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Orthopedics This Week

week in review

picture of success

breaking news

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Orthopedic equities hit an air pocket last week. The average orthopedic equity is off 4.46% over the past 30 days. Higher commodity prices, disasters in Japan and a new war all depress buying. Still rising liquidity in the capital markets should boost demand. If ortho procedure growth rates also recover, equities should keep rising.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	14.49%	3.52%	Ever so slowly buyers are adding OFIX to their portfolios and the stock is holding up well.
2	6	Wright Medical	7.34	4.19	Cleans up the balance sheet by retiring its convertible notes. Lowered interest rate and prospective dilution. Up to #2.
3	8	Medtronic	31.23	(9.11)	FDA rejects Amplify. MDT declines further. But stock was already oversold. Has 30% profit margin company ever been this low?
4	2	Zimmer	27.38	(5.37)	Bidding for AstraZeneca's dental and device business. Has the cash, but can they win?
5	3	Stryker	25.61	(2.35)	Cramer pumped SYK on his TV show last week. Stock drifted down. Needs catalyst.
6	7	Smith & Nephew	23.22	(8.79)	SNN introduced SMF hip last week. SNN wound care business should be stronger in 2011. Up one spot.
7	10	Exactech	9.66	(2.28)	Folding Vertiflex into Exactech's Spine Unit is interesting. For sure. Up 3 spots this week.
8	4	NuVasive	6.69	(18.21)	NUVA just feels like a falling knife right now. But of all the spine companies, NUVA is a certain outperformer. It'll be back.
9	9	Alphatec	1.11	(4.06)	Ten analysts and the consensus sales growth estimate is 20% this quarter. Excellent in today's spine market.
10	5	Integra LifeSciences	15.18	(8.58)	5% earnings growth and 5% sales growth. Yawn. IART needs its own sales growth factor—recombinant or otherwise.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	CryoLife	CRY	$5.69	$158	6.0%
2	Mako Surgical	MAKO	$21.30	$725	5.8%
3	Wright Medical	WMGI	$16.67	$633	4.2%
4	Orthofix	OFIX	$31.77	$573	3.5%
5	RTI Biologics Inc	RTIX	$2.73	$150	0.7%
6	Tornier N.V.	TRNX	$18.63	$714	0.7%
7	ArthroCare	ARTC	$33.11	$902	-1.9%
8	Exactech	EXAC	$18.45	$240	-2.3%
9	Stryker	SYK	$61.52	$24,070	-2.3%
10	Synthes	SYST.VX	$132.34	$15,709	-3.2%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BIHI.OB	$3.65	$133	-22.3%
2	NuVasive	NUVA	$24.75	$981	-18.2%
3	TranS1	TSON	$3.20	$67	-16.9%
4	Orthovita	VITA	$2.05	$158	-16.0%
5	Medtronic	MDT	$37.51	$40,110	-9.1%
6	Smith & Nephew	SNN	$54.90	$9,800	-8.8%
7	Integra LifeSciences	IART	$46.57	$1,330	-8.6%
8	TiGenix	TIG.BR	$1.82	$57	-7.8%
9	Zimmer Holdings	ZMH	$60.31	$11,590	-5.4%
10	Symmetry Medical	SMA	$9.22	$331	-5.0%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$37.51	$40,110	11.04
2	Kensey Nash	KNSY	$25.06	$214	11.63
3	Johnson & Johnson	JNJ	$58.57	160,200	12.61
4	*Average*			*$11,700*	*12.93*
5	Zimmer Holdings	ZMH	$60.31	$11,590	13.66

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$54.90	$9,800	74.63
2	RTI Biologics Inc	RTIX	$2.73	$150	31.25
3	ArthroCare	ARTC	$33.11	$902	24.81
4	Symmetry Medical	SMA	$9.22	$331	21.70
5	Exactech	EXAC	$18.45	$240	20.97

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Integra LifeSciences	IART	$46.57	$1,330	0.64
2	Orthofix	OFIX	$31.77	$573	0.64
3	Alphatec Holdings	ATEC	$2.60	$231	0.97
4	NuVasive	NUVA	$24.75	$981	1.09
5	Exactech	EXAC	$18.45	$240	1.17

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Kensey Nash	KNSY	$25.06	$214	3.24
2	CryoLife	CRY	$5.69	$158	2.90
3	Johnson & Johnson	JNJ	$58.57	160,200	2.16
4	ConMed	CNMD	$26.14	$739	1.96
5	Wright Medical	WMGI	$16.67	$633	1.90

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$9.22	$331	0.89
2	RTI Biologics Inc	RTIX	$2.73	$150	0.90
3	Orthofix	OFIX	$31.77	$573	1.00
4	ConMed	CNMD	$26.14	$739	1.01
5	Wright Medical	WMGI	$16.67	$633	1.19

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$1.82	$57	17.58
2	Mako Surgical	MAKO	$21.30	$725	15.41
3	Bacterin Intl Holdings	BIHI.OB	$3.65	$133	12.14
4	Synthes	SYST.VX	$132.34	$15,709	4.26
5	Stryker	SYK	$61.52	$24,070	3.24

Trends in Trauma

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

Jeff Swafford, U.S. Air Force

Twenty years ago you could recognize trauma surgeons by the circles under their eyes and the fact that they were the only orthopedists doing cases at 3AM. Alas, it was not the most sought-after subspecialty. No longer the stepchild of the field, trauma has found its voice and its strength, and is contributing more to orthopedics than ever before.

Dr. J. Tracy Watson, Fellowship Director and Chief of Orthopaedic Trauma at Saint Louis University in St. Louis, is former President of and currently on the board of directors of the Orthopaedic Trauma Association (OTA). Providing a bit of history, he notes, "Trauma fellowships have become incredibly popular over the last six or seven years. This is in stark contrast to the late '90s when at one point we had 35 fellowship spots and only about eight qualified applicants. This dearth of manpower issue had evolved because of the old model whereby traumatologists were extraordinarily overworked and underappreciated. In the mid to late '80s and early '90s every major hospital had one trauma surgeon; this poor person was inundated with cases all hours of the night and day. Beyond the exhaustion, there was the catch 22 that you were doing lots of cases but were not being properly reimbursed (despite the fact that you were generating substantial revenues for the institution)."

And there was insult to the injury, says Dr. Watson. "To top it off, when you would discuss career advancement

"To top it off, when you would discuss career advancement with your superiors, the response was inevitably, 'Well, you haven't published anything for two years.' At which point of course the roar from the trauma surgeon would be, 'That's because I've been in the OR all the time!"

with your superiors, the response was inevitably, 'Well, you haven't published anything for two years.' At which point of course the roar from the trauma surgeon would be, 'That's because I've been in the OR all the time!' Burn out was rampant, and traumatologists would find themselves getting aggravated and disillusioned, a la 'Hmm, no recognition, insufficient reimbursement, and I'm making everyone else's life easier.' It didn't have the ring of fairness."

"In fact, almost all trauma surgeons from that era left their first one or two jobs because they felt used and abused. Moving into the mid '90s the field became more enlightened. As a trauma surgeon at Henry Ford Hospital in Detroit, I am proud that we were some of the first surgeons to demand dedicated orthopedic trauma rooms. My traumatologist colleagues and I were having to contend with accidents from severe ice storms in the early morning. We would have to wait—and make patients wait—until about 10pm just to *start* our cases."

So did hospital administrators get teary-eyed for the traumatologists? No, says Dr. Watson…their eyes were opened wide when the traumatologists pointed out to them that they were losing money. "Reimbursements to hospitals were declining, and administrators saw that orthopedic trauma patients were sitting around in the hospital for a couple of days before they could get into the OR. So the hospitals began to figure out that if traumatologists operate on patients in a timely fashion then those 'no pay' patients would no longer cost the system money. This applied on the 'back end' also…we demonstrated to the hospital that the 'no pay' patients spend more time post op if surgery was delayed—meaning that they were costing the system money. Bingo… dedicated orthopedic trauma rooms began to pop up in centers where there were active traumatologists who were willing to push this issue."

