VOLUME 5, ISSUE 30 | SEPTEMBER 29, 2009

Orthopedics This Week

week in review

Senator Charles Grassley as doctor, digital manipulation

the picture of success

breaking news

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2009 Orthopedics This Week Spine technology Awards

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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.

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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: This week we drop Symmetry and while we're waiting for good news coming from SMA, we'll take this opportunity to put one of the perennial faves—Exactech—back on. Exactech, which has historically grown at twice the industry rate is introducing a line of new hip and knee products for 2010 that look promising.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Stryker	23.28%	9.90%	#1 for the second week in a row. At 15x trailing earnings, Stryker is under both its growth rate and profit margin.
2	2	Zimmer	29.31	9.93	While ZMH's growth rate may not match SYK, its P/E is lower and its profit margin is higher
3	3	Smith & Nephew	20.95	5.95	Right now, SNN's expected growth rate (analysts' consensus) is among the highest in ortho.
4	4	Orthofix	7.65	4.02	OFIX expands European presence with a major distribution agreement. Watch the cash flow.
5	9	CONMED	8.28	8.96	Someone is buying CNMD. Despite nothing but poor news reports, someone likes the franchise.
6	8	ArthroCare	16.87	16.48	"We don't need no stinkin' financial statements". Shareholder appear untroubled by a lack of financial reporting.
7	5	Alphatec	-8.51	0.87	Turning into a one-note story—when will ATEC cross break even? Consensus says 4Q09.
8	6	Integra LifeSciences	12.32	-4.28	2, 4, 8—those are the expected growth rate percentages for this quarter, this year and next year.
9	7	Medtronic	31.37	-2.83	New product! New cement delivery system. From Kyphon. Yup, that should make the market wake up and take notice.
10	NR	Exactech	12.87	0.13	This is the single most diversified small ortho company we know. Large joints, extremities, spine markets and sales in China, Europe, Japan.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	I Flow Corp	IFLO	$10.44	$255	29.2%
2	Capstone Therapeutics	CAPS	$0.76	$31	18.8%
3	ArthroCare	ARTC	$20.50	$546	16.5%
4	Mako Surgical	MAKO	$9.01	$226	12.6%
5	Zimmer Holdings	ZMH	$52.92	$11,340	9.9%
6	Stryker	SYK	$45.17	$17,960	9.9%
7	CONMED	CNMD	$19.70	$573	9.0%
8	Kensey Nash	KNSY	$27.98	$311	7.5%
9	Smith & Nephew	SNN	$44.49	$7,860	6.0%
10	Wright Medical	WMGI	$17.23	$665	5.3%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$1.25	$12	-37.5%
2	RTI Biologics Inc	RTIX	$4.31	$234	-12.2%
3	TranS1	TSON	$4.98	$103	-9.9%
4	Osteotech	OSTE	$4.49	$81	-4.5%
5	Integra LifeSciences	IART	$33.73	$959	-4.3%
6	NuVasive	NUVA	$39.39	$1,480	-4.0%
7	Orthovita	VITA	$4.44	$339	-3.3%
8	Medtronic	MDT	$36.79	$40,720	-2.8%
9	Symmetry Medical	SMA	$10.67	$382	-2.2%
10	TiGenix	TIG.BR	$6.70	$165	-1.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$10.67	$382	9.73
2	ArthroCare	ARTC	$20.50	$546	12.05
3	Medtronic	MDT	$36.79	$40,720	12.23
4	Zimmer Holdings	ZMH	$52.92	$11,340	12.91
5	Johnson & Johnson	JNJ	$60.62	167,060	13.44

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$10.44	$255	100.20
2	Smith & Nephew	SNN	$44.49	$7,860	77.81
3	RTI Biologics Inc	RTIX	$4.31	$234	74.38
4	NuVasive	NUVA	$39.39	$1,480	37.94
5	Synthes	SYST.VX	$120.77	$14,333	37.55

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$20.50	$546	0.48
2	Orthofix	OFIX	$29.21	$502	0.93
3	Symmetry Medical	SMA	$10.67	$382	0.96
4	CryoLife	CRY	$7.85	$223	0.96
5	Exactech	EXAC	$15.88	$203	1.03

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$39.39	$1,480	4.04
2	RTI Biologics Inc	RTIX	$4.31	$234	2.05
3	CONMED	CNMD	$19.70	$573	1.70
4	Johnson & Johnson	JNJ	$60.62	167,060	1.65
5	*Average*			*$10,262*	*1.52*

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.49	$81	0.82
2	CONMED	CNMD	$19.70	$573	0.86
3	Symmetry Medical	SMA	$10.67	$382	0.94
4	Orthofix	OFIX	$29.21	$502	0.96
5	Exactech	EXAC	$15.88	$203	1.21

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.70	$165	230.17
2	Mako Surgical	MAKO	$9.01	$226	11.07
3	Synthes	SYST.VX	$120.77	$14,333	8.76
4	NuVasive	NUVA	$39.39	$1,480	4.75
5	Orthovita	VITA	$4.44	$339	3.82

Senator Grassley Now Practicing Medicine?

By Walter Eisner

Senator Chuck Grassley just can't let go of the University of Minnesota's spine chief, David Polly, M.D. The senator now says Dr. Polly appears to have made "false statements" about the use of InFuse in a clinical study.

David Polly, M.D.

Senator Charles Grassley as doctor, digital manipulation

In a September 21 letter to the President of the University of Minnesota, Grassley raised a number of questions about Dr. Polly's use of Medtronic's InFuse as part of a $466,644 Department of Defense grant for a two-year study of bone growth products in rat femurs. At the time, because of Dr. Polly's relationship with Medtronic, the University asked Dr. Polly if an alternate non-Medtronic product could be used in the research.

Grassley writes that the University's Review Committee stated that he [Polly] told them that he could not substitute InFuse for another product for which he had no financial interest, because InFuse was the "only available BMP on the market."

Writes Grassley:

> "I pointed out to you [in a July 24, 2009, letter] that another company, Stryker, has come forward claiming it did in fact have a similar product on the market called OP-1."

Dr. Polly addressed the senator's assertion in a subsequent Minnesota Public Radio interview where, according to Grassley, Dr. Polly said:

> *"[T]he OP-1 product was only available through what was called "humanitarian device exemption" which required that a patient fit on a specific protocol and only 4000 units could be sold nationally. And that you had to go through your institutional review board to have approval to use that product.*

So when I make a statement that rh-BMP-2 was the only one that was commercially available at the time, I think that was probably a fair statement, but it has nuances that not everyone would understand.... In this particular instance unless you are someone in the field and understand the particular nuances, it's tough to be a lay, bystander, nonmedical person and understand what those different approval labels mean or imply for treating clinicians."

Grassley wrote Stryker asking about this. In an August 19, 2009, letter from Stryker's Vice President of Regulatory and Clinical Affairs [name redacted], Stryker responded to Grassley's question of how many studies of OP-1 to treat femur fractures in animals were completed or ongoing. According to Stryker, over 30 animal studies were conducted evaluating the use of OP-1 in trauma indications in 2006.

"Stryker never exceeded sales of 4000 units in 2006, so that point appears to be irrelevant...and humanitarian device exemptions do not cover animal studies, such as Dr. Polly's study of rat femurs, so that point appears to be misleading.... As you can see, Dr. Polly has made several statements that appear to be false or misleading," writes Grassley.

John Lundquist, an attorney for Dr. Polly, says in a September 22 St. Paul Pioneer Press article, "[Dr. Polly] believes his statements continue to be accurate. Use of the Stryker product must be approved by an institutional review board and is meant to be used only in specific circumstances for a limited number of users."

"He wanted to study a product that would be generally commercially available, rather than study a product that was not generally available to physicians," the attorney said.

Politics and Science

We now find ourselves watching an argument between a U.S. senator and the head of a major university's spine department over the appropriate clinical use of a medical device. This argument appears to go beyond disclosure and enters the world of clinical judgment.

Subsequent to Dr. Polly's choice to use InFuse instead of OP-1, the FDA's panel of orthopedic experts recommended against FDA approval of OP-1. Perhaps those experts should have been asked about Dr. Polly's choice.

> "I am not in a position to determine the safety, effectiveness and/or superiority of the products sold by either Stryker or Medtronic. That decision is best left to the medical experts. What troubles me is that the University could have easily figured out that at least one competing product to InFuse was available. So, I continue to have concerns that the University of Minnesota has yet to achieve a conflicts of interest policy that monitors its researchers fully," writes Grassley.

Expanded Inquiry

This latest salvo against Dr. Polly included not only two letters to Dr. Polly's employer, the University of Minnesota, but also letters to a spinal device distributor, Team Spine-Minnesota, and a hospital, the University of Minnesota Medical Center-Fairview, asking for more information about statements made by Dr. Polly regarding his involvement with Medtronic and the InFuse bone growth product.

No Good Deed Goes Unpunished

In the second letter to the University, Grassley says he would like to thank Dr. Polly "for his commitment to transparency and assistance in my continued attempts to better understand the relationships between industry and physicians. Accordingly,

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I request that the University of Minnesota provide me with all communications sent and/or received by Dr. David Polly." The time span of his request covers January 2009 to the present.

No good deed goes unpunished.

The letter to Fairview asks for a monthly accounting of all devices used by Dr. Polly in surgery since January 2008, as well as an explanation regarding Dr. Polly's role in Fairview's choice of devices used in spine procedures. The senator also asked whether Dr. Polly disclosed his relationship with Medtronic to Fairview.

The senator's letter to Team Spine asks for a monthly accounting of all Medtronic products used by Dr. Polly since January 2008, the amount of bonus earned by a sales representative, Terry McCord, and all correspondence between McCord and Dr. Polly since January 2008. All communications between McCord and the company since July 24 were also requested, as well as consulting reports filed with the company by Dr. Polly between March and late July.

