quality and performance) have approved the first clinical trial of a novel stem cell bandage aimed at patients with torn meniscal cartilage. Approximately 900,000 people have meniscal tears every year in Europe with perhaps 800,000 to one million more in the U.S. making the total number of patients requiring treatment in this area approximately 1.7 million meniscal tears per year. The current treatment for most tears requires that some or all of the torn meniscus be removed by a surgeon. This procedure may result in the early onset of osteoarthritis, according to some researchers. The phase 1 trial is designed to treat meniscal tear patients with a novel cell bandage which has been seeded by the physician using the patient's own expanded stem cells.


Hellerhof/Wikimedia Commons

The cell bandage was developed and will be produced for the study by Azellon Ltd, a University of Bristol spin-out company that is focused on the research, development and commercialization of an adult autologous stem cell technology that has shown promise for the healing of meniscal tears.

The trial is designed primarily to test the safety of Azellon's cell bandage in ten meniscal tear patients. The principal investigators in the study will also collect data regarding the efficacy of the new "stem cell bandage." The bandage, which will contain the patient's own stem cells, will be implanted by the study investigators by way of a simple surgical procedure using a specially designed instrument that delivers the cells into the injured site. This procedure is designed to function as a first-line treatment for torn meniscus and to present a viable alternative to removing some of the meniscus. Patients will be closely monitored for safety over a five-year follow-up period.

Professor Anthony Hollander, Chief Scientific Officer at Azellon Ltd and head of the School of Cellular and Molecular Medicine at the University of Bristol, said, "The approval we have received from the MHRA is an important milestone in the development of stem cell therapies in the UK. These

cells hold much scientific and medical promise but we can only know if they work or not by testing them out in clinical trials."

—BY (June 8, 2011)

Stem Cells Treat Major League Pitcher

Yankees right-hander Bartolo Colon is the American League pitcher who, in 2005, won the Cy Young Award. He is also the first professional athlete in the public eye to undergo stem cell surgery to repair damaged ligaments and a torn rotator cuff in his right shoulder. The stem cells that were injected into Colon's shoulder were taken from his fat and bone marrow.

Boca Raton, Florida, orthopedic surgeon Dr. Joseph R. Purita, who had done stem-cell surgery before, performed the surgery on Colon. In the past Purita had included injections of human growth hormone to hasten the healing process. Aware that growth hormone was banned by major league baseball, Purita put together a team of doctors to perform the surgery on Colon in the Dominican Republic. No growth hormone was used and Purita worked pro bono.

MLB Pitcher Bartolo Colon Before Stem Cell Therapy/Wikimedia Commons

Dr. Damon Noto, a colleague of Purita's and one of five doctors in the United States who performs surgery similar to that done on Colon, commented on the surgery on station WFAN. When asked how many people in the U.S. have had stem cell surgery he replied, "It's only probably been in the last two years that we've really been doing it, so we've maybe done 500 people in the past two years. It's usually some type of orthopedic injury, so a person may throw out his shoulder or knee or even people [who] are looking for a hip replacement. We're focusing on people right now with largely orthopedic problems."

Noto characterized stem cell surgery as "a very new science. We're calling this 'regenerative medicine.' What we're seeing now is that different doctors are experimenting with different techniques. One of them actually is using growth hormones to make it even more effective, but the research is still out on whether or not that is needed."

Noto predicts dramatic growth. This is really going to explode. In the next five years the field of regenerative medicine, using your own body cells to heal itself is going to explode. I mean athletes are really going to be demanding these types of things. Instead of major surgeries they're going to want to use their own bodies' ability to heal."

Colon recently shut out the Oakland A's with a complete game four-hitter. No walks, six strikeouts, 103 pitches. Colon's fastball hit 97 mph, right where he was in 2005 when he won 21 games.

—BY (June 6, 2011)

large joints

Dog Biomarkers Helping With OA

Canines for progress…A team from the University of Missouri (UM) is tackling osteoarthritis (OA) for dogs, horses and humans alike. The UM group is looking into potential biomarkers in dogs for early diagnosis of OA, which could help identify patients at increased risk of developing this condition.

"By developing methods for earlier diagnosis of osteoarthritis, prevention or even curative treatment strategies to manage the disease become more realistic," said James Cook, professor of veterinary medicine and surgery, and the William & Kathryn Allen Distinguished Professor in Orthopedic Surgery, in the June 6, 2011 news release.

