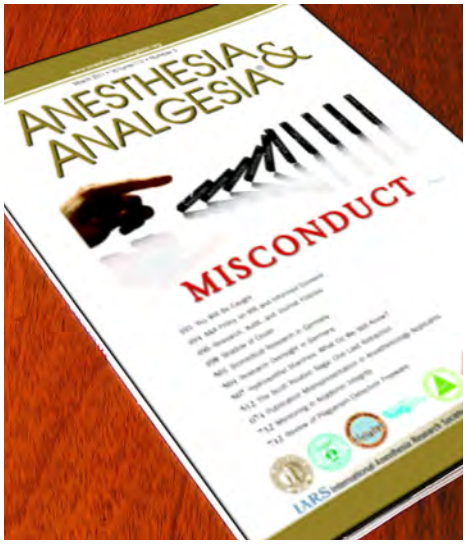
VOLUME 8, ISSUE 22 | JULY 10, 2012

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: Orthopedic equities have been a singular bright spot in an otherwise dismal stock market. Look at the 30-day valuation gains of the Power Ranked companies. On average orthopedic equities have risen 11% in the last 30 days. On a weighted average basis, trailing P/Es are 18x, future P/Es are 14x. No doubt we're seeing bargain hunting.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Johnson & Johnson	24.93	7.71%	Synthes and DePuy are now a single company and the effects are already proving to be accretive to earnings.
2	5	Orthofix	16.23	9.33	OFIX's earnings report this month will, we think, surprise on the upside in terms of cash flow and improving balance sheet.
3	9	Integra LifeSciences	13.34	4.97	Argus upgraded IART from Hold to BUY. IART is now the 2nd least expensive ortho equity. Prime for a solid quarter report.
4	1	ArthroCare	(0.67%)	8.58	Zack's puts ARTC on its Strong Buy list. Can ARTC meet these lofty expectations with solid 2nd quarter sales?
5	4	Zimmer	24.95	4.62	The MoM hip fiasco has had zero effect on ZMH's sales and earnings expectations. Should report 9% income growth on flat sales, say analysts.
6	3	Stryker	23.68	4.47	Shutting down two plants, laying off 100 workers. SYK is taking care of the bottom line. Next up a CEO hire?
7	6	Smith & Nephew	21.50	7.93	The FDA's MoM meeting was not pleasant for SNN but in many ways it was anti-climactic. Now if only SNN could gin up some sales growth.
8	7	Symmetry Medical	5.29	9.20	The predominant rating for SMA among analysts is "Hold." They're missing the evolution of this company.
9	10	Conmed	10.09	4.47	Wow...analysts are saying CNMD could report a stunning 29% rate of earnings growth for the June quarter.
10	8	NuVasive	6.63	25.38	NUVA is expensive—15 other ortho companies are better pure values. But as an M&A candidate, NUVA is extremely attractive.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	$25.54	$1,103	25.38%
2	TranS1	TSON	$2.82	$77	14.63%
3	Bacterin Intl Holdings	BONE	$1.33	$56	10.83%
4	Orthofix	OFIX	$41.59	$779	9.33%
5	Symmetry Medical	SMA	$8.31	$305	9.20%
6	ArthroCare	ARTC	$29.74	$823	8.58%
7	Tornier N.V.	TRNX	$22.59	$894	8.09%
8	Smith & Nephew	SNN	$49.70	$8,914	7.93%
9	Johnson & Johnson	JNJ	$67.64	$199,559	7.71%
10	Wright Medical	WMGI	$21.61	$849	7.51%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.59	$54	-0.12%
2	RTI Biologics Inc	RTIX	$3.65	$204	0.55%
3	Synthes	SYST.VX	$166.16	$19,817	0.68%
4	Exactech	EXAC	$16.88	$222	1.63%
5	Medtronic	MDT	$37.96	$38,911	3.10%
6	CryoLife	CRY	$4.91	$135	3.15%
7	MAKO Surgical	MAKO	$23.89	$1,017	3.20%
8	Stryker	SYK	$53.54	$20,395	4.47%
9	Conmed	CNMD	$28.05	$794	4.47%
10	Zimmer Holdings	ZMH	$62.72	$11,047	4.62%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$37.96	$38,911	11.43
2	Zimmer Holdings	ZMH	$62.72	$11,047	12.72
3	Johnson & Johnson	JNJ	$67.64	$199,559	13.47
4	Stryker	SYK	$53.54	$20,395	14.05
5	Orthofix	OFIX	$41.59	$779	14.91

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$25.54	$1,103	59.40
2	Wright Medical	WMGI	$21.61	$849	55.41
3	Symmetry Medical	SMA	$8.31	$305	33.24
4	Exactech	EXAC	$16.88	$222	23.77
5	RTI Biologics Inc	RTIX	$3.65	$204	21.47

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$41.59	$779	0.83
2	ArthroCare	ARTC	$29.74	$823	1.17
3	RTI Biologics Inc	RTIX	$3.65	$204	1.19
4	Stryker	SYK	$53.54	$20,395	1.30
5	Zimmer Holdings	ZMH	$62.72	$11,047	1.36

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$21.61	$849	6.57
2	NuVasive	NUVA	$25.54	$1,103	6.24
3	CryoLife	CRY	$4.91	$135	4.38
4	Symmetry Medical	SMA	$8.31	$305	2.77
5	Medtronic	MDT	$37.96	$38,911	2.32

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.79	$160	0.81
2	Symmetry Medical	SMA	$8.31	$305	0.85
3	Exactech	EXAC	$16.88	$222	1.08
4	Conmed	CNMD	$28.05	$794	1.09
5	CryoLife	CRY	$4.91	$135	1.13

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.59	$54	46.88
2	MAKO Surgical	MAKO	$23.89	$1,017	12.04
3	Synthes	SYST.VX	$166.16	$19,817	4.99
4	TranS1	TSON	$2.82	$77	4.01
5	Tornier N.V.	TRNX	$22.59	$894	3.42

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

Orthopedics This Week

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What to Make of Orthopedics in China

By Robin Young

RRY Publications

I just booked my fourth trip to China *this year*. Each time I go I visit orthopedic distributors, tour hospitals, talk to Chinese heads of U.S. companies, Chinese CEOs. Last time I even gowned up and observed a case.

While it may be cliché to say, it is no less true that China is big. Huge, actually. That fact hits every new visitor square between the eyes.

Chinese buildings are big and aspirational—extra tall, wide and topped off with a flourish. Chinese trains are new, fast and look like bullets. Cities are muscular, broad and crowded.

Suzhou, a satellite city to Shanghai, has 14 million people and is considered a 2nd tier city. By that measure, New York City with its 8 million residents would also be a 2nd tier city in China.

China's 1.3 billion people live in 22 provinces and 5 autonomous regions. But they are on the move—160 million Chinese have left their home province and migrated to cities, mostly. That would comparable to 50% of every American moving.

Staying with that same number—160 million Chinese are 60 years of age or older—and therefore entering the prime age for orthopedic products and services.

160 Million And Growing

The total populations of Japan and Russia do not reach 160 million. In the

Wikimedia Commons and Tim Hipps

U.S., the number of men and women over 60 years of age is 57 million (U.S. Census estimate for 2010)—which is less than one-third the number of 60 year-olders in China.

In the U.S., approximately 136 people out of every 100,000 have a total knee operation. About 60 of every 100,000 have a hip operation. The vast majority of these patients are over 60 years old and the underlying cause of hip or knee replacement correlates positively with age—and capacity to pay. (Source: Epidemiology of Knee and Hip Arthroplasty: A Systematic Review§ Jasvinder A. Singh*, 1,2,3,4 The Open *Orthopaedics Journal, 2011, 5, 80-85*.)

In China, aging and wealth are growing faster than anywhere else in the world. Here's a statistic that should put starch in your shorts. The size of China's elderly population (60 years and older) will increase by 100 million in just 15 years (from 200 million in 2015 to 300 million in 2030).

Three hundred million grandfathers and grandmothers with aching and arthritic joints. It's as if the entire U.S. population was elderly.

One Million Millionaires

In parallel with this aging is an astonishing rise in wealth. According to the Boston Consulting Group, Inc. (BCG) there are more than one million millionaires in China. Specifically, says Tjun Tang, a partner at BCG in Hong Kong, the number of millionaire households jumped 31% in 2011 to 1.11 million. But, "this grossly underestimates true overall wealth in China," says Tang since it excludes works of art, fine wines and yachts, a growing class of assets among China's wealthier class.

One consistent theme we hear from every healthcare professional we meet in China is that the government is reallocating resources and priorities toward healthcare and pensions. Culturally, we also hear, this is an imperative and is entirely consistent with both modern China and traditional Chinese culture.

An Aspirant Great Power

In March 2011, China's National People Congress approved a new Five Year Plan (the twelfth overall) covering 2011 to 2015. Each Five Year Plan sets the key priorities for China. These are more than simple government documents—they are blueprints for industry, society and government. And they reflect China's complicated political, social and economic cross currents.

James Fallows, who has lived in China for many years and is one of the more prolific western writers about China writes: "The country's successes over the past three decades arise mainly from allowing more and more of its people to apply ideas, ambitions, and energies in ways that benefit themselves and their families, and that build the national economy at the same time. To take the next step in its development, it [China] will have to alter that equation in subtle but significant ways, by granting broader scope to individual ambition than has been possible through the Communist Party's decades in control."

The current Five Year Plan seems to be moving in the direction Fallows is pointing to. Its new focus is not only on the quantity of industrial output but also the quality of life—sustainability and equality are the key overall themes. Chinese Premier Wen Jiabao, in announcing the details of the plan said:

"In some places, I have seen, urban construction is very fast, but as you walk along, you see shabby rural streets and housing, and some farmers are still hard pressed to pay the schools the 100-yuan heating fees for their kids. Therefore, I tell local officials, wouldn't it be better

if we construct fewer high buildings and spend the funds expanding the urban scale on raising living standards?"

Life Sciences as a Chinese Strategic Industry

In the new Five Year Plan China's leaders designated seven "Strategic Emerging Industries" (SEIs) to fund and support. Healthcare is one of them—specifically drug, device and biologic supplies and patient healthcare delivery systems.

