VOLUME 5, ISSUE 33 | OCTOBER 27, 2009

Orthopedics This Week

week in review

the picture of success

breaking news

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2009 Orthopedics This Week Spine technology Awards

Reserve your seats now for the gala banquet!

November 9, 2009 • The Palace Hotel • San Francisco

All of the spine technology submissions have been received, and seats for the Spine Technology Awards and Gala Banquet are going fast.

These awards are the first of their kind and are designed to honor the best spine products, engineering teams and inventors of 2009. Don't miss this unique and important night when 100 attending spine surgeons will vote on entries in eight categories:

- Device Technologies for Cervical Care
- Lumbar Care
- Motion Preservation of the Spine
- Minimally Invasive Care
- Biomaterials
- Diagnostics and Imaging
- Pain Management
- Regenerative Technologies

Each company or individual that submits products for evaluation will be recognized by *Orthopedics This Week* at the podium during the awards ceremony.

The 24 finalists and the first place, second place and third place **awards in each category will be determined by real-time surgeon votes at the November 9 event.** The engineers/inventors for the top three products in each of the eight categories will be invited to the podium to describe their invention. The top three products in each category will receive crystal awards at the ceremony.

Reserve your seats today—the number of spots remaining is extremely limited!

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Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: October has historically been the worst month of the year for equities. This year, however, orthopedic stocks skated through in pretty good shape. New risks, however, are on the horizon as health care morphs into something entirely different. Profit margins, in particular, are likely to come under pressure.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Zimmer	20.90%	3.56%	ZMH repeats as #1 and beats admittedly low analyst estimates in Q3. Fifth lowest valuation in the industry. Still a blue light special.
2	3	Orthofix	7.65	7.89	#2 on the power rankings this week. Q3 results due on Thursday. The market is saying that OFIX will also beat analysts' expectations.
3	2	Stryker	23.28	4.59	For Q3 ortho sales + 5.5%. Earnings were down compared to 2008. Not a growth stock anymore, but a value stock.
4	7	Exactech	12.87	5.21	New buyers coming into EXAC in advance of Q3 report. Consensus EPS estimate is $0.20 vs. $0.16.
5	4	Smith & Nephew	20.95	-2.95	SNN has fewer analysts covering it than Exactech. SNN is also 23x larger. Go figure.
6	5	Medtronic	31.37	-0.76	With a P/E of just 12x earnings, MDT is in value purgatory. Yet (!) earnings growth may be the best of the big companies.
7	9	CONMED	8.28	10.52	Who is buying this stock? Up almost 11% in 30 days. Sales, while down YOY, were up sequentially. Earnings were ugly, but…
8	10	Alphatec	-8.51	0.63	Could ATEC break even this quarter? Sales, say analysts, will be up 27%. $120 million run rate. New analyst coverage.
9	8	Integra LifeSciences	12.32	-10.27	The Rodney Dangerfield of orthopedics. Lowest overall valuation for an end-product supplier in orthopedics.
10	6	ArthroCare	16.87	-4.53	The first down month since 2008. Could it be that investors finally decided that they needed financial statements?

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	I Flow Corp	IFLO	$12.61	$308	19.0%
2	CONMED	CNMD	$22.37	$651	10.5%
3	Orthofix	OFIX	$32.15	$552	7.9%
4	Exactech	EXAC	$16.55	$212	5.2%
5	Stryker	SYK	$48.03	$19,100	4.6%
6	Zimmer Holdings	ZMH	$54.71	$11,720	3.6%
7	Osteotech	OSTE	$4.50	$81	3.2%
8	Mako Surgical	MAKO	$9.04	$227	2.0%
9	Alphatec Holdings	ATEC	$4.80	$251	0.6%
10	Capstone Therapeutics	CAPS	$0.80	$33	0.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$0.53	$5	-73.2%
2	RTI Biologics Inc	RTIX	$3.62	$197	-15.8%
3	Orthovita	VITA	$3.96	$302	-14.1%
4	Kensey Nash	KNSY	$24.20	$269	-13.6%
5	Symmetry Medical	SMA	$9.56	$342	-13.1%
6	CryoLife	CRY	$7.22	$205	-11.2%
7	TranS1	TSON	$4.44	$92	-11.0%
8	Integra LifeSciences	IART	$30.76	$875	-10.3%
9	TiGenix	TIG.BR	$6.07	$149	-9.3%
10	ArthroCare	ARTC	$19.40	$520	-4.5%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$9.56	$342	8.72
2	ArthroCare	ARTC	$19.40	$520	11.47
3	Medtronic	MDT	$36.37	$40,250	12.09
4	Johnson & Johnson	JNJ	$60.54	$166,840	13.29
5	***Average***			***$10,292***	***13.82***

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$12.61	$308	121.03
2	Smith & Nephew	SNN	$44.36	$7,830	77.59
3	RTI Biologics Inc	RTIX	$3.62	$197	62.47
4	Synthes	SYST.VX	$121.42	$14,409	37.75
5	NuVasive	NUVA	$39.59	$1,490	36.24

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$19.40	$520	0.46
2	Symmetry Medical	SMA	$9.56	$342	0.82
3	CryoLife	CRY	$7.22	$205	0.91
4	Exactech	EXAC	$16.55	$212	1.00
5	Integra LifeSciences	IART	$30.76	$875	1.03

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$39.59	$1,490	3.49
2	RTI Biologics Inc	RTIX	$3.62	$197	1.85
3	Johnson & Johnson	JNJ	$60.54	$166,840	1.72
4	CONMED	CNMD	$22.37	$651	1.65
5	***Average***			***$10,292***	***1.59***

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$9.56	$342	0.85
2	Osteotech	OSTE	$4.50	$81	0.89
3	CONMED	CNMD	$22.37	$651	0.99
4	Orthofix	OFIX	$32.15	$552	1.07
5	Exactech	EXAC	$16.55	$212	1.29

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.07	$149	208.69
2	Mako Surgical	MAKO	$9.04	$227	11.37
3	Synthes	SYST.VX	$121.42	$14,409	8.81
4	NuVasive	NUVA	$39.59	$1,490	4.38
5	Regen Biologics	RGBO.OB	$0.53	$5	3.45

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Menaflex's FDA Horror Story

By Walter Eisner

Imagine that you just went through one of the most extensive and grueling FDA reviews ever. The FDA, after massive internal infighting, finally clears your device through the agency's 510(k) process and you are allowed to market your device.

But not so fast.

Out of nowhere, the FDA says wait a minute, we want a "do over" because we screwed up. And you find yourself accused on the pages of *The Wall Street Journal* and *The New York Times* of trying to unduly inf uence the FDA through political payoffs.

Welcome to the story of ReGen Biologics and its Menaf ex surgical knee implant. Welcome to the FDA of the 21st Century.

A Car Crash

ReGen's CEO, Gerald Bisbee, PhD, told *Orthopedics This Week* that he feels like he watched a slow motion car crash and his company got caught in the middle.

ReGen came puttering along as a broken FDA careened through an intersection at the same time Congress was pressuring the agency over a 510(k) program that some said put unsafe products into the marketplace. ReGen became collateral damage from a broken and dysfunctional FDA that crashed from internal infighting between factions of whistleblowing scientists and besieged managers at odds over the agency's review and approval processes.

A Broken 510(k) Process

Who says the 510(k) process is broken? The FDA does.

In a report issued in October, the agency's new leaders say the FDA failed to follow its own procedures, processes and practices as it considered

ReGen's request for clearance of its Menaflex device. In fact, the agency says its 510(k) process is so broken it's paying the Institute of Medicine $1.3 million to review the whole program.

ReGen knew the clearance process was broken long before new FDA leaders came along after last fall's election. When ReGen went to its congressional delegation and asked for assistance to ensure that the agency would treat the company fairly, the company was accused of trying to buy political influence. When you think a government agency is broken and believe you are being treated unfairly, your only recourse is to go to your elected officials.

This is a story that should make any medical device company which has had its device cleared in the last few years by the FDA go weak in the knees. Who will be next and how will the FDA decide who needs a "do-over"?