The Sunshine End Game

Grassley has pursued an unrelenting inquisition into physician and industry relationships as he pushes Congress to pass his Sunshine Act. That Act is currently bottled up in the Senate Finance Committee, embedded within Senator Baucus' healthcare reform legislation. Grassley has publicly opposed the Baucus bill and may well end up having to vote against his Sunshine Act if he makes good on his promise to vote against the reform package.

Make no mistake about it, this is about getting legislation passed, and Dr. Polly has become a high-profile pawn in this political machination because of his ultra-meticulous disclosures of billings and payments involving his consulting contract with Medtronic. His detailed disclosures have provided endless fodder for microscopic inspection of his actions.

The Lone Surgeon

Grassley has been investigating all of Medtronic's relationships with surgeons for years and has the University of Minnesota under fire for what he considers inadequate conflict-of-interest policies.

Both the University of Minnesota and Medtronic have headed for the hills and told the senator they are "investigating" Dr. Polly's actions. They have been nowhere to be found in defense of their employee and consultant. Even Dr. Polly's professional society, the American Academy of Orthopaedic Surgeons (AAOS), accepted his resignation from its board of directors because his efforts to defend himself may cause a distraction from the work of the organization. Dr. Polly has found himself alone in this confrontation with Grassley.

Prior to September 21, the only accusations against Dr. Polly have been about a failure to fully disclose his ties to Medtronic in two situations. In both situations, Dr. Polly was not asked about his ties to industry and he told us in a recent interview that he wishes he would have handled those two situations differently.

But as anyone remotely close to orthopedics knows, Dr. Polly has disclosed his ties to Medtronic over and over again in professional conferences and clinical papers. He's probably disclosing his ties to his newspaper delivery person by now.

For the sake of clarity, predictability and future industry/academic/physician collaborations, we hope Senator Grassley and his Senate colleagues find a way to pass the Sunshine legislation. As Dr. Polly wrote in his resignation letter to AAOS:

> *"I look forward to the day when the rules for consulting are clearly defined, for without clear rules, there are only varying individual opinions of right and wrong."*

It will be a good day indeed.

Orthopedics This Week

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The NDA Bull Market

By Robin Young

We now believe that the market for Non Disclosure Agreements will rise by 7.8% in 2009 to an estimated $7.97 billion in Full Time Work Hour Equivalents (FTWHE). The NDA market has been one of the best performing technology markets for decades and as a result of a number of recent innovations as well as globalization of the NDA, we believe that the quantity of FTWHE chewed up by NDAs will continue to rise at above average rates for the foreseeable future.

The oldest known NDA was written by John the Elder on a deer skin in 1216 as a means to avoid taxation in Banffshire, England. It failed. Word had reached John regarding the Magna Carta and in a flash he deduced that taxation was a form of involuntary disclosure. Using that remarkable historical document as inspiration he wrote the first voluntary disclosure agreement. John the Elder's strategy was to convince the sovereign authority to recognize the "right" of voluntary disclosure for tax purposes. And once that was accomplished, refuse to volunteer any information. Mr. Elder wasn't a particularly bright man nor was he, when he died, a particularly elderly man.

The first paper form of a voluntary disclosure agreement didn't surface until 1674 when Jason Saberattle of Moray, England, sought to include it in an exclusive distribution proposal for the white candy cane (stripes were invented 250 years later) from Christian Andersson—a Norwegian transplant to England. Saberattle stated in his agreement that he was seeking a "monopoly." He did convince Andersson to sign the novel, one-way document in exchange for two heads of cattle, a mattress and three flagons of ale. But when Mr. Saberattle attempted use the document to raise funds for his "candy cane" venture, he was met with almost a total lack of understanding of the power of the NDA. By 1675 the candy cane was on its way to being a staple Christmas confectionary throughout Europe and the colonies with thousands of producers. No copy of Mr. Saberattle's innovative NDA exists today.

For the next 300 years, the NDA remained a little understood concept, particularly with the sovereign authorities in most countries of Europe and the Americas. Most lawyers focused on the more lucrative "letters patent" work, which paid

better and which was generally supported by the courts of the sovereign authority.

The First Major NDA Breakthrough

Most lawyers probably wonder why Winslow Day is a semi-official legal holiday and is noted almost exclusively by members of the bar. It is because of the amazing innovation developed by a John Fitch Winslow of Boston, Massachusetts, in 1908. As students of legal history know, Mr. Winslow invented the first two-sided NDA.

That major breakthrough resurrected the moribund NDA concept and set it on the path to become, as it is today, the bread and butter of most legal bills in the United States.

Prior to Mr. Winslow, those rare attempts at drafting an NDA were based on the one-sided monopoly concept originated by Mr. Saberattle in 1674. The two-sided agreement opened up the entire NDA market. Lawyers were now able to present clients with strong arguments in favor of two-sided protection which, in an era when attorneys were paid by the word ($1 per word, for example), created a lucrative new line of business. Soon lawyers were recommending that every corporate client have an NDA written, negotiated and signed before business discussions ensued. Legal bills tripled, even quadrupled (since legal drafting never increases algebraically, only geometrically).

Hence the now ubiquitous phrase, "to Winslow a client."

On April 10, 1925, the first U.S. two-sided NDA agreement was tested in court. The Winslow-drafted document won. (What happened to the parties in the case is unknown.)

The following table summarizes the range of NDA innovations since Winslow:

It may be hard to imagine that the NDA could ever be improved upon. After all, since Winslow the basic structure of the modern NDA has been laid out. Yet, as we've seen, innovation in legalese will not be denied. Two years ago, the advent of a truly global NDA created new opportunities for legal scribes in vast, virgin legal markets throughout the world.

Like the Jesuits of old, intrepid members of the bar are now

Year	NDA Innovation	Inventors	# of NDAs in U.S.	FTWHEs
1920	Two, 2-sided NDAs per transaction vs. one master NDA for both sides	Wagner, Hardy & Hobbs	33	562
1933	Confidentiality clauses in NDAs	Brill, Duryee, Clint & Marin	165	2,308
1946	Multiple NDAs per invention	O'Grady & Hudnut	6,222	56,000
1953	One-Year Duration NDAs, with re-drafts at annual anniversary	Ignazio, White, Tucker, Sandford & Walker	44,714	313,000
1978	Variable durations requiring lengthy negotiations between parties.	Robertson, Baldwin & Cruikshank	411,200	2,056,000
1997	The concept of "Public Domain"	Schwimmer	3,750,000	18,759,000
2007	Globalization of the NDA	Muscarello, Martin & Lewis	9,122,500	31,890,500

Source: RRY Publications, LLC

setting up shop in every corner of the world and holding seminars, private consultations and, yes, even advertising (!) to convert millions of entrepreneurs to the rigors of an FTWHE-rich NDA.

With globalization and a series of new innovations the NDA market, we expect, will grow to over $10 billion in annual billings by 2015.

While some critics would argue that NDAs often don't fit the intended technology use, that they create unforeseen liabilities, that they are difficult to enforce, that it is difficult for the parties to determine what exactly is and is not covered, that there is no ability to monitor either the discloser or the disclosee, and that multiple and conflicting state laws exist regarding NDA enforceability, we believe the atmosphere around the world is still decidedly pro-NDA. No longer is the NDA seen as simply a business need; it now also is seen as essential protection and therefore has elevated the role of corporate counsel from advisor to deal mediator. The modern NDA has played a decidedly non-trivial role in increasing the complexity of technology, invention, discovery, and business expansion in the United States and, soon, the world. No doubt about it. The bulls are running in the NDA market.

(Publisher's Note: In case any of our readers are confused by the conventions employed in this article, this is fictional satire and the names and events described herein are a figment of the writer's imagination – RRY)

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From the Data Guys at PearlDiver

The end of the quarter is here and our boss, Robin Young, is pushing us to get these reports out the door. We just loaded Medicare data into the system. Then we cross-referenced Medicare with our Private Payer datasets. So now he wants us to start selling. With more than 200 million patient records we have the largest, most granular market studies available for U.S. markets. Robin's telling us that we have to move the inventory. Every report listed below is just $950. If you call us individually, we can give you volume discounts. The sooner we can get back to crunching numbers, the happier we'll be. These are great reports and we want to move them out.

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Spine Procedure	Code
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal fusion	81.04
Posterior dorsal fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Posterior lumbar refusion	81.38
Discectomy	80.51
Spinal Decompression	3.09

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 Implant 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

Cover Your Practice: Risk Management

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

If a lawyer walked into your practice, would he or she leave confident that you are "covered?" Or would he want to bar the door until things could be put in order?

Jayme Matchinski, an attorney with Hinshaw & Culbertson LLP in Chicago, Illinois has seen all manner of legal exposure in doctors' offices. She says, "As physicians go about their daily practices, it is easy to neglect the 'little' things that may leave them vulnerable to liability... things such as proper documentation or taking enough time with a patient. Addressing these and other issues on the front end, however, can save you numerous headaches and expenses later on."

The primary compliance issues, says Matchinski, are as follows: Medicare coverage and payment, billing and reimbursement, Stark Law – Stark III, Anti-Kickback Statute, HIPAA, and state regulations. "Medicare coverage and payment relate to the care provided by the doctor and the claim submitted by the doctor to Medicare for such care. The Stark Law may be triggered if the doctor (or his family member) has an ownership interest in an entity to which the doctor refers a patient for a designated health service, for example, an MRI, unless one of the Stark safe harbors are met so that such a referral is not deemed to be a prohibited referral under the Stark Law. The Anti-Kickback Statute prohibits any payment based upon volume or value of patient referrals. HIPAA requires doctors and other 'covered entities' to adhere to the

HIPAA privacy and security standards to protect against the unauthorized disclosure of patients' protected health information."

And in order to stay in line with these compliance issues, it's important to manage your risks.

But what exactly does "risk management" mean? Jayme Matchinski: "It is the reduction of adverse consequences. One of the most valuable ways of doing this is to communicate appropriately with patients. If there are important test results or information about a major procedure, diagnosis, or treatment option, the doctor should speak with the patient face to face, or at least phone him or her. If the patient is not able to talk to the doctor directly, he or she may be confused or possibly angry."

