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Orthopedics • This Week

week in review

05 CryoLife's Takeover Attempt Gets Weird ♦ Medafor, the manufacturer of a powder hemostat, metaphorically dumped it on CEO Steven G. Anderson's head with last week's strong rejection of CryoLife's hostile takeover bid. Fully 99% of Medafor's shareholders have ignored CryoLife's appeals. Read more.

09 Being Chair: Are You Ready? ♦ Dr. Frank Kelly, Chair of the AAOS Communications Cabinet, along with Dr. William P. Cooney, Chair of the OREF Board of Trustees, discuss how to chair a committee…and how to know if you are ready.

13 Surgical Strikes over Haiti ♦ The debate over the government's medical response to Haiti and the involvement of civilian surgeons continues. Without civilian surgeons, thousands of injured might have gone untreated. How will this debate impact how surgeons join relief efforts in the future? See what we found.

the picture of success

29 Dr. Ray Baker ♦ Dr. Ray Baker, the new President of NASS—and an anesthesiologist—wants people to focus on pain. And he aims to eliminate the turf wars that have cropped up and that distract from patient care.

breaking news

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FDA OKs **Auxilium's XIAFLEX**

Stryker Releases "Personalized" Hip

New **Wrist Surgery** Available

New **Geriatric Orthopedic Journal**

For all the news that is Ortho, read on.

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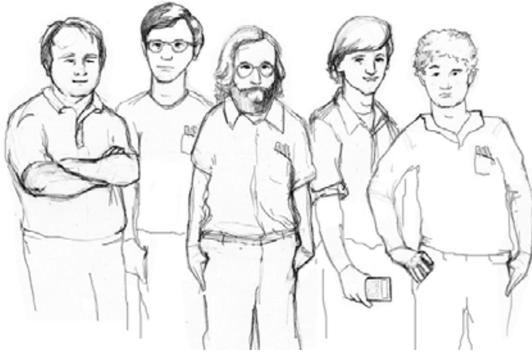

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Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar 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)

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: What a difference two weeks make. Unemployment was lower than expected. Economic consensus improved to saying that U.S. GDP will rise 3% this year. Ortho company sales and earnings reports are solid. OFIX, in particular, is showing that the last four quarters of rising cash flows are NO fluke—2nd least expensive stock in orthopedics, OFIX is clearly on a sustained fundamental rise.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Johnson & Johnson	27.10%	-1.60%	As economic news improves and as the perceived risk of healthcare reform fades, JNJ, ironically, gets less attractive.
2	2	Symmetry	11.48	-1.96	Analyst expectation for this week's report are very low—$0.05 EPS and down sales. Stock action indicates upside surprise potential.
3	6	Smith & Nephew	19.17	-2.28	Analysts are forecasting a huge quarter for SNN in March. Sales up 12% and earnings up 30%.
4	NR	Orthofix	11	7.12	Back on the Power Rankings at #4 with enough momentum to rise to the top. Cash flow is king and OFIX is making it happen.
5	5	Medtronic	31.37	-5.06	Obama's medical device excise tax proposal is an improvement for all device companies—especially MDT/JNJ.
6	4	Integra LifeSciences	15.37	-1.37	Analysts are expecting IART to report 4.6% revenue growth and $0.58 EPS. IART missed last year's 4Q estimate—this year?
7	7	Stryker	24.71	-6.67	Revenue growth rates are rising. Consensus is 9.9% YOY for March quarter. If hospital spending rebounds, then upside possible.
8	3	Zimmer	27.71	-8.81	Slower revenue growth than SYK and SNN. Operating margins down from historic levels.
9	10	CONMED	7.74	-3.04	Big report for 4Q. Earnings beat consensus by 16%. Expectations are rising as well—and that is before the hospital spending rebound.
10	NR	Exactech	12.61	-5.87	Consensus estimate for 4Q is a 10% sales growth and essentially flat earnings. Last year EXAC delivered a 26% upside surprise.

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$0.26	$3	116.7%
2	Capstone Therapeutics	CAPS	$1.09	$44	32.9%
3	Orthovita	VITA	$3.91	$299	11.7%
4	ArthroCare	ARTC	$26.62	$714	9.1%
5	Orthofix	OFIX	$34.47	$591	7.1%
6	CryoLife	CRY	$6.98	$199	1.9%
7	RTI Biologics Inc	RTIX	$3.38	$184	-0.6%
8	Integra LifeSciences	IART	$39.58	$1,130	-1.4%
9	Johnson & Johnson	JNJ	$63.81	$176,060	-1.6%
10	Symmetry Medical	SMA	$9.00	$322	-2.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$4.94	$122	-15.9%
2	Kensey Nash	KNSY	$21.42	$235	-15.7%
3	Synthes	SYST.VX	$119.51	14,183	-12.9%
4	Zimmer Holdings	ZMH	$58.10	12,200	-8.8%
5	Stryker	SYK	$53.16	$21,150	-6.7%
6	NuVasive	NUVA	$29.95	$1,140	-6.4%
7	Osteotech	OSTE	$3.59	$65	-6.0%
8	Exactech	EXAC	$17.48	$224	-5.9%
9	TranS1	TSON	$3.39	$70	-5.6%
10	Alphatec Holdings	ATEC	$5.17	$272	-5.5%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$9.00	$322	8.87
2	Kensey Nash	KNSY	$21.42	$235	12.16
3	Medtronic	MDT	$43.70	$48,270	13.72
4	Johnson & Johnson	JNJ	$63.81	$176,060	13.78
5	Zimmer Holdings	ZMH	$58.10	$12,200	14.44

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$51.33	$9,100	78.32
2	RTI Biologics Inc	RTIX	$3.38	$184	38.25
3	Synthes	SYST.VX	$119.51	$14,183	37.16
4	NuVasive	NUVA	$29.95	$1,140	27.42
5	ArthroCare	ARTC	$26.62	$714	23.42

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$6.98	$199	0.75
2	Symmetry Medical	SMA	$9.00	$322	1.15
3	Wright Medical	WMGI	$17.42	$673	1.24
4	Medtronic	MDT	$43.70	$48,270	1.25
5	Exactech	EXAC	$17.48	$224	1.27

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$22.29	$649	9.18
2	NuVasive	NUVA	$29.95	$1,140	2.37
3	Johnson & Johnson	JNJ	$63.81	176,060	1.86
4	*Average*			*$11,533*	*1.69*
5	Zimmer Holdings	ZMH	$58.10	$12,200	1.48

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.59	$65	0.64
2	Symmetry Medical	SMA	$9.00	$322	0.82
3	CONMED	CNMD	$22.29	$649	0.94
4	Orthofix	OFIX	$34.47	$591	1.10
5	RTI Biologics Inc	RTIX	$3.38	$184	1.11

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$4.94	$122	169.87
2	Mako Surgical	MAKO	$12.88	$428	16.02
3	Synthes	SYST.VX	$119.51	$14,183	8.67
4	NuVasive	NUVA	$29.95	$1,140	3.34
5	Orthovita	VITA	$3.91	$299	3.33

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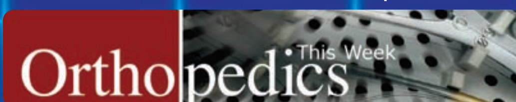

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CryoLife's Takeover Attempt Gets Weird

By Robin Young

Steven G. Anderson, President, Founder & CEO

CryoLife, which is pursuing the purchase of Medafor with all the subtly to a WWF cage match and whose spokesperson was "Golden Goose" in a 2008 stock manipulation scheme (see *OTW* February 2, 2010), appears to be marching into uncharted territory. Could CryoLife have misled Wall Street analysts?

Here is the verbatim Q&A between Gregory Brash, research analyst at Sidoti and CryoLife:

Greg Brash: "Just wanted to clarify one more on Medafor. If this deal doesn't end up going through, you should—there shouldn't be any issues with your ability to distribute the product and it should still be your option to renew when the deal ends, assuming keep hitting the minimum purchase agreements. Am I correct on that?"

CryoLife (either Steven Anderson or CFO Ashley Lee): "That's correct. Our current agreement runs through the middle of next year and assuming that we continue to meet our purchase requirements, which we have done to-date, then the agreement would renew for another three years."

Actually, Medafor twice sent to CryoLife legal notices to terminate the supply agreement. The first one was withdrawn in mid-2009 when CryoLife agreed to stop violating its terms. The second notice of intent to terminate the existing supply agreement was delivered to CryoLife in early December 2009 and took effect January 18, 2010—one month ago.

Did CryoLife fail to mention that Medafor had filed an intention to terminate the agreement? Would this qualify as material information when asked a direct question by Wall Street analysts? The news that the notice to terminate was filed is available on Medafor's website but is NOWHERE to be found on CryoLife's Web site.

