VOLUME 7, ISSUE 13 | APRIL 19, 2011

Orthopedics This Week

week in review

picture of success

breaking news

For all news that is ortho, read on.

Orthopedics This Week

VOLUME 7, ISSUE 13 | APRIL 19, 2011

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Excellent week last week for orthopedic equities. This week's announcement that JNJ and Synthes have entered merger discussions brings the spotlight on these comparatively low priced equities. Traders are no doubt looking at SYK and JNJ's high cash balances to argue further consolidation. We're a tad more cautious.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	14.49%	5.59%	The reason OFIX stays #1 is that it has the industry's lowest P/E to Growth rate and management keeps beating forecasts.
2	2	Alphatec	1.11	14.67	Annual shareholder meeting coming up. Les Cross gets to meet shareholders. The next two years should be outstanding for ATEC.
3	3	Medtronic	31.23	10.65	Should MDT follow JNJ's lead and start shopping for some high quality ortho equity?
4	9	NuVasive	6.69	8.26	Lukianov is in the trenches with spine surgeons fighting for every case. Building loyalty with embattled surgeons.
5	8	Symmetry	8.08	15.03	SMA, which is helping ortho suppliers cut implant costs, expected to report 80% EPS jump for Q1.
6	4	Zimmer	27.38	2.19	Will Zimmer buy Astra-Tech's dental unit? Reuters reports that ZMH in running for $2 billion purchase.
7	7	Integra LifeSciences	15.18	7.28	IART announces a stream of new implant clearances. Analysts looking for modest 4.70% sales growth this quarter.
8	5	Stryker	25.61	(0.87)	SYK starting to get a little expensive. Some profit taking last week. What buying there is appears to be lackluster.
9	6	Smith & Nephew	23.22	2.95	JNJ's interest in SNN and then Synthes is evidence that trauma and wound care is on the ascent. Can SNN participate?
10	10	Exactech	9.66	(2.46)	The few analysts who cover EXAC are expecting flat earnings on about 6% sales growth for Q1.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$5.16	$108	59.3%
2	Mako Surgical	MAKO	$26.27	$1,070	33.8%
3	Synthes	SYST.VX	$155.15	$18,416	19.6%
4	Symmetry Medical	SMA	$10.18	$370	15.0%
5	Alphatec Holdings	ATEC	$2.97	$264	14.7%
6	Medtronic	MDT	$41.05	$43,900	10.6%
7	RTI Biologics Inc	RTIX	$2.78	$152	9.0%
8	NuVasive	NUVA	$27.25	$1,080	8.3%
9	ConMed	CNMD	$27.33	$773	7.4%
10	Integra LifeSciences	IART	$48.48	$1,390	7.3%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Bacterin Intl Holdings	BONE	$3.20	$117	-22.0%
2	Wright Medical	WMGI	$15.66	$595	-4.7%
3	Kensey Nash	KNSY	$24.74	$211	-3.1%
4	Exactech	EXAC	$17.46	$228	-2.5%
5	Stryker	SYK	$60.70	$23,750	-0.9%
6	TiGenix	TIG.BR	$1.81	$56	-0.4%
7	CryoLife	CRY	$5.65	$157	1.1%
8	Zimmer Holdings	ZMH	$62.00	$11,910	2.2%
9	Orthovita	VITA	$2.13	$164	2.4%
10	Smith & Nephew	SNN	$56.94	$10,160	2.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$24.74	$211	11.48
2	Medtronic	MDT	$41.05	$43,900	12.08
3	Wright Medical	WMGI	$15.66	$595	12.95
4	Johnson & Johnson	JNJ	$60.56	165,640	13.04
5	*Average*			*$12,263*	*13.53*

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$56.94	$10,160	77.40
2	RTI Biologics Inc	RTIX	$2.78	$152	31.82
3	ArthroCare	ARTC	$34.27	$933	25.68
4	Symmetry Medical	SMA	$10.18	$370	23.96
5	ConMed	CNMD	$27.33	$773	21.31

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$33.22	$599	0.68
2	Integra LifeSciences	IART	$48.48	$1,390	0.68
3	Exactech	EXAC	$17.46	$228	1.10
4	NuVasive	NUVA	$27.25	$1,080	1.18
5	Zimmer Holdings	ZMH	$62.00	$11,910	1.27

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Kensey Nash	KNSY	$24.74	$211	7.31
2	CryoLife	CRY	$5.65	$157	2.96
3	Johnson & Johnson	JNJ	$60.56	165,640	2.23
4	ConMed	CNMD	$27.33	$773	2.07
5	ArthroCare	ARTC	$34.27	$933	1.95