Making Apologies

Two words you learned as a toddler might just save you from a trip to the courthouse. "A central aspect to proper patient communication is being able to say, 'I'm sorry' without defending or denying. Apologizing, always an art form, has gone beyond that realm into the legal arena. Most

states have a statute on apology; in Illinois, for example, it's on the books that apologizing is not an admission of guilt—nor is it admissible in court."

"In fact," states Matchinski, "nothing is as effective in reducing liability as a genuine apology. Because this is so important, you should practice what you are going to say before you offer the apology and document the discussion afterwards. When someone is debating about whether to file a suit, they think about how the doctor spoke with them. The fact is that people are less likely to sue a physician—even if he made a mistake—if there was good communication. While an apology isn't failsafe, it can go a long way to ameliorating the situation. And medical facilities know that. To see examples of apology policies in institutions, look toward Johns Hopkins Hospital, Vanderbilt University School of Medicine, and the University of Michigan."

"I'm sorry you had to wait, I'm sorry the coffee wasn't hot, etc."…when exactly do you apologize? "Be ready to offer your regrets in the event of expected or unexpected complications, poor results, an error on the part of clerical staff, a surgical error and in the event of unintended consequences. And hopefully you genuinely care about the patient's welfare… because that *has* to come through in the apology."

Keeping It on the Record

And what about the patient's "mirror"—the medical record? Matchinski says, "The patient's record is not only a medical document—it's a legal document as well. From the outset, it should be treated as such, with the proper attention to detail. Remember that everything noted with regard to the history and physical, diagnosis, social data, etc., is critical information that is not only used as the basis for payment claims but may be used in administrative or legal proceedings. For example, the patient's employer might use it for workers compensation or disability claims."

"Under the law," adds Matchinski, "you have a duty to maintain a complete and accurate record for each patient. Failure to do so leaves you exposed to liability under the Medical Practice Act, the Health Insurance Portability and Accountability Act (HIPAA), and the American Medical Association Principles of Ethics and Code of Professional Conduct."

Those who got As in penmanship should consider writing their 5th grade teacher a "thank you" note. Says Matchinski, "Dotting your 'i's and crossing your 't's wasn't just important years ago…it's one way to minimize liability when it comes to patient records. If you do not have neat handwriting, have the record typed. If it is necessary to correct something in the patient record, make sure no one uses 'Wite-Out' *and* ensure that they put their initials adjacent to the error. You can bet that if there are unexplained alterations in the record that this will be a red flag for the plaintiff's attorney. With regard to notes made late, i.e., out of sequence, you should insert an asterisk where the note should have been."

Matchinski, who conducted the risk management presentation at the 2009 AAOS conference, adds, "If you are not writing concisely, and are writing

from an emotional standpoint, the plaintiff's attorney may use this to discredit you, saying that you are biased against the patient. Always make your documentation with an eye toward how the chart might be used in the future."

"The biggest problem," underlines Matchinski, "is incomplete charts. Omissions are often the basis for litigation. A good litigator will look at the chart and notice, for example that the patient came five times, but there are only four documentation entries. Or the attorney may say, 'Well, we know he had this procedure, but there is no documentation to that effect, despite the fact that they billed for it.' You must include enough information to justify the diagnosis and warrant the treatment. And take note of your institution's documentation deadline. Most practices mandate that notes must be done within 24 hours of patient contact."

And while Mrs. Jones' name is on the file, she doesn't own it. "In most cases the medical record is owned by the entity responsible for compiling and maintaining the record. This is part of the larger issue of who has the right to the patient's information. The doctor has got to be well informed in order to release the information only to the appropriate parties. This can get dicey, when, for example, a minor is involved and the parents are separated or divorced. If they are in fact divorced, both parents have a right to information about the child. It can get heated, however, because the parent paying for the insurance may not want to grant this access to the other parent. Release of information is a particular area where you want to make sure your staff is well trained."

"Consider the consequences," advises Matchinski, "of releasing information in a situation involving elder abuse, abuse or neglect of a child, a patient with AIDS, or a domestic violence situation. Under the law you very well could have an obligation as a healthcare provider to report some of these situations. Pick up the phone and call your attorney to be sure."

If you decide to retire or sell the practice, what happens to the medical records? "With regard to destruction, retention or transfer of records, the fundamental issue is to ensure that you are in compliance with state and federal laws. What if you treat minors? In most states, the statute of limitation for retaining medical records is extended until the minor reaches majority age and becomes an adult. Medicare has a seven year requirement for retention of medical records, but the record retention requirements may be shorter for commercial insurance. I advise physicians to go with the longest time requirement for record retention to avoid losing records and information they may need down the road."

So where to begin in assessing your exposure to risk? Jayme Matchinski advises, "Walk into your office one day as if you were a patient and see what's going on. Is the receptionist helpful? Are there patient charts sitting out in the open? Look at your surroundings with fresh eyes and you may very well turn up some areas for improvement. The bottom line: think like a lawyer."

Spinal Motion Preservation: Update and Outlook (Part 3 of 3)

By Matt Menze, PearlDiver Spine Analyst

Over the last several weeks, we've tackled the concept of motion preservation in the spine. At the start of the new millennium, the concept of motion preservation technology took the spine industry by storm. While clairvoyants preached the end of the world, pundits in the spine industry proclaimed "the end of fusion." Neither prediction came true.

Artificial discs, interspinous process spacers, and dynamic constructs continue to evolve, but to what end? What will become the standard of care?

Based on our conversations with leaders in the field, pedicle screw based dynamic stabilization is re-emerging as the most logical solution for most surgeons and patients who seek to preserve motion and treat spinal instability. There is, in other words, a middle road between disc arthroplasty and spine fusion—a middle road that ultimately may be more consistently successful for patients and their surgeons.

Last week we discussed the troubling issue of screw loosening in pedicle-based motion preservation, and we heard the experts explain how some devices can overcome that problem. This week, in our third and final installment, we discuss patient selection and device differentiation.

The Surgeon and Indications

Different types of surgeons evaluate devices in a variety of ways. Their considerations can include: anatomical approach, ease of implantation, and published outcomes/complication rates. Academically based surgeons may evaluate devices differently than active, higher volume surgeons, who may primarily focus on approach and ease of implantation. These different types of surgeons may not have a single standard of evaluation for devices, but we still found that, based on our discussions with leaders in both the theoretical and design aspects of these technologies, the surgeon is the final decision maker regarding which cases require which device. In the end, each surgeon should decide which device he or she is most comfortable working with, but in order to objectively decide which device is best for each

case, it helps to start with the on-label indications for each device.

Pedicle-based systems are designed to address spinal instability facilitated by surgical procedures (such as decompression) or by degenerative spine disorders. According to Dr. Avinash Patwardhan, Director of the Musculoskeletal Biomechanics Laboratory at Edward Hines Jr. VA Hospital and Professor of Orthopaedic Surgery at Loyola University Medical Center "the primary indication is back pain that is somehow related to spinal instability. Some people refer to this as activity related back pain. A secondary indication would be decompressive surgery that creates iatrogenic instabilities. Another indication would be as a 'topping off' device adjacent to a fusion."

According to the FDA 510(k) summaries of the Dynesys, DSS, and Transition, the following are indications for patients:

- ✓ Patients who are receiving fusions with autogenous graft only
- ✓ Patients who are having the device fixed or attached to the lumbar or sacral spine
- ✓ Patients who are having the device removed after the development of a solid fusion mass

Table 1 lists the indications for several of these pedicle-based motion preservation devices. Note that almost all of these devices treat chronic instabilities or deformities of the spine adjunct to fusion. The Transition is on-label for use without interbody fusion, but it must be used with an autogenous bone graft. The Stabilimax NZ also stands out from the crowd in that it treats spinal stenosis adjunct to decompressive surgery.

The indications are as clear as black and white, but a patient's specific needs can often fall in the gray area. Patients present at varying points in the degenerative cascade and in the overall continuum of care. There are many variables that determine the appropriate use of the technology, and the ability of the surgeon to determine appropriate usage is of critical importance. In our view, it will be necessary to continually develop methods for accurately diagnosing spinal disorders in order to complement the technology that treats the disorders.

Table 1: Pedicle-Based Motion Preservation Devices and Their Indications

Company	Product	Regulatory Status	Indications*
Applied Spine	Stabilimax NZ	IDE clinical trials ongoing	Adjunct to decompressive surgery in patients with spinal stenosis
Zimmer Spine	Dynesys	510(k) approved	Adjunct to fusion in the treatment of chronic instabilities or deformities of the spine
Globus Medical	Transition	510(k) approved	Adjunct to fusion in the treatment of chronic instabilities or deformities of the spine. May be used without interbody fusion, but must be used with autogenous bone graft.
Scient'x	Isobar semi-rigid rod	510(k) approved	Adjunct to fusion in the treatment of chronic instabilities or deformities of the spine
Paradigm Spine	DSS Modular Stabilization System	510(k) approved	Adjunct to fusion in the treatment of chronic instabilities or deformities of the spine

**Please see FDA documentation for full description of on-label indications*

Differentiation Between Devices

The devices in Table 1 are all pedicle-based dynamic stabilization devices, and some of them share the same indications, but how do they match up against each other? Are there specific advantages and disadvantages to certain devices? While long-term outcome data isn't yet available, researchers have analyzed key variants in these devices. Dr Vijay Goel, Co-Director at the Engineering Center for Orthopaedic Research Excellence at the University of Toledo, for example, has performed analysis highlighting some key characteristics of Stabilimax and Dynesys.

According to Dr. Goel, "Biomechanical studies have shown that the Dynesys is comparable to rigid instrumentation (i.e., fusion) particularly in flexion. So, the PET cord doesn't seem to allow any motion. Early clinical results also indicate that the device behaves like a fusion device. Lack of interpedicular travel (due to lack of material compliance) seems to be the root cause.