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Medafor Fights Back

Approximately one week ago, Medafor sent a letter to its shareholders disclosing additional information regarding the CryoLife offer including details of the Board of Director's unanimous rejection of the CryoLife bid.

"Grossly Inadequate" was the board's answer to CryoLife's $2 per share cash and stock bid. To start with, said Medafor's board, the supply contract with CryoLife is valued between $40

million to $50 million so why accept, in effect, $40 million now? Next, sales to CryoLife account for only 20% of Medafor's sales, so selling the whole company for $2 per share seems patently ridiculous. Finally, and this is the coup-de-grace, of those sales to CryoLife, Medafor's own sales organization generated $5.1 million of CryoLife's reported $6 million in sales. In other words, Medafor's own sales force accounted for 85% of CryoLife's reported MPH product sales.

As of last week, only five of Medafor's 550 shareholders have accepted CryoLife's $2/share offer. CryoLife has sent several letters to Medafor's shareholders and this week repeated its offer on the conference call with analysts. Less than 1% of Medafor's shareholders have accepted it despite the direct solicitations and implied threats.

The five shareholders who tendered their shares to CryoLife for $2/share represent 11% of Medafor's shares outstanding. After reading Medafor's letter to CryoLife, those five shareholders may want to ask for their shares back.

A Brief History of CryoLife's Hostile Takeover Attempt

This past January 13, 2010, CryoLife CEO Steve Anderson, told Medafor's board that his company had bought 1.6 million Medafor shares, amounting to 8% of the company. Anderson also sent a letter to Medafor's board of directors offering $2 per share in cash and stock for the remaining 92%.

That unsolicited offer was the third one from CryoLife to Medafor. The first one came last November and it had no price attached to it. CryoLife, at the time, was one of Medafor's distributors for its MPH hemostat.

MPH is a micro porous polysaccharide hemostatic powder which stops bleeding in virtually any surgery. It is CE Mark approved (since 2003) and has an FDA ***pre-market approval*** (since 2006). The product works. When applied to the surgical site, it rapidly dehydrates blood and accelerates the clotting cascade. It's easy to use, doesn't promote infection and is absorbed within 24-48 hours. Other surgical hemostats can take three to eight weeks to fully break down. MPH is cheap and generates very good gross profit margins for whatever company is selling it.

Medafor said, in effect, thanks but no thanks to CryoLife's first purchase offer.

Two months after that, CryoLife tried again. This time CryoLife CEO Anderson put a price on his offer—$25 million in CryoLife stock—which trades on the New York Stock Exchange under the symbol "CRY."

Medafor's answer was, again, "No." This time Medafor CEO Gary Shope gave a reason—CryoLife's $25 million price tag for Medafor was less than the $40 million value of the supply contract. Medafor was simply not available at such an obviously low price.

But, of course, CryoLife CEO Anderson has a long and well documented record of employing brute force tactics. Two months after Medafor's second "no", Anderson sued

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Medafor in U.S. District Court for the Northern District of Georgia alleging breach of contract, fraud, negligent misrepresentations and violations of the Georgia RICO racketeering statutes.

The District Court judge granted Medafor's motion to dismiss on December 9th and in the process characterized CryoLife's lawsuit as a "shotgun pleading." Days later Medafor gave CryoLife a notice of intent to terminate the existing supply agreement by January 18, 2010.

And those events set the stage for CryoLife and its CEO Steve Anderson's current attempt to take over the 11-year-old, St. Paul, Minnesota-based Medafor.

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Medafor Keeps Growing

Medafor, which is profitable, has been growing sales at an annual compound rate of 75% per year since 2005. Medafor is a private company and does not disclose its financial performance, but suffice it to say that 99% of its shareholders (all of whom receive copies of the company's financial records) have opted to keep their shares away from CryoLife.

Going forward, Medafor has announced that it is planning to launch different versions of its flagship MPH product into the OB-GYN, orthopedic and urology markets—none of which are served by CryoLife.

CryoLife's Financial Performance

This week CryoLife announced that sales (excluding Medafor's MPH—which is sold as Hemostase by CryoLife) rose 2.1%. Sales of Medafor's MPH product through CryoLife rose 292% to $6 million and tripled CryoLife's overall growth rate from 2.1% to 6.3%.

CryoLife's largest business—BioGlue—declined in 2009. BioGlue's unit sales fell 2% and revenues before the effect of currency changes fell 4%. CryoLife's profit margins continue to come under pressure (gross profit margin fell by 204 basis points to 62% of sales).

The good news is that CryoLife generated strong cash flow in 2009—to approximately $16.6 million. That, in turn, left the company with almost $30 million in cash on its books. Cash, presumably, that CryoLife is offering to Medafor shareholders.

What Are CryoLife's Options?

With 89% of the shares and 99% of the shareholders supporting Medafor's board, it will be nearly impossible for CryoLife to successfully acquire Medafor—at least at the current bid. For the last four years, Medafor's sales have risen at an annual compound rate of 75% and Medafor is profitable. If that growth rate continues and the one fact that both CryoLife and Medafor can agree to is that sales of MPH are likely to continue to grow rapidly, then Medafor's valuation is no doubt several multiples higher than CryoLife's $40 million bid.

Could CryoLife afford to offer, say, $100 million in cash for Medafor? With barely $110 million in equity and eroding profit margins, the short answer is "no." If the offer is CryoLife stock, then the answer is likely "yes" although Medafor would end up owning roughly 50% of CryoLife and, in effect, control the company.

What can CryoLife CEO Anderson do? We see three options:

1. **Attempt to force a Medafor shareholder meeting.** While CryoLife probably can't force a shareholder meeting under Minnesota law, even if it did it would likely be a disaster for Anderson. Not only would CryoLife's bid be rejected, but the vitriol directed at Anderson would, we expect, be astonishing to behold.

2. **File a new lawsuit.** Given the failure of the past lawsuit, all a new lawsuit would do is spend

more of CryoLife's resources. At some point CryoLife's own shareholders would start to wonder about CEO Anderson's use of corporate resources to pursue what is increasingly looking like a misguided use of millions of dollars of corporate funds.

3. **Do nothing.** In this scenario, CryoLife would be compelled find an alternative surgical hemostat since Medafor is ending its distribution agreement with CryoLife and then simply allow its Medafor investment to grow over time—unless, of course, the shareholders who sold stock to Anderson ask for their stock back. Oops.

The Weirdness of CryoLife

While Steve Anderson ponders his next move, Medafor appears to have started pounding the nails into this deal's coffin. At the last call with analysts, CryoLife CEO Steve Anderson forgot to mention the details of Medafor's letter to him and did not address the issues Medafor raised. Ironically, CryoLife's best option may well be to let Medafor's current management build value for its shareholders—sans a distribution agreement with CryoLife. Who knows, maybe CryoLife's $4 million investment in Medafor stock could someday be worth $40 million, $50 million or more.

Being Chair: Are You Ready?

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

Wikimedia Commons

Meetings: You may have had the floor, you may have had a significant seat at the table, but what about taking "the chair"…are you ready?

Passion and Experience

First of all, those with an air of nonchalance need not apply. Dr. Frank Kelly, Chair of the American Academy of Orthopaedic Surgeons Communications Cabinet, states, "It is important that the person stepping into the role of chair be passionate about what it is that the committee is addressing. Being chair takes a substantial amount of one's time and energy, so you need the excitement to carry you through. And of course, you need to know of what you speak, i.e., you must have accumulated a certain level of knowledge about—and experience with—the issues at hand."

Dr. William P. Cooney, Chair of the Orthopaedic Research and Educational Foundation Board of Trustees, has chaired meetings for over 30 years. This voice of experience notes, "The chair should know all the facts on the subject at hand or have people present who do. You are the leader, and if your information base is lacking, you must take the time to read the literature and talk with informed sources."

On a procedural note, says Dr. Kelly, you should also consult what some consider the bible of meeting processes, namely, Robert's Rules of Order. "This guide to running meetings and conferences has practical information about, for example, when a motion is allowed, when you can table an issue, etc. These are traditional parliamentary procedures that can greatly contribute to a smooth gathering."

Get Organized

Yet meetings can at times be unpredictable. So, says Dr. Kelly, the chair should inject as much order as possible beforehand. "The chair must be extremely well organized and should plan the meeting agenda in advance after soliciting input from others. As soon as one meeting is finished, then you should begin outlining the agenda for the next

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meeting. I've also found it helpful to point out to attendees that we need to be punctual and start the meeting on time. Think ahead in order to ensure that you have all the necessary resources such as audiovisual equipment, microphone, etc. Afterwards, you should get the minutes together as soon as possible. That will help facilitate the work that everyone has to do between meetings."