ReGen's Menaflex

That question was partially answered a few weeks after the ReGen report when the FDA announced that 16 spine companies, with cleared spinal stabilization devices, will now have to submit new postmarket studies.

Who is next?

This story is much bigger than ReGen Biologics and its Menaf ex device. This story goes to the heart of the failure of the FDA's 510(k) program to serve as a predictable, transparent and rational process that protects the public and works with industry to get innovative products to market.

In this two-part series, ReGen's Chairman and CEO, Gerald Bisbee, PhD, and John Dichiara, the company's regulatory, quality and clinical senior vice president, tell their side of the story and what their experience means for other device makers.

The Device

ReGen's Menaf ex has been in use in Europe for seven years and has been implanted in more than 2,500 patients. The FDA cleared the device after a tumultuous FDA process and a meeting of the agency's orthopedic panel.

The device is used in patients who have had an injury of the medial meniscus requiring the removal of part of the meniscus. It provides a resorbable scaffold that is replaced by the patient's own tissue that then fills in the defect and reinforces the damaged meniscus.

A multicenter clinical trial started at the end of 1996 and was one of the largest controlled, randomized clinical studies done on an arthroscopic knee procedure.

The company submitted the first module of a Modular PMA in 2004. However, after the FDA cleared other surgical meshes, the company filed a 510(k) submission for the device in December 2005, and the device was ultimately cleared on December 18, 2008.

FDA Report: "Predicate Creep"

Shortly after clearance of the device, the Obama administration installed new leaders at the agency who promised to address the long-standing feud over inconsistent and confusing standards for its 510(k) program. Years of "predicate creep" had created confusion about the definition of predicate devices.

In fulfilling its promise to review the 510(k) program and after conducting an internal investigation of the clearance of Menaf ex, the FDA issued a report in September 2009 entitled:

"REVIEW OF THE REGEN MENAFLEX: DEPARTURES FROM PROCESSES, PROCEDURES, AND PRACTICES LEAVE THE BASIS FOR A REVIEW DECISION IN QUESTION"

The report found that over the 17-year review history of the Menaf ex, multiple departures from processes, procedures, and practices occurred.

The report noted the agency's "failure to respond appropriately to external pressure on decision-makers; the exclusion of individuals, if not viewpoints, from parts of the scientific debate; and the excessive reliance on advisory panel deliberations in reaching the final decision to clear the CS [Menaf ex] device for marketing."

The report concluded that a "focused scientific reevaluation of the decision to clear the device is warranted and that several aspects of the 510(k) review appear to have contributed to confusion and dissent during the review of the device." Finally, it recommends an independent review of the 510(k) program at CDRH (Center for Devices and Radiological Health).

External Pressures

Those external pressures came from ReGen's congressional delegation, and news stories quickly labeled ReGen as a company buying political inf uence. Said ReGen's John Dichiara,

> *"The press story sounds very good. You pay politicians…you got them to put pressure on FDA… you picked the panel…you did this and you did that, and it all sounds like a giant conspiracy. That is the complete opposite of the reality, but the reality doesn't make as good a media story."*

Did ReGen exercise improper inf uence over the FDA? Did the company "buy" its Menaf ex FDA clearance through political contributions? Did a Republican-controlled FDA cave in to Democratic congressmen from ReGen's home state, New Jersey?

According to Dichiara, "What really happened was that as with any 510(k) that would be given to the FDA, it is not unusual to hire advisers and regulatory lawyers. From the beginning we had advisers who worked with the company on regulatory matters."

Dichiara told *OTW* that after 18 months of being under regulatory review, the company received a nonsubstantially equivalent decision (NSE) based on an illegal standard that was issued by the ODE (Office of Device Evaluation) Director. "We tried to resolve this matter internally within CDRH and considered other legal options but ultimately from a timing and cost basis it appeared to be in ReGen's best interest to resolve this matter within FDA."

Gerald Bisbee said that since the company had exhausted all routes possible within CDRH to resolve the matter it needed to try to elevate this matter to the Commissioner's Office to get a fair review based on the appropriate regulatory standard.

"As a small company, we of course did not have a Government Affairs person, so our advisors suggested that hiring a lobbyist would be useful in order to move forward

with bringing this matter to the attention of some of our New Jersey legislators," said Bisbee.

The congressional delegation sent a letter to former Commissioner von Eschenbach that was vetted through the Senate Ethics Committee. Bisbee said this was all very transparent and the letter asked if the commissioner could take a look at the situation. "At no time did the letter or any other approach by any of these legislators, ever ask for the commissioner or the FDA to clear the product. What they were asking for was that this product receives the same sort of review applying the appropriate legal review standard as any other products, of a similar nature, had received."

FDA Applies Wrong Review Standard

In the letter to the commissioner the lawmakers stated that the company had serious concerns about CDRH's process and practices applied to the review of its 510(k) submission.

Specifically, the letter noted:

"ReGen believes that the product should have been reviewed according to the standards applicable to other surgical meshes that the FDA found substantially equivalent to legally marketed devices and not what appears to be another standard. The company believes the differences in the review process resulted in unfair denial of its 510(k) submission. Based on their concerns, we would greatly appreciate your review of ReGen's current submission. As you consider this case if there is an opportunity to meet and discuss this situation we would greatly appreciate it. A fair and equitable process is something we all agree is of utmost importance."

At the heart of ReGen's complaint was that FDA reviewers were comparing the company's device to a procedure and not a predicate device.

> *The FDA's own report states that the "OCC (Office of Chief Counsel) advised that review of the 510(k) involves a comparison of a device to a predicate rather than to a standard of care and that there was no legal foundation for requiring a company to demonstrate clinical benefit in the 510(k)."*

"This interpretation supported ReGen's longstanding argument that the Center was holding the CS device to the wrong review standard," said Dichiara.

Bisbee added, "In essence they admitted that the information that we provided the legislators was correct information and I think that the important point is that the legislators pointed out a problem that ultimately the FDA remedied by providing clearance of the product after the [orthopedic] panel meeting. Importantly, this report is the first time in almost four years of dealing with the FDA that they have actually admitted that they were applying the wrong standard."

Bisbee said the report admits that the whole premise for turning this product down was wrong. "But then, [the FDA] tries to blame it on the company, because the company was too aggressive, or the legislators were too aggressive."

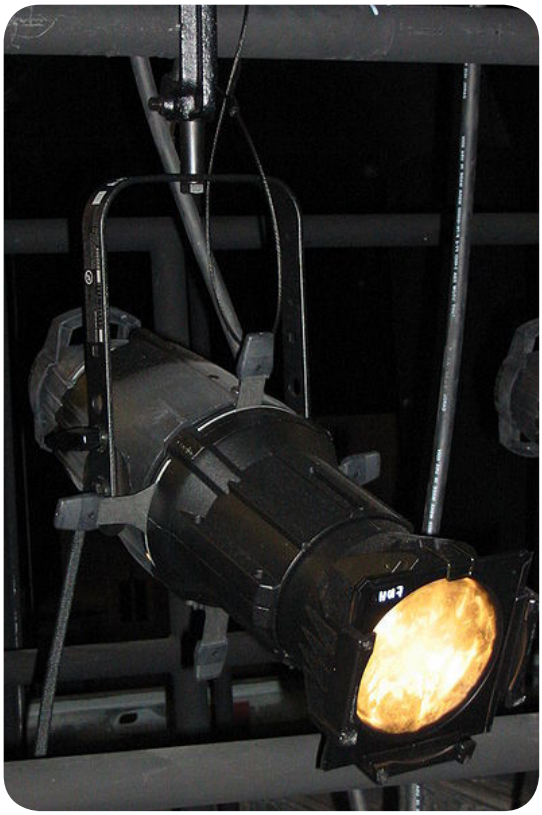
"So, basically it's just a head scratcher that they can say we used the wrong standard but we're going to, you know, re-review the product which basically is the outcome of this report," Bisbee continued.