"Biomarkers could detect the disease before pain and swelling occurs, and owners could take preventative measures, such as modifying activities or diet, helping their pets lose weight and strengthen their joints, to reduce the likelihood of their dogs developing osteoarthritis."

The researchers took samples of synovial fluid from dogs, and found that the quantity and quality were altered in injured stifle joints (the joint in the hind limbs of dogs that is the equivalent joint to the human knee).

"At the MU Comparative Orthopaedic Laboratory, we are particularly interested in identification and validation of biomarkers that can detect early stages of osteoarthritis to provide accurate diagnostic and prognostic information prior to the onset of clinical disease for people and for pets," Cook added. "Our team, led by Drs. Kuroki, Stoker and Garner, is making tremendous progress in developing simple tests on blood, urine and synovial fluid that show great promise for helping us diagnose impending osteoarthritis before it is too late to help the patient in the most effective manner."

Dr. James Cook/University of Missouri

Dr. Cook told *OTW*, "This work is progressing very well. We are pursuing the Canine Osteoarthritis Biomarker Panel and the Human Osteoarthritis Biomarker Panel in parallel. In dogs, we are able to successfully diagnose, stage, and monitor treatment for OA secondary to ACL (CCL) [anterior cruciate ligment/cranial cruciate ligent] problems in their knees and that aspect is ready for commercial use at this point. We are trying to further validate, fine-tune, and apply it to other joints and causes of OA in dogs at this time."

He also commented to *OTW*, "For humans, we are early in the process but the initial work is extremely promising for being able to use this panel for screening, early diagnosis, staging, and treatment monitoring in the knee, and hopefully other joints, as well."

—EH (June 8, 2011)

Huge Joint Arthroplasty Disparities

Degenerative and rheumatic joint diseases of the hips and knees are among the most difficult problems for aging patients to deal with as their mobility and quality of life are profoundly affected. The standard therapy for these patients is the total replacement of the affected joint. A recent international survey, across four continents, comparing the incidence of hip and knee arthroplasty has revealed vast differences in the numbers of patients being served.

The differences ranged from 266.2 annual knee replacement operations per 100,000 inhabitants in Austria to only 11.3 in Brazil. The number of hip replacements ranged from 221.5 in the U.S. to 4.3 in Brazil.

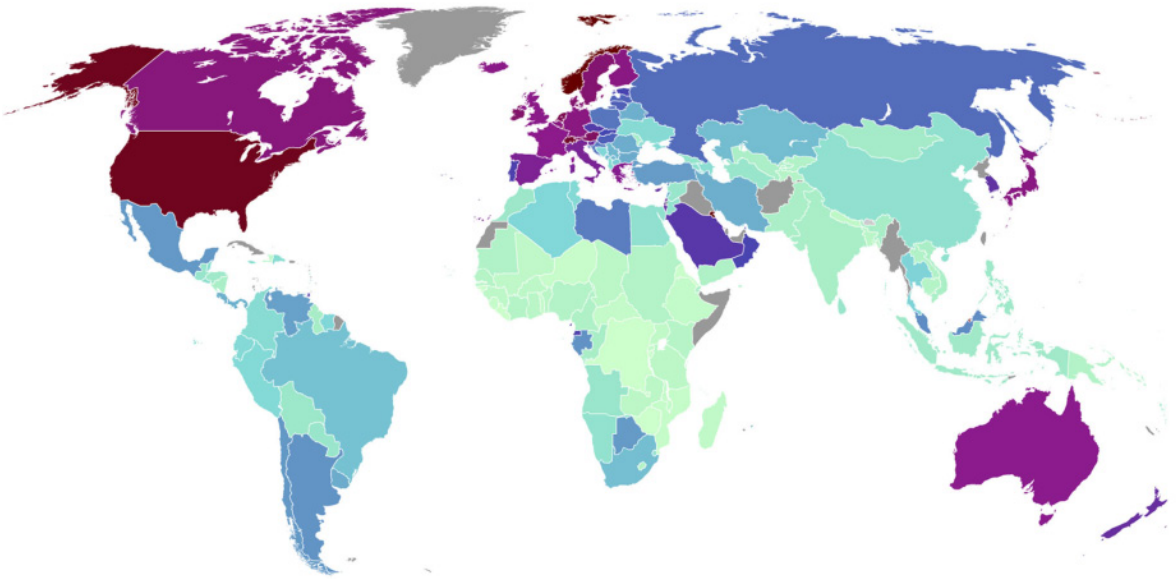
"An in-depth analysis showed that the determinant factors for these disparities cannot be found in different health risks or a different amount of need, but mainly in macro-economic factors. Broad therapeutic coverage of chronic joint disease is more likely to exist in rich countries with well-endowed health care systems," said Dr. Maria de Fátima de Pina, Professor at Porto University, Portugal. She spoke at the 12th Congress of the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) in Copenhagen.