Dr. Cooney emphasizes, "The agenda for the meeting should be precise and clear to all. Making everyone aware of the start and end times—and holding them to it—is critical. Do not have an open ended meeting...the things you and others will have to handle will mushroom beyond what can be reasonably accomplished. Again, keep the agenda items short and specific."

Be Diplomatic

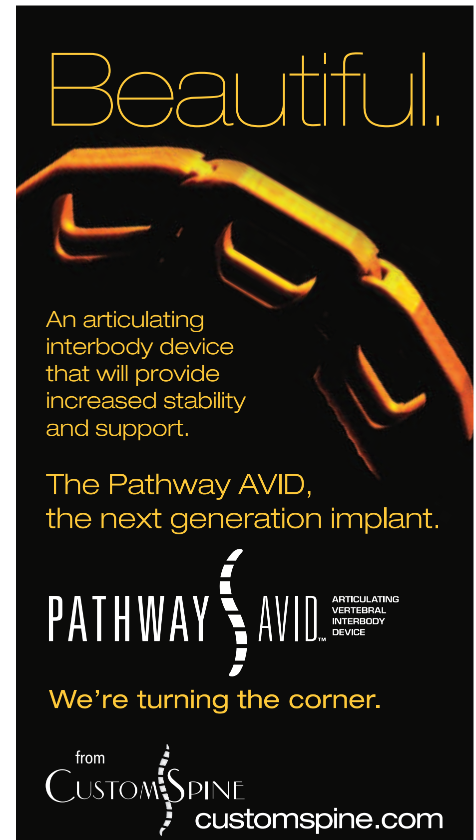
When sitting as chair, the goal is not to show that you were captain of your college debate team. In fact, you must walk the line between passion and diplomacy. Dr. Kelly: "It really helps if you are a 'people person' and can get things done without stepping on people's toes (egos). At times delicate issues are being addressed and you could have 17 people with 17 different opinions. I have seen conflict handled in many ways through the years. One of the fundamentals is that it is important that both sides of the argument be given a fair hearing. Committee members need to feel as if their viewpoints are being respected. This is basic courtesy, yes, but it's also true that feeling heard and involved makes people want to give their best."

With an eye toward fairness, Dr. Cooney states,

> *"Allow all members to speak and be attuned to which people are not participating; call on those not speaking to provide an opinion. Keeping everyone focused and not letting individuals ramble or have their own agendas is very challenging at times. But don't be tempted to dominate the meeting. You might miss out on valuable input and you could end up with some resentful committee members. It's a balancing act."*

And what if you don't reach a meeting of the minds? "One of the most effective ways of diffusing conflict," advises Dr. Kelly, "is through the use of humor; it also helps move things along and keep everyone on track. After injecting some levity into the situation, you can say, for example, 'We can't solve this issue now but we can form a task force to look into it further. Perhaps you might like to participate on the task force or subcommittee.'"

To the point of time management, Dr. Kelly states, "Learning to allocate the appropriate amount of time for a certain topic is an art. You may think that a given topic will not generate much discussion, but then things take on a life of their own, and it becomes obvious that there are a lot of different sides to the issue. This gets to the fact that keeping things moving is probably the most difficult task that a chair faces."



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"On occasion you have someone who likes to dominate the conversation or to change the topic," says Dr. Kelly. "In such a situation, I recommend that you let the person speak, but not go off on a 10 minute dissertation. You can say, 'This is an important issue and we may have time to discuss it at the end of the meeting. If not, we can address it at the next meeting or form a task force to look into it further.' If this individual has developed a habit of 'holding court,' the appropriate step is to speak with him or her between meetings and say that you appreciate their opinion, but that it's important that others have enough time to give their input as well."

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It is also prudent, says Dr. Kelly, to handle other issues between the meetings. "Things like conference calls and webinars can go a long way toward streamlining your work as chair. If you have a task force looking at a specific issue, then you can do calls with a subgroup of the committee, decide what the most relevant issues are and how they should be approached."

Regarding when you should be flexible and when you should stick to your own counsel, Dr. Kelly states,

"The hallmark of a good committee chair is someone who knows not to railroad an issue through. Taking my own practice as an example, every meeting we have budgetary issues. Some individuals are very fiscally conservative, and I have learned to appreciate their viewpoint. On several occasions I have found that being flexible and not spending money that I likely would have spent has been a plus. I am grateful that I listened to those in our practice who are financially conservative."

Yes, hubris is best left at the door, says Dr. Kelly. "There are times when I've met with AAOS staff members who are more knowledgeable than the members of the committee… and they have fairly definite opinions about what has worked in the past and what would work in xyz situation. If you have access to such experienced individuals, be willing to listen to them—it's not their first rodeo. Now, if I feel very strongly about an issue because my past experience has lent me some wisdom in that particular area, I might say to those who are opposed, 'We have tried your suggestions, but they didn't take us where we need to go. Now let's try this.'"

Are You Ready?

And how do you know whether you are ready and/or right for the big chair? Dr. Cooney: "You are ready to become chair if your experience with meetings tells you that you can handle the demands of orderly discussion, statement of facts, drawing conclusions and the need to take action. You should be someone who is action oriented; ultimately, a meeting without an action-oriented outcome is not a good use of time."

Dr. Kelly adds, "If you are someone with a young family, and your time is more limited, then perhaps you won't have enough time to devote to chairing a committee. You can, however, lay the groundwork by becoming a member of the committee. As for personality

characteristics, if someone is too rigid or carries a 'my way or the highway' attitude, then that person won't be an effective chair. If you have a tendency to procrastinate, this could also be a problem. Someone in the role of chair should respond promptly to emails and phone calls and work steadily on issues between meetings."

If you are the right person for the job, but there is someone on your committee who is not a good fit, what should you do? Dr. Kelly: "Sometimes there is someone who does not contribute much, either during the meetings or afterwards. Maybe they don't have the necessary knowledge base or perhaps they just aren't sufficiently motivated. You can say to them in private, 'I appreciate your service, but going forward we are facing a lot of work. I'm not sure if this is the right committee for you.' In my experience the majority of people I say this to are actually appreciative and/or relieved."

Dr. Cooney is also an advocate of discretion. "A poor committee member should be addressed individually and not brought to task at the meeting. A quiet conversation is best, and may result in that person finding their way to a committee that better fits their interests and talents."

So remember to be passionate, organized and diplomatic, and if you want to be chair, be sure you take that step for the right reasons.

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Surgical Strikes Over Haiti

By Walter Eisner

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In response to our story, "Cry, The Beloved Surgeon" (Feb 1, 2010), one of our readers, Glenn Taylor left this comment:

"Undoubtedly noble and altruistic, the HSS orthopedic team nonetheless stumbled naïvely into a real life mass casualty situation with challenges beyond their capabilities. The military was correct in their criticism of the civilian doctors, given lessons learned from the battlefields of the Civil War to Iraq.

"Saving life and limb in such dire circumstances depends on a coordinated infrastructure with rapid transport to disciplined, secure and properly equipped field hospitals with a triage structure. Such organization is not available in the immediate aftermath of a natural disaster. Instead of ex-fixators and IM rods, the team might have been better off bringing lots of plaster of paris and a copy of Dr. Paul Brown's article on his Vietnam War experience in managing open tibia fractures published in JBJS 1969."

Dean Lorich, M.D., one of the surgeons from HHS (Hospital of Special Surgery) that rushed to Haiti before security was established responded to Mr. Taylor:

"This response is offensive. If it weren't for civilians like us there would have been no one treating these patients. We were not bellyaching because of our plight. We were pointing out the complete lack of any organization on the ground to the point that none of the 1,000 patients we saw at the hospital we worked or at the general hospital we originally arrived had any significant medical treatment.

"Our 'naïveté' was that the military was there in force or would be there in force as first responders and we would be supportive to them. Not that they would be essentially nonexistent in the medical care initially after the earthquake.

"I believe one question remains unanswered. Why did we not see one military person during our period in Haiti, with the exception of our departure when we saw them at the U.S. Embassy? If they can give an account that is different, as we were at a hospital that was taking care of a significant # of patients very early and would have expected to see some "official medical team", then I stand corrected.

"If I sound angry now I am getting there, as I hate when 'cover your ass' politics and excuses, detracts from the real message. There was NO organization of medical units on the

Dean Lorich, M.D.

ground by the U.S. 'official contingent' for at least the 1st week and the military should be accountable for their inadequate response to this disaster of unimaginable proportions."

The criticism leveled by Dr. Lorich at the U.S. government's response to the Haitian earthquake and Mr. Taylor's defense of military surgeons who criticized Dr. Lorich and other civilian surgeons for entering a chaotic mass casualty situation, begs the question of what exactly was the immediate U.S. government's
and military's role and response to the catastrophe.

Government Response to Crisis

On January 13, the U.S. Southern Command announced that it was immediately deploying a team of 30 people to Haiti to support U.S. relief efforts. The team included U.S. military engineers, operational planners, and a command and control group and communication specialists. They arrived on two C-130 Hercules aircraft.