> *"Yet in their own report they acknowledge the presence of widespread internal disagreement and confusion about the legal standards for 510(k) review, so they clearly are indicating that the process was not well understood in the first place," added Dichiara.*

The FDA report admitted confusion by reviewers about the 510(k) standard and that the agency had applied a standard to the Menaf ex that was not consistent with the FDA's regulations.

Under The Spotlight

Bisbee and Dichiara are amazed at the implication that somehow the



aggressiveness of the company caused all of these things to happen.

"You have to remember that our review took place in an environment that was pervasive with the so-called whistleblowers and allegations against management of applying pressure on the staff to ignore scientific data. Given what we found out about what was going on in the background, it's clear that there was an incredible amount of scrutiny within the FDA during this decision-making process.

"There is no way that Dr. Schultz [former head of CDRH] could have made this decision in a vacuum and with no input from the Office of Chief Counsel. From the time of our meeting with the Commissioner, the person who was tasked to follow through and make sure that we did the right thing and that FDA reviewers applied the appropriate standard was the person in charge of the Office of Integrity and Accountability," said Dichiara

Who Is Next?

A final warning from Dichiara:

> *"If FDA can re-review the CS product, how do they justify not questioning all of their other product reviews where they may or may not have applied the right regulatory standard?*

"It seems that we were in the perfect storm. We were caught in the middle of a battle between review staff and management about applying scientific principles and it seems that the review staff applied scientific principles without regard to the appropriate regulatory standard. There was also pressure from the Hill on the 510(k) process and questions about whether FDA is doing a good job in regulating medical devices.

"There was also pressure from consumer groups like Public Citizen. All of these things were in the background while ReGen's 510(k) review was taking place. Originally, the whistleblowers didn't include ReGen in their arguments and then once we became headline news with *The Wall Street Journal*, we became part of this debate."

The ReGen experience in this time of FDA uncertainty gives cause for all device makers to wonder who could be next to have a device re-reviewed.

In part two of this series, *OTW* looks inside the FDA report on the Menaf ex clearance to see how the agency plans to fix the deep-rooted problems identified in the 510(k) program. We'll also see how this car crash has impacted ReGen Biologics as it tries to convince surgeons to implant the device into their patients and keep investors funding the company.

Academic Contracts: Proceed With Confidence

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

Horemans, Jan Josef I. - The Marriage Contract

Of all the qualities typically associated with surgeons, trepidation isn't one of them. However, a seemingly generous offer at a prestigious institution can often cause a surgeon's apprehensive gene to emerge.

Steve Harris, an attorney with McDonald Hopkins LLC in Chicago, explains, "I have had numerous physician clients who tell me, 'Just look over this contract. It should be fine. I mean it *is* from one of the most well regarded institutions in the country.' At that point I suspect that they are afraid to rock the boat."

But rocking the boat doesn't mean you have to sink it…just make sure that the contract takes care of your best interests. "One of the biggest misconceptions out there is that all contracts are the same. The surgeon will often be told by the university, 'All of our doctors sign the same contract.' As you can imagine, this puts an immediate chilling effect on any substantive discussions, especially in the case of an inexperienced doctor. What this means in many instances is that if they believe all doctors are signing the same contract—one that can't be changed—then they may not have the contract reviewed until it's too late."

When the monolithic mountain of academia speaks, prospective employees tend to listen. The first thing, says Harris, is to get past the 'set in stone' story. "Let's say a university says, 'This is it. This is what everyone signs.' Stop and think about this for a moment: it is really possible that a first year, new associate doctor coming into a practice has the same contract as a division chief? That is impossible. I also say to my clients, 'If you want to preserve this fiction that all doctors sign the same contract I can help you do that. We will sign this boilerplate, but at the same time I want the university to sign an amendment or letter of agreement that addresses the contract and trumps the terms in the amendment.' I usually don't have any difficulty getting the university to sign such an agreement because doing so means they can perpetuate the aforementioned fiction."

Taking Care of Your Best Interests

Most people wouldn't confuse a lawyer with a psychiatrist, but Steve Harris leans on a skill in the latter's toolbox. "To be a good attorney you have to listen more than anything else. That is the best way to ensure that you're meeting the client's—doctor's—priorities. I listen, and then I push them a little. Many surgeons I've worked with don't even read the contract. I have them review it and then ask them what their thoughts and/or concerns about the document are, and what they think is missing. I have them reflect on the interview process and determine if there were any questions they raised that are not addressed in the contract."

And the hot buttons in most contracts? Steve Harris: "Restrictive covenants, the stipulation that if a doctor leaves for any reason, then he or she may not practice within a certain distance of his former employer/institution, can be controversial. Over the last 10 years these have increasingly crept into academic contracts. And the long term implications of these are often not clear to physicians.

"I've had doctors say to me, 'I have a great opportunity at XYZ prestigious clinic and yes, there's a restrictive covenant, but that's fine. I know that if it doesn't work out I am not staying in that town.' My job is to see what my clients can't, and to help them keep their careers as flexible as possible. The fact is that many doctors *think* they would leave if the job didn't work out, but then they meet someone special or fall in love with the location and want to stay. You have to take that into consideration ahead of time."

It's only one, perhaps two, words… how could such language seriously affect your future? Harris explains, "A doctor may tell me, 'They are offering me a two, three, or four year deal.' I say, 'I know you're thrilled, but let's look more closely at the language in the contract.' These documents often say, 'notwithstanding the terms in paragraph five' – the section which addresses the length of the contract. There it stipulates that the contract may be terminated without cause. The bottom line is that *legally* this is a 30, 60, or 90 day commitment. I ask the doctor, are you really willing to move your family across the country for what may be a 30 day period? When I tell them, 'Read paragraph 15 *in combination* with paragraph 5, they go silent."

Protecting Your Intellectual Property and Compensation

And what of the surgeon who is committed to device development? Whose bone graft/disc is it anyway? Steve Harris: "Physicians who are engaged in product development should have a clear understanding of who owns what with regard to intellectual property (IP). Let's say that either pre or post employment you began working on a new aspect of knee replacement, essentially enhancing xyz device. Before the product enters the development stage both the doctor and the university should have a clear agreement about who owns the IP.

"In negotiating such things most universities will begin from the position of, 'Anything developed here is ours.' Your job during the negotiation is to move their thinking toward the center. But one must be reasonable. If you are doing a patient study out of the university and using university resources, then the IP should be shared with the institution. Some products strike it big…if and when that happens, then the university wants to be at the table. And don't forget that you as the developer create a cache of goodwill, a la 'Dr. Smith of xyz university has developed the first…'"

With regard to compensation, Steve Harris also finds that he has to help doctors put on the brakes. "Physicians look at the base salary and productivity bonus or incentive clause and they get excited. The fly in the ointment is that these compensation arrangements are subject to the policies and procedures of the institution. The doctor is working under the fair assumption that their compensation is base salary plus discretionary bonuses based on ABC formula—then halfway through the term, the institution changes its policies and procedures and the compensation described in paragraph X of the contract goes away. This happens very frequently. Naturally, the frustrated physician is left thinking, 'I'm the most productive doctor in the department, but I'm not getting any bonuses.' To handle this issue up front I advise clients to put in the contract that he or she will make not less than X dollars in any given year."

After one's tenure has come to a close, says Harris, it is wise to ensure that one's malpractice tail is covered. "Continuing liability insurance after

you leave a university, often called tail coverage, means that anything that happened while you were employed by the university, regardless of when the claim is brought, is covered. Specifically, the coverage should be 'occurrence' coverage, rather than claims made."

Proceeding with Confidence

Now back to that boat. Asking a university's leadership for clarifications and modifications leaves many doctors feeling like they are indeed stirring up the waters. Steve Harris says, "Doctors often say to me, 'I'm concerned that if I bring up these topics then I will be viewed as an outlier or problem person.' I tell them that if they ask well thought out questions and probe areas of the contract that are fertile for discussion, then they will leave the exchange with the university in a better position. Why? Because the smarter leadership at any university will understand that someone who has thought through the issues is to be valued. The art is knowing how to raise the right issues. You certainly can't come off as being omniscient in your first year. There is a way to be somewhat deferential, yet specific with your requests. For example, it's fair game to ask the university to forecast volume of cases without specifically locking in a future incentive compensation."