"The Stabilimax design permits interpedicular travel and maintains a near normal center of rotation, which suggests that the stiffness profile is also optimal. The ball-socket design at the pedicle screw head also reduces bending moments at the bone screw interface. Dynesys lacks these characteristics, as indicated both by biomechanical testing and early clinical results. What's interesting is that given the stress relaxation characteristics of the materials used in the Dynesys system, combined with evidence of "ball-socket like" wear patterns on the PCU spacer from long term retrievals, the Dynesys will probably behave more like the Stabilimax, but only after 8-10 years of implantation, which unfortunately might be too late to avoid adjacent level disease progression.

"The Dynesys also has an issue with screw loosening with their 1st generation screws. We will wait to see if HA coating in their 2nd generation screw addresses the issue. The Stabilimax, on the other hand, had issues with the surface finish of their 1st generation pedicle screws, resulting in some cases of screw fracture. Given the notch sensitivity of titanium, grit-blasting as a surface finish is detrimental to the fatigue life of the screw. The 2nd generation Stabilimax pedicle screws are dual shot peened, which improves the surface roughness and fatigue life of the screw, without necessarily making the screw stiffer. This is probably the right solution, as a stronger, stiffer screw could easily result in screw loosening, which is of primary concern with PDS systems."

Dr. Paul McAfee, Chief of Spinal Surgery at Towson Orthopaedic Associates, suggested that the Transition device marketed by Globus Medical offers significant improvements over past tension band based devices such as the Dynesys. The device utilizes a PET cord, but it also contains two bumpers made out of polycarbonate polyurethane. There are titanium spools attached to the conventional pedicle screws. The spools have a collar on them which encircles the sleeves so that the device can maintain stability up to 10 million cycles. The device also works with a posterior disc implant.

Patient Expectations

Some orthopedic companies are now embracing a direct marketing model, advertising to consumers via the Internet and television. This has the potential to attract patients throughout the continuum of care, including those who are undergoing conservative, non-operative treatment as well as those with failed back syndrome or ongoing symptoms. What expectations do these patients have regarding these technologies?

Dr. Manohar Panjabi, Professor Emeritus, Department of Orthopedics at Yale University School of Medicine suggests that patients generally have high expectations regarding new technologies and treatments. Patients tend to be attracted to technologies that will decrease the pain while

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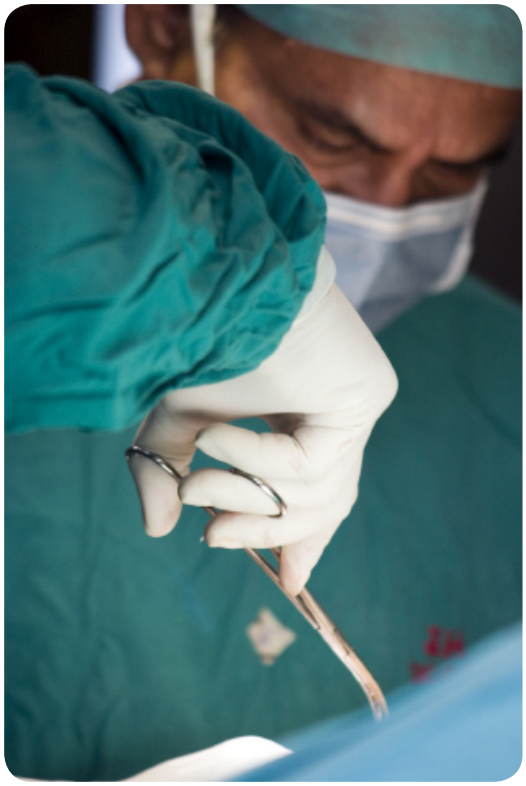

avoiding an irreversible procedure such as fusion. Patients who still have pain after surgical intervention may also be attracted to these new alternatives. Dr. Patwardhan added that an additional benefit to these devices is that the surgeon can use a minimally invasive procedure, reducing the incidence of muscle related trauma associated with fusion.

Moving Forward: A Hybrid Construct?

Treatment with pedicle-based dynamic stabilization technologies allows patients to avoid the potential effects of irreversible procedures such as fusion while still maintaining natural motion in the spine. In the future, dynamic stabilization technologies may work with other devices to not only avoid fusion, but to preserve anatomy. Nucleus replacement technologies seek to preserve the annulus fibrosis of the disc by only replacing the nucleus. Dr. Panjobi, who advocates preserving as much of the anatomy of the spine as possible during treatment, believes that there is the potential to use nucleus replacement technologies with posterior stabilization devices. However, he does not necessarily agree with combining total disc replacement (TDR) technologies with posterior dynamic stabilization because TDR can contribute to instability with the removal of the native disc and affect the anterior longitudinal ligament.

Dr. Goel believes that ultimately, a 360° motion preservation system could be the solution. While several combinations of systems are possible, he suggests that a posterior disc and a posterior stabilization system may be preferential, as an anterior implant would require an additional surgery.

Motion Preservation as Part of Fusion

One of the appeals of motion preservation technologies is that they represent an alternative to spine fusion. However, there is no reason why fusion and motion preservation cannot also co-exist. The focus should not be on which one will eliminate the need for the other. For example, severe spondylolisthesis may require fusion while the adjacent level is treated with a motion preserving device or a hybrid motion preservation construct. We submit that that there will likely be a place for both in the future, and that the technologies may be increasingly utilized together.

Final Words: The Preferred Spine Treatment

Motion preservation technologies are now a permanent part of the evolving spine technology landscape. Pedicle-based dynamic stabilization systems implanted from the posterior approach may prove to be an appealing treatment option for surgeons and patients in search of alternatives to fusion.

Researchers and manufacturers are designing dynamic constructs based on a growing body of quantitative analysis involving anatomical responses to injury in relation to the biomechanics of the spine. Pedicle-based dynamic stabilization technologies are evolving to match a greater understanding of the range of motion in the spine, more specificity regarding indications, and an advanced understanding of device materials. The industry is also exploring ways to use dynamic stabilization with other devices such as nucleus replacement in order to provide a complete solution to spine disorders.

Instead of simplifying spine treatment to a single best treatment option, the future of the spine industry will grow increasingly complex as researchers and surgeons combine devices and methods to find the best solution to each patient's problem.

company news

OrthoWorx Founded and Funded

It's official. OrthoWorx it is.

Lilly Endowment, Inc. is granting the good folks of Warsaw, Indiana, $7 million to establish OrthoWorx, a Warsaw-based, industry, community and education initiative, "to advance

OrthoWorx
Finding STRENGTH in People

and support growth and innovation within the region's uniquely concentrated, globally significant orthopedics device sector."

The announcement, made on September 23, comes only 13 days after the release of a BioCrossroads study titled, *"Warsaw, Indiana: The Orthopedics Capital of the World – An overview, analysis and blueprint for future industry and community growth."*

OrthoWorx is composed of a number of nonprofit organizations supporting local efforts to, "define and drive the best opportunities for regional development." Key among them are a new charitable affiliate of KCCF (The Kosciusko County Community Foundation), the Orthopedic Capital Foundation, and a new business league focused on the orthopedic industry.

The initiative will target educational, workforce, cultural, communication, branding, logistical and entrepreneurial efforts to accomplish its goals.

For example, as part of educational and workforce efforts, OrthoWorx will work with the Indiana Department of Workforce Development, Ivy Tech, Grace College and other higher education institutions, to help identify gaps in training and associate and baccalaureate degree programs. Those institutions will then hopefully work to develop new educational programs through state and federal grants and other sources of funding to fill such gaps.

According to the announcements, OrthoWorx will also, "explore ways to enrich and expand K-12 options in the region and develop further the research collaborations among orthopedic companies and Indiana's research universities. It also will build relationships with the human resources, management and manufacturing departments of the various Warsaw-based orthopedics companies to ensure that companies can get the specifically trained workers they need."

"OrthoWorx will become the voice that promotes the presence and potential of the Warsaw-based orthopedics industry and the community that supports it," said David Johnson, President and CEO of BioCrossroads. "As the epicenter of the orthopedics industry, Warsaw offers both a unique industry and a unique community. OrthoWorx will bridge the two to put the best strategic opportunities into action."

The OrthoWorx Board of Directors was also named at the announcement. Those members are:

- David Johnson, President and CEO, BioCrossroads
- Suzie Light, Executive Director, Kosciusko County Community Foundation
- Cheryl Blanchard, Ph.D., Chief Scientific Officer and Senior Vice President, Zimmer, Inc.
- David Findlay, Chief Financial Officer and EVP of Administration, Lake City Bank
- Toby Buck, Chairman, President and CEO, Paragon Medical
- Jon Serbousek, President, Orthopedics, Biomet Orthopedics
- David Floyd, President, DePuy Orthopaedics
- Ron Manahan, Ph.D., President, Grace College and Seminary

The Directors will be meeting over the next few weeks to organize a staff and begin their efforts.

—WE (September 24, 2009)

ArthroCare Closes on $75 Million Financing

ArthroCare® Corporation

How does a public company raise new equity without filing financial statements with the SEC?

The last time ArthroCare filed financial statements with the SEC was May

company news

12, 2008. Since then the company has filed 4 consecutive notifications of inability to timely file financial statements—as required by law.

Did the institutional investors (most notably JP Morgan) who invested $75 million into ArthroCare receive financial statements? Absolutely.

Financial statements exist, of that there is no doubt. For some reason, ArthroCare hasn't filed financials as is required by the SEC, NASDAQ and state regulators.

Over the past six months ArthroCare's stock has risen from $4.80 per share to over $20.00 today—a 310% increase. Shareholders are happy. But buying under these circumstances (no financials) is little more than speculation.

With the closing of this financing with One Equity Partners (OEP), the global private equity investment arm of JP Morgan Chase & Co., ArthroCare has repaid in full all of its outstanding indebtedness under the Credit Agreement dated January, 13, 2006, with Bank of America and a syndicate of other banks.