China is investing billions to upgrade its healthcare infrastructure. Thousands of new hospitals and clinics are being built around the country. The purpose of this infrastructure investment is to provide universal access to healthcare. Currently, Chinese hospitals receive very little central funding, and are forced to make profits from drug sales and medical treatment in order to cover costs. The new Five Year Plan has a strategy for changing that.

China's drug and device distribution system is highly fragmented with thousands of small local distribution enterprises. That, China's leaders think, is part of the problem. The new Five Year Plan promotes healthcare consolidation by suggesting creation of one or two Tier One companies with national scope capable of generating RMB100bn ($15 billion) in annual sales.

Then, the plan continues, create 20 Tier Two regional companies with revenues of RMB10bn ($1.5 billion). Ultimately, the central planners hope, these companies will form larger distribution networks with better delivery times and lower costs.

Central Planning/Aggressive Capitalism

Think about it, the Chinese government is promoting large, private company consolidation and wealth creation. China is certainly a beguiling mix of central government planning and aggressive capitalism.

A large part of the new Five Year Plan is a program to fund product, service and distribution development at private medical device, pharma and healthcare service companies.

China wants to build a healthcare product and service base that is the equivalent of anything anywhere else in the world. By doing so, its leader's think, China can simultaneously develop an economic engine of the future, while improving the quality of life of its citizens.

China's huge investment into R&D and direct intervention in the national healthcare system is meant to eventually stimulate Chinese-derived treatments and technology. Until then, the demand will continue to grow rapidly for premium priced western brands. But someday, don't be surprised to see advanced Chinese medical technologies.

Orthopedics and Capitalism, China Style

Chinese medical product and service companies now trade on the New York Stock Exchange. We visited one such firm on our last visit. We met with its top executives, more than half of whom were transplants from the U.S., Canada and the UK. English was the designated language of the company. We met in a 400,000 square foot, beautiful facility that would be the envy of ANY pharmaceutical or bio-tech firm in the U.S. or Europe and it was compliant with the strictest regulations from the EU and USA.

China, I think, is focusing its ambitions on itself and looks to the West, generally, for resources with which to ensure that its individuals and families realize some basic dreams—that grandparents live in reasonable health, that students get the most education possible and that every family achieve a level of bourgeois comfort.

These goals should be instantly recognizable to any American. And, for 300 million future elderly, middle class China-resident patients, none of these goals will be possible without the intellectual know-how, products and services of this industry we inhabit. All of which spells an almost unimaginable future for orthopedic products and services in China. ♦

Orthopedics This Week

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Metal-on-Metal Hips: FDA Panel Offers Recommendations

By Walter Eisner

One by one, patients with metal-on-metal (MoM) hips hobbled, shuffled and made their way to the podium to tell their stories. It was a most unusual FDA Orthopaedic and Rehabilitation Device Panel meeting.

For two days in June (27-28), those patients, hip replacement and data experts from around the world, and industry representatives gathered in Gaithersburg, Maryland, to comment, debate and explain what happened to the patients in the room and the thousands more with failing MoM hips implants.

Experts came from the UK, Australia, Canada and America. There were heads of professional hip and orthopedic societies, national registries and governmental regulatory bodies. But, most dramatically, the patients with their walkers, canes and laptops to record the proceedings.

Unprecedented Meeting

Bill Maisel, M.D., the chief scientist of the FDA's Center for Devices and Radiological Health (CDRH) and his staff called this meeting of the 18-member panel together to hear what insights or advice these experts in bio-mechanics, biology, radiology, surgery and clinical practice could offer not only the FDA but also 500,000 American patients with MoM hips implants.

Finally, this was the first FDA meeting in memory where the topic for critical review was not a specific device but an entire class of devices.

The first patient to speak was a physical therapist named Ann Morrison with a DePuy Pinnacle hip. Morrison presented panelists with an impressive array of X-rays and data on her condition. She and six other patients urged the FDA and device companies to withdraw all MoM hips until follow-up care guidelines are developed.

The patients were calm, thoughtful, respectful and brief as they all urged a halt to more implantations until surgeons figure out what to do with current patients.

Britain's Derek McMinn, M.D., FRCS, the co-founder of the Birmingham system was also in the room, listening intently. He would later offer his own data from his clinic. Of the major device companies, Smith & Nephew plc, DePuy Orthopaedics, Inc., Biomet, Inc. and Corin Group PLC, presented scientific data on their devices.

Wikimedia Commons, Starscream, Usien, and National Institutes of Health

First Warning

Since the first warnings of the DePuy ASR failure from the Australian registry and the British Hip Society's call for a full ban on certain MoM hips, surgeons have effectively stopped ordering MoM hips.

DePuy responded to the warnings by recalling 93,000 ASR hips worldwide in 2010, including 37,000 in the U.S., saying more than 12% of the devices failed within five years.

In Britain, surgeons reported that MoM total hip replacements failed at "high rates." Failure was related to head size. Larger heads failed earlier (3.2% cumulative incidence of revision [95% CI 2.5–4.1] for 28 mm and 5.1% [4.2–6.2] for 52 mm head at five years in men aged 60 years).

In December 2011, the American Academy of Orthopaedic Surgeons (AAOS) published an overview of MoM hip systems which summarized the known clinical outcomes in patients with the MoM hips.

By February 2012, the UK's FDA counterpart, the MHRA, (Medicines and Healthcare Regulatory Agency) published a Medical Device Alert with updated advice on the management and monitoring of patients implanted with MoM hip systems recommending more aggressive follow-up of patients with larger total hip systems (>36 mm).

While British surgeons called for a ban, American surgeons at the AAOS opted for member education. Josh Jacobs, M.D., the next President of the Academy told *OTW* that it was not the Academy's place to ban products and it should be left to surgeons and patients to make that decision.

The Patients Talk to *OTW*

OTW met privately with patients after their panel presentations. While they love their own surgeons, they do not believe device companies have their best interest at heart. In their view, companies put their fiduciary responsibilities to their shareholders ahead of patients. These patients also drew a line from their device failures to stories in the press of large consulting contract fees and claims by prosecutors that implant manufacturers were enticing orthopedic surgeons to use their devices through these consulting schemes.

Finally, these patients were also well versed in the legal barriers of "federal preemption" resulting from the *Riegel* Supreme Court case which shields device companies from lawsuits in state courts if they have FDA clearance or approval of their devices.

Panelist Stewart Goodman, M.D., Ph.D., of the Stanford University Medical Center told the patients, "We listened carefully and your comments do matter." The patients told *OTW* that they believed Goodman and told panelists on the second day they were grateful to the FDA for convening this meeting and were, frankly, awed by the level of expertise gathered at the meeting.

Panel Topics

The meeting focused on two main topics:

1. Mechanical design of the hips and resulting damage from the release of ions into the surrounding soft tissue area when the hips are not optimally implanted.

2. Recommendations for monitoring and treating existing patients with MoM hips.

The panel also discussed patient selection. Are there some patients who are at high risk for failure? Low Risk?

The conclusion: Beyond a large male with a physically demanding job, no panel member thought it a good idea to implant any more large-head diameter hips until the mechanical and biologic failure mechanisms were understood.

Physicians Presenters

Paul Manner, M.D., Markus Wimmer, Ph.D., and Young-Min Kwon, M.D., Ph.D., presented from the American Academy of Orthopaedic Surgeons , American Association of Hip and Knee Surgeons (AAHKS), the Hip Society and the Orthopaedic Research Society (ORS).

Dr. Manner presented a history of MoM hip systems with current clinical outcomes and results of the Society's recent technology overview.

Dr. Wimmer discussed preclinical testing, implant retrieval analysis, and tribology/tribocorrosion. He also summarized the current activity and research needs identified by the American Society for Testing Materials (ASTM).

Dr. Kwon discussed local and systemic effects, management strategies, and algorithms and he concluded his talk by saying that further standardization of histological evaluation of periprosthetic tissues is needed.

Industry Presenters

Biomet, DePuy, Smith & Nephew, and Corin made their cases. Biomet discussed the design features of the Biomet MoM total hip arthroplasty (THA) system, metal ion levels, and the performance of their MoM THA system.

DePuy presented registry data on the ULTAMET MoM articulation. Smith & Nephew discussed the design, surgical technique, training and patient selection for the BHR.

Corin discussed the clinical record with the Cormet hip resurfacing device including their U.S. clinical trial data and experience with American surgeons.

All of the manufacturers emphasized the point that not all MoM hip systems are the same and each device should be evaluated on its own merit.

Physicians Presenters/AAOS, ORS, AAHKS, and The Hip Society

Industry Presenters/DePuy, Biomet, Smith & Nephew, and Corin

International Experience/British Hip Society, MHRA, TGA, and COAS

International Experience

The UK's MHRA covered their Expert Advisory Group and the Medical Device Alerts, which include recommendations for metal ion testing, imaging and revision surgery. John Skinner, FRCS, represented the British Hip Society and British Orthopaedic Association and listed his organizations patient follow up parameters.

Australia's Therapeutic Goods Administration (TGA) had not yet reached an official position statement, but were

looking at rising levels of metal ions with growing concern. A representative of the Australian Orthopedic Association (AOA) presented data which showed that fewer MoM hips were being implanted by surgeons in Australia. The AOA also presented their recommended standard follow-up for each implant size.

Finally, the Canadian Orthopaedic Arthroplasty Society (COAS) recommended surveillance of at-risk populations including females and those with poorly oriented components.

Registry Data

The Panel also heard from representatives of the International Consortium of Orthopedic Registries (ICOR) who supplied hip revision data from registries around the world with specific focus on the Australian and UK data as well as the preliminary combined data from ICOR.

The Panel discussed the need to account for key differences between practice of medicine and patients in the U.S. compared with other countries. The Panel specifically discussed increased obesity in the U.S., access to implants earlier within disease progression, surgeon experience and volume, and the interesting point that a larger number of older patients receive MoM hip implants in the U.S. than outside the U.S.

Kaiser Permanente's registry, which someone at the meeting said was the best source of U.S. data currently available, actually showed no difference in revision rates between MoM hips and other bearing surfaces. In fact, the Kaiser registry data also documented a counter-intuitive trend that smaller MoM THA head sizes had greater failure rates than larger! The Kaiser data, however, represents a subset of products available in the U.S. and reports on a very few large diameter heads. Some panel members made the comment that Kaiser's data was probably not be representative of care throughout the U.S.