As these working conditions improved, the number of traumatologists also increased, says Dr. Watson. "The trend reversed, and now we have 80 plus fellowship spots per year with over 100 applications; now there is potentially an oversupply, trending towards a sticky problem. You must have a reasonable number of cases in order to obtain sufficient experience to qualify as an expert. There is a concern that we may be diluting caseloads, as well as the possibility that we have too many fellowships. The OTA is now doing a formal match for fellowships—to participate with the OTA in the match the fellowship has to demonstrate certain benchmarks. We are trying to decide whether or not to work through the Accreditation Council for Graduate Medical Education, something that would mean a rigid process as well as a formal and rigorous evaluation of the educational and surgical experience that the fellowships may or may not be offering."

On the technology front, says Dr. Watson, the need exists to separate the orthopedic wheat from the chaff. "With regard to fracture care, there is a substantial focus on lock plating. We know that these things work, but we don't fully understand the interplay of the biomechanics. Every Joe and Harriet company has locked plates these days… the issue is how to sort out the good ideas from the bad ideas when we don't fully comprehend the subtleties of why locked plating works. Another trend is that we are re-examining surgical indications and perhaps slowly returning to more conservative management for common fractures like humeral shafts, ankles etc. Most trauma patients do need surgery—but not all isolated fractures do. It is our responsibility to work out the indications."

"Fortunately, we are deepening our understanding of the inflammatory cycle, the interleukins involved, and the timing of when they appear in the inflammatory cycle. We now know that you must wait at least seven to ten days to operate on someone with a high energy, periarticular injury."

And if Dr. Watson were handed a one million dollar grant? "I would put it towards determining what else we could do for the geriatric trauma patient, as well as the underinsured. There is a gaping hole in the geriatric orthopedic trauma literature…additionally, we need to know what type of functional outcomes are achieved by our underinsured patients. Most trauma centers have a lot of young and old underinsured patients…and their outcomes are much different than those who have sufficient insurance to allow for post op organized rehabilitation, home care and orthotic management."

Dr. Watson: "The best news—news that affects both surgeons and patients—is that orthopedic trauma is no longer the ugly duckling of the field."

Dr. Frank Liporace, Associate Professor and Director of Trauma and Reconstructive Fellowship at the University of Medicine & Dentistry of New Jersey, concurs, and gives credit where credit is due. "The fourfold increase in trauma fellowship applicants is to a large extent due to the efforts of the OTA. The organization has made great strides in helping applicants understand that being a traumatologist doesn't necessarily mean a difficult lifestyle—and that it can be very rewarding. And the fact that a future traumatologist can almost be assured a dedicated orthopedic trauma room is critical. This is true not only because no one wants to do complex cases at 4am but because cases done during the daytime will almost assuredly have more resources on hand."

As for what has changed in the educational arena, Dr. Liporace says, "In the past few years we have realized that acute, definitive care for large surgeries involving the open reduction of fractures, especially in the areas around the ankle, foot, and knee, may have negative effects. In some cases, the soft tissue does not heal properly, and there is increased risk for infections—particularly in patients with multiple comorbidities. For example, 40 years ago it was suggested that if we 'attack' distal tibial fractures within the first six hours then we would have better outcomes. Unfortunately, this approach resulted in more complications as we moved forward in time and the mechanisms of injury became higher energy and got more complex. While high speed car accidents may leave the patient alive, the injuries are more complicated as opposed to 40 years ago."

Some of the issues they are sorting through involve the impact on soft tissue…others involve the nuances of the inflammatory cycle. Dr. Liporace: "Not only is the bone more catastrophically injured, but the X-ray only shows bone and not soft tissue—so we don't have the whole picture. It may be that these fractures should be treated with external fixation first (the literature has gone back and forth on this). Fortunately, we are deepening our understanding of the inflammatory cycle, the interleukins

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involved, and the timing of when they appear in the inflammatory cycle. We now know that you must wait at least seven to ten days to operate on someone with a high energy, periarticular injury. Otherwise, it's like you are delivering a second hit with surgery…remember, surgery is in essence a controlled trauma. By taking this approach we are respecting the mechanism of injury."

"The main thing is to try early on to get the extremity out to the correct length, stabilize it with external fixators, and then wait until the soft tissue has calmed down and any blistering is re-epithelialized. Doing otherwise means that you are strangling the microvasculature. Whether or not you will know to take this approach depends on what types of mechanism of injury are coming into your institution. If you are primarily accustomed to low energy mechanisms of injury then you may not be as familiar with the negative ramifications of treating a high energy injury too early."

Alas, says Dr. Liporace, the 'Git r done' sentiment seems to have crept into orthopedic trauma. "We reached the point where we felt that immediate care of long bones with intramedullary rods should be done post haste. There are studies saying that using intramedullary rods in long bone fractures within 24 hours results in better patient outcomes. However, much of this information has been widely extrapolated to mean, 'Let's get it done ASAP.' The problem is when you put the rods in after the 12 to 24 hour mark you are causing a second hit in the form of a huge inflammatory response (especially if the patient has a closed head injury or visceral injuries)."

On the product side, states Dr. Liporace, there are new technologies making life easier for surgeons and patients alike. "We now have a number of smaller, low profile implants that give us the ability to address peri-articular injuries. In terms of plates and screws, many of these are now precontoured to the surface of the bone, resulting in less soft tissue disruption and less patient discomfort. Facilitating the development of these products are large databases of bone morphology that show not only the average bone morphology but displays variations between males and females and differences between ethnicities, things that allow implants to be more specific to the patient. Also, there are radiolucent handles that we attach to plates that help us control the amount of surgically induced trauma. There are also carbon fiber guides that are stronger than ever, as well as drills with larger flutes that decrease temperature and reduce the risk of osteonecrosis."

And on the horizon? "While this work is in its infancy, coming down the pike is the ability to have ionized implants, something that would make them more resistant to infection. They might carry time-release antibiotics, growth factors, etc., which is especially important when doing surgeries in high risk area for complications including but not limited to infection and nonunion. These and other new developments are best undertaken with surgeons working closely and appropriately with manufacturers."

Trauma…no longer in critical condition. ◆

Race to the Patent Office

By Walter Eisner

The last time the United States made significant changes to the nation's patent laws, Professor Gyro Gearloose hit the comic pages as America's favorite mad inventor in Walt Disney's Gladstone's Terrible Secret, May 1952.

The art of inventing has changed considerably since then and now a bipartisan group of senators wants to bring the U.S. patent system into sync with patent processes around the world. They propose to move from a "first-to-invent" system to a "first-to-file" system.

Moving to a "first-to-file" system could have a significant impact on inventors such as orthopedic surgeons who "tinker" part-time on their inventions. More on that later in this article.

Senate Passes "America's Invents Act"

The U.S. Senate took the first step towards patent reform on March 8 by voting 95 to 5 to pass the "America Invents Act." The legislation was co-sponsored by Democrat Senator Patrick Leahy of Vermont and Republican Senators Chuck Grassley of Iowa and Orin Hatch of Utah.

Wikimedia Commons/RRY Publications

U.S. Senator Patrick Leahy

President Obama quickly praised passage of the bill and promised to sign it if it passes the House. However, it was unclear whether or not the House would follow suit and act on the measure.

Senator Leahy said during hearings that this would be the first major patent reform in 60 years for a process that was fine for a 1952 economy. Congress passed some reforms in 1999 and expanded ways in which granted patents could be challenged.

Members of Congress have introduced patent reform bills in each of the last three sessions of Congress, but have failed to pass the legislation after several groups, including small companies and individual inventors protested.

Current Backlog

Under our current patent system, an inventor announces his or her invention and goes to the USPO (United States Patent Office) to seek a patent grant. On average, that inventor's application will sit for two years before a patent examiner even begins to consider the request. Then it takes another year before a final decision is made.