So entrust the contractual details of your future academic life to an attorney, be clear about your non-negotiables, and make sure that this is one boat you want to be in.

company news

Stryker Exceeds 3Q Expectations

Saying the downward cycle has bottomed out, Stryker President and CEO Stephen MacMillan told Wall Street analysts on October 20 that nothing was keeping the company from going back on the offense after a challenging year.

Stryker's orthopedic implants reported sales increased by 5.5% for the third quarter of 2009. Its reported medical surgical equipment sales, impacted by decreased hospital capital spending, dropped by 7.7%

"We are pleased to deliver solid results in a challenging environment with all of our orthopedic implant businesses posting accelerated worldwide revenue growth, led by strong performances in the U.S." said MacMillan.

Total net sales in the July-through-September period were f at at $1.65 billion but higher than the $1.61 billion predicted by Wall Street.

On a reported basis, hips were up 4%, knees and trauma up 5% and spine roared in with a 14% gain.

MacMillan attributed the good spine news to the fact that device companies were continuing to see a lot of people in pain who want to get back to work.

There was enough good news in the quarter so that the company's stock soared up by more than 6% on October 21, a day after the quarterly conference call with analysts. The company was able to announce that one of four FDA warning letters has been resolved and a major transformation regarding quality compliance was well on its way. The resolved warning letter was for the company's biotechnology plant in Massachusetts.

The company also added $500 million in cash during the quarter and is well positioned to make an acquisition, buy back shares, or return money to shareholders. MacMillan said the company would prefer to make an acquisition, but would not "do anything stupid."

MacMillan said 2009 was one of the most challenging years the company has ever faced, but will meet its full year revenue and earnings goals.

A Quality Journey

Stryker's quality compliance journey with the FDA comes at a time when the FDA is undergoing a significant reevaluation of its review process. Other companies will be watching to see if Stryker's quality reorganization efforts will help them in a possible new FDA review environment.

Said MacMillan: "Our compliance initiative involves the collective efforts of our entire organization, and the magnitude of these actions can't be overstated. Against this back drop, the resolution of a warning letter is a key milestone for us as we continue on our journey toward achieving a world-class compliant system. But again, much work remains."

Wells Fargo senior analyst, Mike Matson, wrote in an investor note on October 21 that based on results from Biomet, DePuy, and Stryker, (49% of market), "we estimate that global [constant currency] growth rates were as follows: hips, 6%; knees, 7%; and recon cc. This is well above our Q3 2009 estimate of 3% recon growth and

company news

may indicate that the recon market has rebounded although this will depend on Q3 results from Smith & Nephew and Zimmer, both of which have been losing share recently."

—WE (October 22, 2009)

Cardo Medical Acquires Vertebron Assets

You've got to have a lot of backbone—and a large wallet—to raise your hand at an auction. Cardo Medical, makers of the Align 360 Uni-Compartmental Knee System, fits the bill. The company is announcing that it has acquired substantially all of the assets of Vertebron Inc., a spinal implant device company located in Stratford, Connecticut, for $1.3 million in cash. On April 21, 2009, Vertebron filed for Chapter 11 bankruptcy protection in the District of Connecticut; this acquisition is the result of a Chapter 11 auction process.

PSS Pedicle Screw System/Cardo Medical, Inc.

Vertebron brings to the table a history of design, development, manufacturing, and sales of spinal implant products focused on fusion technology for the lumbar and cervical spine (as well as motion preservation technologies). In addition to retaining 100% ownership of all Vertebron's implant technologies for spinal surgery, Cardo has also acquired all intellectual property rights owned by Vertebron (which includes over 20 U.S. issued patents and patent applications). Through a previous licensing agreement, Cardo Medical currently markets and distributes the PSS Pedicle Screw and SCP Cervical Pate systems. Cardo Medical will expand its distribution domestically with this acquisition.

In the news release, Dr. Andrew Brooks, Chairman and CEO of Cardo Medical, stated, "We are pleased to have been able to extend our licensing agreement into full ownership rights of this innovative and solid portfolio of spinal technologies. This acquisition will provide a great springboard to our expanding product portfolio of innovative spinal technologies; and we look forward to a smooth incorporation of these significant assets in the coming quarters."

When asked what about Vertebron's technology made Cardo so interested, Dr. Brooks told OTW, "Cardo was interested in acquiring their unique low torque pedicle screw system, which has significant clinical advantages, particularly with use in osteopenic bone. We were also attracted to the low profile, simple to use, one-step locking cervical plate. In addition to these well-accepted fusion products, Vertebron had a number of other very novel patented technologies which are at various stages of development."

Align 360® Uni-Compartmental Knee System

In the news release, Michael Kvitnitsky, President and Chief Operating Officer of Cardo Medical, stated, "As a company, Cardo Medical is now in unique position to build on multiple entries in many segments of the high growth spinal market. We are bringing the same kind of energy and expertise we devoted to the development of our homegrown products to extending our competitive advantage in innovation with the Vertebron clinically successful product portfolio."

Regarding how Cardo goes about integrating Vertebron and its assets, Dr. Brooks told *OTW,* "Cardo is a fast growing innovation company, and we had already begun using these products on a limited basis through a previous business development relationship. We have enhanced these

company news

initial product lines by releasing modifications and improvements which had already been initiated prior to the acquisition. We intend to expand the product line rapidly with various innovative PEEK products for treatment of the aging spine, as well as other novel technologies from our Cardo extensive patent portfolio."

—EH (October 21, 2009)

Eden's PERFX-2 Receives CE Mark

Eden Spine CEO Guillaume Viallaneix says that an estimated 35% of fusion cases produce adjacent disc disease symptoms within a five-year period following surgery, requiring additional follow-up surgeries. "This ratio is not acceptable clinically for the patient, and economically for the payer."

Eden Spine's Perfx-2, which Viallaneix says was specifically developed with a team of orthopedic and neurosurgeons to address this problem, has now received CE Mark approval in Europe.

The Perfx-2 is a proprietary posterior dynamic stabilization technology utilizing a complete polyaxial pedicle screw system.

The company says that biomechanically, the dynamic rod component of the system "possesses a unique proprietary dual spring mechanism allowing it to remove pain by:

- first stabilizing the diseased spinal segment
- second controlling abnormal motion and abnormal load
- third reproducing the natural kinematics of the spinal segment

PERFX-2 Dynamic Rod/Eden Spine

The system has been designed to simply adapt itself to the motion characteristics of each patient, positively impacting the neutral zone, reducing the disc and facet loading, and maintaining sagittal balance."

Eden Spine is launching this product as the FDA is requiring new post market studies for dynamic stabilization devices sold in the U.S.

Viallaneix told *OTW* that a U.S. version of the system, the Perfx-1, was submitted to the FDA for 510(k) clearance earlier this year. "It is a different pedicle screw system than the Perfx-2 and has been specifically designed as a fusion technology. We are in discussion with the FDA regarding the best and most efficient way to get the technology cleared swiftly."

The Perfx-2 is only available for international distribution and will be launched officially at the North American Spine Society meeting in San Francisco, California, in November.

—WE (October 21, 2009)

Fall From a High Horse

"A high horse is a difficult thing to ride," wrote Dan Murphy in a New Jersey's Star-Ledger editorial about former orthopedics prosecutor Chris Christie back in August. (*The*

legal & regulatory

Ledger has endorsed the independent candidate in the race.)

At the time, Christie, who had accused many orthopedic surgeons of putting their pocketbook interests ahead of their patient's interest, was riding high in the polls as a white knight fighting corruption and looked to be a lock in his campaign for governor against an unpopular Democratic incumbent.

Now the polls are even after the former prosecutor had to explain his own ethical lapses in the wake of deferred prosecution agreements that put tens of millions of dollars into the pockets of his friends and former colleagues through no-bid contracts.

In August, Christie, the Republican candidate, apologized for failing to disclose a loan to one of his former top aides while he was U.S. Attorney. That aide and former prosecutor, Michele Brown, is now accused of using her position in the U.S. Attorney's Office to help her former boss campaign for office. Brown allegedly interceding in a Freedom of Information Act (FIA) request from Christie's opponent related to Christie's travel and expense records, which included trips to speak with orthopedic medical device companies.