Complexity of Heterogeneity

By the end of the first day's talks, the Panel had come to agree that there is evidence of heterogeneity of devices, as well as heterogeneity of outcomes, making this an extremely complex issue with a multitude of variables. A difference in gender outcomes was mentioned as a concern and the panel said that there must be a biological aspect to the MoM hips that had not yet been addressed.

By the end of the second day's talks, the panel moved to follow-up recommendations for symptomatic and asymptomatic patients. Members of the panel highlighted such key issues as the limits inherent in reading and interpreting imaging and ion testing results, therapeutic alternatives to MoM hips and

the need for a better explanation for the sources of heterogeneity in outcomes.

After two days of testimony, debate and analysis, the expert panel offered the FDA unofficial recommendations. (See Figure 1)

younger, more active patients. From 2005 to 2006, 32% of hip replacement surgeries were MoM devices.

The FDA received 16,800 negative event reports involving metal hips between 2000 and 2011. The reports

Figure 1: The panel did not take a formal vote at the end of the meeting, but their discussions produced this informal consensus on questions posed by the FDA

- Despite the many limitations of metal ion testing, it is useful to perform such tests serially in patients with well-functioning MoM implants as well as those experiencing problems.
- Ion testing should be performed on serum or whole blood samples, not urine.
- There are no identifiable patient groups for whom MoM devices should be the first choice.
- Metal sensitivity testing, though also flawed, should precede implantation of MoM devices.
- Special MRI scans for evaluating hips with metal implants are generally not needed in asymptomatic patients, or in patients in whom device failure is otherwise obvious, but should be routine for patients with symptoms that may or may not reflect impending failure.
- Labeling should include language that conveys what one panelist called the "extreme sensitivity" of MoM implants to correct positioning in their subsequent longevity.
- Patients should be informed about special risks associated with MoM devices—so-called pseudotumors adjacent to implants and elevations in metal ions in circulation, especially in those with femoral heads =36 mm.
- Asymptomatic patients with MoM devices should be evaluated yearly; patients with problems should be seen at least every six months until the need for revision becomes clear.

The markets have spoken and the juries are about to convene. Figure 1 outlines what the experts had to say about MoM hips.

MoM Hips: The Markets Have Spoken

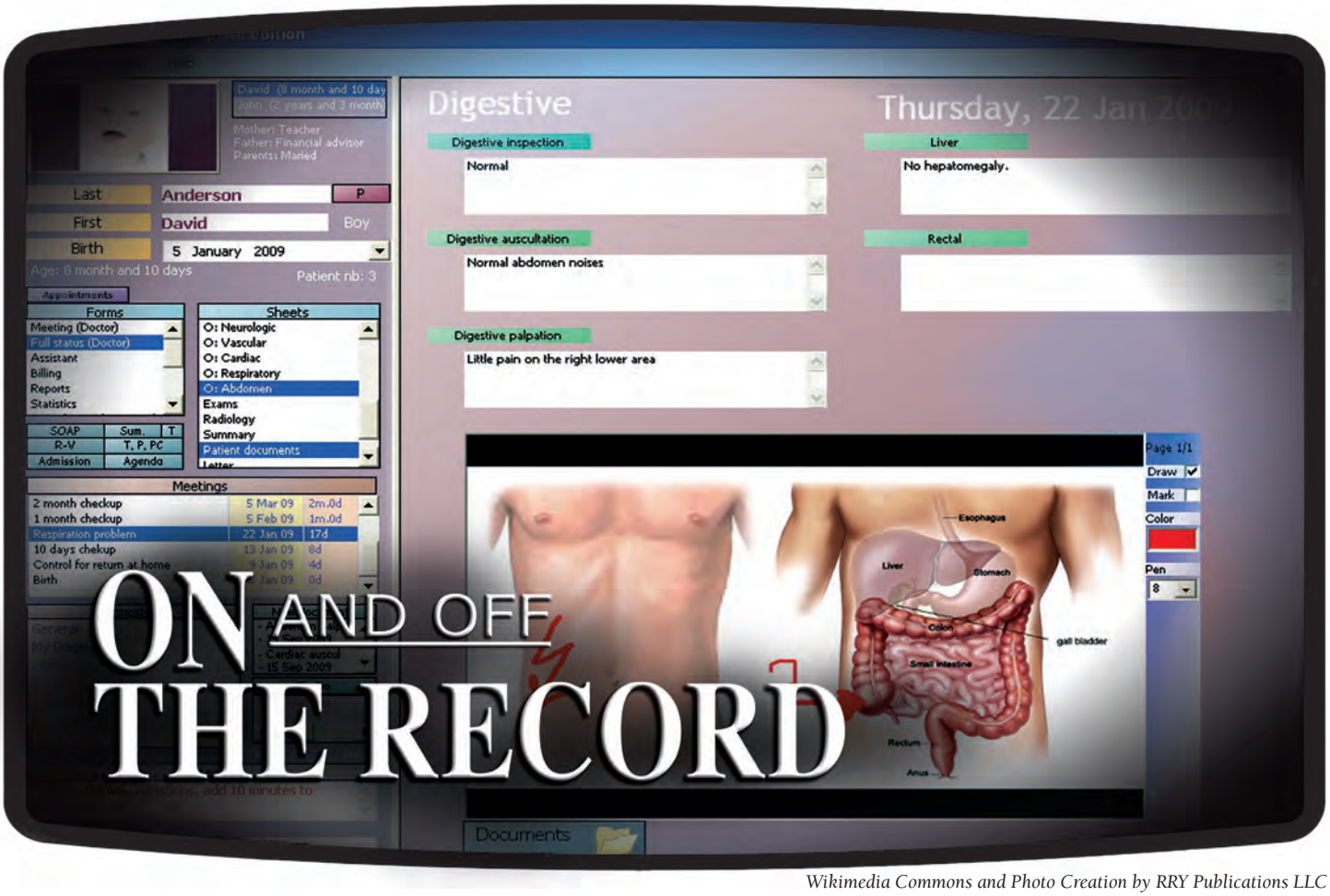
What does the future hold for MoM hips?

About 285,000 hip replacements are performed annually in the U.S. Over the past 10 years, these implants and less invasive resurfacings were used to treat almost quadrupled to 682 in 2008 from the year earlier, and rose again after DePuy began recalling hip devices in 2010. Adverse event reports in 2011 totaled 12,137 for MoM devices, compared with 6,332 associated with other types of hip implants.

DePuy faces more than 6,000 lawsuits related to the hip devices in federal and state courts. The ASR hips made by DePuy account for 9,006, or 74%, of the incident reports in 2011. More lawsuits have also recently been filed against Biomet.

According to *Orthopedic Network News,* U.S. MoM hip use peaked at 37% of the market in 2007 but fell to 3% last year. Ceramic-on-ceramic hip use also fell during the same period though not as dramatically. Metal-on-polyethylene and ceramic-on-polyethylene hip use increased, however, offsetting these declines. And, writes Mizuho Securities USA Inc. analyst Mike Matson, since hips with ceramic heads and newer polyethylenes are priced similarly to MoM, this prevented a negative mix shift.

This unprecedented FDA meeting in June highlights the rise of the FDA's new of Office of Chief Scientist. While FDA critics continue to question the agency's clearance process, no one criticized this FDA effort to get to the bottom of this problem with the most successful surgery of the 20th Century. ♦



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On (and Off) the Record

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

Early Warning Signs of Modular Hip Failures?…EHR spoiling orthopedists workday?…Good Spine Surgeries Getting Bad Name?…Sgaglione New President of AANA…Schon New President of AOFAS…and more.

Good Spine Surgeries Getting Bad Name? An orthopedic spine surgeon tells *OTW*, "The success of spine surgery depends significantly on the indication. Unfortunately, we have a certain group of spine surgeons who are doing some surgeries at a higher-than-necessary volume and for unindicated purposes. This means that good surgeries are getting bad names. I have patients coming to me saying, 'You are my third opinion because the other two doctors say I should have decompression and fusion and I don't want fusion because I've heard it's bad.' I tell these patients that they are hearing bad things because some surgeries are being done for the wrong indications and thus the patients don't do well. And despite studies showing that fusion really works for correct indications, insurers—who are hearing the same negativisms that everyone else hears—are clamping down on the approval of fusion."

"One of the biggest insurers in our region has 'gone Draconian' and will not approve any fusion unless the patient has emergent neurological problems such as bowel and bladder incontinence, and has undergone a long line of conservative care. So what is driving all of this? Well, reimbursement rates are higher for fusion so that is certainly some financial motivation for a more aggressive surgery. If we don't regulate ourselves and agree on strict surgical indications, ultimately the insurers and the government will do it for us. And at this point, I don't think there is any coordinated national effort to get spine surgeons to regulate themselves."

Nicholas A. Sgaglione, M.D. Now President of the AANA Dr. Nicholas A. Sgaglione, chair of orthopedics at North Shore University Hospital in

Manhasset and LIJ Medical Center in New Hyde Park, was recently elected president of the Arthroscopy Association of North America. Dr. Sgaglione, who specializes in sports medicine and joint replacement, also holds the position of chairman and professor of orthopedic surgery at the Hofstra North Shore-LIJ School of Medicine.

Dr. Sgaglione earned his medical degree from the Mount Sinai School of Medicine, and completed his residency in orthopedic surgery at the Hospital for Special Surgery, and a fellowship in sports medicine and arthroscopic surgery from the Southern California Orthopaedic Institute and Southern California Sports Medicine and Orthopaedic Group.

And the Next Wave of Device Failures Will Be…Ryan Nunley, M.D., assistant professor of orthopedics at Washington University in St. Louis, tells *OTW*, "While the recent FDA meeting was focused on metal-on-metal articulation at the bearing surface, the next line of metal related issues that we're beginning to see is with modular metal necks. Traditional total hips were all one piece (monoblock), but more recently some companies have jumped on the modular neck bandwagon. We are seeing corrosion at the location where the modular metal neck snaps into the body of the femoral stem, which is leading to a significant amount of metal ion release."