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	RTI Biologics Inc	RTIX	$2.78	$152	0.91
2	Symmetry Medical	SMA	$10.18	$370	1.03
3	Orthofix	OFIX	$33.22	$599	1.06
4	ConMed	CNMD	$27.33	$773	1.07
5	Wright Medical	WMGI	$15.66	$595	1.15

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Mako Surgical	MAKO	$26.27	$1,070	23.70
2	TiGenix	TIG.BR	$1.81	$56	17.49
3	Bacterin Intl Holdings	BONE	$3.20	$117	7.13
4	Synthes	SYST.VX	$155.15	$18,416	4.99
5	TranS1	TSON	$5.16	$108	3.81

Trauma Care in the Developing World

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

A farmer in Nigeria is struck by a car and suffers multiple fractures. The sole breadwinner for his economically distressed family, before the accident this man had hopes of his children rising out of poverty. But it will take everything the family has saved to pay for his trauma care. Why? In so many countries families must pay for hospital treatment with their own, out of pocket resources. Due to a dramatic rise in traffic accident injuries, this economic burden of treatment often leads to multigenerational cycles of poverty. If your first instinct is not, "How awful! What can I do?" then think of it this way: the less trauma care these countries provide their citizens, the more the economically developed world will likely provide in the way of broader economic or other financial support.

U.S. Navy photo by Mass Communication Specialist 2nd Class Roger S. Duncan/Wikimedia Commons

Dr. Charles Mock, a general surgeon who has quite literally "written the book" on trauma care in developing nations, drives home the magnitude of the problem. Dr. Mock, who has worked extensively with the World Health Organization (WHO) says, "There are multitudes of individuals in the developing world who die from their injuries. But, for each person who suffers a fatal injury, there are perhaps 50 who survive and who are left to deal with traumatic injuries and their aftermath."

Alarmed, as the year 2000 dawned, those at the WHO and the International Association for Trauma Surgery and Intensive Care (IATSIC) began to develop what would become known as the Guidelines for Essential Trauma Care (EsTC), recommendations that map out the basic elements of trauma care that should be accessible to everyone around the globe. Dr. Mock, a professor of surgery at the University of Washington in Seattle, states, "EsTC encompasses 10 core essential services that every injured person in the world should receive. In order to concretize these we developed 260 individual resource guidelines regarding life threatening and disabling injuries—resources which vary depending on the treatment level (clinic/small hospital/large hospital) and where the country falls on the economic spectrum. The guidelines, which can be utilized by whoever wants to advocate for change, are meant to serve as a basis for needs assessments. To date the EsTC recommendations have been used in ten countries with some success."

Dr. David Spiegel, assistant professor of orthopaedic surgery at the Chil-

"The university I used to work for in Ghana has run a week long course for the past fifteen years that emphasizes fitting trauma care to the needs of rural doctors. Under normal circumstances, even when a referral is possible, it takes two to three days to arrange, meaning that skilled irrigation and debridement of open fractures is critical in order to prevent infection. It is very positive to see—from the nature of the referrals—that the patients arriving at tertiary referral centers are in better condition these days. Whereas the doctors used to get patients with open wounds that had gone untreated for three days, conditions are now much improved."

dren's Hospital of Philadelphia and the University of Pennsylvania School of Medicine, has also participated in a WHO essential surgery initiative, a project that includes a trauma care component. And, after 15 years of volunteering "on the ground" in Nepal, Dr. Spiegel is a strong advocate for a broad, public health view of trauma care. He says, "Treatment for injured persons in developing countries will only improve if we approach trauma care in a comprehensive, system-wide fashion. To that end, health planners in developing countries would be well served by considering the Guidelines for Essential Trauma Care produced by the World Health Organization. The EsTC contains two checklists: a brief one that helps to identify major deficiencies and a full checklist of the 260 individual resource guidelines."

"The checklists are sorted by levels of health care facility: a basic clinic, a medium-sized hospital with primary care physicians, a hospital that contains specialists, and a tertiary care facility. There are several categories of resources: essential, desirable, possibly required, and irrelevant. An example of an essential resource—one that should be provided at any type of healthcare facility regardless of the country's economic level—is basic fracture care. Anything deemed essential was also done so because these are the most cost-effective ways of addressing trauma."

Picking up the thread, Dr. Mock elaborates, "A resource that falls under the category of 'essential' would be something like a backboard or Xray capability, things that are affordable in countries at all economic levels. 'Desirable' resources include those such as image intensification. These are items that add value, but are costly and not as universally applicable as the essential items. These guidelines have been used to undertake the assessment of trauma care capability in Vietnamese clinics and hospitals, with measurable improvement shown. Specifically, they were able to demonstrate an improve-

"Treatment for injured persons in developing countries will only improve if we approach trauma care in a comprehensive, system-wide fashion. To that end, health planners in developing countries would be well served by considering the Guidelines for Essential Trauma Care produced by the World Health Organization."

ment (especially in the larger hospitals) with regard to skills training, as well as some basic supplies like materials for spinal immobilization."