Process for Obtaining a Utility Patent

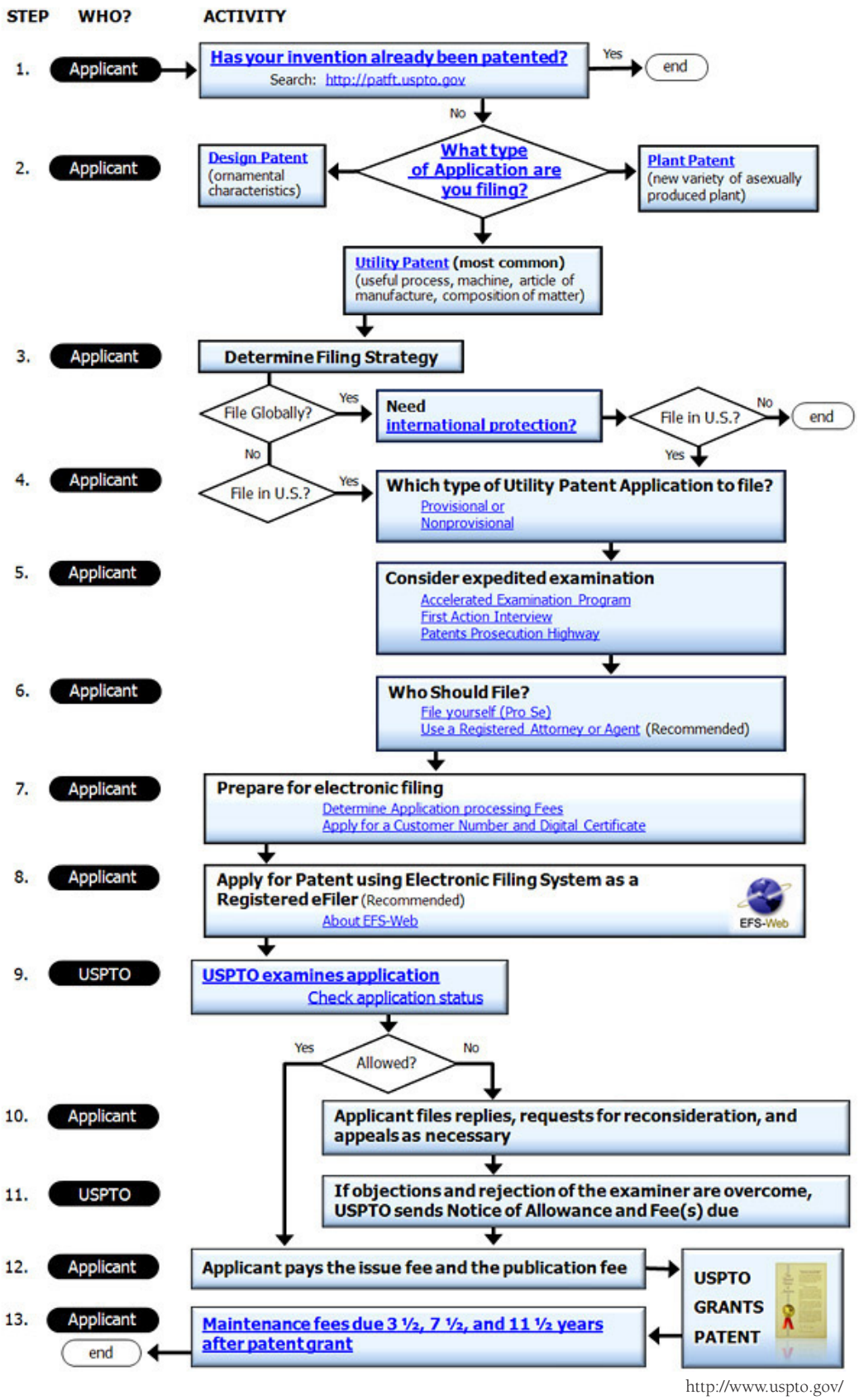
In 2009, the patent office received some 483,000 patent applications and granted 192,000 patents. According to the USPO, there are approximately 1.2 million applications currently under review or waiting for a review, including 700,000 applications waiting to be acted on and 500,000 in process.

Opposing Views

According to published media reports during public testimony, reforming the U.S. system is favored by large international companies so they can get in sync with other patent application processes around the world. However, some smaller companies and inventors opposed the bill saying large companies have all the lawyers, will win the paper battle and race to the patent office.

"The bill favors multinational and foreign firms over start-up firms seeking an initial foothold in U.S. domestic markets, and favors market incumbents over new entrants with disruptive new technologies," said the letter signed by groups such as American Innovators for Patent Reform and the U.S. Business and Industry Council.

John Dolan, an attorney with the Fredrikson & Byron law firm in Minneapolis and a former patent examiner,



http://www.uspto.gov/

John Dolan

told *OTW* that the change from first-to-invent to first-to-file would be a major change for inventors and will likely make it more difficult for part-time "tinkerers" to file for a patent.

The biggest difference in the proposed legislation is that under the current system, an inventor needs to demonstrate to the USPO that he was the first person to come up with the idea and concept of the invention.

Under the proposed bill, the inventor doesn't have that requirement and simply needs to be the first to race to the USPO to file for a patent.

Inventor Safeguards

To assure fairness and protect an inventor who believes his idea was stolen, Dolan says the proposed bill has a post-grant review process where inventors can challenge someone else's filing. According to proponents of the bill, this would also keep more disputes out of court.

The bill would create a nine-month "first window" post-grant procedure to allow challenges to patents that should not have been issued and to cut down on litigation and harassment of patent owners by improving the review system for challenges. It provides more certainty to damage calculations.

Senator Hatch reportedly said it can cost $500,000 in legal fees if there is a dispute over who is the first to invent a product. Under the new system, said Hatch, an inventor can pay $100 for a provisional application to protect his invention.

New Patent Office Fee Authority

The proposed legislation also gives the patent office authority to set its own fees at a level that will give it enough funds to reduce its backlog of applications. It requires that smaller businesses continue to get a 50% reduction in fees and creates a new "micro-entity" class—with a 75% reduction—for independent inventors who have not been

named on five or more previously filed applications and have gross incomes not exceeding 2.5 times the average. The standard fee for filing a patent is now $1,090, with additional maintenance fees over the life of the patent.

There would also be an expedited process, for an extra fee, that would guarantee a final decision within one year compared to the current three-year wait.

Impact on the Tinkerer

Now back to what the proposed changes mean to the part-time inventor/tinkerer.

Attorney Dolan, also an inventor, told us that trying to make an invention reality takes time when only spending minutes or an hour each day. The inventor thinks he's described the concept but still wants to take more time to flesh it out.

The inventor, said Dolan, would have to change his mentality in terms of having a good idea of having generally met the things he needs to file a patent application:

- What are the components of the invention?
- How does he make it?
- How does he end up using it?

It will now be beneficial to write it down and file as quickly as possible.

If the inventor has spoken to colleagues or friends about the concept, how does he protect himself?

This is a post-filing issue, says Dolan. Currently if a patent application has been filed by an individual and somebody later files an application and both cover the same invention, there's a procedure called interference where both parties go in front of a reviewing board and they'll try to determine who was the first-to-invent.

Under the first-to-file proposal, the interference practice will be gone because first-to-invent is gone. But, says Dolan, there will be a derivation hearing.

"For example, the tinkerer invents something and discloses it at a conference or to his buddies down the street. He then sees a patent application down the line. He can file for a derivation proceeding and will be able to show that he developed the invention. But, he must be able to show a link to individuals disclosing it. If the inventions have truly been developed independently, whoever gets to the patent office first will win."

Race to the Patent Office

Dolan thinks we'll see an even bigger backlog of patent applications initially as many inventors will file relatively quickly to win the race to the patent office. Inventors will believe he has to file quickly.

Tinkerers will have to understand that if they have an invention, they need to put it on file once they have met the legal burdens. Dolan said in essence, many times it's a race to the patent office anyway because once you're in the first-to-invent process you have to actually show that you were the first-to-invent.

His experience with individual inventors is that many times they have difficulty in providing that evidence. Companies have an easier time with that because they have protocols in place with workbooks, daily entries, witnessed and dated and it's easier for them to show first to invent.

Removing the first-to-invent burden may be of help to the tinkerer, but the patent process is expensive. Before you had time to flesh out ideas and spend more time in the lab, do more tests and prove your concept more clearly. They could do that because they had the records showing they were the first to invent.

Now, they won't have that luxury and may end up filing more in increments. So instead of filing one application, they may file more frequently because they've made changes. Filing more applications to cover what they want.

"The first-to-file concept is something that is inevitably going to happen," says Dolan. "We have been operating outside the norm with the rest of the world for some time." ◆

Forget Asia, World Class R&D Outsourcing in Mexico

By Biloine Young

If you manage a medical device company and you want to get your innovative new products to market faster but ALSO cut your R&D costs and stay on the cutting edge of technology maybe the impossible is possible if you look south of the border.

For world class new product design and development work as well as clinical trial design and implementation you might want to talk with David Hite. Hite is the CEO of Alandra Medical, Inc. located in San Geronimo, a suburb south of Mexico City, Mexico.

IP Portfolio/Alandra Medical, Inc.

The Alandra Medical, Inc. TeamAlandra Medical, Inc.