"Companies are saying that these necks have been tested and are stable—and yes, they are likely not overly susceptible to fracture anymore. But there is clearly micro motion rubbing at the junction generating the metal debris and causing tissue necrosis and pseudotumor formation. The use of larger diameter heads on these modular necks with the same size trunion might also be causing more micro motion. While a bigger head may be a good thing in some respects for reducing dislocations, the downside is that the larger you make the head the more you increase the torque on the trunion taper, which causes the metal to shear and flake. This could be our next wave of failures with use of modular femoral necks in total hip replacement surgery."

Patrick F. O'Leary, M.D. Receives Lifetime Achievement Award Dr. Patrick F. O'Leary, an associate attending spine surgeon and former chief of the Spine Service at Hospital for Special Surgery (HSS), received the Lifetime Achievement Award at the hospital's 29th Annual Tribute Dinner on Monday, June 18, at the Waldorf Astoria. Dr. Patrick O'Leary has focused on the fundamental principles and evolving techniques of spine surgery over the past 35 years. He specializes in the surgical management of disorders of the cervical, thoracic and lumbar spine, including revision surgery. He helped co-develop the Spine Section in Biomechanics in 1990 and establish the Biomechanics Fellowship at HSS in 1991.

A native of Ireland, Dr. O'Leary attended medical school at the National University of Ireland and then completed a rotating internship at LDS Hospital in Salt Lake City, Utah. Three years of a general surgery residency at Roosevelt Hospital in New York City was followed by a residency in orthopedic surgery at HSS. Dr. O'Leary then traveled north for a spine fellowship, completing his training at the University of Toronto.

Mismanagement Holding Up Residencies Want or need more residents for a growing program? Be sure and have

your act together, says a certain 5th year resident. He tells *OTW*, "At my institution we have struggled to add residency slots. While this has been good from the existing residents' perspective—we get to do a lot more surgeries—the fact that the Residency Review Committee keeps turning us down is frustrating. I can understand, however, because I have seen some administrative mismanagement—and I know we're not the only institution where this is happening. I just returned from a meeting where residents at other facilities told me that they have dedicated administrative faculty so that they can guarantee all of their paperwork is in order… and their program may appear to be in better shape than it truly is."

EHR: One Size Fits None An orthopedist with his eye on efficiency tells *OTW*, "At my institution, as at many, the transition to electronic health records (EHR) has been bumpy from two fronts, the institution and the larger healthcare system. First, from a policy perspective, much of the early meaningful use criteria is not specific to orthopedists… it's in danger of being a 'one-size-fits-none' situation. The information that a primary care doctor needs isn't typically what an orthopedist would collect. An immunization record, for example, has zero relevance to our work. There is also some angst that we are being made to collect information that doesn't reflect the quality of what we do. Take this physician quality reporting initiative—antibiotic use in surgery. The surgeon must give the right type of medication, the correct dose, in the correct time period, but there is no evidence that antibiotics even prevent surgical site infection for orthopedic procedures that do not involve implants! But I still have to focus on that metric, utilizing precious resources that could be focused on actually improving quality."

"EHR are the vehicle for quality reporting allowing policymakers to expand this idea requiring information to be collected at every patient interaction. Don't get me wrong, transparency and quality are paramount to improving our health care system and if meaningful use and PQRI (The Physician Quality Reporting Initiative) are a true reflection of quality of care then it's worth the effort. But if not, we run the risk of negatively impacting access to care—if I spend more time and resources collecting data, I may not be able to see as many patients, therefore, limiting my ability to meet the increased demand for musculoskeletal care. On an institutional level the issue is, 'Can you develop a system that works for everyone?' It starts with engaging each department and finding out what they need in an EHR. What can this information be used for internally and academically? If we need to increase volume to meet rising demand, is this going to help or hurt those efforts? Additionally, EHRs are yet another force that is encouraging physician/hospital alignment; the systems necessary to meet the new requirements require substantial financial investments, and individual practices may have an extremely hard time handling this requirement themselves."

Lew C. Schon, M.D. Installed as President of AOFAS Dr. Lew Schon, director of Foot and Ankle Services and director of the Foot and Ankle Fellowship at Union Memorial Hospital in Baltimore, is the new president of the American Orthopaedic Foot & Ankle Society. Dr. Schon will also serve on the Board of Directors of the Orthopaedic Foot & Ankle Outreach & Education Fund (OEF). Dr. Schon is a two time recipient of the prestigious Roger Mann Award and the J. Leonard Goldner Award.

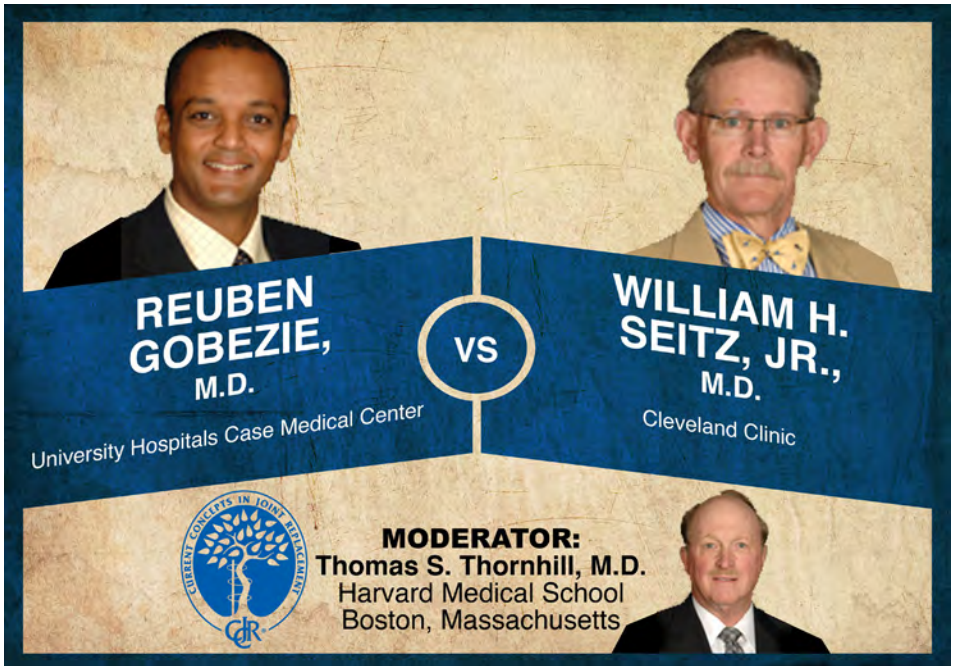
Dr. Schon is assistant professor of Orthopaedic Surgery at the Johns Hopkins University and clinical associate professor of Orthopaedic Surgery at Georgetown University School of Medicine. Dr. Schon received his medical degree from Albany Medical College in Albany, New York, and did his residency at Hospital for Joint Diseases Orthopaedic Institute in New York. He then completed a foot and ankle fellowship at the University of Texas Health Science Center in Houston. Dr. Schon was an AO Scholar in Foot and Ankle Surgery at the University of Washington/Harborview Medical Center in Seattle. ♦

Gobezie and Seitz Square Off on Reverse CTA

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

"You get much better range of motion with the reverse," says Reuben Gobezie. "Nope," argues Bill Seitz, "The reverse has been tried repeatedly over the last 30+ years and it has failed."

This week's Orthopaedic Crossfire® debate is "Reverse Shoulder for Cuff Tear Arthropathy: Optimal Implant Solutions." For the proposition was Reuben Gobezie, M.D. from University Hospitals Case Medical Center. Against the proposition was William H. Seitz, Jr., M.D. of Cleveland Clinic; moderating was Thomas S. Thornhill, M.D. of Harvard Medical School.



Current Concepts in Joint Replacement/RRY Photo Creationon

Dr. Gobezie: "I'm going to call this 'one and done.' My colleague has been around for a long time. If we look at the evolution of aviation in reverse you'll see a lot of parallels. In 1496 DaVinci came up with the Aerial Screw and thought this was a good idea. Bill [Seitz] thought this was good too, but it never made it off the paper. If we look at the first steps in shoulder arthroplasty…1893 with Pean who did the first total shoulder replacement. While it was a major advance, the operation failed due to infection. In 1868 Jean Marie Le Bris developed the Albatros II. Bill said, 'That's weird. I'd like to try it.' The plane crashed and the pilot died. Likewise, the Stanmore Shoulder."

"From 1969-1975 we see a lot of attempts to make a hemiarthroplasty—or, in this case—a total shoulder—work. These are semi-constrained glenoid designs that came out of Europe and failed miserably. Bill and I are both from Ohio and despite what the Carolina guys say, the Wright brothers are from Ohio. In 1978 a Frenchman, Paul Grammont, came up with the idea of a reverse ball and socket prosthesis which relied solely on the deltoid for movement and stability. A great idea…and what it looked like was a glenoid sphere, which was large, and a ball with no neck, and a humeral cup with an inclination of 155 degrees. This would put the deltoid in tension. The next step in aviation is the development of jets; likewise there have been very significant developments in arthroplasty. The question is, 'Where is my colleague, Bill?'"

"Let's define the current problem. The case: a massive rotator cuff (RC) tear with pain in a 70-year-old female. Function is not a problem…yet. But, is she 70 going on 60 or 70 going on 90? What happens to this massive tear over time, and how long can we expect her to live?"

"The average female in this country lives about 80 years, so we need to choose something that will give her at least 10 years of relief. If we treat her with a hemiarthroplasty what's going to happen to her cuff? There's a study in the *Journal of Bone and Joint Surgery (JBJS)* on symptomatic progression of asymptomatic rotator cuff tears; of 195 patients with RC tears, 44 developed pain. They were followed for only 1.93 years. Conclusion: if you develop pain, there is a high probability of increasing your tear size and worsening your function."

"Another study on nonoperative RC tears; 59 shoulders followed by MRI for 20 months, with 58/59 having an isolated supraspinatous tear. And 52% had progression of the tear. Conclusions: factors associated with tear progression: age>60, full thickness tear, and fatty degeneration (note: all in this case)."

"Hemiarthroplasty was originally described by Charles Neer as 'Limited Goals' surgery for the treatment of these tears. That meant that patients had no or mild pain, were pleased with the outcome, and were capable of independent self care. How much shoulder function do you need for that? Not much. If you set your goals low, every case is a winner. Let's look at the results."