Osteoarthrosis, brought on by age or by weight-related degeneration, knows no boundaries and, in the absence of effective therapy only gets worse. Since modern medicine mastered the total replacement of the hip joint 25 years ago, this procedure has relieved patients of pain and disability while also saving on long-term costs for health care.

Biomechanically much more complex, the replacement of the knee joint was employed more cautiously up until about 10 years ago. "Studies show a steep increase in knee arthroplasty in many countries during the last 10 years," Prof. de Pina said. "The rates have tripled, for example, in Switzerland, Italy and Spain. That was not due to more cases of osteoarthrosis, but rather to improved materials and insights in biomechanics that enabled surgeons to safely operate in many more cases than they were able to do a decade ago."

These joint surgeries, however, remain limited to privileged regions of the world, the Portuguese study points out. Leaders in hip arthroplasty were Austria (266.2 annually per 100,000 inhabitants), Luxembourg (226.0) and Switzerland (225.8). Topping the list in knee arthroplasty were the United States (221.5), Austria (183.6) and Switzerland (173.6).

The laggards in hip arthroplasty were Brazil (11.3), Mexico (15.9) and South Korea (16.7). In knee arthroplasty, the lowest rates were found in Brazil (4.3), Romania (5.3) and Mexico (7.8). "Just as remarkable as the dimension of those disparities is the fact that not even the EU exhibits homogenous incidence rates," Prof. de Pina said. "Very low rates in some Eastern Europe countries contrast with middle range rates in countries like Italy, Spain or Finland and very high rates in a cluster of countries in Central Western Europe, including Austria, Germany, Switzerland, France, Belgium, the Netherlands and Luxembourg."



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—BY June 6, 2011)

extremities

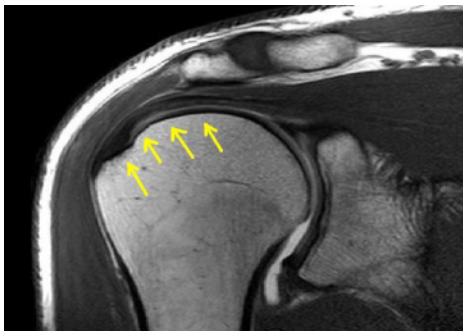
BioMimetic Enrolls CuffGraft Patients

Nothing humorous about a rotator cuff injury…bad jokes aside, one company is pleased to be making progress to help these patients. BioMimetic Therapeutics, Inc. has announced that they have enrolled 30 patients in a pilot clinical trial to assess the safety and clinical utility of Augment Rotator CuffGraft for the repair of large rotator cuff tears. The team is aiming to assess the safety and performance of Augment Rotator Cuff for primary surgical treatment of full thickness rotator cuff tears. To date there have been no product related serious adverse events attributed to Augment Rotator Cuff in the study.

Robert Litchfield, M.D., principle investigator for the Augment Rotator Cuff pilot study, said in the June 7, 2011 news release, "Rotator cuff tears are one of the most common problems encountered by orthopedic surgeons, and their repair is among the most commonly performed procedures in orthopedic soft tissue indications. The rapid enrollment of patients in this pilot study speaks to the surgeons' desire to improve the outcomes of this frequent and difficult-to-treat condition. Biologic enhancement of cuff repairs is undoubtedly the next major advancement in the management of these challenging cases, and as principle investigator I am delighted by the ease of use and the absence of any adverse events associated with the application of this product. Additionally, the clinicians involved in this study are very enthusiastic about the potential benefits and safety of this product."

Hans Kestler, VP of orthopedics and sports medicine for BioMimetic told *OTW*, "We are extremely fortunate to work with an excellent group of investigators who enrolled this study ahead of our own expectations. We think this speaks to the large unmet need to enhance rotator cuff repair in this patient population."