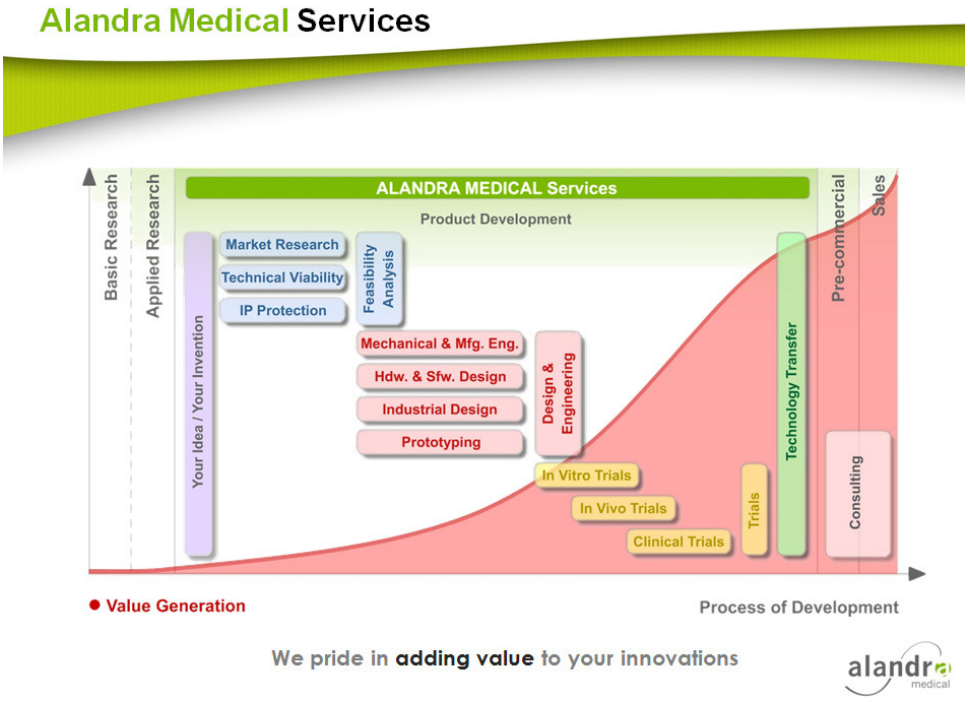
It is Hite's location in Mexico that, he says, gives him his competitive edge. As he explains it, "Medical device innovators, who need design and development service, get their most efficient use of capitol by working with us." Alandra Medical, Hite says, offers the same quality design and development expertise that is found in the United States. The difference, he says, is that he "operates under a very favorable cost structure by basing the business in Mexico." Given his cost structure, he claims, his clients can make more efficient use of their capital. With Alandra Medical a company's investment dollars develop more.

Hite's company is made up of 35 mostly doctors and biomedical, electrical and software engineers who offer clients three areas of expertise. The first is in conception and design leading to the development of an early prototype. Hite says his firm is exceptionally good at getting the original concept out of the innovator's mind, working it through the design stage, turning it into a 3-D model and taking it to early prototypes where a client can then do animal studies and cadaver trials.

The second area of expertise is in the convergence of electronic equipment with software development. "We benefit from 15 years of intellectual capital working on a handful of our own ideas, developed in Mexico. We have several projects in later stage development—all done within our own shop," he said.

The third division is a clinical trial group inside of Alandra, "We can conduct clinical trials within Mexico for either animal or human studies," said Hite.

"Medical device innovators, who need design and development service, get their most efficient use of capitol by working with us."



Services/Alandra Medical, Inc.

A fourth dimension is one that Hite believes may make Alandra unique. It relates to the fact that Alandra is backed by a venture capitol firm. As Hite puts it, "We have a high recognition of the value of equity in the best innovations. We have our own internal scientific evaluation and investment criteria and may create a strategic partnership with our client. We will provide the service for a piece of equity in the company or on the client's innovation."

While the names of the firms' clients are protected by confidentiality agreements, some of its products are illustrated on the company's web site (http://alandramedical.com/). Among them is an epidural space localizer, a novel nasal airway device, a migraine headache mitigation device, a device for the early detection of cervical cancer and an electromagnetic device for chronic wound treatment. The company is also working on a device for the home care of the diabetic foot.

Alandra Medical expects to complete three ISO certifications by May. Two are the ISO standards 13485:2003 and ISO 0991:2008 related to a comprehensive management system for the design and manufacture of medical devices. The third is ISO 14971 that represents the requirements for a risk management system for medical devices. The projects the firm completes for its clients are run using the Project Management Institute's (PMI) *Project Management Body of Knowledge*.

All Alandra project managers are PMI certified. Hite believes that intellectual property is better protected in Mexico than it is in Asia because of the enforcement provisions for IP contained in the NAFTA agreement.

A Californian, Hite has spent most of his working years outside of the U.S. His first nine years, after graduating from college in 1984, he worked in Silicon Valley. Then Intel hired him and he began his life abroad, living in China (two times), Hong Kong, Singapore, Brazil, Colombia and Mexico. Though much of his work was in sales and

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David Hite, CEO/Alandra Medical, Inc.

marketing, during his final years with Intel he worked closely with engineering teams in design, development and manufacturing work. His final assignment at Intel was as world-wide director of platforms for emerging markets. He left the company in 2007 when it asked him to return to the United States in a headquarters management position.

Hite came into Alandra Medical three months after its founding by Gerber Capitol Venture Equity Fund which brought together the assets of two Mexican medical device companies and one California-based medical device company. Hite said that they "selectively chose intellectual property and brought over what they believed to be the most talented of the intellectual capitol."

Alandra Medical was formed from the fusion of these two Mexican medical device companies, one medical device company from the United States and the venture capital firm.

He was hired as CEO, Hite said, based on his solid U.S. business and management skills, because of his long affiliation with a U.S. multi-national corporation and his awareness of and sensitivity to working in Latin American and other culturally diverse markets.

Questions of distance and of the drug problem invariably come up. "Being an American living in Mexico I get emails from friends asking me if I am not afraid to live here," he said. "Unfortunately, the drug business in Mexico operates as any large business does. The leaders are very affluent people who like to live in the wealthy large cities, but also close to their market. The larger cities of Mexico, which are located close to the U.S. border, are the home base of that industry. The drug dealers not only enter into conflict with the policing of the border, but with their competitors. To put it in sales terms, it is conflict over 'territory management.' The vast majority of everyone living in Mexico live lives completed separated—isolated—from that kind of violence."

As for the problem of distance, Hite does not believe it is a problem. "The Internet is a way of life," he said, "We are able, with video, to share files and keep the client up to date and very comfortable with the design and development process. In Asia and Europe it happens every day." The company has sales offices in the U.S. operating out of Palo Alto, California and Phoenix, Arizona. Through a cooperative technology agreement between the U.S. and Mexico, Alandra Medical has access to medical device segments through five other offices in the U.S. and Canada.

All in all, Hite makes a very compelling case for looking to Mexico for world class medical technology design, development, clinical testing and eventual commercialization. Sometimes, the keys to the future are right in our own backyards. ◆

Designers/Alandra Medical, Inc.

company

Boy Advocate on Capitol Hill

Not only can he now walk, but six-year-old Ismael Vega is heading straight to Capitol Hill. Thanks to a novel surgery performed by Dr. Daniel Green of Hospital for Special Surgery, Ismael, who was born with osteogenesis imperfecta (OI), will no longer have to experience the world from a wheelchair.

When Ismael and his mother go to Washington, D.C., they will talk of how the telescoping rods used for his surgery mean that he will not need repeated operations as he grows. Dr. Green will also be in attendance at this American Academy of Orthopaedic Surgeons-sponsored event; he and Ismael are representing the Pediatric Orthopaedic Society of North America.

Born with weak, brittle bones, by the time he was three Ismael had suffered 12 broken bones and more than 100 microfractures. But his operation was a success. In the news release, his relieved mother said, "I have no words to explain how happy I was when Ismael walked for the first time. We feel that Dr. Green was sent from heaven. Without him, Ismael would not be walking."

"There have been tremendous advances in the treatment of OI in the past decade, and Ismael's case is a very positive illustration of what can be done," Dr. Green added. "It's a combination of surgery and medication that has improved the opportunities for children with this disease. I've seen patients in their 40s with OI who, unfortunately, did not have these treatments available when they were children. They have the same type of OI as Ismael, but have spent most of their lives in a wheelchair."