"Another study on hemiarthroplasty for RC deficient shoulders; 34 shoulders with RC arthropathy. 'Limited goals' was the outcome measure and the mean American Shoulder and Elbow Society average score postop was 67; no difference between the cuffs they could repair and the cuffs they couldn't."

"There's one looking at reverse replacement in RC tears by Mark Frankle; only four patients…something that looked like our case here, and they had a tough time with that. But 95% of the patients were satisfied; flexion was 134 degrees."

"Overall, if you look at outcomes for hemiarthroplasty for massive cuff tears you see that all of them were evaluated according to limited goals. Whereas if you look at the reverse—you'll see much better range of motion."

"Conclusion: it's like a scene from the Deer Hunter…how lucky do you feel?"

Dr. Seitz: "Reuben, that was great. I noticed on your disclosure that you have a lot of stock in the History Channel. So I'm going to discuss not using a backwards shoulder prosthesis for this case with a contained rotator cuff tear arthropathy. It is a 70-year-old woman with 170 degrees of elevation. By definition, that is a contained grade one or two RC tear. There's no escape—or the patient would not be able to get this motion. There is a posterior RC or she would not be able to get 40 degrees of external rotation. There is some wear of the shoulder surface, although the congruence is pretty good. What she does have is a high riding humeral head, and the tuberosities are hitting against the top of the arch. But it's contained within the arch; there is no superior/anterior escape."

"So let's accept the new, stable center of rotation…not by putting one of those old stemmed, half a joint hemiarthroplasties in, but by doing a procedure which burns no bridges, maintains good motion, offers pain relief, but not complications."

"Looking back over the reverse, it's been tried repeatedly over the last 30+ years. Time and again, with long term follow-up, these have failed. Albeit the new generation of reverse shoulder has shown some very good outcomes in sedentary patients, even in a first report, there were only 49/70 good or excellent results and three very early glenoid failures. When this operation fails at the glenoid side you have a salvage procedure on your hands. In a report by Sirveaux, 18.7% major complications requiring revision; he described a classification of progressive degeneration or osteolysis of the inferior glenoid, resulting in notching."

"Walch was one of the developers of this system, and reported in 2006 very significant problems in active patients who are physiologically young; he stated categorically that it should be reserved for patients over 70 years old."

"So Reuben, you have this active person who starts out with 170 degrees of ele-

vation, 40 degrees of external rotation, you perform a reverse total shoulder arthroplasty and wind up with something worse than when you started. Now what is your bailout?"

"We reported in 2004 on a successful use of a hypervalgusly placed resurfacing arthroplasty which resects virtually no bone. It provides a seamless resurfacing so that you basically have an ice cream cone sitting smoothly within that arch…not a hemiarthroplasty with incongruous edges. But it does require an intact arch. The cuff tears in these cases are irreparable, but the use of this technique gives very good pain relief and surprisingly good motion."

"There is a role for the reverse—when there is no arch containment. We must be conscientious stewards of our shrinking healthcare dollars. The operation Reuben has recommended… the implant alone costs more than the DRG [Diagnosis-Related Group] that the hospital gets for doing the operation—and it's about three times the cost of the other surgery."

"So what cup arthroplasty or resurfacing arthroplasty with a smooth, seamless head offers is: resurfacing without taking away bone, in-growth/on-growth fixation without cement, is conservative, and is an excellent procedure for a physiologically younger, active patient with good bone stock and a stable joint. When you look at these patients—and you look at 3D reconstructions, you see that in many of these the medialization and superioralization into the glenoid creates more of an acetabulum. In these cases this resurfacing procedure is an excellent way of maintaining motion and alleviating pain."

"Reuben, use your head…is there really a choice here?"

Moderator Thornhill: "Let me just clarify something unrelated to this. Do you both agree that in somebody with an intact cuff and severe osteoarthritis of the shoulder you're better off with a total shoulder than a hemi?"

Dr. Seitz: "Yes."

Dr. Gobezie: "Yes."

Moderator Thornhill: "This patient had 170 degrees of forward elevation so she's really not escaped through. And her joint surface didn't look terrible, but maybe superiorally where she's out a bit it's OK. The X-ray was somewhat lordotic, making the acromial space look smaller. Would you do a CT to see what cuff was there before you made a decision?"

Dr. Gobezie: "What is this patient's physiologic age? On the slide it's fine, but is she young and healthy-looking? If not, I'm not going to put a reverse in her. On this case—the 70-year-old lady—I would do a reverse all things being equal."

Moderator Thornhill: "Bill, would you resurface her glenoid?"

Dr. Seitz: "No. the glenoid here is almost out of play. The head is sitting up under the CA arch [coracromial arch]… it's already migrated up and posteriorly as opposed to anteriorly. So I would let the head sit in that area, but give it a smooth contour with a resurfacing."

Moderator Thornhill: "You could just do a large hemi and let it articulate with the CA arch. You could do an offset cam to try to get you to clear; or you could do a resurfacing. I remember years ago Steffee just popped a hip on top. You were showing several cases of just putting resurfaces up in valgus. What would you do for this lady?"

Dr. Seitz: "Just that. When you saw the MRI there was extensive fat replacement of the supraspinatous; the other muscles were clearly involved in their upper portions. But she still had lower external rotation; she still had her teres minor intact. And by being seated she was using her deltoid. Now the stemmed implants have a problem. Even the ones with a little edge in that the head goes where the stem dictates. With this you cover everything, including the tuberosities; you shape down the tuberosities and put the cup over the top in this hypervalgus—about 165 degree—posture—a bit posteriorly angulated—and it stays in the arch."

Moderator Thornhill: "Reuben, oftentimes associated with the problems that you see in CTA is a fair amount of osteopenia. These tend to be elderly people,

which would threaten glenoid fixation. Are you concerned about less than optimal glenoid fixation—and component failure with that—and what determination do you make intraoperatively?"

Dr. Gobezie: "I'm concerned, no question. Most of the outcomes for reverse arthroplasty show failure at the base plate and if you look at Gilles Walch's biggest series you see 92% survivorship at 10 years, although there's a drop-off 7-9 years into it—mostly from glenoid failure…from notching. I think it depends on what reverse design you're using. Bigliani's reverse with a more shallow neck shaft angle…less notching; Encore prosthesis/DJO…far less notching; the Grammont style…a lot more notching has been reported."

Moderator Thornhill: "Thank you for a timely, entertaining debate." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

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July 6, 2012
Retraction of the Week – Fujii, Record Retractor

By Walter Eisner

Instead of just a single Retraction of the Week, we go macro this week and look at overall retraction rates in scientific journals and highlight one particular retraction record breaking scientist, Professor Yoshitaka Fujii, M.D.

Each week, *OTW* publishes a recent scientific journal retraction arising from shoddy, lazy or downright fraudulent research. These are examples of researchers who omitted or falsified data, used data out of context or employed such awful logic that they were forced to retract their study.

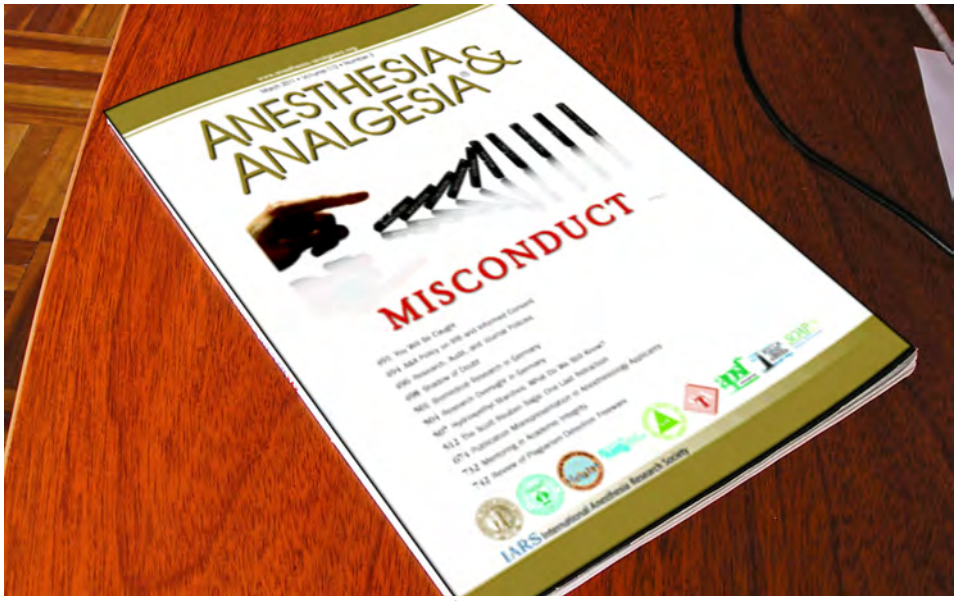
These examples are collected by *Retraction Watch*(*RW*) and we are honored to be able to present them with permission from *Retraction Watch* to our readers. *Retraction Watch* was started in 2010 by Adam Marcus and Ivan Oransky, M.D.

Retractions on the Rise

The number of retractions in scientific journals has been rising rapidly the last few years. According to June's *Harper's Index*, there were only three retractions in such journals in 2003. By 2009, that number had risen to 180 retractions per year.

What's going on? Is science getting less honest? Is it a byproduct of more papers being published?

We don't have answer to the question of scientific honesty, but our friends at *RW* write that retractions are actually rising much more quickly than the number of papers, citing reports in the *Wall Street Journal* and *Nature* based on Thomson Scientific data. There have been ten times as many retractions in the past decade as in the past, compared to just 44% more papers.



retractionwatch.files.wordpress.com and Photo Creation by RRY Publications

Fujii's Record

RW's Oransky wrote on June 29, (http://retractionwatch.wordpress.com/2012/07/05/is-science-becoming-less-honest-join-retraction-watch-in-a-live-chat-with-science/) that 2011 was a record-breaking year, with a new record for retractions by one person alone. Yoshitaka Fujii, a Japanese anesthesiologist suspected of widespread data fabrications, faked his results in at least 172 published studies.