Kestler also commented to *OTW*, "From this study we will demonstrate the safety and clinical utility of the



Dr. Harry Gouvas/Wikimedia Commons

product. As we move into future clinical trials we would look to replicate the efficacy seen in our large animal studies (as were discussed in the manuscript recently accepted for publication in AJSM), which showed statistically significant improvements in the strength of the repair and the reattachment of the tendon to bone with use of Augment Rotator Cuff Graft. Additionally, rotator cuff tears are among the most common shoulder injuries in the U.S. Operative repair of rotator cuff tears may reduce pain and function, however previous studies have demonstrated that a significant percentage of these repairs fail to heal when evaluated radiologically. We believe this product could benefit patients in faster return to work/play and better lasting outcomes long-term."

—EH (June 10, 2011)

Chocolate Milk Tops Gatorade, Really!

Low-fat chocolate milk is the winner. Three new studies, presented at the American College of Sports Medicine, found that athletes, both amateur and professional, who drank low fat chocolate milk had improved training times, better body composition and were in better shape than their peers who drank typical sports beverages.

Researchers at the University of Texas, Austin, compared recovery benefits of drinking low fat chocolate milk after

Sugar Bear/Wikimedia Commons

exercise to a carbohydrate beverage with the same calories, and to a calorie-free beverage.

Performance improved among the chocolate milk drinkers. Following an exhausting ride, trained cyclists had significantly more power and rode faster, shaving about six minutes on average, from their ride time when they recovered with low fat chocolate milk compared to a carbohydrate sports drink and calorie-free beverage.

Compared to the other recovery drinks, chocolate milk drinkers had twice the improvement in V02max—a measure of aerobic fitness and adaptation—after

a 4.5 week cycling regimen that included intense exercise five days a week, followed by one of the three recovery beverages. The study included 32 healthy but untrained male and female cyclists.

Chocolate milk drinkers gained more muscle and lost more fat during training, with a three pound lean muscle advantage at the end of the 4.5 weeks compared to athletes who drank a carbohydrate drink. The 32 healthy but untrained male and female cyclists rode for one hour, five days a week and drank one of the three recovery beverages immediately following and one hour post-exercise.

"Collectively, our research suggests that low fat chocolate milk—easily accessible for most athletes—can improve performance and aid training for trained and amateur athletes faced with tough routines," said John L. Ivy, Ph.D., lead researcher on the University of Texas at Austin studies. "We may need more research to understand the exact mechanisms, but there's something that chocolate milk naturally has that likely gives it the post-exercise advantage."

Low fat chocolate milk *naturally* has many of the nutrients most commercial recovery drinks have to add in the lab—including high-quality protein and key electrolytes like calcium, potassium, sodium and magnesium. Plus, it has B vitamins for energy and the combo of five bone-building nutrients—calcium, vitamin D, phosphorus, protein and potassium—to help athletes build and maintain strong bones and reduce risk for stress fractures.

—BY (June 7, 2011)

Arthritis Nixes Wrist Surgery

Wrist arthroplasty with Universal wrist prosthesis has a high failure rate in patients with rheumatoid arthritis, mainly due to carpal component loosening, according to a study conducted at the University of Minnesota, St. Paul, and published in the May 18 issue of *The Journal of Bone & Joint Surgery.*

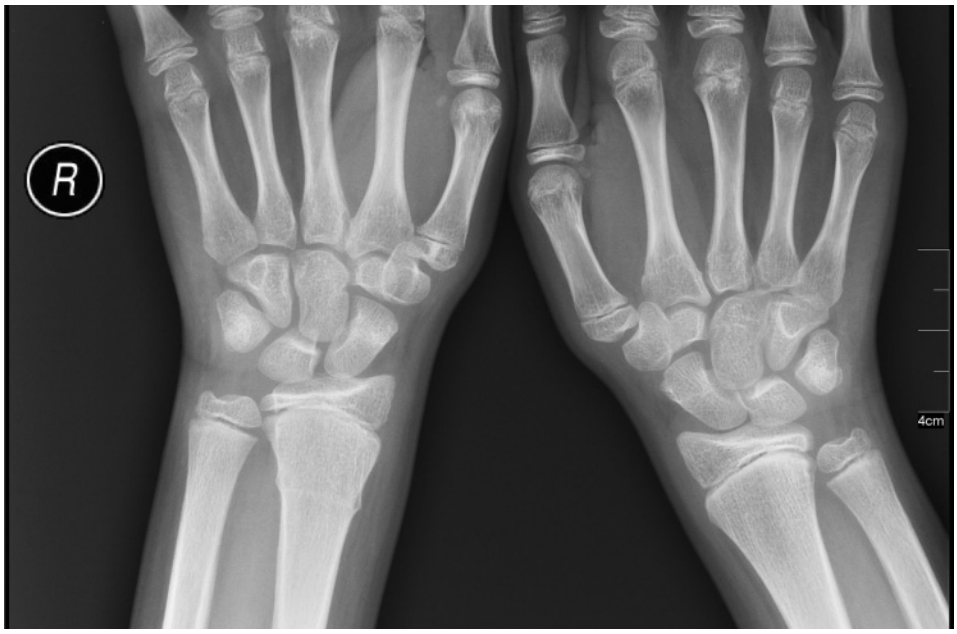
Christina Ward and her colleagues studied the outcome of 24 total wrist arthroplasties with Universal wrist prosthesis in 20 patients who also had rheumatoid arthritis. After the patients received the procedure, the researchers followed up 19 of the wrists from 15 patients, both clinically and radiologically, for an average period of 7.3 years.