"The team at HSS seeks to educate parents about the disease. We believe education is the key to empowerment," Dr. Green also said. "We're very impressed by Mrs. Vega. She's a strong advocate for her child."

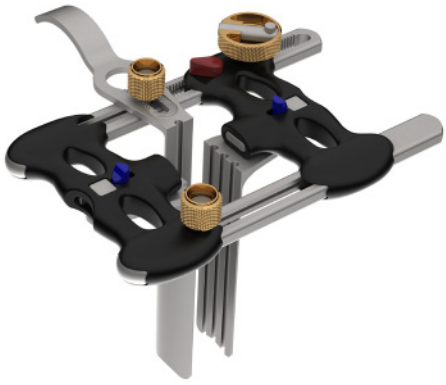
—EH (March 18, 2011) ◆

Ismael Vega with his mom, Patricia. He can now climb the steps on the school bus.

CE Clearances for K2M

K2M. Inc.'s Ravine Lateral Access and Aleutian Lateral Interbody Systems have received CE Mark clearance.

The company's March 15 announcement stated the Ravine, "provides a dual flat blade platform for a true muscle splitting transpsoas approach. The system offers rigid fixation to the spine and an option for both a third and fourth blade. It represents an innovative design departure from the tubular retractors, while providing tremendous adaptability to both patient anatomy and surgeon technique."



K2M Ravine Lateral Access System/K2M

In addition, the statement continued, the Aleutian Lateral, "is comprised of anatomically designed interbody implants made of PEEK material that are used in conjunction with the Ravine Retractor. The implants feature radiolucent properties, which have the potential to increase visualization of bone graft while aiding in accurate fusion assessment. The bulleted nose allows for ease of insertion and the circumferential rings provide 360 degrees of grip to the endplates."

"RAVINE is simple and easy to use," said Colin Natali, an orthopedic surgeon at the Royal London Hospital.

"The retractor fixes to the vertebrae, as opposed to the operating table, and has a small footprint to potentially reduce the risk of surgical damage. It uses the anatomy of the muscle and the plexus to its advantage with the split and twist technique. The system evolved from the collaboration of surgeons and engineers working in unison to provide leading, rather than following, technology."

The Ravine was introduced at the North American Spine Society (NASS) 2010 Annual Conference in Orlando.

The company's portfolio of products includes: spinal stabilization systems, minimally invasive systems, and other technologies, such as motion preservation, annular repair, and nucleus replacement.

K2M has received two *Orthopedics This Week* Spine Technology Awards: in 2009 for the Serengeti Minimally Invasive Retractor System (Minimally Invasive category and in 2010 for the Deformity Cricket (Lumbar Care category), a threaded anvil instrument.

—WE (March 16, 2011) ◆

Medtronic's New Cervical Plate and Rod

Medtronic launched two spine products for the U.S. on March 10: an anterior cervical plate system and a new rod. The announcement was made at the 27th annual meeting of the American Association of Neurological Surgeons/ Congress of Neurological Surgeons Section of Disorders of the Spine and Peripheral Nerves in Phoenix.

Vertex Chromaloy Rod and Atlantis Cervical Plate/Medtronic

Anterior Cervical Plate System

The Atlantis Vision Elite Anterior Cervical Plate System is a titanium implant used to treat patients with degenerative disc disease that affects the cervical spine.

A diseased disc can lose height, compressing nerves and causing pain in the neck. There are an estimated 180,000 cervical fusion procedures performed in the U.S. each year to relieve compression on the spinal cord or nerve roots. The company said the new plate is designed to provide stability during spinal fusion.

The system combines two existing Medtronic technologies in one plate—a quarter turn locking mechanism designed to prevent the screws from backing out or loosening during fusion, and a plate design that offers surgeons visibility to better view the spine.

This system is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

Doug King, senior vice president and president of Medtronic Spinal, said the system is the result of merging two of the company's technologies, with over 12 years of clinical history, into one implant.

Chromaloy Rod

The Vertex Select Chromaloy Plus Rod is a supplement to the company's Vertex Reconstruction System. During a procedure, a surgeon uses the rods to connect existing or new fusion systems in the patient's occipitocervical and upper-thoracic spine.

The rods consist of cobalt chrome alloy material with engineered features, including a blend of three metals which, the company says according to mechanical testing, help improve the rod's biomechanical characteristics and maintain a more rigid overall construct.

The Vertex system consists of implants and general instruments that can be used to surgically treat patients with a variety of conditions that can contribute to spinal instability, including degenerative disc disease, spinal stenosis, fracture, tumors, and/or spondylolisthesis. According to the company, the product line has more than 10 years of clinical experience and has been used in more than 100,000 cases.

—WE (March 14, 2011) ◆

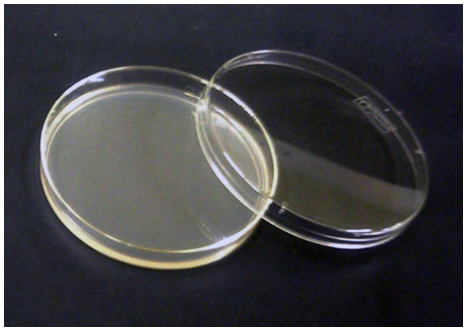
biologics

New Culture Medium Clears FDA

A stem cell culture medium called StemPro MSC SFM has received FDA 510(k) clearance as a medical device, according to a release by Life Technologies Corporation (LTC). StemPro MSC SFM is a liquid medium designed to efficiently grow large amounts of human mesenchymal stem cells (MSC) while maintaining their undifferentiated state.

"Anytime a research-related tool receives prior clearance from the FDA it has the potential to accelerate the field's move to the clinic...so this clearance is good news for our mission and good news for patients," said Alan Trounson, president of the California Institute for Regenerative Medicine, the state stem cell agency created by Proposition 71.

As an FDA-cleared device, StemPro MSC SFM can potentially expedite the regulatory review process associated with investigational medical studies because it allows the reviewers to focus on the science rather than the manner in which the cells are grown.



Y Tambe/Wikimedia Commons

According to LTC, StemPro MSC SFM is the first and only product of its kind to receive clearance by the FDA. It was first introduced on the market in May 2009 as a serum-free medium for research-use-only and marked the next step in this technology over serum-enriched media. Several of Life Technologies' cell culture media were used in the process to grow and culture the world's first tissue-engineered organ transplant in 2008 when surgeons in Spain successfully reconstructed a patient's windpipe from her own stem cells.

Traditional serum-rich media, widely used by researchers to grow MCSs in the laboratory, is supplemented with non-human origin components such as fetal bovine serum and other growth factors that are not fully defined. The ill-defined nature of serum-based media is undesirable for downstream research and therapeutic applications and puts a heavier burden on clinical researchers

who must provide verifiable data on all the components used in their study.

"An FDA-cleared, serum-free medium certainly provides a positive step toward moving away from mostly animal-based products for growing mesenchymal stem cells," said Stanton L. Gerson, M.D., director, University Hospitals Seidman Cancer Center and the National Center for Regenerative Medicine, at Case Western Reserve University.

—BY (March 14, 2011) ◆

Off-The-Shelf Parts

In the past, when a surgeon needed a piece of bone for a foot or ankle repair he usually took it from another part of the patient's body—often the hip. Harvesting a patients' own bone, once considered the gold standard, now "should be thought of as the historical standard," said Dr. Glenn M. Weinraub, president of the American College of Foot and Ankle Surgeons at the annual scientific conference in Fort Lauderdale on March 11.

Instead of making an incision in the hip and removing a piece of bone to use in the repair of a foot or ankle, he says that surgeons are now getting bone material and stem cells "off the shelf."

"The quality of the material that is available in a prepackaged format has been shown to be just as effective for bone healing and may yield fewer complications for the patient," said Weinraub.

Among the conditions for which bone grafts are especially useful are open fractures with bone loss, bone tumors, reconstructive procedures and to deal with those patients such as smokers, diabetics and obese individuals whose bones may not heal normally. "These are patients who may need a higher level of biologic activity to enhance bone healing potential," Weinraub said.

Like bone graft material, stem cells can come from either the patient or a laboratory which harvests the cells and makes billions of copies. "The advantage of using lab-harvested stem cells in foot and ankle surgery is it allows us to skip the step of cell recruitment from the patient having the procedure. We're putting the cells right there on the defect, and because they are in a bone environment, these cells may direct and partake in the process of bone formation," Weinraub said.