The team was to work with U.S. Embassy personnel as well as Haitian, United Nations and international officials to assess the situation and facilitate follow-on U.S. military support.

On January 19, Major General Daniel Allyn, deputy commander of Joint Task Force Unified Response held a press briefing to describe the military efforts underway to that point. (http://www.army.mil/media/amp/?bctid=62473135001)

www.army.mil/media/

This was the same day civilian surgeons from HSS were already returning to the United States.

Allyn made it very clear that the United Nations had the primary responsibility for securing order in Haiti **and the U.S. military's top priorities were to increase the distribution capacity to get humanitarian aid into the country, bring in ground vehicles to distribute water and begin efforts to open the port.**

The primary military medical effort was to facilitate the arrival of the navy hospital ship, the Comfort, which arrived on the 20th.

Allyn told reporters that the military was "employing as fast as we can." He noted that 800 Marines would arrive within the next few hours and that 1,000 airborne soldiers would be added to facilitate the distribution of food and water.

When asked about medical relief efforts, Allyn responded that those efforts were continuing to grow with the arrival of international fields hospitals. He added that the military's efforts were to loosen the "supply logjam". He said the military's understanding was growing of where the need was the greatest. He also stated that the World Health Organization was leading medical relief efforts.

On Wednesday January 20, eight days after the earthquake, the White House held a press briefing on the U.S. government's response to the earthquake. The briefing was conducted from Haiti by Captain Andrew Stevermer, Commander of the Incident Response Coordinating Team, National Disaster Medical System.

In this role, Captain Stevermer was in charge of all on-the-ground assets in Haiti for the Department of Health and Human Services in order to provide medical response to this disaster.

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Said Stevermer:

> *"We are just a part of the international medical response…. We currently have more than 270 medical personnel in Port-au-Prince, which include doctors, nurses, paramedics, emergency medical technicians, and others. These members work for the United States Public Health Service Commissioned Corps and the National Disaster Medical System. They have taken time out of their daily jobs in the U.S. to come here and to assist with the relief efforts.*

> *"To date, these medical teams have been seeing patients beginning on Sunday and since that time have seen 5,100 people. We currently have five disaster medical assistance teams and one international medical surgical response team in Port-au-Prince."*

Defining The Mission

Given these briefings by military leaders on the ground, it seems clear that the military's immediate mission and priorities were not focused on medical relief and provides some explanation for the questions asked by Dr. Lorich.

Presumably, the military was executing a mission defined by civilian leaders. It's also worth noting that America's military resources, which are not infinite, are focused on other places at the moment.

The Next Crisis

The criticism from the HSS team of our nation's response the Haitian catastrophe raises important questions about how the U.S. government and orthopedic surgeons will respond to the next mass casualty situation that is sure to come.

The American Academy of Orthopaedic Surgeons (AAOS) has indicated it would follow-up on working on ways for civilian surgeons and the military to work together in the future. We hope there will be a lot of discussion about this at the upcoming annual AAOS meeting in New Orleans next month.

So what now?

We asked the United States Agency for International Development (USAID) what they would tell civilian surgeons who want to offer their services and supplies in the immediate aftermath of a catastrophe and whether there were plans to create a more coordinated response in the future that utilizes civilian surgeons.

The Agency responded via email to our questions on February 11.

> *"...There are hundreds of volunteer physicians from the United States currently serving the medical needs the people of Haiti.*

> *"USAID is the lead federal agency for the U.S. response and has set up a Web site where individuals c an learn more about current needs and how to help. Please visit http://www.USAID.gov/helphaiti/ for more information.*

> *"The immediate and long-term health and medical needs of Haiti are currently being assessed by the United Nations and the Pan American Health Organization with the Haitian government.*

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"Health and Human Services (HHS) has set up an email where medical professionals can send offers of volunteer medical care services. Medical professionals interested in volunteering, can send an email to Haiti.volunteer@hhs.gov. Include your name, clinical area, specialty skills, degrees, and language capabilities (in particular, whether you speak Haitian Creole or French and if so, your level of fluency).

"HHS would like to make it easier to take advantage of medical skills and willingness of medical professionals to volunteer in future health emergencies, whether domestic or international.

"There are two important disaster relief programs that would greatly benefit from medical personnel expertise, the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) (esarvhp@hhs.gov) and the Medical Reserve Corps."

Whether or not the experience of Haiti will change how our government and civilian surgeons work together in the immediate aftermath of a mass casualty crisis in the future is unknown for now. We do know that in the next crisis, surgeons will pack up their supplies and rush into the fray regardless of what governments do. Let's hope they do it together.

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Orthopedics This Week
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company news

Biomet Offers $3.1 million in Aid

Biomet, Inc. recently announced a donation of $3.1 million in medical devices to aid the relief effort in Haiti. Many aid groups are designed to deliver immediate, short-term relief, but as with any major natural disaster, there will also be a need for steady, long-term care. These medical devices, along with many other donations from the orthopedic community, will help physicians continue to care for the victims of the earthquake.

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Biomet's donation includes two shipments of adult and pediatric devices to treat fractures and other orthopedic trauma. The company has also donated 16,000 leg braces. Biomet donated the first shipment to the United Aid Foundation (UAF), which currently has a team of 11 doctors and nurses treating patients at the border between Haiti and the Dominican Republic. The second shipment went to the World Vision organization, which recently opened a large distribution center in Miami, Florida, to direct emergency supplies to Haiti.

In the company's February 11th press release, Jeff Binder, President and CEO of Biomet, Inc., said, "We have an obligation to help the people of Haiti heal from the devastation they have experienced. The challenges facing Haiti, and the volunteers from the medical profession, cannot be overstated. We are proud to be part of this global aid effort to alleviate the suffering of the Haitian people, and to support the medical volunteers who are working around the clock to treat the injured."

Biomet has also contributed funds to the American Red Cross, and company officials intend to continue the company's support of the Haitian relief effort as physicians on the ground identify the need for more supplies.

OTW will continue to update readers as the orthopedic community delivers aid to Haiti, including an upcoming feature article on the lessons learned by doctors who took part in the first wave of support.

—DK (February 19, 2010)

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The $4 Billion FDA

The FDA released a $4 billion budget request for 2011 to Congress on February 1.

Part of the requested $4 billion comes from a $2.51 billion appropriation from Congress, with the balance coming from user fees paid by the medical industry. The proposal boosts the overall 13,586 FDA workforce by 1,251 employees.

The largest increase comes for food safety programs, but the Center for Devices and Radiological Health (CDRH) will also see a 3% increase with a $325.7 million appropriation from Congress. An additional $59 million from an 11.9% increase in user fees brings the total CDRH budget to $384.8 million, an overall increase of

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4%. The device center will hire 65 new employees

AdvaMed Senior Executive Vice President David Nexon reportedly said that the center could use more funding, but just getting an increase in this budget was a positive.

The new budget, according to the agency, allows for the approval of more generic drugs and biologics and improves the safety surveillance of medical devices. It will make the data the agency collects more widely available to the public.

Registry and Comparative Effectiveness

The proposed budget also includes $4 million to develop a national device registry that will link unique device identifiers to electronic health data. The registry will receive $2.3 million under the “advancing regulatory science” initiative and $1.7 million under the “protecting patients” initiative.

While not specifically part of the FDA's budget request, the Department of Health and Human Services, the FDA's parent, included a $286 million request for the Agency for Healthcare Research and Quality for research that compares the effectiveness of different medical options. The Department expects the dissemination of this research to lead to higher quality, evidence-based medicine, arming patients and physicians with the best available information to allow them to choose the medical option that will work the best for them.

The House will now consider the President's budget proposal. Where that ends is, as we've seen, anyone's guess.

—WE (February 10, 2010)

extremities

RA Doesn't Slow Keyboarding

QWERTYU for me and you… even if I have RA. Researchers from the University of Pittsburgh have published an article indicating that workers with rheumatoid arthritis (RA) were comparable to non-impaired individuals in keyboarding speed. Those trained in touch typing were faster than those using a visually-guided (“hunt and peck”) method, regardless of impairment. However, individuals with RA did have slightly impaired mouse skills.

According to the news release, workers with RA may have difficulty with computer use due to impairment in hand range of motion (ROM) and strength caused by inflammation of their joints due to the disease.

“With more arthritic workers using computers, understanding the associations between hand function impairment and peripheral device (keyboard and mouse) limitations is essential and the focus of our current study,” said lead author Nancy Baker, Sc.D., MPH, OTR/L, in the news release.

Forty-five participants from the University of Pittsburgh Medical Center (UPMC) Arthritis Network Registry participated in the study. A full 100% of this group using computers at work. Eleven test items measured active ROM of the thumb, fingers, wrist, forearms and elbows. Another test contained 10 items to evaluate pure and applied strength and dexterity in a variety of hand tasks.