A web site called Jiji Press writes:

> *Tokyo, June 29 (Jiji Press)–A Japanese anesthesiologist made up a total of 172 fictitious research papers between 1993 and 2011, an academic society said Friday.*
>
> *Yoshitaka Fujii, a 52-year-old former associate professor at Toho University, has denied fabricating research, according to the Japanese Society of Anesthesiologists.*
>
> *The number of papers that he allegedly faked is the largest ever for any medical researcher, both in Japan and overseas, according to sources familiar with the field.*
>
> *The society surveyed 212 articles written by Fujii that were published*

in a total of 41 Japanese and international journals. Of them, it found 172 fake research reports and three articles backed by real research. It was unable to assess 37 articles due to lack of scientific evidence.

Co-authors of Fujii's articles were not sure of the content of his research, the society said.

Fujii's retractions, according to *RW*, nearly doubles that of the current unofficial retraction record holder, German anesthesiologist, Professor Joachim Boldt, M.D., Ph.D., a leading researcher into colloids. He has been stripped of his professorship and is under criminal investigation for possible forgery of up to 90 research studies.

False Data, Fabricating Signatures

RW reports that a consortium of 23 journals led by Steven Shafer, editor of *Anesthesia & Analgesia* (*A&A*), earlier this year announced that it would retract any article of Fujii's based on falsified data. "Already, several journals have retracted articles by the researcher. The investigation concluded that Fujii's co-authors, with at least one exception, were unaware of his misconduct. Indeed, it appears he fabricated their signatures in many, if not most instances."

According to a July 2, 2012 story in *ScienceInsider*, Fujii's findings have been under a cloud since March when an analysis in the journal *Anesthesia* raised questions about his data. In April, 23 journal editors publicly asked 7 Japanese institutions named in the papers to investigate. The anesthesiology society took on the task because "it would have been difficult for any one institution to clarify what happened," says Koji Sumikawa, an anesthesiologist at Nagasaki University who headed the investigation.

Scientific Advocacy Journalism

We don't know if science is getting less honest, but we have seen and reported on scientific journals entering the world of advocacy journalism. Such an editorial policy can only embolden researchers to push the envelope of interpreting data. ♦

company

$25 Million for Benvenue Medical

No one is sneezing at Benvenue Medical…at the recent $25 million the company has acquired, that is. This Series D windfall will be used for the continued global commercialization of its three minimally invasive products to treat degenerative disc disease (DDD) with spinal fusion and vertebral compression fractures (VCFs), as well as for additional initiatives to bring its fusion and VCF products to the U.S. market. The Series D financing was completed with existing investors DeNovo Ventures, Domain Associates, Technology Partners and Versant Ventures.

Benvenue Medical has three minimally invasive products to treat VCFs and DDD. The Kiva VCF Treatment System, commercially available in Europe, has now been used to treat more than 800 VCFs globally. Kiva is distributed by Zimmer Spine in Europe. The Blazer Vertebral Augmentation System, also used in treating VCFs, is the first clinical product in Benvenue Medical's portfolio to be commercially available in the U.S. Then there is the Luna Interbody Spacer System, meant for spinal fusion procedures; it received CE Mark approval in 2010. It is currently enrolling patients in a European post-market study, the Luna Interbody System for Fusion Trial (LIFT). After the completion of enrollment in the LIFT study, the Luna Interbody Spacer System will be commercially available in the EU.

Robert Weigle, Benvenue Medical's CEO, told *OTW*, "We plan to use the funds for continued global commercialization of our three minimally invasive products for spinal fusion and vertebral compression fractures. One is to treat degenerative disc disease with spinal fusion, and two are to treat VCFs. The funds will also be used to bring the fusion and VCF products to the U.S. market. One, the Blazer which is used in VCF procedures, was launched in the U.S. earlier this year. Another, the Kiva VCF Treatment System, is undergoing a clinical trial in support of a 510(k) clearance process. The company plans to submit a 510(k) in the U.S. later this year for the third product, the Luna Interbody Spacer System."

—EH (July 2, 2012)

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LifeGift Becomes Corporate Member of AlloSource

AlloSource, a leading non-profit provider of skin, bone and soft tissue allografts for use in surgical procedures, has added LifeGift, of Houston, Texas, to its family of Corporate Members. LifeGift will have a representative on the AlloSource Board of Directors and AlloSource has opened an office near LifeGift and the hospitals the company serves. Officials report that, as a Corporate Member of AlloSource, LifeGift will receive additional resources through financial and community support.

"We are honored to welcome LifeGift as our newest agency because their reputation as a quality leader in the organ procurement community (OPO) will only elevate the work all the OPOs in AlloSource's family of Corporate Members do within their communities," said Suzanne Conrad, chair of the AlloSource Board of Directors and CEO of Iowa Donor Network, in the June 13 news release.

AlloSource's team of scientists has designed a technique to recover adult mesenchymal stem cells from cadaveric adipose tissue, creating AlloStem Cellular Bone Growth Substitute. This allograft combines adult mesenchymal stem cells with a bone matrix from the same donor, making up the biological components necessary for bone formation.

Company officials anticipate that the use of adult mesenchymal stem cells together with LifeGift's donated tissue will have the possibility of saving and enhancing up to 200 lives from one donor.

"Saving and enhancing lives is our mission and that is perfectly aligned with what drives AlloSource," said Sam Holtzman, president and CEO of LifeGift. "We feel strongly about the Texas communities we serve and made this decision after careful deliberation because we believe it is our communities that will benefit the most. We look forward to serving Texans through a long and successful relationship with AlloSource."

In partnering with AlloSource, LifeGift is expanding the distribution of the company's tissue that has served areas such as Denver, Chicago, Des Moines, St. Louis, Buffalo, San Diego and Cincinnati for nearly two decades.

AlloSource is a non-profit company that offers more than 200 types of bone, skin, soft-tissue and custom-machined allografts for use in an array of medical procedures. According to company officials, it is the world's largest processor of cellular bone growth substitutes and is the leading provider of skin allografts for the treatment of life-threatening burns. The company is accredited by the American Association of Tissue Banks and is headquartered in Centennial, Colorado.

—BY (July 2, 2012)

Courtesy of LifeGift and Allosource/ Wikimedia Commons and Nevit Dilman

Stryker to Cut New York Jobs

According to a "WARN" notice filed with the state of New York, Stryker Corporation will close two plants used by its subsidiary, Gaymar Industries, by the end of 2012.

Image by RRY Publications LLC, Source: Corporate logo.

The closings, due to begin in September, will result in cutting 107 jobs. Eleven positions will be eliminated at the company's West Seneca plant and another 96 at a facility in Orchard Park. A third office in Puerto Rico will remain open. No impact on service or delivery of operations was expected by the company.

MassDevice reported on June 25 that the Stryker previously announced the layoffs as part of the company's larger effort to save more than $100 million by reducing its worldwide workforce by about 5% in order to cut costs ahead of upcoming 2.3% medical device tax which takes effect in January 2013.

Stryker acquired Gaymar in 2010 for approximately $150 million in all-cash transaction.

Gaymar, founded in 1965, specializes in support surface and pressure ulcer management solutions as well as targeting the temperature management segment of the healthcare industry, with a portfolio of capital and disposable products in both the U.S. and international markets.

At the time of the purchase, then CEO Stephen MacMillan said Gaymar's portfolio of high-performance support surface and pressure ulcer management products target an approximately $1.8 billion worldwide market.

Before the acquisition, Stryker's Medical division and Gaymar had had a 10-year original equipment manufacturer (OEM) relationship whereby Gaymar provided Stryker with exclusive rights to sell support surface and pressure ulcer management products to acute care customers in North America. Gaymar achieved sales of approximately $77 million in 2009, of which approximately $14 million were related to the existing OEM relationship with Stryker.

—WE (July 8, 2012)

NuVasive Gets Tax Break to Expand in Memphis

NuVasive, Inc. may have to pay a new 2.3% excise tax to help pay for Obamacare staring in 2013, but the city of Memphis and Shelby County in Tennessee are going to give the company a tax break to add jobs and expand its facility in Memphis.

NuVasive is planning on adding 17 new jobs and spending $75 million to expand the company's facility in Memphis. The new jobs will bring the operation's workforce to 163, with an average salary of $49,478, not including benefits.

That's according to a recent proposal presented to the Economic Development Growth Engine board in Memphis by the company. NuVasive was seeking a 10-year tax break in return for making the investment. The board unanimously approved a graduated, 10-year plan payment-in-lieu-of-taxes (PILOT).

The development board's staff, according to the *Memphis Commercial Appeal*, calculated the project will generate $1.24 in new tax revenue for every tax dollar the local jurisdictions give up as an incentive. There will be $4.5 million in new tax revenue in Memphis and Shelby County, compared to $3.6 million in abated taxes over the 10 years.

NuVasive currently operates a 123,000-square-foot regional office and distribution facility in Memphis. The company received a PILOT in 2006 when it first opened the then 100,000-square-foot facility, employing 50 people. The San Diego-based company needed a centrally located distribution facility to serve customers. There was no word of whether the company would have undergone the expansion without the local government tax break.

Wikimedia Commons and AutisticPsycho2/NuVasive, Image Created by RRY Publications LLC

Memphis and Shelby County have been aggressive in economic development efforts in a friendly competition with Warsaw, Indiana to become the orthopedic capital of the world.

—WE (July 8, 2012)

legal

Unique Device Identifier (UDI) Is Upon Us

After years of talking about it, the FDA has officially proposed that most medical devices distributed in the U.S. be required to carry a unique device identifier, or UDI.

Under the proposal announced on July 3, manufacturers would have to identify the product's make and lot number. The codes would be accessible to the public through a database so that regulators, physicians, patients and companies could monitor safety issues with devices. Before finalizing the requirement, the FDA is giving the public four months to comment.

Bipartisan Support

Physician associations, group purchasing organizations and others working through the Advancing Patient Safety Coalition asked Congress to set defined guidelines and mandate a two-year timeline for launching the system in the latest bipartisan FDA user fee agreement.

There currently is no uniform labeling system for medical devices. In 2007, Congress voted to support the FDA's plan to create a UDI system for medical devices. In July 2011, the FDA sent its proposal to the Office of Management and Budget (OMB) for review, but OMB has yet to release a proposed rule based on the FDA's plan.