—BY (March 14, 2011) ◆

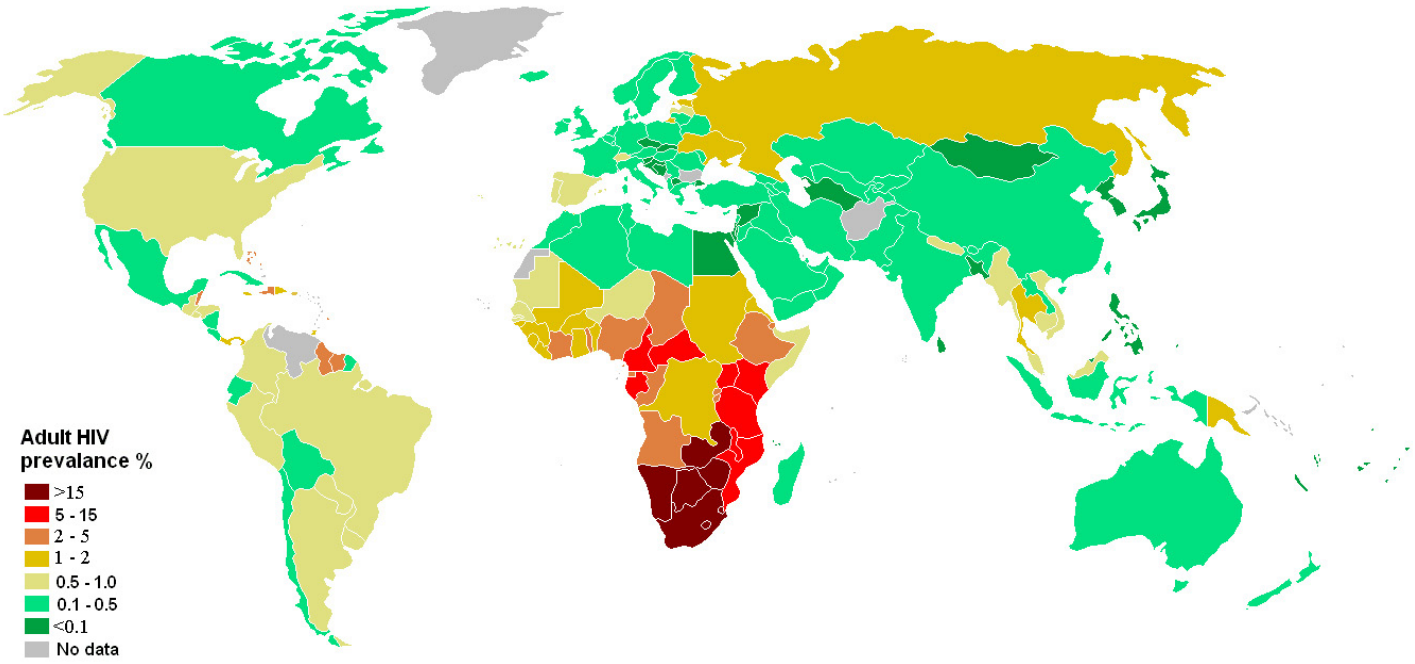
Chelle and morqueFile.com

large joints

Fractures Higher Among HIV Patients

Adding clarity to a murky area… Researchers from Colorado have found increased fracture rates among HIV-infected patients as compared to the general population. The study, published in *Clinical Infectious Diseases*, involved 5,826 HIV-infected patients who were analyzed from 2000 to 2008 in the study; annual fracture rates among HIV-infected patients were between 1.98 and 3.69 times greater.

"We confirmed that several established risk factors for fracture, such as age, substance abuse, hepatitis C co-infection, and diabetes, were associated with fractures among the HIV-infected patients," said study author Benjamin Young, M.D., Ph.D., in the news release. Dr. Young, who is with the Rocky Mountain Center for AIDS Research, Education, and Services in Denver, added, "This study also highlights for the first time a potential association between fracture risk and CD4 cell count. The optimal



Grcampbell/Wikimedia Commons

clinical management of bone health in HIV-infected individuals is not well defined and remains controversial."

Elaborating, Dr. Young told *OTW*, "There remain significant areas of controversies around HIV and bone health. These include understanding the role of HIV and HIV therapies in causing metabolic bone disease and fractures. Our data is among the first to clearly associate the extent of HIV-related immunosuppression (i.e., CD4 count nadir) and the risk of fractures. This observation would further the concept of earlier initiation of antiretroviral treatments. There is also a growing literature that links certain HIV medications, including HIV protease inhibitors and tenofovir, with accelerated bone loss during initiation of treatment. The extent to which HIV medication-induced loss of bone mineral density contributes to fracture risk is unclear, but a topic of intense interest."

As for how bone health in this population is being managed currently, Dr. Young commented to *OTW*, "Awareness of the increase risk of fractures among persons living with HIV is predicated on long-term AIDS-free survival—an outcome that depends on access to well trained health care providers and antiretroviral medications. While there is a growing appreciation of the concerns of bone health in HIV-infected persons, there are no U.S. management guidelines to date; the only current treatment

guidelines were issued by the European AIDS Clinical Society in 2009.

Conventional management of bone health is restricted to older persons, after age 50. Such strategies focus on the prevention of low bone mineral density, either through behavioral or dietary changes, such as weight bearing exercise or improving dietary calcium and vitamin D intake; additionally prevention of falls is an important element of fracture prevention. Our data suggests that persons younger than age 50 are at increased risk of bone fractures and therefore that preventive and screening strategies should be considered for most adults living with HIV."

—EH (March 16, 2011) ◆

New Rules for Smokers and the Obese

Individuals who smoke and those who are obese in North Yorkshire, England, will be denied routine hip and knee replacements beginning in April, according to new rules of the British National Health Service (NHS). Smokers will have to quit and the obese lose weight before they can be considered for routine joint replacement surgery.

"Hip and knee replacement is major surgery, which is painful and carries a degree of risk," said Dr David Geddes, medical director at NHS North Yorkshire and York. "We have to make sure that patients are as fit for surgery as possible before going forward for it. By managing a patient's weight and stopping them smoking we can reduce the surgical risk and improve their outcomes afterwards."

Adriaen van Ostade: The Smiling Smoker and Wikimedia Commons

Geddes eased the strictures somewhat by adding, "We are not imposing a blanket ban for those who are overweight or smokers. We will consider on a case by case basis any weight loss a patient has achieved and any progress in smoking cessation. We will also consider all patients who have other complicating factors for surgery under our individual funding panel system." More than one in five people in North Yorkshire is obese and a similar proportion are smokers.

—BY (March 14, 2011) ◆

AAOS: New Distracted Driving Campaign

You might not think you have a second home, but in a way, you do. So many of us have gotten overly comfortable in our cars that without thinking about it we may use the phone, send a text, apply makeup, etc…all to the detriment of ourselves and everyone around us. The American Academy of Orthopaedic Surgeons (AAOS) is announcing that on April 6, 2011 at the National Press Club in Washington, D.C. the national "Decide to Drive" Campaign and Web site will be launched.

As indicated by AAOS, distracted driving kills or injures more than a half a million people each year. Leaders from AAOS, working in concert with the Orthopaedic Trauma Association, are launching this initiative and urge people to decide to drive each and every time they get behind the wheel.

The campaign Spokesperson will be boxing legend Smokin' Joe Frazier, a crash survivor himself. There will also be a presentation by a 20-year old driver who was texting right before a highway crash with a semi truck when he broke both legs and suffered serious and long-term injuries. He wants his story to help others.

Silver13/Wikimedia Commons

There will also be a live webcast from The National Press Club's Web site (log in information to be distributed closer to the event date). The campaign website, **decidetodrive.org**, is also where drivers all across the country can report incidents of distracted driving.

—EH (March 14, 2011) ◆

extremities

Limb Loss Awareness Month

The Amputee Coalition, a national nonprofit organization based in Knoxville, Tennessee, is launching a nationwide effort in April to help the public become more aware of and tuned into limb loss. Limb Loss Awareness Month will involve amputee support groups, veterans, prosthetists, rehabilitation centers and those with limb loss, all of whom will be participating in a number of activities in their local areas to raise awareness. There will also be an online limb loss risk assessment tool.