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The researchers found that 73% of participants were trained in touch typing and used the computer an average of 18 hours per week. Keyboarding speed was significantly associated with touch typing training and age. Mouse speed was significantly associated with age only (younger folks typed faster). Impairments in hand function were associated with two of seven keyboarding tasks and no mouse tasks. "Our research suggests that if individuals with motor impairments have the capacity to learn touch typing it may increase their overall speed," added Dr. Baker. Researchers further compared the current study group results with an impaired and non-impaired subject group from a normative study by Dumont et al. to benchmark ACTP (Assessment of Computer Task Performance). "We found that our RA workers had similar keyboarding speed compared with the non-impaired sample," Dr. Baker stated. "However, we found that mouse speed was much slower in some participants in our RA sample."

Commenting on what they were surprised to learn, Dr. Baker told *OTW*, "First, how little physical limitations (such as reduced ROM) were associated with reductions in typing and mousing speed. Second, that people with mild to moderate RA had typing speeds comparable to those without RA. Both of these outcomes point out how well people with RA can compensate for limitations and continue to perform tasks such as typing."

Asked about strategies to maintain productivity in computer users with RA, Dr. Baker told *OTW*, "An evaluation of the computer workstation by an occupational therapist who will assess problems between the worker/workstation fit and provide suggestions for environmental adaptations (e.g., equipment, workstation set up) which will facilitate performance."

—EH (February 11, 2010)

New Wrist Surgery Available

Wrist problem? Don't sit on your duff. Breaking a fall with your hand can result in a fracture to the radius bone or one of the smaller wrist bones and ligaments. Left untreated, these injuries could mean wrist arthritis. Fortunately, Dr. Peter Tang, Assistant Attending Physician at New York-Presbyterian Hospital/ Columbia University Medical Center, has developed a new surgery called OCRPRC (OsteoChondral Resurfacing in Proximal Row Carpectomy)—one which has been shown to reduce pain and improve hand function.

"I often see patients who had a wrist injury in the past who either did not seek medical attention or whose original injury was not diagnosed. As with most things in medicine, the earlier a diagnosis is made, the better the outcome. So if you continue to

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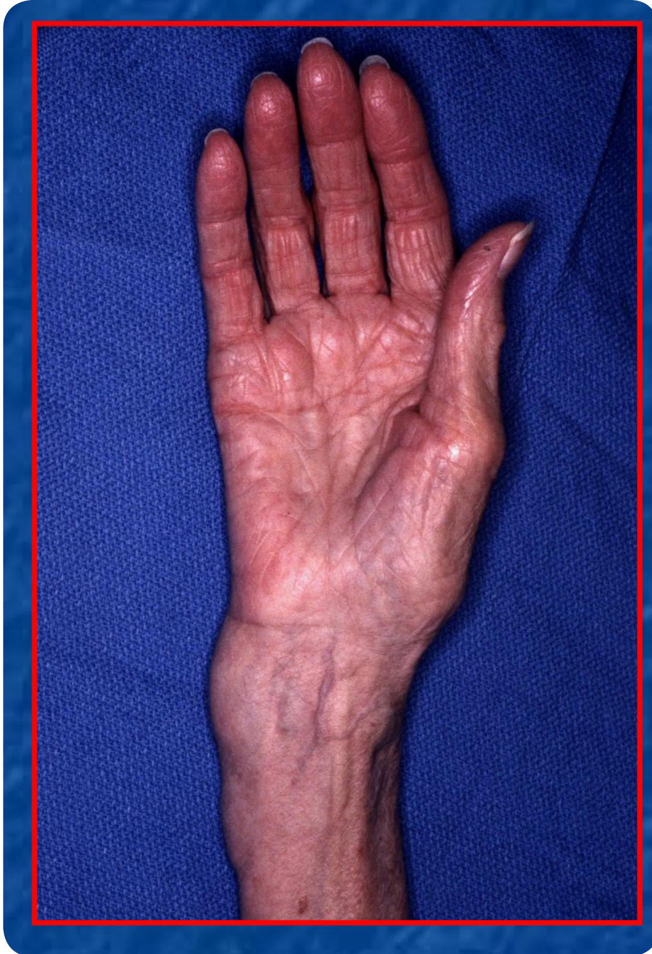

Malreduced distal radius fracture / Wikimedia Commons

have pain after a month, you should make an appointment to see a hand surgeon for an evaluation," said Dr. Tang in the news release.

"The goal of this new procedure is to give the best possible outcome by improving the cartilage status of the capitate bone. Another plus is that we do not have to take the graft from another part of the body. Even though we take out the three carpal bones for arthritis, there is usually one area of the bones where we can find undamaged cartilage for grafting," says Dr. Tang.

Dr. Tang told *OTW,* "Most hand surgeons recognize the benefit of the proximal row carpectomy (PRC) procedure for wrist arthritis. When compared to the alternative procedure, scaphoid excision, four bone fusion, the PRC has a quicker recovery, no issues of nonunion or hardware, slightly more motion, and no need for immobilization. However, the outcome is dependent on the status of the articular surface of the capitate bone which becomes the new articulating surface of the wrist. Sometimes the wear on the bone is a small focal area. The PRC procedure involves removing the proximal row of bones but there will be areas of undamaged cartilage. We wondered whether we could remove some of the good cartilage of the resected bones and use it to replace the focal defect on the capitate. The technique of replacing damaged cartilage with good cartilage from a different part of the joint or body has been used before, so we adapted the technique for the wrist."

Dr. Tang also commented to *OTW,* "As for research, I have a particular interest in wrist biomechanics and contact biomechanics which involves contact pressure, area, and kinematics at joint surfaces. Over the last five years I have been looking at how the contact biomechanics change after our various wrist operations for arthritis. Soon we will be submitting our research comparing the contact biomechanics of the PRC and four bone fusion wrist. Furthermore, we are currently analyzing data on how the biomechanics are affected by different capitate morphologies in the PRC wrist."

—EH (February 15, 2010)

Enrolling Thumb Pain Patients

If you can use that painful thumb, you may want to pick up a pen and sign up for a new study. Researchers from Hospital for Special Surgery (HSS) are recruiting adults with thumb osteoarthritis (OA) for a study in which injections of a hyaluronan product will be tested for pain relief.

The lead investigator, Dr. Lisa Mandl, is a rheumatologist at HSS who is studying whether two injections of hyaluronan (Synvisc) into the joint, in the area where the thumb meets the wrist, can alleviate pain and restore function. Synvisc is currently FDA-approved to treat OA of the knee.

Dr. Mandl and colleagues at HSS previously conducted an open-label

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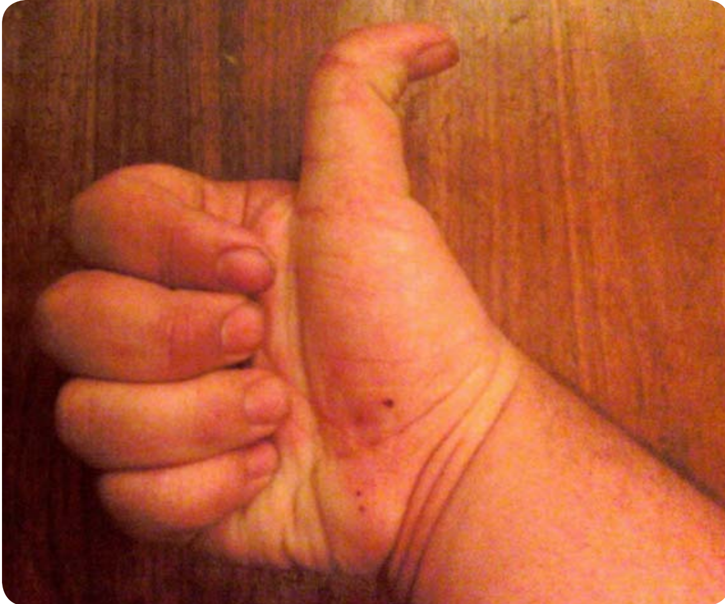

Hitchhiker's Thumbs/Wikimedia Commons

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trial of Synvisc to relieve thumb arthritis—the data looked promising. "In the first study, we saw a significant decrease in pain," she said in the news release. "That's why we decided to go forward with a much larger double-blind, placebo-controlled trial and applied for funding from the NIH [National Institute of Health] and the Arthritis Foundation. Genzyme Biosurgery is supplying the medication free of charge."

Dr. Mandl is seeking to enroll and randomize 213 patients; the first group will receive hyaluronan, a second group will receive a cortisone shot and the third group will receive a local anesthetic. Patients will be followed for six months to see how they fare.