The outcomes they measured and reported were the wrist range of motion, standard radiographic findings and the Disability of Arm Shoulder and Hand scores (DASH).

The investigators found that there was an improvement in the average DASH scores, from 62 points preoperatively to 40 points at the last follow-up. A mean improvement in the total flexion-extension arc of 14 degrees at the latest follow-up resulted from mean wrist flexion and extension of 42 and 20 degrees. At the time of the last follow-up, revision surgery for loose carpal movement had been done on nine wrists in eight patients, and one patient had wrist arthrodesis due to wrist instability.

Radiographic evidence of carpal component subsidence was identified in two wrists from two patients. The five- and seven-year survival rates for the original prosthetic components were 75% and 60%."Carpal component loosening remains an obstacle to predictable good long-term survival of this implant in patients with rheumatoid arthritis," Ward said.

—BY (June 7, 2011)



Nevit Delman/Wikimedia Commons

people

Dr. Fotios Tjoumakaris Joins Rothman

Fotios P. Tjoumakaris, M.D./The Rothman Institute

There is another new team member at Rothman…this time it's a sports medicine specialist. Fotios P. Tjoumakaris, M.D., previously an Assistant Professor of Orthopaedic Surgery at the University of Pennsylvania School of Medicine, has just joined the Rothman Institute in Philadelphia.

"We're thrilled to have Dr. Tjoumakaris join the Rothman organization," said CEO Mike West in the June 2, 2011 news release. "His wealth of knowledge in sports medicine will be a wonderful addition to our team."

Dr. Tjoumakaris is Board Certified in Orthopedic Surgery and holds a certificate of added qualification in sports medicine. He specializes in all areas of sports medicine including but not limited to fractures, ruptures, tendon repairs and arthroscopy. Dr. Tjoumakaris earned his medical degree at the University of Medicine and Dentistry of New Jersey/Robert Wood Johnson Medical School. He completed his internship and residency at the Hospital of the University of Pennsylvania and earned his Fellowship at the University of Pittsburgh Medical Center.

As for what he most looks forward to about his new role, Dr. Tjoumakaris told *OTW*, "What I look forward to most in my new role with the Rothman Institute is serving the South Jersey population with high quality orthopedic sports medicine care. I grew up in South Jersey and I am eager to reacquaint myself with the area and begin taking care of patients from the Jersey Shore. Combined with the ability to work with the premiere orthopedic group in the Delaware Valley makes this a really exciting opportunity."

He also commented to *OTW*, "My first steps are to meet with local physicians, athletic trainers, and physical therapists in the community to find out what needs they may have so that I can better serve my patients. In addition, I anticipate getting research projects off the ground and collaborating with the physicians in Philadelphia to help make the Rothman Institute as integrated as possible through both clinical and academic missions. There really is no better place to be an orthopedic surgeon than the Rothman Institute and I look forward to a great partnership in the years to come."

—EH (June 7, 2011)

spine

Mazor's Newest Spine Surgery Robot

On June 6, Caesarea, Israel-based Mazor Robotics, Ltd., introduced its next-generation spinal robotic surgical guidance system called Renaissance.

Renaissance is powered by Mazor's core technology which the company says has been clinically validated with SpineAssist, Mazor Robotics' previous system for spine surgery. SpineAssist has been utilized in over 2,000 spinal surgeries worldwide, placing more than 12,000 implants. According to the company's announcement, investigators of a recent 14-site international multicenter study published in the peer-review journal *Spine* concluded that Mazor Robotics' technology "offers enhanced performance in spinal surgery when compared to freehand surgeries, by increasing placement accuracy and reducing neurologic risks."