Dr. Spiegel acknowledges that most surgeons in advanced countries are not often given to thinking about the politics and workings of global trauma care. But if they were to get involved, he says, they would find another exciting initiative that has a real chance of changing the trajectory of lives and communities. "In 2004 the WHO initiated the Emergency and Essential Surgical Care Project, an effort to improve global healthcare with regard to surgery and anesthesia. This was the culmination of the WHO's recognition that surgery plays an important role in population based health care in developing nations' provision of primary health care."

"This multifaceted project addresses not only what needs to be in place for safe surgery and anesthesia in terms of infrastructure, physical resources and supplies, but also training in essential interventions," says Dr. Spiegel. "The materials are directly applicable at the level of the district health center and represent services that should be available to all members of a society, such as Cesarean section, splinting a fracture, or draining an abscess. You can imagine the challenges in determining what constitutes 'essential,' or services that should be universally available, keeping in mind that the majority of district hospitals are staffed by either general physicians or paraprofessionals who have received little or no surgical training. In Malawi, for example, nine trained orthopedic surgeons serve a population of 27 million. The majority of orthopedic services are provided by

Wikimedia Commons

trained paraprofessionals or 'orthopedic clinical officers.'"

Those in the know understand that in lesser developed countries you must work with what you have, but, in order to make improvements that last lifetimes, you must also strive for more. This means that any plan to improve global trauma care must include a training component. Dr. Mock states, "The needs assessments carried out as part of the Essential Trauma Care project have shown a severe limitation in the extent of use of continuing education for trauma care, both for doctors and nurses. Such continuing education courses (e.g. CME) can play an important role in strengthening trauma care and should be much more widely utilized. Generally, these would be two to three day CME courses whose goal is to provide a baseline level of training on how to care for injured people. These include information on what anyone in an ER should know about recognizing a limb threatening injury, how to recognize major fractures, how to handle spinal immobilization, etc. Depending on local needs, these courses could be extended to include more definitive care."

Dr. Mock has also been encouraged to see other evidence of growing knowledge and skills. "The university I used to work for in Ghana has run a week long course for the past fifteen years that emphasizes fitting trauma care to the needs of rural doctors. Under normal circumstances, even when a referral is possible, it takes two to three days to arrange, meaning that skilled irrigation and debridement of open fractures is critical in order to prevent infection. It is very positive to see—from the nature of the referrals—that the patients arriving at tertiary referral centers are in better condition these days. Whereas the doctors used to get patients with open wounds that had gone untreated for three days, conditions are now much improved."

So what is interfering with further progress in global trauma care? Dr. Mock: "The fundamental goal is to improve the quality of care without spending much more money (because there is already a substantial amount of funding being spent). To a great extent this means that improvements in program planning are needed. The most recalcitrant problem, however, is just human nature…inertia. Everyone is busy and it takes a 'squeaky wheel' to get things done, especially with severely limited budgets. Not surprisingly, another obstacle is how to pay for equipment and supplies. In many countries patients must pay for implants, surgery, and medications upfront and in cash. When you are dealing with life or limb threatening injuries, however, that means a lot of people won't get the treatment they need. Simple improvements in hospital finance mechanisms could change this problem, at very limited cost."