It took about $39.0 million of the $75 million 3.00% Convertible Preferred Stock offering to repay all outstanding indebtedness under the Credit Agreement and to cash collateralize another letter of credit.

The preferred stock is convertible into common at $15 per share—which was a premium above the closing price on August 14—when the deal was struck. The investors have already made $5 per share or 33% on their investment.

Finally, the investors have put Chris Ahrens and Greg Belinfanti, both Partners of OEP, on ArthroCare's board of directors.

—RRY (September 25, 2009)

legal & regulatory

Humana "Called Out" For Scare Tactics

President Obama told Congress that he will work with anyone who has constructive ideas to contribute to the health care reform debate. But he also threatened to "call out" those who were simply using scare tactics to frighten folks into opposing health care reform.

He wasn't lying.

On September 18, CMS (Centers for Medicare and Medicaid Services) sent a letter to Humana, Inc, instructing the company to "end immediately" a mailing it had sent to enrollees in its Medicare Advantage (MA) program.

CMS said it had learned that Humana was contacting enrollees in its Medicare plans and telling them that current health care reform legislation affecting Medicare could

hurt "millions of seniors and disabled individuals [who] could lose many of the important benefits and services [emphasis in original document] that makes Medicare Advantage plans so valuable."

legal & regulatory

In addition, CMS says Humana's mailing, "makes several other claims about the legislation and how it will be detrimental to enrollees, ultimately urging enrollees to contact their congressional representatives to protest the actions referenced in the letter."

Teresa DeCaro, Acting Director of Medicare's Drug and Health Plan Contract Administration Group, wrote Humana that, "CMS is concerned that, among other things, this information is misleading and confusing to beneficiaries, represents information to beneficiaries as official communications about the Medicare Advantage program, and is potentially contrary to federal regulations and guidance for the MA and Part D programs and other federal law, including HIPAA."

She told Humana:

CMS takes this matter very seriously and,"based upon the findings of our investigation, will pursue compliance and enforcement actions."

According to the Kaiser Family Foundation, Humana reported 1.5 million enrollees in its Medicare Advantage plans as of June 30. Overall, more than 10 million of Medicare's roughly 45 million enrollees opted for such plans in 2009. MA programs receive a premium over standard Medicare payments. The President has called for removal of those premiums.

Humana spokesman Tom Noland reportedly said the company was cooperating with CMS.

The letter to Humana was released by Senate Finance Committee Chairman Max Baucus, Democrat of Montana.

Humana should consider itself "called out."

—WE (September 22, 2009)

Neurosurgeons Say "No" to Baucus

The organizations representing approximately 7,600 neurosurgeons worldwide have weighed in on Senator Baucus' health care plan. They oppose it.

The American Association of Neurological Surgeons (AANS) voiced its opposition to the Senate Finance Committee Chairman's "America's Healthy Future Act of 2009," in a press release on September 21. It was joined by the Congress of Neurological Surgeons (CNS).

Both oppose the Act because issues important to those organizations are missing from the Baucus bill. Those include medical liability reform and an assurance that patients will be able to contract privately with their physicians.

Said AANS President Troy Tippett, M.D., "As it [the bill] is now drafted, it is extremely detrimental for physicians and our patients."

Tippett continued, "As surgeons, we are especially concerned that this bill fails to recognize or address the looming workforce shortages in surgery and specialty care which will greatly impact the next generation of Americans. In the year 2025, we'll need 41,000 surgeons who simply won't be there."

P. David Adelson, M.D., CNS President, was happy to see that the "public option" had been dropped in

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the Baucus bill, but was concerned that the co-op proposal was a slippery slope to a government-run plan. "Unfortunately, this bill fails patients and doctors because it imposes new agencies and more bureaucracy and government than currently exists, which will ultimately interfere with the doctor/patient relationship."

Specifically, the organizations were "alarmed" about these six provisions.

- A requirement that all unused medical residency training slots be allocated to primary care.
- A lack of medical liability reforms.
- A mandate that physicians participate in the Physician Quality Reporting Initiative (PQRI).
- Only a one-year SGR "patch" for physician payments.
- Unchecked HHS Secretary powers to, "arbitrarily reduce reimbursement for valuable, life-saving specialty care for elderly patients."
- Curtailing the development of physician-owned specialty hospitals and changes to office-based imaging.

The organizations were not only unhappy with provision in the bill, but also in process. Tippett said the organizations were, "disappointed that virtually none of our recommended changes are reflected in this bill, calling into question the value of this process."

The Senate Finance Committee is currently considering the Baucus bill. If it passes that committee, the bill will be consolidated with a bill passed earlier by the Senate Health Committee and go to a vote on the Senate floor. If that passes, the bill will be sent to a House/Senate conference committee, which will reconcile differences in the House and Senate versions of the legislation. The reconciled proposal will then go back to both legislative bodies for a final vote.

—WE (September 23, 2009)

FDA Studies 510(k) Process

The FDA 510(k) premarket notification process has been at the heart of bureaucratic and political infighting within the FDA for a number of years. On occasion, device companies have been the pawn in this battle and navigating through the FDA process has been confusing, contradictory and expensive. Just ask the folks at Regen Biologics.

Now the FDA is hiring the Institute of Medicine (IOM) to study the program.

According to an FDA September 23 announcement, the IOM study will examine the premarket notification program, also called the 510(k) process, for medical devices. While the IOM study is underway, the FDA's Center for Devices and Radiological Health (CDRH) will, "convene its own internal working group to evaluate and improve the consistency of FDA decision making in the 510(k) process."

Speed vs. Safety

The 510(k) process was established under the Medical Device Amendments of 1976 to make safe and effective devices available to consumers and to promote innovations in the medical device industry. Those two goals have often been at odds as speed and safety collided. The Government Accountability Office recently identified two-dozen device types that were approved without close scrutiny, including hip replacements.

The FDA says that over the past three decades, medical device technology has, "changed dramatically," and it's time to review the adequacy of the program in meeting those two goals.

The Questions

The IOM will convene a committee to answer two principal questions:

- Does the current 510(k) process optimally protect patients and

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promote innovation in support of public health?
- If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) process?

The IOM will receive $1.3 million for the study to be completed in 2011.

Jeffrey Shuren, M.D., the acting director of CDRH, outlined the following priorities for the CDRH review:

- Creating an internal task force on the use of science in regulatory decision-making
- Developing an effective compliance strategy
- Optimally integrating premarket and postmarket information
- Increasing transparency in decision-making
- Establishing clear procedures to resolve differences of opinion.

Post-Shultz Era

Shuren takes the spot that was vacated in August by Daniel Shultz, M.D. Shultz was frequently at the center of the bureaucratic fight and left "for the good of the agency."

The IOM will hold two public workshops during the next nine months as part of its review, and will publish a final report in March 2011 containing its conclusions and recommendations.

If the end result of this study and review is a more predictable and transparent clearance process, it will benefit the industry.

—WE (September 24, 2009)

extremities

FDA Committee Recommends XIAFLEX for Dupuytren's

One step closer to getting a handle on this rare hand condition…Auxilium Pharmaceuticals, Inc. has announced that the FDA's Arthritis Advisory Committee has recommended by a vote of 12 to 0 that XIAFLEX (collagenase clostridium histolyticum), be granted marketing approval for the treatment of Dupuytren's contracture, a rare hand deformity that affects the connective tissue under the palm of the hand. XIAFLEX is a novel, first-in-class, orphan-designated, biologic.

"We are very pleased with the Advisory Committee's recommendation, which supports our view that XIAFLEX has a favorable benefit to risk profile in the treatment of Dupuytren's contracture," said Armando Anido, CEO and President of Auxilium, in the news release. "XIAFLEX has the potential to provide an important new non-surgical treatment option for patients with Dupuytren's contracture, a debilitating hand condition severely affecting patients' quality of life."

The Advisory Committee's (nonbinding) recommendation will

Dupuytren's contracture/Auxilium Pharmaceuticals, Inc.

extremities

be taken under advisement by the FDA in its review of the Biologics License Application that Auxilium has submitted for XIAFLEX. The original target Prescription Drug User Fee (PDUFA) action date for the FDA's decision as to whether to grant marketing approval for XIAFLEX was August 28, 2009. The FDA has not updated the target PDUFA action date.

Dupuytren's contracture is a progressive disease that most commonly affects the metacarpal phalangeal joint and the proximal intra-phalangeal joint. Nodules develop in the palm as collagen deposits accumulate. Over time, these deposits form a cord that stretches from the palm of the hand to the base of the finger. This leads to the contraction of the fingers, which impairs the functioning of the hand. Currently, surgery is the only effective treatment; there are no drugs yet approved by the FDA for Dupuytren's contracture.

Commenting on some of the steps to be undertaken in the next few weeks, Will Sargent, Auxilium VP of Investor Relations and Corporate Communications told *OTW,* "We will continue to work with the FDA toward approval of XIAFLEX for Dupuytren's contracture as quickly as possible. All of field sales management, field reimbursement specialists and medical science liaisons have been hired. We continue to interview highly experienced sales representatives and will be making contingent offers that will be made solid upon approval and then prepare the sales force to launch within approximately 60 days of approval."

When asked about U.S. physicians who are prepared to diagnose and manage this condition, Sargent told *OTW*, "We believe at least 7,000 hand surgeons, plastic surgeons, orthopedic surgeons, general surgeons and rheumatologists are experienced in the diagnosis and treatment of Dupuytren's contracture. Obviously, training and education on XIAFLEX and its administration are key for these physicians, and we will use multiple approaches (web, sales reps, etc.) to support physicians, and their office staff, after launch."

—EH (September 24, 2009)

large joints

First Genetic Test for Psoriatic Arthritis

Buying critical time… PsoriasisDX, LLC, a subsidiary of PharmaGenoma, Inc., is announcing that it has launched the first genetic test for psoriatic arthritis (PsA), a progressive irreversible joint disease associated with psoriasis. As indicated by the company, approximately 20% to 40% of psoriasis patients will eventually develop PsA.