Each day 507 people lose a limb, largely to vascular-related diseases, and 60% are preventable.

"Limb loss is not uncommon and, sadly, becoming less uncommon every day," said Kendra Calhoun, Amputee Coalition president and CEO in the news release. "More than 2 million Americans live with limb loss and that number grows by 185,000 each year. Our goals for Limb Loss Awareness Month are to heighten public awareness about limb loss and increase people's understanding of prevention—especially those most at risk."

"Many people are unaware of the causes of amputation and often see limb loss in just a few categories: the wounded warrior or the accomplished athlete," added Calhoun. "The fact is, limb loss affects every generation, from young to old and people from all walks of life. Those at greatest risk are people who have diabetes or a vascular impairment such as peripheral arterial disease. Cancer is also a cause of limb loss, but traumatic limb loss can happen to anyone—from lawnmower and farm equipment accidents to motorcycle and car accidents."

A sampling of statistics are as follows: The main causes of limb loss are:

- Vascular disease (54%)
- Trauma (45%)
- Cancer (less than 2%)
- 60% of limb loss is preventable
- Diabetes and vascular disease are the leading causes of limb loss
- In 2008, hospital charges associated with having a limb amputated totaled more than $7.2 billion in healthcare costs
- Nearly 60% of the amputation procedures performed in 2008 were paid for by Medicaid and Medicare, totaling more than $5.2 billion in healthcare costs.

Photo Courtesy of U.S. Army/Wikimedia Commons

—EH (March 17, 2011) ◆

reimbursement

MedPAC Recommends Physician Pay Increase

The Medicare Payment Advisory Commission (MedPAC) is urging Congress to increase Medicare payments to hospitals and physicians by 1% in the government's 2012 fiscal year. The recommendation was made in the commission's annual report released on March 15.

MedPAC

The call for the increase comes with a warning that a scheduled 29.5% cut to physician payments will go into effect on January 1, 2012 if Congress does

not act to fix the sustainable growth rate formula.

Last year, MedPAC recommended a 2% annual reduction for three years to compensate for overpayments made in 2008 and 2009.

The suggested increase for 2012 would apply to both inpatient and outpatient services. The recommendation reflects a 2.5% payment hike for inpatient services, but also a 1.5% point reduction to account for mandatory documentation and coding improvements resulting from the overpayments in 2008 and 2009.

MedPAC also recommended that Congress make a 2.4% pay cut to hospitals in future years to fully recuperate overpayments caused by the implementation of MS-DRGs (Medicare Severity Diagnosis Related Group) in 2008.

The MedPAC report finds that most Medicare beneficiaries have access to physicians and that despite threats to turn away Medicare patients, most physicians continue to accept beneficiaries.

MedPAC also reiterated comments made in last year's report urging Congress to move away from a fee-for-service payment model and consider a system that incentivizes quality care.

Congress has not shown a great willingness in the past to adopt recommendations from the MedPAC annual report.

To read the entire report, click here:

—WE (March 17, 2011) ◆

people

Nawana Named DePuy Spine President

DePuy Spine has a new leader.

His name is Namal Nawana. Nawana was appointed to the position of Worldwide President on March 15. He replaces Gary Fischetti, who was promoted to Company Group Chairman for all DePuy franchises in January.

Namal Nawana/DePuy Spine

A company spokesperson told *OTW* via email that Nawana began his career as a research engineer at Royal Adelaide Hospital in 1992, then, serving as a Product Development Engineer with Howmedica International.He has been with Johnson & Johnson and DePuy for more than 13 years, serving in roles in Engineering, Marketing, Sales and General Management in Canada and ASPAC.

In 1997, Nawana joined Johnson & Johnson Orthopaedics as a Technical Support Manager in the UK. He was promoted to Sales Director, DePuy Orthopaedics and Trauma, France, and where he led a team that achieved a sales turnaround. In 2004, Namal was promoted to General Manger for DePuy Canada and later was appointed to lead and build the DePuy business in Australia. When promoted to Area Vice President of Johnson & Johnson Medical, Australia and New Zealand in 2009, he assumed responsibility for MD&D (medical devices and diagnostics) franchises in Australia and New Zealand, leading a team of over 700.

He earned Medical Engineering and Master of Medical Science degrees from the University of Adelaide in South Australia and an MBA at Henley Management College in the UK. He also earned a Johnson & Johnson's Six Sigma PE Black Belt.

Nawana is taking charge of DePuy's spine business at a time of pushback for some spine procedures from payers, pricing pressure from competitors and a low-single-digit growth rate for the spine market. Some analysts are predicting that market to grow in the 3% to 4% range in 2012.

—*WE (March 17, 2011)* ◆

Medtronic

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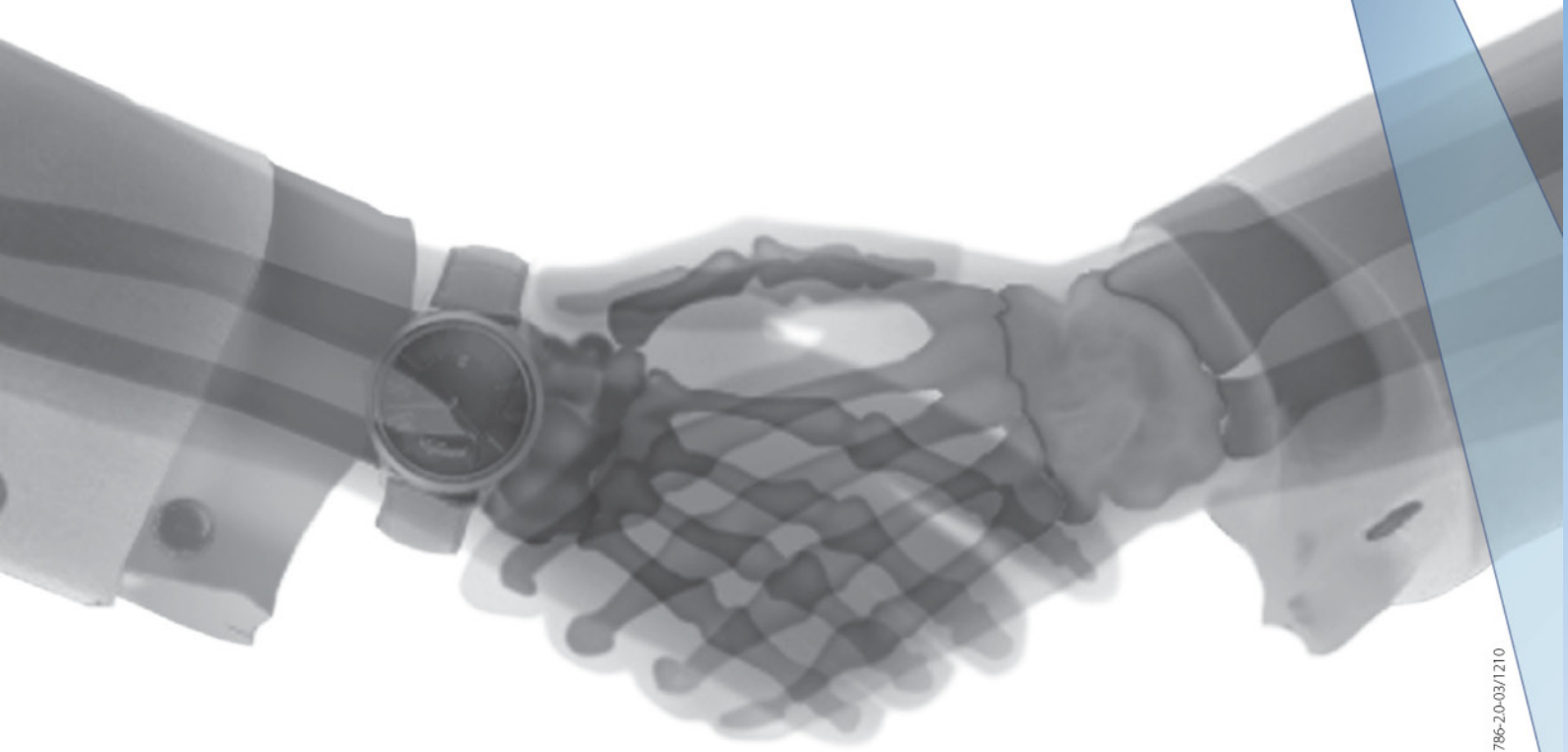

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THE PICTURE OF SUCCESS

Dr. Randy Rosier, M.D., Ph.D.