The New York Times reported on October 19, that Brown resigned her position in the U.S. Attorney's Office the same day the Justice Department ordered her removed as coordinator of the FIA requests about Christie because of the obvious conflict of interest. According to the Times, Brown took a job with a law firm that represented one of the device companies targeted by Christie. "Ms. Brown had led the case and, with Mr. Christie, negotiated a settlement in which the company paid a fine and avoided criminal charges," stated the article.

Christie answering reporter's question/Tony Kurdzuk/The Star-Ledger

Brown has reportedly called the allegations "outrageous and inaccurate."

When the documents requested by Christie's opponent were finally released five months later, they revealed that in August 2008, Christie's wife joined her husband and Brown, among others, for a trip to London, where Christie spoke at a meeting of compliance officers at one of the orthopedic companies under a federal monitor program. The *Times* reports that the Christies and Brown stayed two more days for another meeting. Christie paid his wife's

legal & regulatory

airfare, but the government covered the couple's and Brown's $401-per-night lodgings.

Christie and Brown also traveled to the Venetian casino hotel in Las Vegas last year, where he addressed a sales convention of another one of the hip and knee makers.

Falling off the "high horse" may not be the primary reason for the former prosecutor's drop in the polls. As Tip O'Neill famously said, "All politics are local" and property tax issues are at center stage in this campaign. But somewhere there must be some orthopedic surgeons who have always acted in the best interest of their patients, taking note of the former prosecutor's ethical problems and going back to surgery.

—WE (October 20, 2009)

CBO: Malpractice Reform Can Save Billions

Changing medical malpractice laws could save taxpayers over $50 billion over the next 10 years, according to a new report from the nonpartisan Congressional Budget Office (CBO).

In a report released on October 9, the CBO responded to a proposal from Sen. Orrin Hatch (Republican-Utah) that would cap non-economic damages on medical malpractice claims against doctors and health practitioners. The CBO said that caps would now lead physicians to alter their practice of "defensive medicine"

Das gute Schicksal/Georges de La Tour

by ordering fewer unneeded tests. Some of the proposed caps included: setting a $250,000 cap on awards for non-economic damages, imposing a one-year statute of limitations for adults, and capping punitive damages.

Not only would Medicare save around $40 billion over the next 10 years, but reductions in private health care spending would increase wages and bring the federal government an additional $13 billion in taxes over 10 years.

The estimated $40 billion in savings is, according to the *AP*, nearly 10 times greater than what the CBO had projected last year.

CBO Director Douglas Elmendorf explained the big turnaround to Hatch this way.

"Recent research has provided additional evidence that lowering the cost of medical malpractice tends to reduce the use of health care services."

Without clear evidence that physicians would actually change their approach to treatment, the CBO had previously ruled that any savings [to the taxpayer] would be limited to lower malpractice insurance premiums for doctors.

One of the lawyers lobbying organizations didn't buy it. "Medical malpractice claims have almost no effect on overall health care spending," said Anthony Tarricone, President of American Association for Justice.

If the actual malpractice claims have almost no effect on overall health

legal & regulatory

care spending, practicing defensive medicine certainly does.

—*WE (October 21, 2009)*

biologics

curasan AG Investing €1 Million (Euros)

Engineering excellence...curasan AG, makers of Cerasorb, a synthetic bone regeneration material, is ramping up its growth with a €1 million (Euro) investment in a technological program. The company, based in Germany, is aiming to significantly strengthen and expand its research, development and production capacities and to integrate modern technologies.

curasan AG will be relocating its Frankfurt production and development activities to larger premises in the immediate vicinity of the current location, something the company expects will be completed by mid-2010.

"We have a wide range of products that will be ready for market launch in the near future and this investment is therefore necessary in order to be able to provide sufficient supplies to future sales partners," explained Hans Dieter Rössler, Chairman of the Management Board, in the news release.

By the close of 2009, curasan AG plans to begin negotiations regarding the award of a sales

curasan AG Cerasorb

license for a product that helps to retrieve autologous growth factors (ATR). Additionally, its synthetically manufactured, non-resorbant bone replacement material (Osbone), will be ready for licensing this year.

The development of a paste version of Cerasorb could also be pushed forwards during 2009. The company indicates that this form is easier for physicians to handle than granulates when used in places that are difficult to access ("bone out of a syringe").

Andrea Weidner, Head of Public Relations for curasan AG, told *OTW,* "ATR (Advanced Tissue Regeneration) is a disposable which does not require any additional expensive equipment like a centrifuge. The process is designed to work by means of gravity and results in a cell-free platelet-mediator-concentrate (extracted contents of thrombocytes). Pilot batches of the Cerasorb paste version are already produced. A tolerability test in animal skin was successfully performed, and further animal tests are running."

—*EH (October 21, 2009)*

large joints

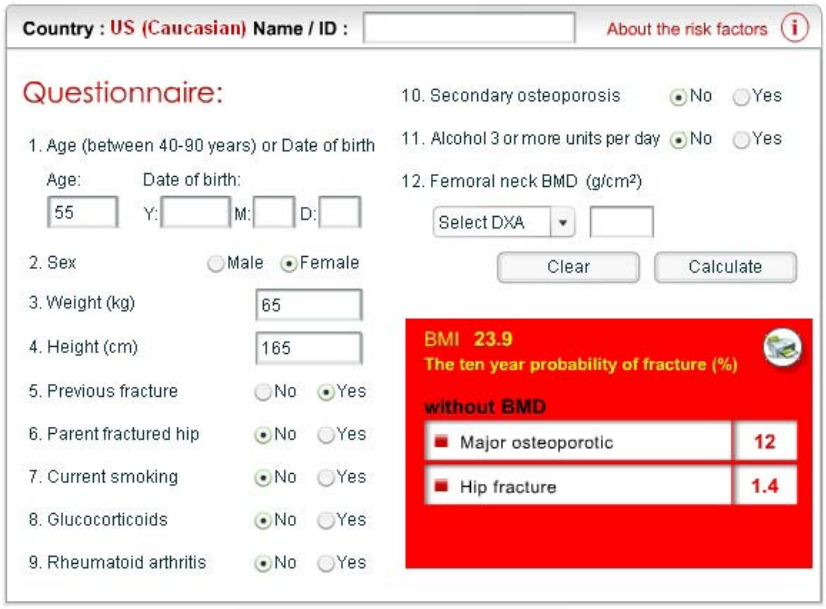
New Tool for Osteoporosis Management

While it's not a crystal ball, it may be the closest thing we've got…In honor of World Osteoporosis Day, the International Osteoporosis Foundation (IOF) has issued a new 16-page report on FRAX (World Health Organization Fracture Risk Assessment Tool). A free online tool, FRAX helps clinicians identify women and men who are at the highest risk of fragility fractures.

Along with bone mineral density, FRAX utilizes several other clinical risk factors to calculate a patient's 10-year fracture probability, thus, says the IOF making it particularly useful in regions where DXA [dual-energy x-ray absorptiometry] technology is scarce or not available.

Regarding the other risk factors and their calculation, Dr. Eugene McCloskey of the University of Sheffield and author of the IOF report, told *OTW*, "In the final FRAX model, the risk of fracture is

large joints



FRAX-US Model/International Osteoporosis Foundation

calculated in men or women from age, body mass index (BMI) computed from height and weight, and independent risk variables comprising: a prior fragility fracture, parental history of hip fracture, current tobacco smoking, ever long-term use of oral glucocorticoids, rheumatoid arthritis, other causes of secondary osteoporosis and daily alcohol consumption of three or more units daily. Femoral neck (hip) BMD [bone mineral density] can additionally be entered, preferably as a T-score. A unique attribute of FRAX is that it also examines the interaction between risk factors and mortality."

In the news release, IOF President John Kanis said, "In issuing this new easy-to-read report, IOF hopes to bring understanding of FRAX to a broad audience of health professionals so that more people at risk of debilitating fractures are identified and treated before these fractures occur."