This past February, on a bipartisan basis, Senators Charles Grassley, Herb Kohl and Richard Blumenthal sent a letter urging OMB to release the delayed rule. In April, Senators Tom Harkin and Michael Enzi (an orthopedic surgeon from Wyoming) added language to the FDA user-fee bill that would require the FDA to issue a final rule by the end of 2012. A House and Senate conference committee currently is ironing out the details of the final user-fee legislation before it goes to the President. Given its wide bipartisan support, the bill is expected to be signed into law within the month.

FDA/Fictitious Medical Device UDI Example

UDI Details

In the July 3 announcement, the FDA said a UDI system has the potential to improve the quality of information in medical device adverse events reports, which will help the FDA identify product problems more quickly, better target recalls, and improve patient safety. The FDA has worked with industry, the clinical community and patient and consumer groups and conducted four pilot studies in the development of this proposed rule. The FDA is seeking comment on the proposal for 120 days.

With certain exceptions, under the proposed rule, a UDI would include:

- Device identifiers, which are a unique numeric or alphanumeric code specific to a device model; and
- Production identifiers, which include the current production information for a device.

The FDA is proposing a risk-based, phased-in approach to implementation, focusing on the highest-risk medical devices first and exempting low-risk devices from some or all of the requirements.

According to the FDA's definition, a UDI is a unique numeric or alphanumeric code that acts as a key to certain basic identifying information about a device, such as the name of the manufacturer and the type of device, and may represent certain other information about the device, such as its expiration date and batch or lot number. This information will be contained in a publicly available UDI database, and no identifying patient information will be stored in this device information center.

To minimize industry costs and expedite implementation, the FDA says the proposed rule builds upon current standards and systems already in use by some companies.

Get Your Comments In

Read the Unique Device Identifier Proposed Rule here. (Note: this document was sent to the Federal Register on 7/2/12 and will be published within the week.)

http://www.ofr.gov/OFRUpload/OFRData/2012-16621_PI.pdf

—WE (July 3, 2012)

85% of MedTech-CEOs Say FDA Hurts MedTech Values and Innovation

Minnesota is home to more than 350 medical technology companies employing more than 35,000 people, making it a heavy-weight in the industry. But, according to James Walsh, writing June 18 in the *Minneapolis Star Tribune*, the leaders of those companies have an unfavorable view of their own industry. Some would avoid investing in medtech because of delays and uncertainty about FDA approval for new, potentially life-saving devices.

Walsh quotes Jim Hickey, who has been the CEO of four medtech companies, as commenting, "It is like the government is saying to the medical device business, 'Go Away.'"

A study, commissioned by the Medtech Resource Alliance and conducted by Introworks, found that 64% of Minnesota med-tech CEOs have an unfavorable impression of their own industry, in large part "because of regulatory difficulty FDA poses." The study went on, "Respondents said the unpredictable and unresponsive FDA stifles their ability to innovate and be competitive because of its risk-aversion and uncommonly long approval process—28 to 76 months on average to clear products for market."

Leaders of 59 medical device companies in Minnesota, who were polled by Introworks, responded to the survey. Most companies were small with annual revenues of $1 million to $10 million. Twelve percent had revenues of $11 million to $25 million. No responding company had more than $500 million in annual revenues.

Walsh reported that 36% of the survey respondents said they would not invest in the medical device industry today. In fact, "more than half of those surveyed said their growth strategy is to focus on market releases outside of the United States—with 40 percent focused on Europe and 12 percent on developing countries." Eighty-five percent said the U.S. regulatory environment negatively affected their ability to create jobs, according to Walsh.

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Walsh quoted an e-mailed response to the survey from a spokeswoman for the FDA. She wrote, "This survey sheds no new light and is less informative than many prior surveys" of med-tech industry leaders. Bob Freytag, president of Introworks, said the survey results show a loss of trust in the regulatory process. He told Walsh, "Perception is reality. What people believe becomes reality in the marketplace. One person's opinion is one thing. But this is really a collective voice."

Walsh looked beyond the med-tech companies to find frustrations with the FDA. Dr. Robert Schwartz, a cardiologist at the Minneapolis Heart Institute at Abbott Northwestern Hospital, said delays in getting FDA approval for new devices mean that new technology is available outside the U.S. years before it can be used here.

A new replacement heart valve that can be implanted without open heart surgery was recently approved for the U.S. market, Schwartz said. It was made in the United States, but "we were No. 43 in the world to get that valve," he said. "No. 42 was Algeria. No. 41 was Brazil."

Schwartz said people at the FDA are well-meaning. They're also caught between the rock of consumer groups who say the FDA isn't stringent enough and the hard place of industry pressure to speed device approval.

But, wrote Walsh, "the result is that patients here are getting "the Model T" of devices because the process is so slow."

—BY (July 3, 2012)

Spinal Malpractice Award Upheld in Alabama

An Alabama neurosurgeon's $2 million jury malpractice judgment resulting from medical malpractice has been upheld by the state's Supreme Court.

Legal Newsline has reported that Zenko Hrynkiw, M.D., a neurosurgeon who performed two spinal fusion surgeries on Thomas Trammell in July 2005 to relieve pain in Trammell's lower back, and pain and numbness in his right leg and foot, was ordered to pay Trammell and his wife, Barbara, just over $2 million in compensatory damages after a trial in February 2011.

Hrynkiw filed a postjudgment motion, seeking, alternatively, a judgment as a matter of law or a new trial. That was denied, so the surgeon appealed all the way up to the state's Supreme Court. Hrynkiw argued that couple failed to present substantial evidence that any of Trammell's injuries were probably caused by his postoperative care; and that the Court erred in allowing hearsay testimony under the learned-treatise exception.

Cauda Equina Syndrome

The Court, in a May 11 ruling, found that the Trammells presented "sufficient evidence" of the surgeon's failure to adhere to the standard of care applicable to postoperative treatment of cauda equina syndrome (CES).

"As a result of this failure, [Trammell's] condition became irreversible in whole or in part," Justice Michael F. Bolin wrote for the Court, adding that "some or all" of the injuries were the proximate result of Hrynkiw's delay in performing a second surgery.

Soon after the first surgery, Trammell experienced weakness, numbness and pain in his lower extremities, along with numbness in his perineal area and urinary and fecal incontinence. The conditions are symptoms of cauda equina syndrome, or CES, a compressive neuropathy involving multiple nerve roots affecting motor, sensory, bowel, bladder and sexual function.

Hrynkiw performed a second surgery days later. The second surgery provided Trammell with no relief and he is now permanently partially disabled.

Expert Testimony Upheld

Legal Newsline also reported that the Court also held that the circuit court did not exceed its discretion in allowing another doctor, Robert Hash III, M.D., to reference medical treatises during his direct testimony.

"In the present case, Dr. Hash's testimony did not amount to mere generalized statements that the earlier an injury or disease is treated, the better the outcome for the patient," Bolin wrote in the Court's 39-page ruling.

"Instead, Dr. Hash testified that early diagnosis and earlier decompression surgery would have relieved the pressure on the cauda equina and the nerve endings that had been compressed."

Legal Newsline.com

—WE (July 8, 2012)

Biomet Sales in "Terrorist States" Scrutinized

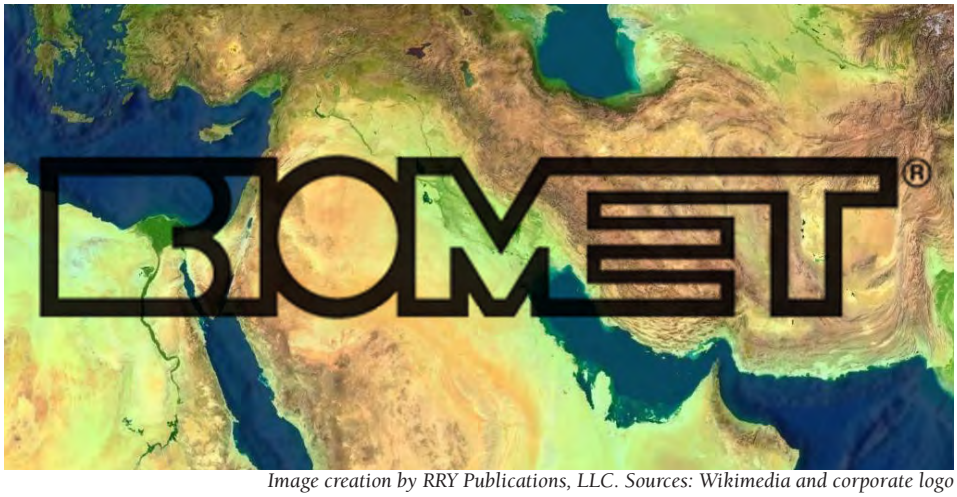

Image creation by RRY Publications, LLC. Sources: Wikimedia and corporate logo

Was Biomet, Inc. doing business within terrorist states?

That's the question the Securities and Exchange Commission's (SEC) Office of Global Security Risk asked in a letter dated August 12, 2011 inquiring about the company doing business in Iran and Syria.

The staff at the SEC had noticed a job posting on the IranTalent.com's website for a company in Tehran, Iran, which claimed to represent products made by Biomet. The staff also noticed that Biomet listed Iran and Syria as countries covered by the company's Middle East region on its website in 2010, but did not disclose in the company's 2011 10-K. Iran and Syria are listed by the U.S. government as state sponsors of terrorism and subject to economic sanctions.

The SEC asked the company to describe the nature and extent of Biomet's contacts with Iran and Syria, including a description of any services or products provided to those countries.

Biomet responded and on May 23, 2012, the SEC wrote the company to say the agency had completed its review of the matter.

Biomet said its products are sold to, and then marketed and resold by, independent third-party distributors.

"All sales of Company products made to customers in those territories, including...the government of Iran or Syria, are through independent third-party distributors. To our knowledge, neither the Company nor any of its distributors has entered into arrangements with or sold products to persons included on the Specially Designated Nationals List administered by the U.S. Office of Foreign Asset Control. The Company does not maintain any direct sales activity or operations, nor does it employ any persons, in Iran or Syria. The Company's non-U.S. subsidiaries do, however, have certain limited, non-sales related contacts with customers in Syria."

The company told the SEC that a distributor broke an agreement with sales of dental products to Iran. Total sales to the distributor of dental products that were determined to have been resold to Iran, were $434,205, $540,749 and $379,967 for fiscal years ended May 31, 2009, 2010 and 2011, respectively.