"Often, this type of arthritis is the only problem in very active, healthy people. It's the one thing that's really interfering with their life," Dr. Mandl noted in the news release. "They wake up at night, they can't work, they can't pick up a pen. It disproportionately ruins their life. If we had a good treatment that didn't have side effects, their lives would improve dramatically."

Other treatments, such as non-steroidal anti-inflammatory medications, can have side effects or don't work for many patients. "Cortisone shots are a common treatment, but not everyone is a candidate, and these injections are not great for maintenance therapy." Dr. Mandl added.

Adults over 45 with painful thumb arthritis may be candidates for the trial. They will be screened by a study questionnaire, hand x-ray and hand exam. All medication will be provided free of charge.

Regarding patient enrollment, Dr. Mandl told *OTW*, "Enrollment is steady. We are about two-thirds of the way to our goal, and we will likely be enrolling through 2010."

As for what are some of the questions/issues that will disqualify people, Dr. Mandl commented to *OTW*, "Patients cannot enroll if they have any rheumatic disease (SLE< RA psoriatic arthritis etc...), if they have ever had surgery on their thumb, if they take oral steroids for another reason, if they have diabetes that requires insulin or if they have any active cancer. There are other exclusion criteria but these are the main ones that disqualify people."

—EH (February 16, 2010)

extremities

FDA OKs Auxilium's XIAFLEX

Stay out of the OR with XIAFLEX…the biologics veterans at Auxilium Pharmaceuticals, Inc. have announced that the company has received marketing approval from the FDA for XIAFLEX (collagenase clostridium histolyticum) for the treatment of adult Dupuytren's contracture patients with a palpable cord. In this condition, knots of connective tissue form under the skin and render normal hand functioning difficult. Auxilium expects to begin shipping XIAFLEX, a novel, first-in-class, orphan-designated, biologic, to its distribution partners in early March in advance of a launch planned for late March.

"We believe the approval of XIAFLEX represents a major breakthrough for patients suffering from the debilitating effects of Dupuytren's contracture," said Armando Anido, CEO and President of Auxilium, in the news release. "XIAFLEX is the first and only FDA-approved nonsurgical treatment for Dupuytren's contracture. I want to thank the employees of Auxilium and all of the clinical investigators who worked so hard to make this breakthrough a reality."

Auxilium will market and sell XIAFLEX in the U.S. through approximately 100 field sales managers and representatives, reimbursement specialists, and managed market account directors. Also, 11 highly trained medical science liaisons will provide medical support for XIAFLEX. A new distribution network will allow health care providers to access XIAFLEX through specialty distributors and specialty pharmacies or in the institutional setting after they have undergone training on XIAFLEX and its administration.

Auxilium Pharmaceuticals, Inc.

"With the safety and effectiveness of XIAFLEX demonstrated across multiple clinical trials, physicians can now use XIAFLEX to treat any symptomatic cords in patients with Dupuytren's contracture," said Larry Hurst, M.D., study investigator and Professor and Chair, Department of Orthopaedics at SUNY Stony Brook. "I believe that XIAFLEX, as a new nonsurgical treatment, could potentially become the standard of care for Dupuytren's contracture."

The FDA has required a risk evaluation and mitigation strategy (REMS) program for XIAFLEX, which consists of a communication plan and a medication guide. This REMS is designed:

(1) to evaluate and mitigate known and potential risks and serious adverse events
(2) to inform healthcare providers about how to properly inject XIAFLEX and perform finger extension procedures
(3) to inform patients about the serious risks associated with XIAFLEX

Concerning challenges along the way, Will Sargent, VP of Investor Relations and Corporate Communications, told *OTW,* "I think the challenge was that since our unanimous 12-0 advisory committee vote for approval occurred after our PDUFA date, the duration of time before an approval decision on XIAFLEX was unknown, unlike other drugs under FDA review where the PDUFA date/approval decision date is widely known. The high point would be finally being able to move forward on our launch plans with what we believe is a major breakthrough for patients suffering from the debilitating effects of Dupuytren's contracture." Regarding the sales training, he told

extremities

OTW, "They will be learning from hand surgeons and other subject matter experts on Dupuytren's disease, XIAFLEX clinical data, current treatments, reimbursement, physician training programs and product distribution."

—EH (February 17, 2010)

large joints

Stryker Releases "Personalized" Hip

Stryker Orthopaedics released a new hip system on February 9.

The Rejuvenate Modular Primary Hip System is designed, according to a company statement, to recreate the anatomy and hip biomechanics of individual patients.

Does that mean the company would design specific implants for specific patients?

In response to that question, the company stated, "The Rejuvenate Modular Primary Hip System was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version and offset, the Rejuvenate Modular Primary Hip System is designed to enable surgeons to better personalize the implant to a patient's unique anatomy."

What kind of combinations?

The company says the system is comprised of separate femoral stem and neck components and offers a variety of sizing options intraoperatively. By allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of a patient's hip replacement.

"These options can add up to hundreds of combinations through the use of instruments designed to have the potential to streamline the surgical workflow," according to a company statement to *OTW.*

Rejuvenate Modular Primary Hip System/Stryker Orthopaedics

The system is a femoral stem and neck. The stem is made of TMZF alloy, a proprietary Stryker material with a plasma sprayed coating of commercially pure titanium and PureFix HA. The necks are made of CoCr alloy.

When asked if the Rejuvenate was a replacement for the sometime squeaky Trident, the company said no, the system is the latest addition to Stryker's modular hip portfolio which "provides surgeons with treatment options that can be personalized to fit each patient."

"Every patient's anatomy and lifestyle are different, which is why we have invested in developing cost-effective personalized hip solutions," said Bill Huffnagle, Vice President and General Manager, Hip Reconstruction, Stryker Orthopaedics.

More than 250,000 Americans get total hip implants each year and generally costs close to $45,000 per procedure. Hip replacements have a success rate of more than 90%, based on patients' achieving relatively pain-free mobility after recovery periods that range from a few months to a year.

—WE (February 12, 2010)

large joints

Beer Good for Bones

Evidence that a beer gut is healthy? While that's likely stretching it, researchers from the Department of Food Science & Technology at the University of California, Davis, have found that beer is a significant source of dietary silicon, a key ingredient for increasing bone mineral density.

"The factors in brewing that influence silicon levels in beer have not been extensively studied," said Charles Bamforth, lead author of the study, in the news release. "We have examined a wide range of beer styles for their silicon content and have also studied the impact of raw materials and the brewing process on the quantities of silicon that enter wort and beer."

Silicon is present in beer in the soluble form of orthosilicic acid (OSA), which yields 50% bioavailability. As indicated in the news release, the NIH (National Institute of Health) states that dietary silicon (Si), as soluble OSA, may be important for the growth and development of bone and connective tissue, and beer appears to be a major contributor to Si intake. Based on these findings, some studies suggest moderate beer consumption may help fight osteoporosis.

Credit: Luca Galuzzi - www.galuzzi.it

The researchers examined a variety of raw material samples and found little change in the silicon content of barley during the malting process. Most of the silicon in barley is in the husk, which is not affected greatly during malting. The malts with the higher silicon contents are pale colored which have less heat stress during the malting process. The darker products all have substantial roasting and much lower silicon contents than the other malts for reasons that are not yet known. The hop samples analyzed showed surprisingly high levels of silicon with as much as four times more silicon than is found in malt. However, hops are invariably used in a much smaller quantity than is grain. Highly hopped beers, however, would be expected to contain higher silicon levels.

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No silicon was picked up from silica hydrogel used to stabilize beer, even after a period of 24 hours and neither is there pick up from diatomaceous earth filter aid. The study also tested 100 commercial beers for silicon content and categorized the data according to beer style and source. The average silicon content of the beers sampled was 6.4 to 56.5 mg/L.

"Beers containing high levels of malted barley and hops are richest in silicon," concluded Dr. Bamforth in the news release. "Wheat contains less silicon than barley because it is the husk of the barley that is rich in this element. While most of the silicon remains in the husk during brewing, significant quantities of silicon nonetheless are extracted into wort and much of this survives into beer."

Regarding what precipitated this work, Dr. Bamforth told *OTW*, "There had been prior reports about beer containing silicon, some drawing attention to its potential relevance to human health. We sought to get a deeper understanding of just how much silicon is in different types of beer and what are the factors that influence those levels."

—EH (February 12, 2010)

Osteoarthritis Campaign Launched

While you may not be ready for a salsa class, if you have osteoarthritis (OA), you *do* need to get moving. Hospital for Special Surgery, (HSS) has just

Wikimedia Commons

announced its support of the Arthritis Foundation and Ad Council newly launched campaign, "Moving is the Best Medicine," to raise awareness of OA, increase public health education and support breakthrough research. "Like the Arthritis Foundation, we are focusing our extensive clinical and research resources on raising awareness of the potentially debilitating effects of osteoarthritis in this country," said Stephen Paget, M.D., physician-in-chief and chair of the division of rheumatology at HSS, in the news release. "We applaud the efforts of the Arthritis Foundation and the Ad Council as they begin a multi-year initiative to improve the understanding of osteoarthritis, and we join them with our commitment to identify better methods to diagnose, treat and prevent the disease," Dr. Paget continued.