Andy Goren, CEO of PharmaGenoma, Inc., told *OTW* "Psoriatic arthritis develops years after the onset of skin psoriasis, providing an opportunity for preventive therapy. The PsoriasisDX test is the first genetic screening test for developing psoriatic arthritis, providing physicians with the toolset to practice preventive therapy."

In the news release, University of California, San Francisco (UCSF) psoriasis expert Dr. John Koo noted, "Until now, doctors have screened patients after the onset of the inflammatory arthritis. FDA-approved medications for the treatment of PsA are most effective at controlling inflammation and arresting joint destruction, but are ineffective at reversing joint damage."

The process involves collecting a genetic sample via cheek swab; the

large joints

sample is then mailed for analysis to the PsoriasisDX laboratory. Testing is performed at a CLIA-certified laboratory. Once the genetic analysis is complete, test results will be reported to the doctor.

"Dramatic advances in science mean that genetic tests hold the promise of identifying those at highest risk for developing psoriatic arthritis," said UCSF pharmacogenomics expert Wilson Liao, M.D.

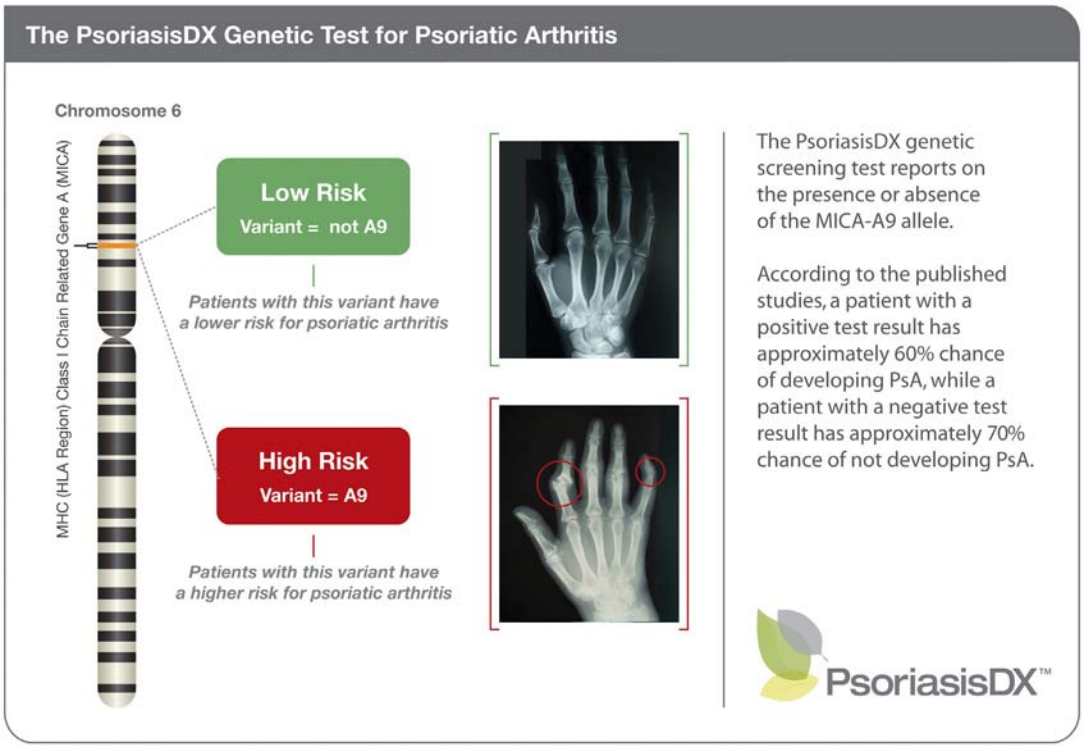
In particular, says the company, an immune response gene variant called MICA-A9 is found in approximately 60% of patients who develop PsA. The MICA-A9 association was replicated by four peer-reviewed and published studies involving over 900 patients from multiple ethnic populations.

Positive tests for the MICA-A9 variant result in an approximately 60% chance of developing PsA, while negative tests for the MICA-A9 variant result in an approximately 70% chance of not developing PsA, according to Nathan Vandergrift, Ph.D., Assistant Professor of Medicine and Biostatistics at Duke University, and Professor Doron Lancet, Ph.D., Head of the Crown Human Genome Center at the Department of Molecular Genetics, Weizmann Institute of Science.

The PsoriasisDX Genetic Test kit, which is available through qualified doctors, sells for $399.

Goran told *OTW,* "There is currently no insurance reimbursement but we will pursue it in the near future."

—EH (September 23, 2009)



people

Timothy Early, Tim Lucenti Join Millstone

Definitely not loaners…they want them to stay. Millstone Medical Outsourcing has announced that Timothy J. Early, a packaging specialist, has come aboard as Vice President of Technical Services, and Tim Lucenti, a veteran operations manager, will serve as Program Manager for the Memphis, Tennessee, processing and distribution center.

"We are excited to welcome Tim Early and Tim Lucenti to the Millstone team. They each bring the kind of knowledge and experience that will enable them to exceed customer

people

Tim Early

expectations," said Christopher Ramsden, CEO, in the news release. "At Millstone, we are continually improving our ability to meet the growing needs of our customers.

Hiring experienced personnel helps us expand capacity and deliver unparalleled service."

Early's 27 years worth of experience include packaging engineering, quality engineering and management, and medical packaging marketing and business development. He is the holder of two patents for laparoscopic packaging innovations and was a founder of a medical package design and validation company. In the past, he has worked at Boston Scientific, DUPONT TYVEK, Johnson & Johnson, C. R. Bard, and Cordis Corporation. Early is a frequent speaker at industry conferences, is a published author of several packaging documents, and has held a number of prestigious industry leadership positions.

When asked what he learned from the patent process that will help Millstone and its customers, Early told *OTW*, "I spent more than 25 years working closely with the end-users of medical products—doctors, nurses, and supply chain associates. The knowledge I gained will enable Millstone to provide: cost-efficient packaging configurations that offer the product protection needed to withstand global distribution; better designs that incorporate user needs and human factors; and more environmentally-friendly primary, secondary, and tertiary packaging. I am confident that these experiences will enable Millstone to deliver packaging options to satisfy the needs of our current and prospective

people

customers throughout the entire product life cycle."

Tim Lucenti

Lucenti brings to Millstone his years working in manufacturing engineering, research and development, continuous process improvement, and new product start-up. He most recently served as Value Stream Manager/Lean Manufacturing Manager at Federal Mogul Friction Products where he was responsible for launching new products and process changes. His experience also includes 12 years in a customer-focused environment, direction of companywide preventative and corrective action activities, responsibility for departmental quality defect reductions, and the application of six sigma methodology to facility-wide continuous improvement initiatives. Lucenti is trained in Engineering Data Analysis of manufacturing processes and improvements and is a trainer of Six Sigma Concepts and an ASQ Certified Quality Engineer.

Asked to comment on one particularly important element of a product launch that he will keep foremost in his mind going forward, Tim Lucenti told *OTW,* "Every successful product launch starts with thorough planning. The process involves a complete understanding of the needs and expectations of the customer. Once you understand your client's requirements, you can assign the proper resources and priority to every aspect of the program. By establishing this relationship upfront, we will insure seamless transition from launch to implementation to total customer satisfaction."

—EH (September 22, 2009)

spine

Kyphon Offers Safer Cement Delivery

Kyphon says it has launched a new bone cement delivery system that is safer for surgeons exposed to radiation during kyphoplasty procedures.

On September 22, the company announced the full U.S. launch of the Kyphon Cement Delivery System (CDS).

Patient safety is paramount in the operating room. But what about the physician who is bombarded with radiation when performing minimally invasive procedures such as kyphoplasty?

Kyphon's press release states its new bone cement delivery system is designed to allow physicians to be further away from the radiation source during the cement delivery phase than with its current system used in the balloon kyphoplasty procedure. It also allows for the delivery of Kyphon HV-R bone cement with a one-handed operation. The company announcement said this preserves some tactile feel during the delivery with the ability to halt bone cement flow on demand with a quick-release button.

Brian D. Giordano, M.D., is an orthopedic resident at the University of Rochester Medical Center who has researched the effects of radiation on both patients and surgeons. He told *OTW* in a September 18, 2009, story titled, *Glow-in-the Dark Doc,* that he was concerned. "Orthopedists are increasingly reliant on radiographic imaging for our diagnostic and

Photo courtesy: mrbaco.co.uk

spine

therapeutic work, thus putting our patients and ourselves in a vulnerable position. While patients are only occasionally exposed to radiation, surgeons may be exposed on a daily basis.

"In the last 20 years there has been a focus on making interventional procedures less invasive. While that has its upsides, of course, the downside is that we are now even more heavily reliant on indirect visualization, such as intraoperative fluoroscopy, which can be used to help guide the placement of various implants and facilitate reductions."

Alex DiNello, Vice President and General Manager, Kyphon Products, said the company will continue to deliver products, "that are designed with clinician safety in mind."

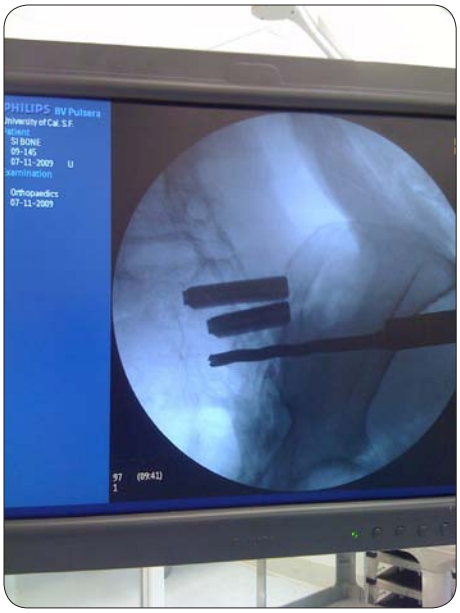
"The CDS increases physician safety by decreasing the radiation exposure exponentially," said Thomas Andreshak, M.D., an orthopedic surgeon with St. Vincent Hospital in Maumee, Ohio.