Mazor's CEO Ori Hadomi said, "With the launch of Renaissance, we have set the bar even higher and will allow surgeons to significantly improve the standard of care they can provide for their patients."

The company says Renaissance features an, "entirely new design and human interface, as well as next-generation hardware and software technologies. These are designed to increase surgical safety as well as extend the range of clinical applications, enabling osteotomies, transfacet and translaminar-facet implant placements, in addition to procedures such as spinal fusions and scoliosis corrections currently performed with Mazor Robotics' technology. Renaissance also serves as a platform that will support future clinical applications, such as robotic-guided cranial surgeries."

Of special interest to surgeons is that Renaissance, according to the company, reduces radiation protocols for preoperative CTs by up to 50%.

—*WE (June 6, 2011)*

Mazor Robotic's Renaissance/Mazor Robotics, Ltd.

THE PICTURE OF SUCCESS

One Ortho Entrepreneur's China Venture

By Elizabeth Hofheinz, M.P.H., M.Ed.

Peter Slate and Bonovo Orthopedics

There are many opportunities to do business abroad. There are even more opportunities to get it wrong. Bonovo Orthopedics, Inc., is taking the time to discover the secrets of getting it right.

What is the secret? According to Peter Slate, CEO of this burgeoning company, "There are no quick fixes. Making a business successful in China requires a strong local Chinese team that buys into a company's goals, and intimately understands the unique aspects of the Chinese business environment. It must be built over time."

Is it worth the effort? According to Slate, "China will be the fastest growing economy over the next 50 years. Companies that wish to be global leaders and fail to implement a strong China strategy run a great risk of losing their competitiveness."

You've probably never heard of the Louisiana cookbook named, "Who's Your Momma, Are You Catholic, and Can You Make a Roux?" The sentiment behind the title applies equally as well to China, namely, "Why should I trust you?" and "Is there a connection here?" Peter Slate knows that to go beyond the stereotypical way of doing business abroad—flying in for a few days, having an "appetizer" with the Chinese orthopedic world, and leaving—is a recipe for failure. Slate says, "China seems like a large country with a strong central government that efficiently dictates national policy. But more accurate is that China is a group of provinces with differing competitive needs. The economy is decentralized, and business relationships in one province don't necessarily help you in another. As a result, to do business throughout the country you must have relationships throughout the country."

With oceans of potential misunderstandings between East and West, says Slate, it is vital to understand Chinese culture. "In the East, business relationships take longer to build than in the West, where the code of conduct is more along the lines of, 'Let's get down to business.' Chinese companies place more of a premium on getting to know a partner ***before*** the discussion of pricing or products takes place. This can be frustrating for many Western partners. It can be wrongfully viewed as a lack of willingness to do business."

Communication is hard enough between native English speakers that share the same culture. When it's a different country with a very different language, things can get interesting. "It is important to realize that communication is not only complicated by the obvious differences between English and Chinese, it is compounded by the multiple dialects and phrasing in China.

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"Where is Slate betting that the Chinese population will spend their money? "Despite cultural differences between the East and the West, everyone wants what is best for their families…this includes quality healthcare."

It is safe to say that your American football metaphors will not be as effective in China as they are in the U.S."

And to be effective, you have to know what works and what doesn't. When asked to provide some basic tips for a Westerner attending a business dinner in China, Slate advises, "While in the U.S. it may be fair game for a guest to make a first toast, in China, that honor is strictly reserved for the host. That said, if the guest doesn't make a personal toast to the host during the meal it may be perceived as disrespectful. When toasting someone to whom you are showing great reverence, you should hold the lip of your glass just below theirs. Also, if someone begins to eat before the host it can be considered bad form. Time and again I have seen that Westerners who take the time to learn these things are viewed very positively."