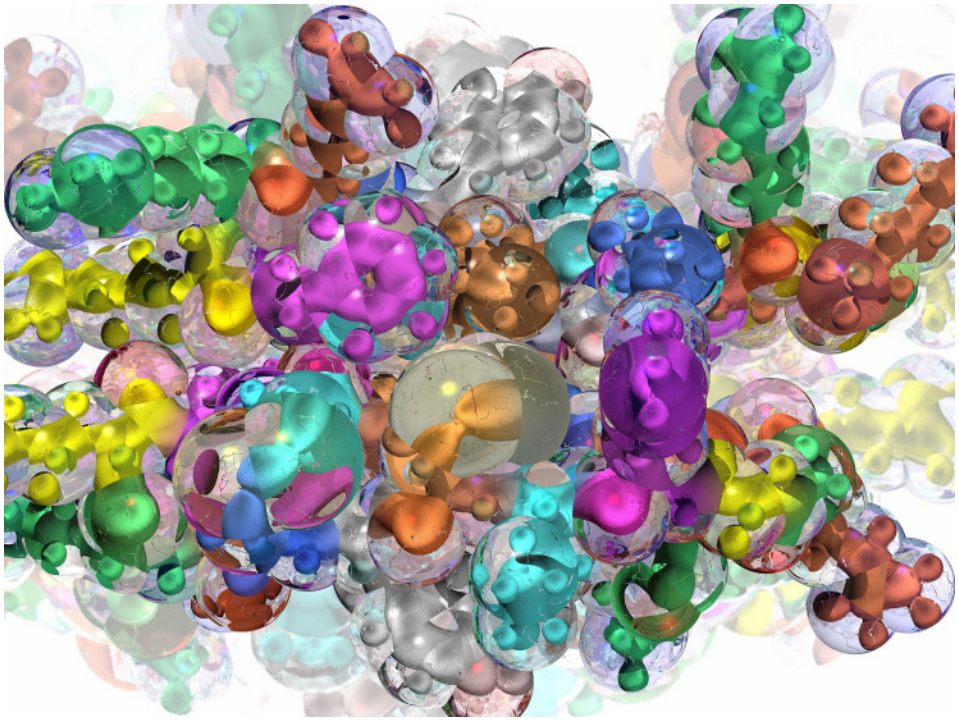
Stay tuned for a follow up article about what specific countries are doing to improve trauma care for their citizens. ◆

Biologics as Megaphone Medicine

By Robin Young

Within evolutionary biology there is a body of work called signaling theory which examines communication schemes between organisms. These scientists study bird calls, green tree frog croaks, peacock tail waves—any expression that is designed to elicit a response from another organism.

Recently, signaling theorists have been moving into the realm of molecular signaling and are reporting the models they've developed for, say, bird calls, are similar to signaling patterns of the endocrine system, the neural system, proteins, peptides and cells.



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Whatever Is Old Is New Again

Within orthopedics, the framework for understanding bone remodeling has long been based on the model of a signal transmission (or expression) and reception. The model we are all so familiar with, of course, started with a young fellow who, in 1948, decided to make the long trek from Mass General in Boston (where he'd just completed his medical training) to balmy Los Angeles and the hospital at UCLA. We're referring, of course, to Marshall Urist. The way he turned a commission to research strontium 90, tetracycline and the treatment of osteogenic sarcoma on behalf of the U.S. Atomic Energy Commission into a master theory of bone remodeling and signaling is legendary.

At the time, which was less than five years after the first atomic bombs were dropped and the effects of radiation on the human body were being documented, the Atomic Energy Commission had a strong interest in understanding the role of radiation in triggering or treating bone cancers.

Dr. Urist's genius was his ability to descend into the complexity of that question and organize it into a model that clinicians and others would understand. Bone, apparently, was receiving some "signal" that triggered a growth response. What was that signal? Where did it come from? How could he replicate it in a controlled test?

In 1965, 15 years after he started his work, he presented a test which seemed to prove the existence of just such a signal. A protein sourced signal. In his seminal article in *Science* titled, "Bone Formation by Autoinduction," he offered up a narrative of how the body generated bone remodeling signals as follows:

> "Wandering histiocytes, foreign body giant cells, and inflammatory connective-tissue cells are stimulated by degradation products of dead matrix to grow in and repopulate the area of an implant of decalcified bone. Histiocytes are more numerous than any other cell form and may transfer collagenolytic activity to the substrate to cause dissolution of the matrix. The process is followed immediately by new-bone formation by autoinduction in which both the inductor cells and the induced cells are derived from ingrowing cells of the host bed. The inductor cell is a descendant of a wandering histiocyte; the induced

cell is a fixed histiocyte or perivascular young connective-tissue cell. Differentiation of the osteoprogenitor cell is elicited by local alterations in cell metabolic cycles that are as yet uncharacterized."

The "dead matrix" Urist was referring to was demineralized bone matrix and the chemical signal that stimulated bone formation or remodeling was a protein. A bone morphogenic protein.

Probably the key word in Urist's article was "inflammation." We know now that inflammation is the first signal from which a rich "conversation" develops between cells to organize remodeling, repair and regeneration of damaged tissues. This is now big business in orthopedics. Last year, 2010, more than $1.5 billion of products were sold with bone morphogenic protein as the principal therapeutic agent for orthopedic applications.

Megaphone Medicine

Earlier this month scientists at Osaka University and King's College London reported that they had isolated and identified the particular signal that summons stem cells from bone marrow to the site of a wound. The study, which was published in the *Proceedings of the National Academy of Sciences*, identified the distress signal as HMGB1. In their own words, the study's authors believe it can be used to put "a megaphone in the system" to improve the treatment of injuries.