Medtronic will introduce the system at the annual meeting of the Congress of Neurological Surgeons (CNS) in October and at the North American Spine (NASS) meeting in November.

—WE (September 23, 2009)

SI-BONE Organizes SI Joint Experts

Where do you go from *this* summit? Only up… SI-BONE, Inc. a San Francisco Bay-area company dedicated to sacroiliac (SI) joint pathology, has pulled together the first ever summit of thought leading spine surgeons to review data and develop a clinical diagnostic process for identification of SI joint pathology. According to the news release, estimates are that 15%–25% of individuals who present with lower back complaints actually had problems in their SI joint.



The summit group, including Dr. Steven Garfin, former President of NASS and Chief of Orthopedics at UCSD, and Dr. Mark Reiley, founder of Kyphon, was chosen to have a balance of academicians and private practitioners with significant clinical expertise in diagnosis of LBP (lower back pain) due to SI joint pathology. The group reviewed over 80 peer-reviewed publications on SI joint diagnosis to ascertain what diagnostic methodologies would yield the most practical clinical applications in spine surgery.

Dr. Mark Reiley said in the news release, "Orthopedic surgery residents are rarely taught to consider SI joint arthritis and/or old SI joint trauma as the cause of the patient's problems and few, if any, lumbar imaging extends below S1 to examine this joint."

Commenting to *OTW,* Dr. Reiley stated, "It's less about what programs are getting it right and more about the limited number of surgeons actually evaluating all aspects of low back pain and using a comprehensive diagnostic approach. Spine and neurosurgery have had a significant focus over the last two decades on discogenic pain with fusion and arthroplasty as solutions. The literature is quite clear that a significant portion of low back pain is SIJ in origin. Further, SIJ pain frequently mimics discogenic pain. A more comprehensive approach to low back pain should include more imaging below S1, provocative testing, fluoro guided injections to assess pain response—and this would distinguish more SIJ pain from discogenic pain."

Because diagnosing SI joint issues can be difficult and individual clinical tests are not highly reliable, the orthopedic community has not turned much attention to this joint, instead leaving it to physical therapists. The tide may change, however, with this meeting. The summit group

determined that a combination of 3 to 5 diagnostic tests are optimal for evaluating an LBP patient suspected of having SI joint pathology, including provocative maneuvers, positioning and pain injection exams. While most of these tests alone have low sensitivity in determining the SI joint as a source of LBP, combined they have a greater likelihood of providing the rationale for intervention to treat SI joint pathology. However, it was the consensus of the attendees that the diagnosis of SI joint disease should include one injection that alleviates at least 75%, or two injections that both alleviate at least 50%, of the patient's pain.

The moderator, Dr. Steven Garfin, was quoted as saying, "I came into the meeting with a modest amount of knowledge regarding SI joint pathology related to chronic LBP and came away, as I suspect the other attendees did, with an increased awareness that there may be instances where the SI joint should be considered in the diagnosis, and that many surgeons do not evaluate this possible cause/source for complaints."

And on the treatment front? According to the news release, SI-BONE's iFuse Implant, which is FDA-cleared for treating pelvic fractures due to sacroiliitis and traumatic disruptions, has shown early efficacy in reducing SI joint symptoms. A multicenter study is being planned to determine the implant's effect on SI joint pathology as far as pain reduction and implant stability over time. At essence, says the company, is that referring specialists and physiatrists need to have an outlet for unsatisfied LBP patients. Some patients have residual issues after hip arthroplasty or lumbar spine procedures. For some, the SI joint is the sole symptom generator. The surgeon can now focus further treatment appropriately and avoid unsuccessful repeat procedures often seen in failed lumbar spine surgery syndrome.

As more people became aware of the role of the SI joint as a symptom generator, SI-BONE, Inc. developed its intramedullary implant for the SI joint such that the procedure only requires a minimal incision and uses small, titanium implants. The implants are coated with a porous plasma spray that acts as an interference surface to help decrease implant motion. These implants, says the company, have greater thickness and improved metallurgy and are able to produce a much stronger construct than that of pins or screws. The implant system from SI-BONE has been used successfully in approximately 1,000 cases of dysfunctional foot joints.

When asked if they will share their findings with other spine surgeons via meetings and presentations, Jeff Polack, VP Marketing and Clinical, told *OTW*, "Yes, developing a best consensus algorithm for evaluation of low back pain to distinguish SIJ pain from discogenic pain is the first step of the expert panel. Communication to the surgical community is the subsequent step. This will be accomplished through publications, presentations, special symposia and distribution of the diagnostic approach that is being developed by this group. Additionally, in the future, it is within the realm of possibility that we will see CME courses covering SI joint diagnosis and treatment."

—EH (September 25, 2009)

trauma

Shock Trauma Part of New Consortium

Pleased, but perhaps not shocked…The University of Maryland R Adams Cowley Shock Trauma Center has just learned that it will be one of 12 core

Photo courtesy: http://www.umm.edu/shocktrauma

trauma

clinical centers in a newly established Extremity Trauma Clinical Research Consortium funded by the U.S. Department of Defense (DOD).

With the goal of conducting multi-center clinical studies, the consortium will join forces with several military treatment centers and the U.S. Army Institute of Surgical Research (USAISR) at Fort Sam Houston, Texas, to address issues relevant to the treatment and outcomes of severe orthopedic trauma sustained on the battlefield. These studies will help establish treatment guidelines and facilitate the translation of new and emerging technologies into clinical practice.

"This clinical research network offers us a unique opportunity to investigate treatments for a variety of injuries common in military and civilian patients," said Andrew N. Pollak, M.D., in the news release. Dr. Pollak, Co-Chair of the consortium and head of the division of orthopaedic traumatology at the R Adams Cowley Shock Trauma Center at the University of Maryland Medical Center and Associate Professor of orthopaedics at the University of Maryland School of Medicine, added, "We needed more funding to conduct definitive studies on severe wounds to the legs and arms. The results of this research will give us better insight into the best ways to treat severe, high-impact injuries to the limbs."

Dr. Pollak, previously Chair of the American Academy of Orthopaedic Surgeons' Extremity War Injury Project Team, will lead the orthopedics studies at Shock Trauma as part of the new initiative. The Johns Hopkins Bloomberg School of Public Health, which will serve as the coordinating center for the consortium, was awarded $18.4 million from the DOD's Orthopaedic Extremity Trauma Research Program (OETRP) over five years to establish the consortium.

Commenting on the researchers' next steps, Dr. Pollak told *OTW,* "The consortium leadership will be meeting within the next couple of weeks to discuss finalization of specific study plans, plans for facilitating IRB applications at the participating centers and development of specific study timelines."

"The need for such a consortium is evident," said Ellen MacKenzie, Ph.D., in the news release. Dr. MacKenzie, principal investigator and the Fred and Julie Soper Professor and Chair of the Bloomberg School's Department of Health Policy and Management, added, "Eighty-two percent of all service members injured in Operation Iraqi Freedom and Operation Enduring Freedom sustain significant extremity trauma. Many sustain injuries to multiple limbs. The research to be conducted by the consortium will help us better understand what works and what doesn't in treating these injuries and ensure that our service members are provided with the best care possible."

The top priorities? Establishing the research network and putting resources toward addressing some of the critical needs in acute clinical care identified by the military. These include the reconstruction of significant bone defects and the management of musculoskeletal infections. Over time, says the news

trauma

release, the consortium will expand and leverage its expertise to address many other priority topics relevant to the long-term management of severe extremity trauma, including the prevention of osteomyelitis, chronic pain and disability. As the work continues, the number of participating clinical sites will increase, with more than 30 U.S. trauma centers having already pledged support for the consortium and expressed an interest in participating in one or more of the studies.

"We are thrilled to be partnering with the consortium and the incredible team of investigators they have assembled," says Joseph Wenke, Ph.D., of the USAISR, in the news release. "Together we will develop the infrastructure critically needed to address some of the most pressing issues in orthopaedic trauma care. Without a large, multi-center effort such as this, many of these issues would never be solved."

Thus far, the other core clinical centers: Boston University Medical Center; The Florida Orthopaedic Institute; Carolinas Medical Center; Denver Health and Hospital Authority; OrthoIndy and the Indiana Orthopaedic Hospital; Orthopaedic Associates of Michigan; The Orthopaedic Trauma Institute at the University of California at San Francisco, San Francisco General Hospital; The University of Mississippi Medical Center; The University of Texas Southwestern Medical Center; The University of Washington Harborview Medical Center and Vanderbilt University Medical Center.

As for future milestones, Dr. Pollak told *OTW*, "We hope to get full IRB approval at the multiple study institutions and begin recruiting patients as soon as possible."

—EH (September 21, 2009)

The Picture of Success: Dr. William Horton

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

Before he *performed* surgery, Dr. William Horton, Professor of Orthopaedic Surgery at the Emory Spine Center, *transported* people to surgery.

Growing up in Atlanta, Georgia, a young Bill Horton was looking for a unique summer experience. "I knew several physicians growing up, and in my senior year of high school I took a summer job as an orderly at a local hospital. After cleaning the ORs I would observe the surgeons as they worked. I was fascinated by the anatomy and what could be done for people. My time as an orderly also gave me a window into the anxiety that patients experience. When I transported them to surgery from their rooms I paid attention to the nurses and doctors who took time to comfort them and help diffuse some of their fear."