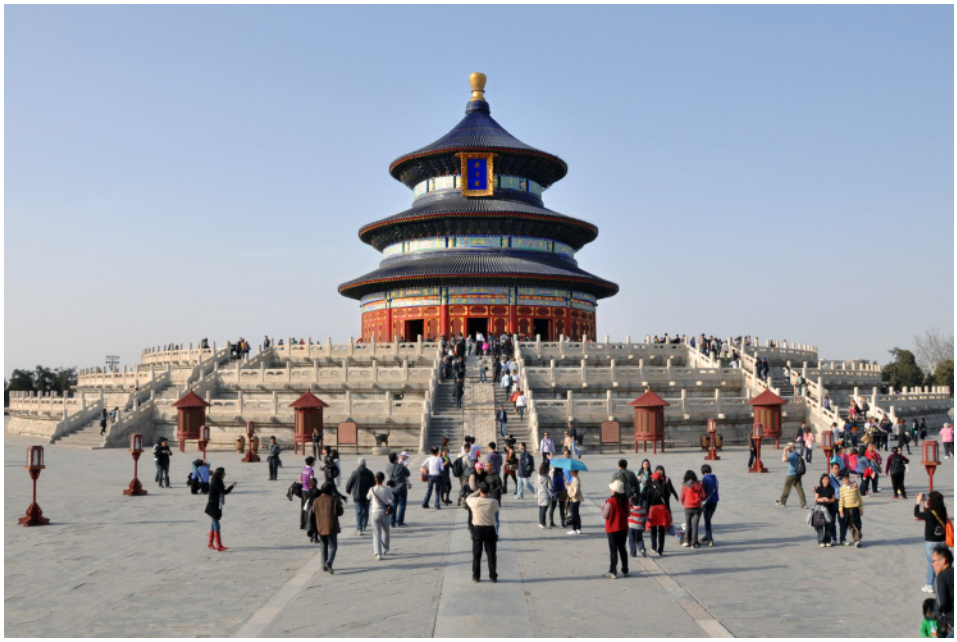
Slate notes that there are many aspects of the Chinese business opportunity that are hard to see from the outside looking in. "The buying power in China can be disproportionate to the level of spending. While the high savings rate in China is well documented, the high number of cars on the road as compared to the low average income in China illustrates how powerful this buying power can be when it is unlocked. While China's emerging middle class is small as compared to its overall population, it is larger than many countries and will soon surpass the total population of the United States."

Where is Slate betting that the Chinese population will spend their money? "Despite cultural differences between the East and the West, everyone wants what is best for their families…this includes quality healthcare."

Bonovo places a premium on cultural expertise within its corporate framework. Slate notes, "Chip Bao, Ph.D., is the head of Bonovo Asia, and is the former Chief Technology Officer for Pioneer Surgical Technology. He has risen to the highest levels within Western organizations and understands Chinese business culture. Based in Beijing, Dr. Bao is able to overcome business and cultural hurdles 'on the ground.' He has truly brought an eye toward branding to Bonovo's Chinese business that is driving sales growth."

Cultural difference also come into play when setting employee expectations. "In Western culture, consensus building within an organization is a priority. Chinese companies are more often led from the top down, and the desire to build consensus can sometimes be seen as weakness. It may trigger responses like, 'Why is he asking me?…Doesn't he know what we should do?' As a result, to be successful in building a team, your management style may need to be modified a bit."

So what has Slate found to be the inner workings of the Chinese orthopedic world…and where can Westerners effect change? "In the U.S. we have addressed many of the challenges that China is facing today, meaning that ideally we can be of some help regard-



Charlie fong/Wikimedia Commons

ing certain pitfalls. In the U.S., privatization and managed care have forced a level of expertise in hospital management that is very different from other parts of the world. Even our public hospitals must be run with a clear view toward 'profitability.' This kind of hospital management expertise in the U.S. has taken years to build and can bring a lot to the Chinese healthcare market. "