According to Professor John McGrath from King's College, bone marrow plays a role in repairing damaged skin, but the exact process was unknown. So he and his colleagues in Osaka injected mice with bone marrow cells that can be tracked while moving around the body (they glow green). The mice were "wounded" and then given skin grafts. In mice without grafts, very few stem cells travelled to the wound. Those with grafts had many stem cells travelling to the wound.

The investigators' interpretation of the study was that the engrafted skin tissue, which had no blood vessels and therefore no oxygen, released HMGB1—which called stem cells to migrate to the wound. The signal was also an inflammatory transmission.

As envisaged by Dr. McGrath, future clinicians might one day use a signaling drug similar to HMGB1 to speed healing. He said: "It would be like putting a megaphone in the system," bringing stem cells to the injury.

Osaka University

At Osaka University researchers are developing a drug to mimic HMGB1 and hope to begin animal testing this year to be followed with human clinical trials.

Inflammation as the Foundational Signal

As researchers decode the language of biologics and find ways to guide the "conversation" between cells, more and more biologic therapies will be communicative therapies. Urist opened the door with bone morphogenic proteins.

Probably the most dramatic example of where these signaling therapies can go are Osiris' Prochymal work which, ironically, brings us back to the original U.S. Atomic Energy Commission study which Urist used to launch this entire arena.

In 1948, the Atomic Energy Commission was studying acute radiation sickness. In 2008, Osiris' product Prochymal was selected by the U.S. Department of Defense to be the preferred treatment for Acute Radiation Syndrome (ARS). ARS results from exposure to nuclear radiation.

The clinical manifestation of ARS is massive inflammation including such gastro-intestinal symptoms as abdominal pain, nausea, vomiting and diarrhea which typically last from two to six days. Depending on degree of radiation exposure, there may be a latent phase during which the patient experiences a brief abatement of symptoms. However, within days to weeks, a hematopoietic (blood-forming) crisis ensues as a consequence of the depletion of both white blood cell and red blood cell progenitors within the bone marrow. The manifest illness is characterized by immunosuppression, fever and diarrhea. Victims can die within days to several months following initial exposure.

Prochymal, which is a highly purified form of mesenchymal stem cells (MSCs) grown in culture, vigorously attack the effects of ARS. Prochymal has been shown in several studies to be able to receive the inflammatory signals emanating from radiation damaged tissues, migrate through the body to those sites of injury and then down-regulate the inflammation.

Because, in the case of ARS, inflammation is responsible for much of the tissue destruction, this down regulation by MSCs rebuilds damaged tissue. The cells also express their own set of signals which are received by growth factors and other cells so that the healing cascade can continue.

Prochymal, by the way, has demonstrated safety and efficacy in seven clinical trials, and has advanced into Phase III for three indications, each of which has been granted FDA Fast Track status.

From Bird Calls to Protein Signals

As the signaling theorists apply their bird call models to the cellular domain, they are reporting remarkably consistent patterns. For example, while different species of birds may cackle, chirp, display certain feather colors or emit chemical signals in millions of theoretical combinations—these same birds are programmed to be able to ignore most of the messages and only respond to highly specific subset of messages. Just like human cells. Each type of cell is programmed to respond to only a select subset of either chemical or mechanical signals. Similarly, cells themselves have "ears", "eyes" and "noses" in form of surface receptor proteins which function to pick up these various signals. Again, birds or mammals convert these received signals into a series of instructions that determine how they will behave. Do they divide or stay quiescent, or live or die or move to a new location or just change form altogether?

There are even "relay teams" of enzymes, proteins, and other intracellular mediators (or second messengers) that hand off signals and move them from, say, point of injury to bone marrow where stem cells receive the signal and use it to determine what to do next.

Slowly but inexorably, we are building models for understanding the communications that occur at the cellular level. By learning to communicate at the cellular level clinicians will drive new and more effective therapeutic solutions. ◆

Corporate Raiding Vegas Style

By Walter Eisner

The surgeon allegedly called and said, "Just remember Cara, snitches get stitches."

Cara Casalenuovo was a Stryker Corp. sales rep in the company's Las Vegas office on March 21, 2011, when she, Stryker branch manager Tom Fallon, and her fellow sales reps Brian Rowan, Alex Poulemanos and Ruben Burciaga all resigned to accepted sales positions with Zimmer Spine.

However, according to a lawsuit filed by Stryker against Zimmer and ten individuals on April 1 in New Jersey, the next day Casalenuovo contacted David Sponsel, Stryker's Las Vegas Area Manager, about her resignation and changed her mind.