According to the IOF, FRAX is currently receiving nearly 60,000 hits per day, with numbers increasing as it is expanded to include more country-specific calculation tools. Now in web version 3.0, it is available in six different languages and for 18 different countries. The latest country models include Argentina, Belgium, Finland, Hong Kong (China), Lebanon, and New Zealand.

FRAX is continually upgraded and enhanced for greater efficiency and ease-of-use in clinical practice. For example, following the recent link between the UK calculation tool and the UK national guidelines website, the U.S. model now also integrates an accompanying statement from the U.S.-based National Osteoporosis Foundation, based on their 2009 Clinician's Guide. Additionally, manufacturers of DXA scanners will soon integrate FRAX into their operational software, combining BMD measurements with the calculation of absolute 10-year fracture probabilities.

Dr. McCloskey stated in the news release, "I encourage clinicians to make FRAX a part of their clinical assessment of patients. With timely treatment and advice, fractures and their serious repercussions can be prevented."

As for what obstacles might prevent physicians from using FRAX, Dr. McCloskey told *OTW*, "Potential obstacles include access to the calculation tool itself as at the moment it is a largely web-based program. In the very near future, however, the FRAX calculation will

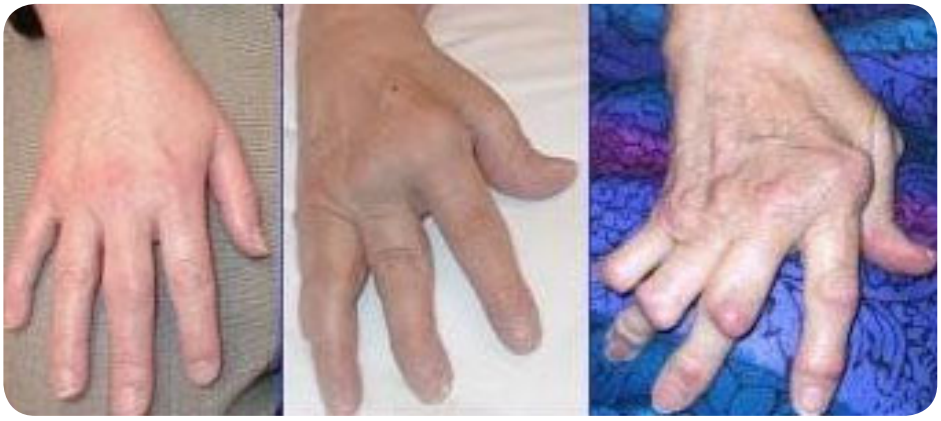
large joints

be imbedded with the DXA scanning equipment as well as being made available through a variety of hand-held devices (e.g., mobile phones, palm-held computers, dedicated calculators, etc.) as well as primary care software systems. The use of FRAX to target intervention also requires evidence that patients identified by the calculator also respond to anti-osteoporosis therapies, particularly anti-resorptive drugs. This evidence is already available from a couple of studies and others will be published shortly. The final major obstacle is education and awareness of osteoporosis itself, and in this regard FRAX provides an ideal educational platform."

—EH (October 22, 2009)

Trubion: Positive Data for RA

Nothing inflammatory here… just positive results from a double-blind, placebo-controlled study from Trubion Pharmaceuticals, Inc. The company is announcing favorable safety and efficacy data after patients were given a second course (R2) of re-treatment with 800 mg of TRU-015 for rheumatoid arthritis (RA). These are the latest results from the ongoing open-label re-treatment portion of the Phase 2b (15002) RA study of TRU-015. Pfizer Inc. and Trubion are collaborating on the development of TRU-015 for the treatment of a number of autoimmune and inflammatory diseases.



Rheumatoid Arthritis/Wikimedia Commons

The researchers in this open-label re-treatment phase of the Phase 2b study demonstrated that repeat administration with TRU-015 is generally well-tolerated and results in sustained improvement in the signs and symptoms of RA. TRU-015 is Trubion's lead small modular immunopharmaceutical (SMIP) product candidate directed against CD20+ B-cells.

The randomized 2b trial, recently presented at the 2009 American College of Rheumatology (ACR)/ Association of Rheumatology Health Professionals (AHRP) Annual Scientific Meeting, was designed to evaluate the safety, tolerability, pharmacodynamics, pharmacokinetics and clinical activity of repeat doses of TRU-015. Of the 276 original patients who began the study, 240 (204 of whom were rheumatoid-factor positive, or RF+) entered the first open-label re-treatment portion (R1) of the trial. Trubion announced the first course of re-treatment data from this study at the 2009 EULAR Annual Meeting in June 2009.

A total of 226 patients from R1 were enrolled in the second re-treatment portion (R2) of the trial. At 24 weeks after the second re-treatment course, subjects in the group that had received 800 mg of TRU-015 in the initial treatment and re-treatments R1 and R2 achieved ACR 20, 50 and 70 response rates of 72%, 39% and 21%, respectively. Results were similar to the response rates achieved in R1 (70%, 40% and 23%, respectively).

Numeric reductions in the Disease Activity Score 28 (DAS28), the Health Assessment Questionnaire (HAQ), and C-reactive protein (CRP) seen at the end of the double-blind treatment and first re-treatment periods were maintained or continued to improve during the open-label re-treatment period.

Infusions were generally well-tolerated and no patient experienced a serious adverse event on the day of infusion. Eight patients enrolled in the trial experienced serious adverse events during the second re-treatment period, which, says Trubion, is similar to observations made during the initial double-blind phase of the study.

large joints

"We have now administered more than 1,300 doses of TRU-015 over four and a half years and continue to see positive and sustained results in RA patients. This reinforces our belief that TRU-015 could represent a differentiated treatment option when compared to other offerings on the market or in development," said Peter Thompson, M.D., FACP, President, CEO and Chairman of Trubion, in the news release. "We believe a key to this differentiation should include data demonstrating both initial improvement in signs and symptoms and sustained improvement following multiple courses of re-treatment."

Regarding details on TRU-015, Jim DeNike, Senior Director of Corporate Communications at Trubion, told *OTW*, Our custom drug assembly technology permits us to build protein therapeutics to predetermined specifications. We call these protein therapeutics small modular immunopharmaceutical, or SMIP, product candidates. By selecting from our polypeptide libraries and uniquely combining polypeptides called hinge domains, effector domains and binding domains, we create customized SMIP product candidates that are intended to bind to a specified target cell and elicit specific biological activity in a targeted disease state."

He continued, "We designed TRU-015 for a desired therapeutic label surrounding B-cell depletion in multiple indications, including autoimmune and inf ammatory diseases and different types of cancer. TRU-015 binds to its target, CD20, and is engineered to promote specific biological activity designed for optimized safety and efficacy. Specifically, general systemic complement activation is thought to initiate or exacerbate symptoms in RA patients. There is evidence that CDC (complement dependent cytotoxicity) may be associated with certain side effects, particularly intravenous infusion reactions observed in currently marketed protein immunopharmaceuticals. We have designed TRU-015 for reduced CDC activity, while preserving potent ADCC (antibody-dependent cell-mediated cytotoxicity) activity and apoptotic signaling. In addition, TRU-015's smaller size may provide improved therapeutic options for patients through more rapid diffusion to disease sites. We believe TRU-015 could represent a differentiated treatment option when compared to other offerings on the market or in development and the key to this differentiation should include data demonstrating both initial improvement in signs and symptoms and sustained improvement following multiple courses of re-treatment."

—EH (October 19, 2009)

FDA Clearance for Axis-Shield/Abbott

Early diagnosis=more opportunities for a good outcome. Axis-Shield plc is helping to put patients on that track. The company is announcing that it has received FDA marketing clearance for an assay for anti-CCP (anti-cyclic citrullinated peptide antibody), used in the diagnosis of rheumatoid arthritis (RA), to run on Abbott's ARCHITECT family of automated immunoassay analyzers.