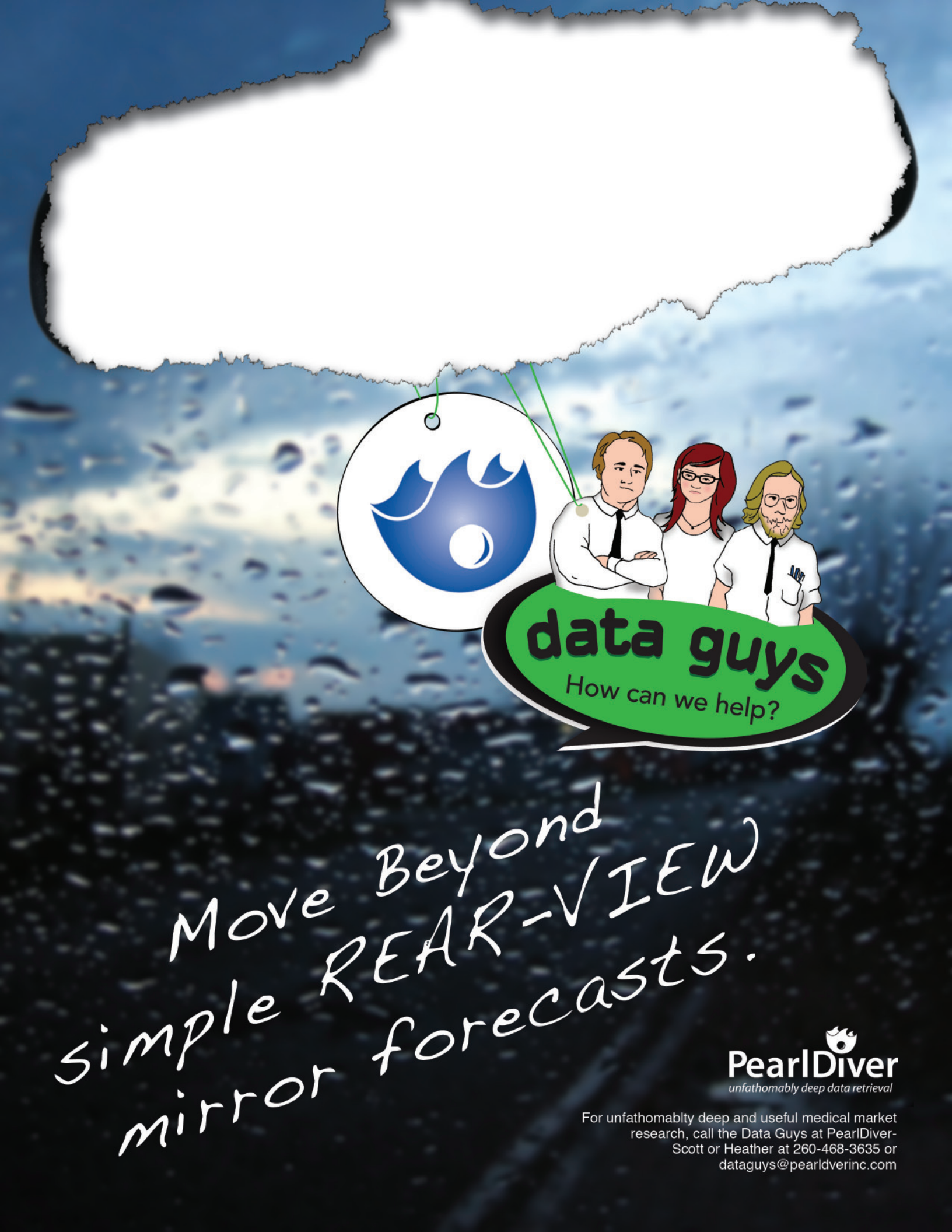
Using his laser focus, Slate has homed in on a certain type of hospital in China—those with the highest prospects for growth. "We focus on top provincial hospitals that set the standard of care for the region and where we see strong positive trends in procedures volume. As the healthcare system grows, this is where the lion's share of the procedure volume will be. There is a bidding process in China that requires Bonovo to have strong regional relationships through multiple distributors. This bidding process occurs every 12 to 24 months across China; if we miss a bid then we are not selling in that region until the next bid. The bids set the maximum price and then we negotiate the final price with the individual hospital. This all means that you must be as effective at bidding as you are at developing great products. We spend significant resources on bidding…and it's always a mad rush of activity to prepare for the bids."

Macro-level changes now in play mean that the Chinese orthopedic market will only continue to mature. "We are seeing changes in clinical requirements and government reimbursement. Also, the market dynamics are changing such that there are more domestic products of good quality and more investment by large multinational players. The phrase, 'A rising tide raises all boats' comes to mind. Large companies investing in the market and working with the government to change materials and product approval standards improve the market for all players. The Bonovo team works closely with our U.S. distribution partners, Pioneer Surgical, NuVasive and Elliquence, to push the regulatory agenda forward."

When asked to reflect on some things that may get in the way of progress, Slate notes, "The payer system is critical. Despite the growing middle class in China, growth of government reimbursement and private insurance to pay for products is critical. Something else that we keep our eyes on is the privatization of hospitals in China. Private hospitals can make purchases faster, and are beginning to push new and innovative products into the marketplace."

And five years from now? "I want Bonovo to be a globally competitive healthcare company that is based in China. We have tried to create a seaworthy vessel on which we can put different types of cargo. The infrastructure is scalable such that in five years *everything* will have grown."

Peter Slate and Bonovo...altering the landscape of a nation's healthcare. ◆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