Ethics, Morality, and Medicine

Philosophy and/or ethics are often not uppermost in someone's mind when filling out a college application. But they were for Bill Horton. "I left high school excited about medicine, but I didn't want to do the traditional major in chemistry or biology. The University of Virginia had a unique program that allowed undergrads to design their own major program, and at the end, tie everything together with a thesis. I was fascinated by the ethical dynamics of caring for people, so I designed a course of study that combined biology, psychology, philosophy, and religion, and wrote my thesis on euthanasia and infanticide."

The term "bedside manner" has been tossed about for years. But Dr. Horton, with his tendency to reflect and dig deeper, would take a path few have experienced. "It was the mid-1970s, the period when Raymond Moody was featured in *Time* magazine for his work on near death experiences. His findings opened new territory, and made me think deeply about what is involved in the morality of caring for one another. In particular, I came to see that medicine is highly ethically charged. Doctors are often making decisions for those who can't decide for themselves…the newborn, the unborn, the infirmed."

Surgeons typically like black and white…concreteness. Dr. Horton, however, was willing to stay in the gray. "It was also during this thesis time that I began to think about the paradoxes inherent in medicine. No one has a crystal ball; we're often dealing with mystery and the unknown despite all the data and objectivity because science is not fully developed in certain areas."

"We have to help patients deal with the paradoxes inherent in their experience and the emotions it brings," states Dr. Horton. "They are frightened and frustrated that their bodies are failing and often ask, 'What does it mean that the doctor can't fix me?' Partnering with them to work through these issues is an important way of honoring the mystery of how our physical body and spirit interlace and influence one another. As a doctor it is essential to understand that we're working on the body, and, by default, on the soul and mind. In the end they are one in the same."

Opening Doors to a Fulfilling Career

Some people have their career plans firmly in hand. Others "wait and see." Dr. Horton: "Instead of being calculating about my career, I saw that doors just began to open and I stepped through one, and then another, and another. Instead of a fixed career

highway it was more like stepping stones."

The doors then opened to the Medical College of Georgia. "During medical school I was very influenced by Dr. Gene Colborn, an anatomy professor whose teaching deepened my thinking of anatomy and its dazzling complexity to the point that knowing the human body was like marveling at the Sistine Chapel—except this was far beyond the normal human creative powers. When I later worked with a rheumatologist named Dr. Joe Bailey, I told him of my interest in orthopedics. He quickly referred me to Dr. Jim Harkess at the University of Louisville, a true renaissance man who had an incredible grasp of the art of orthopedics."

Embarking on an orthopedic residency at the University of Louisville, Dr. Horton learned the importance of integrating X, Y, Z coordinates…i.e., 3D. "I was drawn to the spine because of the brain-body connection. But I also learned a great deal from the hand surgeons at Louisville, including Dr. Graham Lister, one of the best teachers I have ever encountered. Trained in plastic surgery, Dr. Lister had an amazing way of examining the external hand and then showing you how to visualize everything that is ***under*** the skin, and then to transfer that insight along with the diagnostic images to mental 3D and imagine exactly what you're going to find once you're in the OR. It was incredible to create this bridge between the exam room, the office, and the OR."

Now an active advocate for such knowledge, Dr. Horton notes, "While some have a natural gift for such 'vision,' others must work to develop it. If you can't transition between 2D and 3D it is difficult to achieve maximum safety and effectiveness in the OR. There are times during surgery when you simply can't yet see what you ultimately need to—you must visualize and imagine beyond where you are. Fortunately, these concepts are increasingly emphasized in surgical training."

Specializing in Spine

Even as a resident, Dr. Horton carried a sense of humility that would open his eyes and open new doors. "I became fascinated by the spine because I saw it as one of the great diagnostic and treatment challenges that remained to be solved. It became clear that diagnosis was still in the infant stages and that there was so much that needed to be developed. I was also aware that the talents of other healthcare professionals were not always well integrated. If a patient says, 'I saw a chiropractor and he relieved my pain,' then we should respect that and realize that all sorts of healing has its place."

By the third year of residency, Dr. Horton had found a subspecialty that brought great emotional rewards. "I was so fortunate to work with Dr. Ken Leatherman, the head of spine at Louisville who did complex spinal deformity surgery. It was thrilling not only to do these elegant operations, but also to see the look on the patients' faces that said, 'I've got my life back!'"

"The deformity touches so many areas of their lives…they have physical pain, functional issues, and often a low self image. I saw how spinal deformity work could deeply enhance life and the sense of self, helping people feel that they were as good as the next person. Treatment uncorks a sense of confidence that's incredibly powerful in both adults and children."

Beginning his fellowship in 1986, Dr. Horton learned avant garde spinal techniques from the master. "I spent my fellowship year at the Kenton D. Leatherman Spine Center at the University of Louisville, a facility that was really cutting edge. Dr. Leatherman was the first in the U.S. to use the revolutionary Cotrel instrumentation system from France. He also did the first anterior vertebrectomy for congenital deformity in the U.S., which was dangerous pioneering work. Because there was a good working relationship between

orthopedics and neurosurgery I also had a chance to learn neurosurgical techniques in spine. There was so much complex surgery going on that I became extremely comfortable with virtually any problem or unusual anatomy that presented itself."

During this time the already empathic Dr. Horton got to see a bedside master. "Dr. Leatherman was the kind of person who would say to me, 'Come sit beside me in Mrs. Gordon's room and watch how we talk about her problem.' He was able to walk with patients through their illness—and he was present to patients in a way that let them know that he was truly with them on their journey. He taught us to carefully weigh all risks and benefits and make patient decisions very personal ones. "

Worldly Knowledge

To gain an even deeper understanding of the technical aspects of a patient's surgical journey, Dr. Horton would take his own journey. "After finishing in Louisville I embarked on a European traveling fellowship, having my eyes opened to the many different ways of approaching the same surgery. In England I learned from Drs. Robert Dixon and Greg Houghton the British trait of being incredibly thoughtful about differential diagnoses. In France I found that they approach surgery like an art form—finely nuanced. Drs. Yves Cotrel and Daniel Chopin would make subtle but important adjustments during the surgery because they used a geometric 3D process. It was a more creative surgical approach than I had ever seen."

And what was the surgical zeitgeist in Germany? "Germany was the anti-France, with a style that is very precise, completely black and white. I learned from Professor Klaus Zielke, a master of preoperative planning. You did steps 1 through 6 and you didn't deviate. What is helpful about the German approach is that it is predictable. The downside of their process was that once the preop plan was done you weren't allowed to question it…the professor is top dog and that's that."

Research and Academia

Returning to the U.S., Dr. Horton surveyed his career options. "I was initially turned off by academics because I had witnessed how politics and egos sometimes resulted in unhealthy and unfair treatment for many faculty members. I had been approached by Dr. Pierce Allgood, who I respected enormously. He drew me into joining his large private practice in Atlanta. It was a busy, challenging spine practice…without the bloodshed of academics. That experience was fantastic."

The intellectual stimulation of a scholastic environment, however, remained alluring. Dr. Horton: "In 1989 I got a call from Dr. Tom Whitesides at Emory who told me that he and Dr. Lamar Fleming wanted to build an international spine center. I had long admired Tom's creative thinking and technical innovations, as well as his rich character. The more he talked the more I became interested. It was an opportunity to enhance a fulfilling clinical practice with teaching and research. So I accepted their offer, to a great extent because they were focused on building something special while getting past the strife of academia."

Free to treat patients and conduct research in a collegial environment, Dr. Horton set off to explore biomechanics. "I could see that current methods of treating kyphosis, a condition which has the highest risk of paralysis, had shortcomings. I developed a technique for reducing severe kyphosis that was a different clinical approach; instead of working from the ends of the deformity I reversed the paradigm and started from the apex using gradual reductions…one vertebra at a time."

"That study involved complex kyphosis cases with some of the best correction rates ever reported," says Dr. Horton. "But more importantly,

there were virtually no complications related to the correction, which was usually fraught with neurologic complications and problems at the ends of the system. This new technique nearly eliminated that kind of problem, and has had a significant effect on how surgeons reduce all types of kyphoses."

"I then became curious about the biomechanics of the sternum," continues Dr. Horton. "We all get blinders on from time to time…and spine surgeons are guilty of looking at the spine but forgetting about the torso. Our work was honored with the Russell Hibbs Award for Basic Science, given by the Scoliosis Research Society. The research elucidated the value of doing osteotomies to correct the spine, and highlighted the importance of the sternum in spine biomechanics. A sternal osteotomy is rarely indicated, but this work shed light down a dark hole in spinal biomechanics, and is relevant in trauma and tumor reconstruction as well as deformity."

Yet another area that drew his interest and knowledge is international orthopedic education. Dr. Horton: "A year and a half ago we started the Emory Spine Center for Outreach and Medical Education. Having worked with Orthopedics Overseas in underdeveloped areas I was sensitive to the power of international relationships and how important it is to learn from one another. The program is focused on delivering mentored education for doctors in developing countries, with China hosting the pilot program. Doctors in the developing world are often extremely bright and desperately looking for seasoned teaching and advice, and they can't often find it. We want to change that."

Life at Home

He really shouldn't have any time left to himself. But alas, he constantly tries to live a balanced and active personal life. "For 31 years I have been married to my wife Leah, who is an incredible woman and a pastor with Trinity Presbyterian Church in Atlanta, a place we love very much. We have three daughters. One is a senior in college who has a penchant for English and French, another is going to medical school, and the third is studying for a Masters in Public Health. They are three wonderfully adventurous women who have all lived near a pig sty in the West Indies, gone sailing in the Pacific, and enjoyed the messiness of trout fishing in North Georgia."

"I enjoy the outdoors," adds Dr. Horton, "and I am fortunate to have a group of buddies who bike together and coax each other into doing things we probably shouldn't—like Olympic triathalons. Music is a passion of mine (a lot more passion than talent) and I goofed around in a bluegrass band in medical school. I enjoy reading nonfiction and writings about spirituality. I enjoy grilling food, and am a major enthusiast of The Green Egg for steaks or anything."

Dr. Bill Horton…orthopedist, philosopher, renaissance man.

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