As indicated by Axis-Shield, with the advent of tests recognizing antibodies to cyclic citrullinated peptides there has been a revolution in rheumatology. The antibodies may occur in the blood long before the onset of symptoms and it is believed the anti-CCP test is superior to rheumatoid factor (RF) regarding diagnostic specificity for RA, and is often associated with potentially more severe disease course and outcome.

Not only has the European Union League Against Rheumatism added the anti-CCP test to its diagnostic criteria for early-stage RA, but recent U.S. studies have also advocated the inclusion of anti-CCP testing into the American College of Rheumatology guidelines for diagnosing RA. Abbott launched the Architect anti-CCP assay in non-U.S. markets earlier this year and it will introduce the test in the USA later this month.

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Call Heather at 260-469-4161 or email one of the data guys at www.pearldiverinc.com.

Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine Refusion	
Posterior lumbar refusion	81.38
Other Spine Procedure	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revision of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	83.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Internal Fixation	79.37

(2004-2008 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)

PearlDiver
unfathomably deep data retrieval

large joints

In the news release, Ian Gilham, Axis-Shield CEO, commented: "We are pleased to have received FDA clearance for this proprietary assay for RA on a major laboratory system. We believe this will help to address the growing demand for the anti-CCP test in the important American market and allow larger volume batch testing. Rheumatoid arthritis is a potentially debilitating disease and early disease diagnosis facilitates improved treatment options and offers substantial patient benefits.

Robert Doss, Ph.D., Divisional VP of Research & Development for Abbott Diagnostics told *OTW*: "Anti-CCP is the name given to a family of auto-antibodies directed against citrulline-containing proteins (CCP). The ARCHITECT anti-CCP assay is an automated immunoassay, including an automated sample pretreatment for the semi-quantitative determination of the IgG class of auto-antibodies specific to cyclic citrullinated peptide (CCP) in human serum or plasma, using Chemiflex patented technology.

He added, "Detection of anti-CCP antibodies is used as an aid in the diagnosis of rheumatoid arthritis (RA) and should be used in conjunction with other clinical information. Autoantibody levels represent one parameter in a multicriterion diagnostic process, encompassing both clinical and laboratory-based assessments."

—EH (October 23, 2009)

reimbursement

Senate Says No to "Doc Fix"

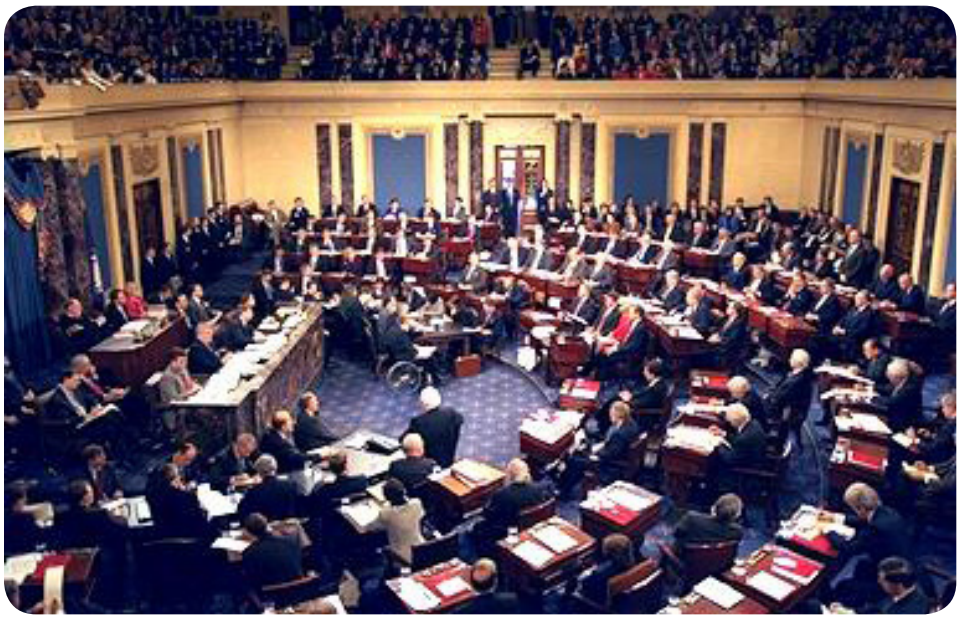
On October 21, the U.S. Senate failed in an attempt to fix a 21.5% mandated cut in physician Medicare reimbursements scheduled for January 1, 2010. A dozen Democrats and one Independent voted with all the Republicans against moving forward on the fix because the $247 billion price tag would be added to the national debt over the next ten years. It wasn't long ago that former Vice President Dick Cheney uttered the phrase that made true conservatives shudder, "deficits don't matter." These are many of the same Senators who had no problem voting for Medicare Part D, which was added to the national credit card.

The motion to move ahead to address physician reimbursement separately from the health care reform bill failed 47 to 53. Supporters of the bill to prevent the cuts needed 60 votes.

AMA Defeat

Politico.com reported that the size of the failure was surprising given how hard the American Medical Association (AMA) had lobbied for passage. "The AMA has always been seen as a major lobbying force, but today's vote calls into question its effectiveness."

Senate staffers told Politico that the "doc fix" was being considered separately from the health care bill because its inclusion would raise the total reform bill from $900 billion to $1.2 trillion. And it would have increased the deficit by $200 billion. Democrats figured that Republicans who voted against this fix would vote to include it in the health reform bill in order to run up the cost of the bill and the deficit.



The U.S. Senate/wikimedia/commons

reimbursement

The 12 Democrats and 1 Independent joining all 40 Republicans in voting against the bill were: Sens. Byron Dorgan (N.D.), Robert Byrd (W.Va.), Kent Conrad (N.D.), Joe Lieberman (ID-Conn.) Jon Tester (Mont.), Jim Webb (Va.), Mark Warner (Va.), Ron Wyden (Ore.), Herb Kohl (Wis.), Russ Feingold (Wis.) Bill Nelson (Fla.), Evan Bayh (Ind.) and Claire McCaskill (Mo.).

Docs vs. Deficit

The message for physicians from this early legislative procedural squirmish is that, for the moment, their financial needs lost out to the fear of rising deficits.

Senator Mitch McConnell, the Republican leader in the Senate, issued the following statement: "In the Senate's first vote on health care spending this year, a bipartisan majority rejected the Democrat leadership's attempt to add another quarter trillion dollars to the national credit card without any plan to pay for it. With a record deficit and a ballooning national debt, the American people are saying enough is enough. Today's vote shows that this message is finally starting to get through to Congress. Hopefully it's a sign of things to come in the health care debate ahead."

—WE (October 22, 2009)

The Picture of Success: Dr. William Grana

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

Perhaps it was divine intervention that steered William Grana away from divinity school...and saved a congregation. Yes, if he hadn't met the right role models at the right times, he could have ended up in front of a congregation instead of a class of medical students.

Dr. William Grana, the former head of orthopedics at the University of Arizona and now a professor in that department, says, "I was raised in St. Louis by my dad, a second generation Italian American, and my mom, a second generation German American. Neither of my parents was able to attend college, but my father in particular stressed the value of education. I was a good athlete and had my sights set on the University of Missouri or University of Illinois, both football schools. My homeroom teacher 'collared' me, however, and convinced me to apply to Harvard, Dartmouth, and Princeton. I applied, was accepted at all three institutions and chose to attend Harvard. The whole family drove me there."

As for a higher calling, it was a toss up between God and medicine. "In high school I was a member of a Lutheran church where there was a very dynamic minister who had been an athlete. That led me to consider attending divinity school. When I got to Harvard I met my freshman advisor, who played on the football team and was in medical school. After some reflection I decided that my temperament was not suited to life as a minister. I like things done in a certain way, and that doesn't always happen when you are leading a congregation."

Medical Training in Sports and War

So instead of going to divinity school, Dr. Grana completed medical school. But it wasn't long before he heard from another higher calling: Uncle Sam. "At that time all physicians took part in the Berry Plan, something that helped you predict when you would be on active duty. I was in the Air Force as a general medical officer (GMO), and was assigned to Tucson, Arizona. Since I was the first GMO in Tucson, they made me head of the general medicine clinic. Halfway through my first year, I got orders to go to Vietnam.