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

Dr. Randy Rosier

There is a quote by the poet Masahide that goes, "My barn having burned to the ground, I can now see the moon." It is unlikely, however, that a young Randy Rosier and his family were feeling quite so philosophical as they watched their home burn to the ground years ago. Indeed, tough times have both strengthened Randy Rosier and softened him to the suffering of others.

Dr. Rosier, a former Chair, and now a professor in the Department of Orthopaedics at the University of Rochester Medical Center, also stands out in the research arena. He received the Alfred R. Shands Jr, MD Award from the American Orthopaedic Association and the Orthopaedic Research Society, as well as the prestigious Kappa Delta Award for Outstanding Orthopaedic Research. And he can make a claim that outshines virtually all others in the orthopedic research world: he built (with a lot of help from his colleagues) a program that for years received more funding from the National Institutes of Health (NIH) than any other orthopedic program in the United States."

Dr. Rosier: "I grew up on a farm in central Pennsylvania, something that gave me a deep appreciation for nature. There were plenty of animals around, which led me to consider the study of biology. But I was also interested in math, so I planned to study the synthesis of science and math—physics—in college. We didn't have much money… but I would become the first person on the family tree to attend college."

Yet by the time the college years rolled around, the Rosier family had already seen more than most families have to bear. Dr. Rosier explains, "One fateful day when I was seven years old a heater exploded and burned down our home…we had no insurance. This, coupled with the fact that my parents had three sons who died as infants from a genetic neurologic disease, meant that our family had to pull together in order to survive. I was taught to persist at all costs. As a clinician I can look into people's eyes and better understand their suffering because I know what suffering looks and feels like. And in orthopedic oncology you do need a special kind of compassion."

Although he works with human beings, chondrocytes, and cartilage now, Dr. Rosier's hands-on talents once involved molten material. "My dad was a welder who took me under his wing and taught my brother and me how to use tools, build things, and think 'on the fly.' My mom, who had the fortitude to survive our family tragedies, was a superb role model."

When Randy Rosier was being drawn in by a variety academic interests, it was an in-the-know advisor who pushed him to consider a novel path. "Physics, biology…I didn't know what to do. My college advisor—who was the Chair—said very matter-of-factly, 'I know what you should do. You should enter one of these new M.D./Ph.D. programs where you can study medicine, biology, and even attend graduate school in biophysics.' The lightning bolt hit. At my advisor's suggestion, I sent off my application to the University of Rochester."

And he sent off his paperwork on a wing and a prayer. "I was scraping to get by financially, and had no idea how I would pay for this fantastic program. The day I received a note saying that not only had I been accepted to Rochester's M.D./Ph.D. program, but that I would be fully funded…well, I nearly passed out with joy."

While Randy Rosier had little to work with financially, he was blessed in that his creativity and resourcefulness burst forth…and pointed him right in the direction of orthopedics. "I had built all of the furniture in my apartment, and it felt very natural to work with my

"In 1995 I was honored with the Kappa Delta Award for Outstanding Orthopaedic Research. This was in recognition for my work on how growth factors regulate cartilage growth. Borrowing a technique from hematologists, I used a centrifuge to separate different types of blood cells based on size. From that work I was able to publish several papers discussing at what stage specific genes were being expressed."

hands. One day at Rochester I had an epiphany. I was taking a class on membrane transport calcium and was scrubbing in on orthopedic procedures and it hit me—'Hey, I am interested in calcium metabolism and transport and this orthopedics thing seems like a great tie in—and I get to work with my hands.'"

When the orthopedic societies came calling years later, it was also in recognition of Dr. Rosier's brain. "In 1995 I was honored with the Kappa Delta Award for Outstanding Orthopaedic Research. This was in recognition for my work on how growth factors regulate cartilage growth. Borrowing a technique from hematologists, I used a centrifuge to separate different types of blood cells based on size. From that work I was able to publish several papers discussing at what stage specific genes were being expressed."

The Alfred R. Shands Jr, MD Award was bestowed on Dr. Rosier for his lifelong contribution to cartilage research. Of his continued work in this area, Dr. Rosier notes, "We are now trying to understand how to harness existing growth factors or drugs in order to change the program of events that happens in arthritis. This is based on the idea that the parathyroid hormone receptor is expressed in the growth plate but is not expressed in normal joint cartilage. We have found that when there is an injury or arthritis there is very early expression of this receptor. I spent five years developing models where we could create arthritis in mice, and we found that it was possible to partially reverse the arthritis by treating the mice with Forteo. We are now trying to get a grant for a pilot clinical trial in humans."

"My team and I recently mined the extensive Osteoarthritis Initiative database and found 20 patients that during the time they were being monitored were put on Forteo. We found that there was a dramatic—and statistically significant—improvement in those taking Forteo as compared to the controls."

Dr. Rosier, who served as the Chair of orthopedics at Rochester for seven years, had the structure to do such elaborate work. Why? Because he created it. But there was more to come…"When I became chair I established the Center for Musculoskeletal Research; later I was able to secure a $7.8 million NIH grant so that we could become a Center for Research Translation, something that is enabling us to perform clinical studies that will lead to improved treatments for a variety of orthopedic conditions. I consider these to be the standout accomplishments of my professional life."

Looking back down the mountain he has climbed, Dr. Rosier talks of a time when he had to forage for resources…and in doing so found his rallying cry—enough! Dr. Rosier: "When I was a junior faculty member at Rochester I was being promised sufficient OR time, but it wasn't happening. I was a tumor surgeon working on children with cancer, and these were massive surgeries whose timing was critical. It's not like a meniscus surgery where you can wait a month. I would get pushed to the tail end of somebody's OR day, and would have to start a long, complex surgery in the afternoon or early evening. The anesthesiologists ran the ORs and they would start canceling cases mid afternoon. I would have patients and families waiting all day for surgery, and it would get cancelled (and this happened repeatedly). Finally, it was the parents

"I walked into the Chair's office and said, 'I know you are busy and I am not a complainer but if I don't have my own OR block within 30 days I won't be here.' I was tired of families screaming at me (albeit understandably), and was fed up with having to do surgeries at midnight. Nowadays, I pass this lesson on to my trainees: advocate for yourself and for your patients."

who drove me to action. I walked into the Chair's office and said, 'I know you are busy and I am not a complainer but if I don't have my own OR block within 30 days I won't be here.' I was tired of families screaming at me (albeit understandably), and was fed up with having to do surgeries at midnight. Nowadays, I pass this lesson on to my trainees: advocate for yourself and for your patients."

Dr. Rosier knows how to get his ideas across, but he also knows how to make room for the ideas of others. When asked about the reasons for his success, he reflects, "When I was hiring faculty, many 'newbies' had grand ideas about having their own labs and making breakthrough discoveries. I told them that they needed to join a team of people who were already working on something they were interested in. For one thing, who is going to keep your experiments going when you are called to the OR for an emergency? I tell them that no one is going to discover the cure for cancer by themselves. Being a good team builder and team player has served me—and my patients—well."

But even the most impressive team cannot always prevent what nature brings on. "The most frustrating parts of my career are those times that I have performed a complex surgery to remove a cancer and then, despite a successful surgery, the cancer returns."

To up-and-coming surgeons Dr. Rosier says, "When you fail…and you will… keep in mind that this type of thing happens to every one of us eventually. Most of us are ethical and will naturally feel horrible when something goes wrong. It's the people who are not fazed by mistakes or complications who worry me. I think that if you don't have the appropriate emotion then perhaps you are not going to learn as much from the situation. Frankly, those people who just blithely move on to the next case tend to be those individuals who are driven by financial motives."

He adds, "Clinicians should always maintain a strong sense of curiosity and ask themselves *why* they are doing something, why such and such happens, and how it happens. The majority of my research has evolved from things that I have observed at the bedside that led me to ask questions."

Given that he is so thorough, anyone walking into Dr. Rosier's self-built house should feel comfortable that the walls will stay up. "I designed and built my house…everything…the kitchens, wiring, cabinetry, etc. I revel in creating things. Actually, I think I have a half built violin around here somewhere. Fundamentally, I enjoy my life. And I owe who I am to my parents, who were totally ethical, honest people."

Dr. Randy Rosier…using the lessons from his own life to rebuild lives, assemble careers and construct the foundations for the scientific future of orthopedics. ◆

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