"One key focus of our research," added Thomas P. Sculco, M.D., Surgeon-in-Chief at HSS, "is identifying new and better surgical solutions for advanced cases involving novel biomaterials, the development of inventive implant designs and minimally invasive surgical techniques. Joint replacement registries will also play a central role in benefiting the next generation in a national effort."

John H. Klippel, M.D., President and CEO of the Arthritis Foundation, stated in the news release, "There are steps people can take today that can change the course of this disease. We are proud to have Hospital for Special Surgery helping with others to communicate the preventative steps and demonstrate the treatment success that is now possible for people with osteoarthritis."

Laura Robbins, DSW, VP of education and academic affairs at HSS and past chair of the Arthritis Foundation, said in the news release, "At HSS we have a broad spectrum of community-based programs focused on prevention offered through our Education Division and we recently introduced a comprehensive online resource on OA at www.hss.edu/osteoarthritis. The public awareness and voice for osteoarthritis that this new campaign provides—coupled with the knowledge scientists and clinicians now seek—make this initiative an important public health advance for every American."

Robbins told *OTW*, "HSS has several decades of experience working with

communities on program delivery. We use public health programs, some that are New York State Department of Health programs and others are evidenced Arthritis Foundation programs such as the Self Management Course, PACE (people with arthritis can exercise) as well as our own programs promoting movement such as Pilates, Yoga and Tai Chi."

Robbins also commented to *OTW*, "HSS' initiative is a long-term one coinciding with the CDC, Arthritis Foundation, American College of Rheumatology and other groups for the next decade, and the Ad Council, which is a three-year initiative."

—EH (February 18, 2010)

New Geriatric Orthopedic Journal

A forward thinking orthopedist, along with the sages at SAGE Publications, are announcing the launch of *Geriatric Orthopaedic Surgery & Rehabilitation*, a new bimonthly journal to commence in September 2010. The new publication will cover a broad range of musculoskeletal disorders in the aging patient through peer-reviewed research reports and reviews, technical perspectives, case studies, and other evidence-based articles.

"The fastest growing portion of our population is the segment over 65 years old. Most older individuals will experience an orthopaedic problem as they age," said Stephen Kates, MD, the journal's founding Editor, in the news release.

Konstantin Stoitzner/Le Petit Journal Wikimedia Commons

Dr. Kates told *OTW*, "We have started this journal to fill a perceived void in the academic orthopaedic surgery literature concerning care of the elderly orthopaedic patient and their subsequent rehabilitation. It can be a challenge to find the appropriate home for articles about geriatric orthopaedic topics. As you know, the population is aging rapidly and the 78 million Baby Boomers will begin to turn 65 next year. The fastest area of growth in our population is the segment over 85 years."

Contributors and readers will include orthopaedic surgeons, geriatricians, physiatrists, anesthesiologists, and other physicians specializing in care of the older adult.

"The projected incidence of musculoskeletal problems among the aging Baby Boomer population is staggering," said Ron Epstein, SAGE Director of STM Journals, in the news release. "We anticipate that *Geriatric Orthopaedic Surgery & Rehabilitation* will prove a critical resource for the physicians and other health care providers who work with older patients with bone fractures, joint replacement, and related problems. Dr. Kates is one of the foremost clinicians and teachers in this field, and we are excited to work with him as the journal's Editor."

Dr. Kates also commented to *OTW*, "Developing this journal has been straightforward with the help of Sage Publications and recruitment of surgeons, geriatricians, scientists, physiatrists and physical therapists to join our editorial board has been met with great enthusiasm. Our main task prior to September is to recruit manuscripts for the journal."

—EH (February 19, 2010)

Colorado Docs Settle Anti-Trust Case

An independent practices association (IPA) in Garfield County, Colorado, has

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reached an agreement with the Federal Trade Commission (FTC) to settle charges of price fixing by agreeing to halt its use of allegedly anticompetitive negotiating tactics against health insurers.

Docs Refused Medicare-Based Rates

The FTC accused the 85 physicians in the group of refusing to enter into contracts with insurers except through the IPA...and the IPA refused to enter into any agreements with insurers who used Medicare-based rates.

Anti-Trust

Roaring Fork Valley Physicians I.P.A., Inc., was formed in 1994 to enter into contracts with health maintenance organizations and other insurers. The group was charged with violating the FTC act by orchestrating agreements among its members to set higher prices for medical services and to refuse to deal with insurers that did not meet its demands for higher rates.

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The FTC charged that Roaring Fork entered into these agreements between 2003 and 2006. According to the FTC, the group's doctors used the agreements to demand that contracts with insurers include a cost of living adjustment that automatically raised reimbursement rates every year. The group's doctors also used the agreements to ban a cost-lowering provision commonly used by insurers that links reimbursement rates to Medicare rates.

The FTC also charged that the group discouraged its members from entering into individual contracts directly with insurers in order to enhance the bargaining power of the IPA. At the same time, Roaring Fork would accept contracts only if at least 80% of its primary care physicians and 50% of its specialty doctors accepted the proposed contracts.

The FTC settlement announced on February 3 bars the Roaring Fork doctors group from engaging in collective price negotiations and collectively refusing to deal with insurers. In addition, the group must:

- Terminate any contracts with insurers that were reached using price-fixing tactics.
- Notify the FTC before acting as an agent communicating contract offers and counter-offers between doctors and insurers.
- Notify the FTC before participating in any collaborative arrangement with doctors and allow the agency to review and approve the details before implementing any such arrangement.

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Speechless and Stunned

Some physicians on Sermo, an online community of physicians, wrote they were "somewhere between speechless with rage and stunned by the announcement." According to a surgeon, "It seems that the only group in the U.S. that is subject to the anti-trust laws is physicians. We have been divided and conquered." An anesthesiologist summed up the sentiment, "...the insurance companies can collude to their hearts content, but let physicians refuse to provide a service below its cost of production, but one that the Fed insists you take, and you are breaking the law."

reimbursement

We wonder how this would work if all the car mechanics in the county got together and negotiated with insurers.

—WE (February 10, 2010)

trauma

Minimally Invasive Procedures Injure Surgeons?

Minimally invasive surgery is a wonderful option for patients—there is less scarring, less internal trauma and it often comes with a quick recovery. But is it also helpful to surgeons? A new study from the University of Maryland shows that surgeons who often perform complex minimally invasive procedures could be in danger of injuring themselves.

In the University of Maryland news release, Dr. Adrian Park, the study's lead author, said, "We face a pending epidemic of occupational injuries to surgeons, and we can no longer ignore their safety and health…Sadly, it is easier for a surgeon to obtain an ergonomic assessment and direction to improve his golf swing than his posture or movement during surgery." Dr. Park is chief of general surgery at the University of Maryland Medical Center and professor of surgery and vice chair of the Department of Surgery at the University of Maryland School of Medicine.

Surveying Surgeons

The study focused on gastrointestinal and endoscopic surgeons performing minimally invasive, laparoscopic surgery. A total of 317 surgeons completed a comprehensive, 23-question survey, and 86.9% (272 surgeons) reported experiencing physical discomfort caused by performing minimally invasive procedures. The symptoms ranged from eye strain to, in a few surgeons, muscle spasms and carpal tunnel syndrome. Those surgeons with higher annual case volumes generally reported higher levels of pain and discomfort. The full survey results are now available online, and they will also appear in the March 2010 *Journal of the American College of Surgeons.*

Although the study focuses on gastrointestinal and endoscopic surgeons, orthopedic surgeons are increasingly turning toward minimally invasive procedures and could be at risk of injury. Dr. Park told *OTW,* "Many of the challenges we see in abdominal and G.I. procedures are replicated in other domains. We don't yet have the data to back it up, but it is my strong opinion that the research will be broadly applicable to other specialties as well."

A Clarion Call

Dr. Park calls the study a clarion call not just for surgeons, but for everyone involved in patient care. "Some

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surgeons pay so little attention to their own health, especially while they are in the operating room," explains Dr. Park. "And most surgeons are not forthcoming about occupational pain or injuries."

Dr. Park is also the executive director of the Maryland Advanced Simulation, Training, Research, and Innovation Center at the University of Maryland Medical Center—the world's first facility to focus on surgical movement. Dr. Park admits that they are only at the start of a long research project: "We know so little now—we have almost no baseline data. We should focus on more research so that we can make recommendations to physicians. I think that the research will show a need to profoundly revisit the surgeon-patient interface and the surgeon-technology interface."