"During my time there—June '71 to May '72—I got an appreciation for working in a Third World environment with no technology. We had to use cone ether anesthesia, which involves dripping ether on paper. And no one knew how to intubate or resuscitate. During my time there an anesthesiologist came to our facility out in the boondocks and taught the staff how to intubate. Overall, my memories of the country are positive ones. I now give a talk called 'Christmas in Vietnam' in which I discuss my experiences there and the commonalities between the Vietnamese and American people. I hope to be able to return for a visit one day."

Returning to the U.S., and to his training, in 1972, Dr. Grana entered a residency program at Barnes Hospital, Washington University in St. Louis. "Those were the days in which residents undertook two years of general surgery followed by three years of orthopedics. It is unfortunate that students don't have this now as there is no question that the two years of general surgery makes one a better surgeon."

He then headed to the land of football to "do" football (and other sports). Dr. Grana: "In 1975 I joined the faculty at the University of Oklahoma, essentially because Dr. Joe Kopta, who

had been at Washington, was hired as Chair of the Oklahoma orthopedics department. He recruited me to sports medicine, in particular because during residency I had helped take care of the St. Louis Cardinals."

Like his sports medicine colleagues of the day, Dr. Grana was left to hone his skills without the benefit of structured training. "At the time there were few organized fellowships in sports medicine, and there was no accreditation or certification. A faculty member from OU suggested that I spend six months working with Donald Donahue, the past head of Orthopaedics at the University of Oklahoma and someone who had written ***the*** textbook on treating injured athletes."

"I learned one on one from Dr. Donahue, both in the office and the OR; we did an average of 70 to 80 cases per month. He had the foresight to recognize that there was something important about a new tool called arthroscopy, so he had me spend several days with a friend of his to learn the procedure. As a result, I became the first person in Oklahoma City to perform arthroscopy."

A Practice of His Own

Armed with this new skill, and with a bird's eye view of high level athletics, Dr. Grana had put himself in a good position to build his own facility. "During my time at OU I had my first experience with the U.S. Olympic Committee (USOC) when I went to work with athletes at the USOC Colorado Springs training center. Based on my time there, I decided that I wanted to create an especially organized approach to treating active people. I began to plan for a facility where athletes could come in and get their problems taken care of and have access to all aspects of patient care at one location. In 1983, in conjunction with the hospital on the university campus, we started the Oklahoma Center for Athletics. That facility merged with others in Oklahoma City after I left."

Expounding on his work with athletes, Dr. Grana says, "Working with the USOC is in a sense like dealing with any other large organization—it is bureaucratic. But when you are at a competition, it's just you and the athletes and that's always rewarding. The athletes I dealt with were very professional and understood what they were there to do. I never covered professional teams and my personal experience with them was that they were difficult to deal with and did not bring as much gratification."

As for the clinical side of things, in-game changes have brought progress. Dr. Grana: "The rules have changed with regard to blocking and tackling because there was a spate of lower extremity and head and neck injuries. There were a number of reports in the media about problems with concussions during football games; now we have concrete ways of evaluating concussions. One of the conclusions we came to was that even minor injuries can create a cumulative effect on the athlete's cognitive functioning over a period of time."

And Dr. Grana's leadership roles didn't stop there. "In 1983 I began a private practice adventure that lasted 17 years. During that time I had the largest orthopedic practice in town with 7 offices and 17 doctors. In 1999 I began to think that I had missed out on the opportunity to head a department and so began exploring several such opportunities. At the time the University of Arizona (UA) was starting a new department in orthopedics, and I was recruited to start the program. It is a complex task and not nearly completed as of yet."

Athletes shouldn't wander aimlessly around the field, and neither should the team physician. Speaking of how things have become less random in the team doctor arena, Dr. Grana notes, "Programs are much more organized now, with every aspect of training and conditioning more regimented. We know so much more than we used to about organizing game day care, setting up practice on the field, court, etc."

"Part of my experience included writing whitepapers on the roles of team doctor and what they should do and should not do with regard to things such as large event coverage, etc. You can't just walk out on the field and say, 'I'm here to care for your athletes.' Prevention, evaluation, and management of injuries are all a team effort, and you must have a plan ahead of time. I don't walk into the OR without thinking through what I am going to do—it should be the same when approaching game day."

Dr. Grana, who stepped down as head of the UA orthopedics department in 2007, continues to work in the department he built. "My biggest 'kick' now is teaching an elective for the second year students. We meet once a week for an hour and do an overview of orthopedic topics such as emergencies, compartment syndromes, infections, and pulmonary embolism."

Research and Education

Those second year students and other trainees also benefit from Dr. Grana's expertise in the research arena. "The majority of my research now is on healthcare policy. In one study we looked at the costs related to treating isolated wrist fractures and how those expenses might be modified based on changes in how people are allowed to code and bill for those conditions. We have found that if you modify the way ER docs and orthopedists bill for this—just this single isolated fracture—you can save $37 million annually. I sent this information to my state representative but have not yet received a reply. This work has been submitted to *The Journal of Bone and Joint Surgery (JBJS)*, and we are also hoping to present it at next year's AAOS meeting."

Dr. Grana, who encouraged the development of the UA orthopedic laboratory when he arrived as Chair, states, "Our lab, which is focused on the mechanical treatment of articular cartilage problems and arthritis, is now growing cells and working with bioresorbable materials that you can grow cells on and implant to treat the local surface of the joint. We can implant these in an animal model, but we are five years away from clinical trials. While we had a National Institutes of Health grant for $1.3 million, that funding has just run out. Fortunately, we have recently received $300,000 from the National Science Foundation."

Dr. Grana affects the future through research, as well as education. "I am the Editor in Chief of Orthopaedic Knowledge Online, the AAOS online education program. Eight years ago I had an opportunity to create an educational program for the members and residents that would be available all of the time. The fact that it's so comprehensive makes it very unique. And of course it's backed up by the credibility of AAOS and its history of outstanding educational programs. I hope my legacy is that I have provided leadership and vision for what this kind of educational program can be—multifaceted, and with topics like those you would see in a peer reviewed journal."

He continues, "The self study structure includes questions from the intraining exams and self assessment exams. There is a great opportunity for Continuing Medical Education, and in fact, we are now approaching 200

credits. My next task is to create a portal for all AAOS online educational programs above and beyond ours. For example, JAAOS has online materials—going forward those will be accessed through this portal. The public will also be able to use this site. I dare say it is likely the single largest repository of orthopedic information in the world."

Retirement: What's Happens Next?

As he looks toward retirement, Dr. Grana considers the generational shifts in orthopedics. "While I was part of the early move towards subspecialization, somewhere out there we must continue to have general orthopedists. If no one is willing to take ownership of a patient's problems, we are in trouble as a field. For example, I don't do back surgery but I don't turn someone away. I at least evaluate the patient and refer him or her to the appropriate caregiver."

"Now we have people who are only willing to treat one or two joints and won't even evaluate other problems. I don't think much can be done about this situation, however, because it seems to be generational. So many people are not interested in the 24/7 approach that doctors of my generation were accustomed to. This trend is happening all across medicine. Some days I wonder who is going to be there for us when we have a problem, and I wonder if it will be the same quality of care that I would have given to a patient."

Although retirement is on the horizon, Dr. Grana plans to stay active. "I will probably quit operating at the end of this year and officially retire from practice in June 2010. My plans are to continue teaching at the medical school and running Orthopaedic Knowledge Online. Some of my peers who have gone through the retirement process find it very difficult while others feel it is a great stress reliever. I will probably be one of those in the latter category because I take surgery very seriously."

One thing he can't do in retirement, however, is stay home. "My wife has mandated that once I retire I am not allowed to be home from the hours between 8am and 5pm. I don't see that being a problem, however, because in addition to my work, I exercise regularly on a treadmill and play tennis and golf. My wife and I love spending time with our children and grandchildren and having everyone over to our house in Colorado. We especially enjoy the summers when we can do lots of hiking and fishing."

Dr. William Grana…bringing order to the sports world and refining orthopedic education.

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