The above surgeon made the alleged comment to Casalenuovo on March 28 after she refused to join the mass move to Zimmer. Stryker alleges that the surgeon was calling "at the direction of, or in coordination with Burciaga and/or Fallon, on behalf of Zimmer." The surgeon allegedly said that if she was telling Stryker anything disparaging about her former co-workers, he would never do business with Stryker again.

The same scene played out in Arizona on March 21, when Stryker Branch Manager Christopher Loughran and Sales Manager Ryan Lively submitted their resignations to join Zimmer along with their sales reps, Ryan Hermansky, Zach Hilton, Rob Borcherding and Chris Duffy.

Joe Gauder/Wikimedia Commons

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOWMEDICA OSTEONICS CORP., a subsidiary of **STRYKER CORPORATION**, a New Jersey corporation;	**ECF CASE**
Plaintiff,	Civ. A. No.
- against -	**COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF**
ZIMMER, INC., a Delaware corporation; **ZIMMER US, INC.**, a Delaware corporation; **ZIMMER SPINE, INC.**, a Delaware corporation; **PAUL GRAVELINE**, an individual; **CHRISTOPHER GIEBELHAUS**, an individual; **CHRISTOPHER LOUGHRAN**, an individual; **RYAN LIVELY**, an individual; **RYAN HERMANSKY**, an individual; **ZACH HILTON**, an individual; **THOMAS FALLON**, an individual; **RUBEN BURCIAGA**, an individual; **ALEX POULEMANOS**, an individual; and **BRIAN ROWAN**, an individual;	
Defendants.	

Souce: Court documents

Stryker Responds

Stryker didn't wait long to act.

On April 1, Stryker sued Zimmer, Zimmer Spine's new COO and former Stryker VP of Sales Paul Graveline and nine other former ex-Stryker employees. Stryker accuses the defendants of corporate raiding by, "willfully and maliciously targeting" Stryker employees as part of an alleged scheme to establish a spine-related products division "without expending any effort to built it."

Zimmer's scheme was simple, states the lawsuit.

> "Using the recommendations of former Stryker Spine sales leaders it previously recruited, Zimmer first identified high-potential Stryker employees—who each had strict contractual obligations not to directly or indirectly solicit other Stryker employees to leave their employment—and induced them to breach these contractual obligations by asking them to gauge their coworkers' initial level of interest in an 'opportunity' with Zimmer.
>
> "Once these trusted 'ringleaders' planted the bait, Zimmer would make contact with the new Stryker recruits, offering significant salary increases and additional perks….
>
> "Next, Zimmer would redeploy these 'ringleaders' into the groups of recruits, where they would exert subtle peer pressure by urging them not to 'disappoint the team' or 'throw a wrench' in the team's plans to go to Zimmer en masse.
>
> "Finally, when these subtle pressure tactics failed, one employee faced threats and intimidation."

These actions, according to Stryker, escalated in March and resulted in Stryker's loss of nearly two entire sales branches in the West Region.

Stryker says that the company has been notified by several surgeons that former Stryker sales reps have contacted them about shifting their allegiance over to Zimmer products. Stryker expects to lose millions of dollars in sales as a result of Zimmer's alleged targeted recruitment of its employees.

Stryker also claims the en masse departure poses harm far beyond just significant monetary losses. "Stryker's former Branch Managers and Sales Representatives will be able to exploit Stryker's

confidential and proprietary information to unfairly compete against Stryker on behalf of Zimmer," stated the Stryker lawsuit seeking an injunction to stop Zimmer and the defendants from pursuing business.

The lawsuit shines a light on the details of the competition for sales territory rarely seen by the public.

Stryker says the targeted Stryker employees were given instructions to state that they were first contacted by Zimmer managers, not the alleged Stryker ringleaders. Further, the ringleaders were instructed to falsely deny whether they knew if other Stryker employees had been made offers by Zimmer.

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Las Vegas

Zimmer, according to the suit, first used Fallon, Stryker's Las Vegas Branch Manager, along with Rowan and other sales reps within the branch to spark interest about leaving Stryker.

The effort began in late December 2010, when Fallon, Rowan and other sales reps allegedly began making off-handed comments about leaving to form a Stryker distributorship or to work for a competitor.

For example, at a dinner on December 23, 2010, Fallon and Casalenuovo were discussing the departure of another Stryker sales rep when Fallon allegedly asked Casalenuovo, "What if the rest of us left?"

On March 13, 2011, Rowan allegedly told Casalenuevo that Zimmer' Kevin Brothen, a former Stryker employee, was going to contact her.

The next day Brothen sent Casalenuovo a text message asking her to meet with him. Brothen had allegedly flown to Las Vegas to meet with each of the sales reps. Stryker says Fallon and Rowan coordinated these meetings with Brothen, and that Zimmer was particularly interested in recruiting the entire Las Vegas group to come over to Zimmer as a team.