"Product sales to these distributors were and currently are conducted through 1 or more non-U.S. subsidiaries of the company and products are shipped from manufacturing facilities outside the United States," Biomet said. "All products sold are of European, not U.S., origin, and to the extent that any of them has U.S. content, the U.S. content amounts to less than 10%."

"Therefore, the Company believes neither the sale nor the export of products requires a U.S. export license. From time to time and on an infrequent basis, non-U.S. employees of the Company's non-U.S. subsidiaries have had and are expected to continue to have contact with Syrian customers, which may include employees of public (government-owned) hospitals, regarding training in the proper use of Company products. The Company has no commercial contacts with Syrian customers."

"Material Investment Risk"

Citing various institutional investors that have proposed divestment initiatives regarding investments in companies that do business with terrorist states, the SEC said it was concerned whether those contacts constitute a "material investment risk" for security holders. The agency also wanted the company to address materiality in terms of qualitative factors that a reasonable investor would deem important in making an investment decision, including the potential impact of corporate activities upon a company's reputation and share value.

The SEC said it has completed its review, but the episode should remind all device companies of the complexities of selling products outside the U.S.

—WE (July 8, 2012)

biologics

Conditioning Sessions Hazard for Athletes

It may not be the heat of the game that imperils athletes, but, instead, the conditioning workouts they take part in before they play. Twenty-one college football players have collapsed and died while participating in conditioning workouts since 2000. Conditioning sessions typically include running sprints, lifting weights, and various kinds of endurance exercises. These sessions are often poorly regulated or supervised. As athletic trainer Douglas Casa said, "A lot of them are not focused on health and safety issues."

The most common causes of the 21 NCAA deaths were heat stroke, heart conditions and a genetic trait related to sickle cell anemia that affected 10 of the athletes who died. The pushing too hard of athletes who have the trait can disrupt the blood's ability to transport oxygen to muscles. Casa said about 10% of black athletes carry the trait while a smaller number of whites and Hispanics have it as well.

The NCAA in 2010 began requiring blood tests for sickle cell anemia in Division I athletes after Rice University football player Dale Lloyd, II died during a conditioning workout in 2006. The requirement for Division II athletes took effect this year.

The football conditioning deaths "generally occurred with excessive exercise under the direction of a coach, often in extreme conditions, and in some cases with staff inadequately prepared to deal with the emergency in a timely or appropriate fashion," said Dr. Jolie Holschen, an emergency medicine and sports medicine specialist and co-author of the new guidelines.

As reported on June 27 by Lindsey Tanner, of the *Seattle Times*, the new recommendations stress that conditioning workouts should be phased in rather than start at maximum intensity. Exercise should not be used as punishment. Conditioning coaches should be trained in:

- health and safety issues
- certified in first aid, resuscitation and heart defibrillation
- know which athletes have sickle cell trait
- know how to recognize signs and treat exercise-related complications from the condition.

And a knowledgeable professional should be present during all conditioning sessions.

—BY (July 1, 2012)

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trauma

Indiana Rules on Concussion Prevention

This week Indiana joins 38 other states in passing a law aimed at making sure youths do not return to play after suffering a concussion. The law requires schools to remove student-athletes suspected of sustaining a concussion from play or practice immediately and not allow them to return until they have written clearance from a licensed health care provider trained in the evaluation and management of concussions.

The intent is to remove the pressure on athletes to return to play before they are fully healed, said Dr. Joseph O'Neil, a neurodevelopment pediatrician in Indianapolis. "The last person to ask is the athlete, because he is going to want to get back in no matter how bad he feels. This will educate athletes, parents, coaches, teachers, school officials, athletic directors and athletic trainers about what concussions are and their risks," said O'Neil in the June 29 news release.

Senator Travis Holdman, one of the law's authors, said it was modeled after a Washington state law that applies to all youth sports. That law is named after teenager Zackery Lystedt, who suffered a debilitating brain injury in 2006 when he returned to a football game shortly after suffering a concussion.

The NFL supports the new Indiana law and others like it. The Indiana law covers only high school sports because there is no governing body there for middle school sports or youth sports to oversee its implementation.

—BY (July 5, 2012)

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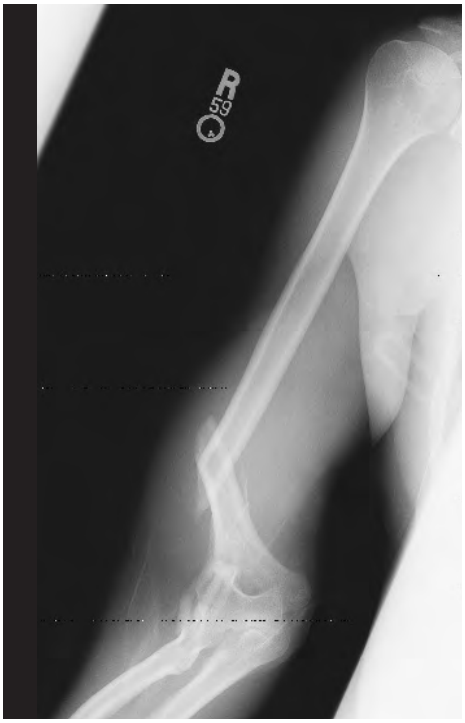
extremities

Osteoporosis in Young Adults

While we often don't think of this, osteoporosis can affect younger adults between 20 and 50 years of age. However, the diagnosis and management of osteoporosis in young adults is complicated by special challenges, including a complex pathophysiology and the related fact that there is no clear definition of osteoporosis, or of intervention thresholds, in this age group.

An International Osteoporosis Foundation (IOF) scientific working group has now published a review which outlines the pathophysiology, diagnosis and management of osteoporosis in young adults, providing a clear screening strategy that includes the use of clinical and laboratory exams.



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In the June 19, 2012 news release Dr. Serge Ferrari of the University of Geneva and chair of the IOF Working Group on Osteoporosis Pathophysiology, explained the diagnostic challenge faced by clinicians, "Low bone mass in this age group may not necessarily represent a pathological condition, but result instead from low peak bone mass in relation to body size, late puberty, or genetic and environmental background."

On the other hand, there are young adults who may truly have osteoporosis

with bone fragility at a young age. This may result from altered bone modeling and/or remodelling during growth or later due to a chronic disorder or a genetic or idiopathic condition.

A truly low bone mineral density (BMD) and/or unusual fractures (such as low-trauma, multiple and vertebral) should prompt investigation for secondary causes of osteoporosis, say the experts. Bisphosphonates may improve BMD in young subjects with osteoporosis due to various disorders, however the evidence is scarce so far and there are no data on their anti-fracture efficacy. In any case, the indications and duration of anti-resorptive treatment in the young should be as restrictive as possible, particularly in the absence of secondary causes, multiple and/or fragility (vertebral) fractures, and high bone turnover accompanied by documented bone loss.

Asked about the challenges of coming up with these guidelines, Dr. Ferrari told *OTW*, "One was whether to use a Z-score (as suggested by ISCD [International Society for Clinical Densitometry] and derived from pediatrics standards) or a T-score, as used in postmenopausal women (our choice). Deciding whom should be treated was challenging…there is so little evidence in that age range, particularly in osteoporosis without secondary causes. Lastly, we had to decide when/how to use bone turnover markers. Here again there is so little evidence of their use in predicting fractures at that age."

—EH (July 3, 2012)

Health Insurers Prefer STAR Ankle Implant

The Tufts Health Plan, an insurance company covering approximately 936,000 members in Massachusetts and Rhode Island, has become the first in the nation to provide reimbursement for 'on-label' implantation of total ankle replacement (TAR) prostheses.

That is according to a release by Small Bone Innovations, Inc. (SBi), the manufacturer of the total ankle replacement system approved for uncemented use through the FDA's premarket approval (PMA) process. All other total ankle replacement systems available in the U.S. have FDA 510(k) marketing clearance and must be implanted using bone cement, say Small Bone Innovations officials. Their STAR ankle, they say, is the only implant to have this PMA approval.

Tufts' current official policy document states, "the (total ankle replacement) procedure is becoming the treatment of choice for patients, replacing the conventional use of arthrodesis, meaning fusion of the bones. The relief of pain and restoration of range of motion is the key feature in favor of ankle replacement with respect to arthrodesis."

The policy document goes on to stipulate that any other ankle replacement device not approved by the U.S. Food and Drug Administration (FDA), or implanted in a manner not approved by the FDA, will not be covered by Tufts.

In the PMA process, the STAR ankle's safety and effectiveness was compared with ankle fusion in a prospective FDA-regulated, multi-center, multi-year, concurrently controlled, Investigational Device Exemption (IDE) study. The IDE study results, published in 2009, demonstrated STAR to be superior in efficacy and comparable in safety to fusion.

The IDE and other subsequent studies show that the STAR ankle has better pain relief, greater clinical success, less blood loss and a shorter operating time than fusion.

Courtesy of Small Bone Innovations, Inc.

Anthony G. Viscogliosi, SBi's Founder and Executive Chairman, said: "The policies governing certain private health insurance plans and the guidelines used by state Workers Compensation Insurance programs favor exclusive use of PMA-approved ankle replacements, thereby reducing the potential for 'off-label' approaches to implantation. This explains why the STAR ankle has quickly become the first choice among surgeons in appropriately diagnosed patients suffering from painful ankle osteoarthritis and rheumatoid arthritis."

Roger A. Mann, M.D., co-lead investigator in the IDE study and co-author of a recent long-term study of STAR recipients, said: "I believe that the reason insurers are moving towards exclusively reimbursing PMA-approved total ankles is because of STAR's superior effectiveness when compared to fusion—along with most surgeons' preference for using the prosthesis without bone cement. Recent research documents 91% prosthesis survival at 9.1 years follow-up and 92% patient satisfaction—demonstrating STAR's long-term durability and improvement in ankle function."

The STAR ankle is now available to 100% of privately insured health plan members in the U.S. and all eligible individuals covered by governmental insurance programs such as Medicare, Medicaid and TRICARE. Most individuals covered by state workers' compensation programs also have access to STAR, according to the June 28 press release.

—BY (July 1, 2012)

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