—DK (February 12, 2010)

Orthopedics This Week
VOLUME 6, ISSUE 6 | FEBRUARY 23, 2010

The Picture of Success: Dr. Ray Baker

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

Dr. Ray Baker, the newly elected President of the North American Spine Society (NASS), knows how to put things together…he learned from taking things apart. Dr. Baker, who practices at Washington Interventional Spine Associates in Bellevue, Washington, is the first anesthesiologist to serve as head of the organization.

Traversing several continents as a youngster, Ray Baker learned the value of humor and quick thinking. "My father was in the Air Force, and we moved from my birthplace, Cambridge, England, to Turkey, then Texas. Following that we settled in California when I was six years old. Moving around so much meant that I learned the importance of assessing my environment and having a sense of humor, things that helped me make friends quickly."

The analytical Ray Baker has a natural bent for curiosity and has never shied away from examining things. "Within days of having my first computer, I ripped it apart and had to rebuild the operating system. This sense of wonder led me to enroll in engineering classes at my undergraduate institution—Berkeley. I found the classes boring, however, and realized that I would rather work with human beings. I was dating someone at the time whose father was a physician, and after several discussions with him, I enrolled in premed classes and signed up to volunteer at a hospital. I read EKGs in the ICU; from there my interest in medicine only grew."

Specializing in Pain

Perhaps it was witnessing so much pain in the ICUs that sent Ray Baker in the direction of interventional medicine. "I began medical school at the University of California, Irvine in 1981, after which time I did a rotating internship at Valley Medical Center in Fresno and was exposed to all different specialties—with the exception of spine."

Remaining at Irvine for residency, Dr. Baker would connect with spine via pain. "The program was not particularly strong in regional anesthesia so I became interested in interventional pain as a way of making up for the deficiency…which got me curious about spine. Soon realizing that I needed a fellowship that would allow me to emphasize regional anesthesia, I did six months in obstetric anesthesia and six months in interventional pain management. This was a period in which people were transitioning from performing 'blind' injections into using fluoroscopy."

Seeking familiar territory, in 1989 Dr. Baker left Irvine and headed to Washington State. "The climate and ambience are similar to Northern California where I grew up. I secured a job at Overlake Hospital as an anesthesiologist, but, interestingly, they were acutely uninterested in pain. 'We are fine just doing OR anesthesia' was their response to me. After two or three years I struck out on my

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own. Because my partners had not been interested in pain, I got all the patients, meaning that I garnered a lot of experience. I 'had the market' so to speak, in that there were not a lot of people doing injections in the Seattle area at the time."

Learning From Spine Specialists

You might say his entrée to spine was via a needle. "Because of this work, I became acquainted with a lot of spine surgeons, and could tell that it was time to make up for some more deficiencies in my education. I spent many days watching spine surgeons operate, and spent about three years (part time) in Dr. John Oakley's office. A neurosurgeon well known for his work on spinal cord stimulation, Dr. Oakley told me, 'I will teach you how to do an exam and read films like a neurosurgeon.'

"I was pleased to find myself comfortable in the language of spine, which has given me the ability to speak with orthopedic surgeons in a different way. Orthopedists are accustomed to pain doctors not understanding the way they think. This makes sense, of course, because as an anesthesiologist you do heart and lung exams, not musculoskeletal exams. The joke that floats around me is that I'm an anesthesiologist trying to become a physiatrist."

Dr. Baker spent five years at the University of Washington as director of their interventional pain program. His spine colleagues got used to the eager anesthesiologist popping up at their events. "I was able to attend Tuesday morning orthopedic conferences and did spine rounds with orthopedists and neurosurgeons—I was the only pain doctor who showed up. Some of my mentors were Drs. Paul Anderson and Jens Chapman, spine surgeons who taught me to take the entire patient under consideration. For instance, they took standing films that included the back, hips, pelvis, etc., and checked the patient's alignment and their hips, not just the spine. Dr. Ted Wagner also leant me a great deal of practical advice. His tremendous experience provided insight about when not to operate on patients as well as when to operate, and he served as a superb role model of how to be kind with patients."

"Dr. Stan Herring, a former President of NASS, along with Dr. Stuart Weinstein and Paul Dreyfuss, helped me develop a knowledge base of physiatry. I watched as they discussed their cases, and then they asked me questions to ensure that I understood what was going on. These regular meetings strengthened my ability to see from another perspective. I learned that while orthopedists strongly focus on imaging because they have to operate on something, physiatrists are more interested in the physical exam. Different parties…different sides of the elephant."

The Need for Improved Diagnoses

This is one anesthesiologist who is fully alert to the human tendency to want to believe things are solved. Dr.

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Baker: "It has been enlightening—and a little discouraging—to learn how deficient spine care is with regard to diagnostics. Just when you think you know the pain generator, you find that you are wrong. We fool ourselves about how well we can actually do that, especially in the surgical disciplines. We think we know what the problem is and just need to find a better way to fix it. It is not that simple. There remains a lot of work to be done in this area."

"Spine is sexy" goes the current aphorism. Where some see ambrosia, however, Dr. Baker sees haste. He notes, "To paraphrase Alf Nachemson, 'Perhaps time, effort, and monies are better spent improving diagnosis and patient selection before developing the next generation of hardware.'

"A couple of years ago I was part of designing a study on lumbar discography in which we were trying to predict who would be a good candidate for fusion. While I was used to a private practice model, in this situation they were getting many university patients, a population that sometimes has a good deal of psychological issues. I got a number of floridly mentally ill patients and subsequently thought, 'This is an injustice. I will not send these people to surgery.' I met with the participating orthopedic surgeons and said, 'We have to do psychological testing on your patients.' They assented, ordered the tests, but the team never looked at the results. They were just going through the motions."

"We need prescreening of patients in order to select out the folks who are doomed to fail. We have the data showing that patients who are anxious or depressed, or those in moderate psychological distress, fare poorly after surgery. It is not simply a matter of finding a structural abnormality and then doing the surgery, as is often the case with low back pain patients.

"This gets back to the fact that we don't understand the pain generators. Let's say you have three patients: one who has hit his thumb with a hammer, another who is normal/healthy, and a third who has fibromyalgia. If I put a certain amount of pressure on their thumbs, the person who hit his hand with a hammer is going to withdraw, while the normal person won't react. The issue is that the person with fibromyalgia is sensitized to pain and will withdraw as well. That's where discograms and other tests get us into trouble…the ultimate solution is to have a special kind of imaging or blood test to define the pain marker that isn't altered by psychopathology."

Urging Improved Collaboration

In the mind of Dr. Baker, a "red state/blue state" mentality just means that patients wait…wait for someone to remember that *they* are the reason doctors exist. "Now more than ever spine care requires collaboration…requires that we earnestly try to see all sides of the picture. I hope to bring this mentality to NASS so that we can eliminate some of the turf wars. For example, some orthopedists are wondering why NASS is holding injection courses. Meanwhile, some physiatrists are wondering why we have so many surgical courses. The bottom line: we must be able take off

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our political hats and think of what's best for the patients."

Elaborating, Dr. Baker says,

> *"There are a number of us who are strongly focused on stopping the infighting–both within our organization and between organizations. This kind of behavior is quite detrimental whether it's either ego driven or driven by the size of the organization. Let's get together and talk; we have multiple disciplines within our society that are a natural fit."*

As for his experience in viewing all sides of the spinal elephant, Dr. Baker states, "Before I became part of the NASS presidential line, I did consulting for United Healthcare and saw how the major insurers view spine care. I also participated in a local spine advisory board that brought together representatives from the state and county, as well as people from Microsoft (as an employer of those who have spine problems), hospital CEOs and private practitioners. Each person had different perspectives, of course, which was very enlightening. These and other experiences have given me a broad view of where we need to go from here."

When Dr. Baker is sorting out patient and NASS-related issues via text message at 10pm, he has a lot of support on the home front. "My wonderful wife Jennifer and I have been married 16 years and have three children. The eldest, Kris, is attending law school at William and Mary, while our daughter Jennifer, 25, has just married and is living in Ireland and teaching literature. Our youngest son Geoff is 23 and has decided on a premed track. My wife and I really enjoy skiing and boating, and we take every opportunity to go to our vacation home in Sun Peaks, British Columbia."

Dr. Ray Baker…elevating spine and its practioners.

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VOLUME 6, ISSUE 6 | FEBRUARY 23, 2010

Orthopedics This Week | RRY Publications LLC

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

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

Walter Eisner
Senior Writer
walter@ryortho.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Julia Cecil
Marketing & Promotions
julia@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Eileen Mesi
Creative Director
Red Line Design
eileen@ryortho.com

Main Contact Information:
RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-877-817-6450
Fax: 610-260-6451

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