According to the suit, when Brothen and Casalenuovo met, "despite the fact that she never interviewed with Zimmer or submitted a resume," Brothen

offered her a job on the spot. Brothen allegedly told Casalenuovo that Zimmer was pouring a substantial amount of money into its spine group. Brothen also told Casalenuevo that Zimmer would fully back her departure from a legal standpoint, if necessary.

"A New Stryker"

Rowan, allegedly told Casalenuovo that with Brothen, Fallon and Graveline in place at Zimmer, Zimmer would essentially be a "new Stryker."

On March 23, when Fallon came into Stryker's office to return his laptop, he saw that Casalenuovo was still there. The suit says that Casalenuovo, "Almost immediately" received multiple phone calls and text messages from Fallon and the other reps that resigned on March 21 to join Zimmer.

That same evening, fellow rep Poulemanos allegedly came to Casalenuovo's house. He told her that if she told them [Stryker] anything, "it could ruin our lives."

Casalenuovo, according to the suit, called a surgeon on March 27 who was a long-standing customer of Stryker and had worked extensively with Burciaga. She told him that Stryker hoped to continue its relationship with him. The surgeon allegedly replied by saying, "Don't sell Ruben [Burciaga] out." He told her that he would continue to use Stryker as "a second" but that "Ruben [Burciaga] is my guy," and that he planned on moving his business to Zimmer.

The following day, Casalenuovo received an unsolicited call from the same surgeon who then made the alleged comment about snitches getting stitches."

Arizona

Stryker alleges that a similar scene played out in Arizona with Loughran and Lively paving the way for Brothen to recruit the branch's sales reps. The result was a mass resignation on March 21 by managers Loughran and Lively and sales reps, Hermansky, Hilston, Borcherding and Duffy.

During a March 17 meeting between Brothen and Borcherding, Brothen allegedly told him that Zimmer would fully back their departure from Stryker, from a legal standpoint and "indemnify" them if necessary. In addition, Brothen also told Borcherding that Zimmer was pouring a substantial amount of money into its spine group, and that it was personal between him and Stryker. Brothen also told him that if anyone asked, Borcherding should say that Brothen was the first person to contact him about the opportunity to join Zimmer.

Between March 23 and March 25, 2011, after speaking with a handful of Stryker employees, Borcherding and Duffy decided that they were going to rescind their resignations and come back to Stryker.

On March 25, 2011, after Borcherding decided that he would not join


Phoenix, Arizona/Wikimedia Commons

Zimmer, Brothen allegedly requested that Borcherding "keep quiet" and not tell anyone the "specifics" of what had occurred, so as not to burn any bridges.

Chicago

Zimmer's efforts were not limited to the Southwest.

According to the suit, at the behest of Zimmer, Christopher Giebelhaus, a Stryker sales rep at Stryker's Chicago branch, met with fellow Stryker sales reps Brian Miller and Will Williams to discuss the possibility of the three of them joining Zimmer.

Williams then allegedly received a call from Dana Lyons, a Zimmer manager, in which Lyons referenced conversations with Giebelhaus and asked Miller and Williams to meet with him and Giebelhaus to discuss an opportunity with Zimmer.

Giebelhaus, according to the suit, then arranged for himself, Miller and Williams to meet with Lyons and Steve Leshey, the manager of the Zimmer St. Louis Distributor, Patriot Medical, on January 10, 2011. Both before and during this meeting, Stryker claims Giebelhaus acted as the ringleader.

Soon after that meeting, Giebelhaus and Williams travelled to Zimmer's spine headquarters in Minnesota to meet with Zimmer personnel. A week later, Miller went to Minnesota where he was introduced to the company's COO, Paul Graveline. Stryker claims, Graveline, despite his post-employment contractual obligations owed to Stryker, allegedly said to Miller that Zimmer would love to have him, and that Miller would be successful at Zimmer.

William and Miller eventually declined to join Zimmer.

The Accusations

Stryker accuses Zimmer and the defendants of: Breach of Contract and Fiduciary Duty, Misappropriation of Trade Secrets, Tortious Interference, Corporate Raiding and Unfair Competition. In addition Stryker seeks an injunction to prevent any Stryker business moving to Zimmer.

The court has not issued a ruling. ◆

company

Biomet's Below Market 3Q11

Disappointing third quarter sales results announced on April 12, caused Biomet Inc.'s President and CEO Jeff Binder to say, "We did not meet our goal of sustainable above-market growth."

Biomet Corporate Headquarters

The results prompted Mizuho Securities analyst Mike Matson to comment that the sequential slowdown of the company's hip and knee business appeared to get third quarter orthopedic earnings "off on the wrong foot."

Reported sales of $678 million were up 1% over the previous year. Hips sales were flat, knees were down 2% and spine rose 1%. One bright spot was extremities sales which rose 18% driven, according to the company, by the Comprehensive Primary and Reverse Shoulder Systems.

Binder said the company believes the hip and knee market continued to remain sluggish during the quarter, with continued pressure on both volume and price. "Our focus is on improving our execution in new product introductions, and selling and marketing effectiveness so that we can regain the momentum that we have built over the past four years. We have also launched two important new hip systems, the Arcos Modular Femoral Revisions System and our Active Articulation E1 Dual Mobility Hip System."

Biomet, Inc. 3Q11	Sales $ in million	% Change
Total Reported Sales	**$678**	**1%**
Reconstructive	$516	1%
Hips		flat
Knees		down 2%
Spine	$54.40	1%
Extremities	25.1	up 18%

Source: Biomet, Inc.

Biomet also got its Signature custom cutting block cleared by the FDA in the quarter.

Jeffries research analyst Raj Denhoy noted that knees however took a turn down, with U.S. knee sales posting -5% growth and worldwide -1%. "These were a sharp deceleration from the positive 3% growth shown last quarter in both geographies. The company has been showing the effects of a move away from metal-on-metal constructs in hips and it looks like the trend continued in the quarter. The fall off in knees, particularly in the U.S., was concerning."

Wall Street Debt

The company's debt is another concern to some analysts as its major competitors are sitting on significant cash reserves to spend on strategic objectives.

A reported loss of $11.6 million for the quarter was almost a fourfold increase over the $3.1 million loss posted for the same three months a year ago. The company reported $117.9 million in non-recurring expenses, including $95.7 million in amortization and depreciation related to the company's 2007 merger with LVB Acquisition, Inc. LVB is indirectly owned by investment partnerships directly or indirectly advised or managed by The Blackstone Group, Goldman Sachs & Co., Kohlberg Kravis Roberts & Co. and TPG Capital.

Excluding those special items, the company would have reported earnings of $63.8 million for the quarter.

—WE (April 14, 2011)

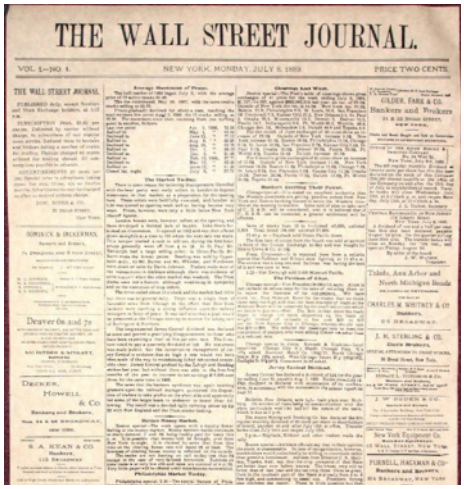
legal

Smoking Gun or Just Smoke?

The *Wall Street Journal* reported on April 13, (link here) that California-based Omega Solutions, "sometimes pays surgeons to use its products."

The *Journal* goes on to say that the company "enters into partnerships with surgeons who agree to use its products and pays them a 'dividend' based on the number of surgeries they perform."

Paying surgeons to use implants for Medicare patients is a serious federal offense. The *Journal* must have had


THE WALL STREET JOURNAL.

The Wall Street Journal/Wikimedia.org

quite the smoking gun to make such a serious charge.

What was that smoking gun?

The story includes a document on Omega Solutions stationary and signed by an Omega consultant. The document is a sales pitch to potential surgeons to use implants sold by Omega. Among other things, the pitch includes an "opportunity" to participate in Omega's 25-year-old Medical Buying group. The document shows a payout summary for an unnamed Los Angeles surgeon involved in a Medical Distribution program. The figures are, according to the Omega document, "based off of 2-3 instrumented cases per week."

The article offers no evidence of the business and investment structure of Omega's Medical Buying Group.

The *Journal* however claims the program outlined in the document is a physician-owned distributorship (POD). The article goes on to say, "Distributorships act as middlemen between medical-device makers and the hospitals and surgery centers that buy their products. In exchange for marketing the devices and nurturing client relationships, they get a cut of each sale."

To be legal, PODs must do much more. The physician investors in the POD must put their own capital at risk in the form of purchasing, stocking and distributing implants. Again, to be legal, dividends are paid to the investors based on their ownership percentage of the business, not on the number of specific surgeries they performed.

Concluding that a POD distributing dividends to owners is, "paying surgeons to use its products," is a stretch and the *Journal* uses poor evidence to accuse the company of a felony. The *Journal* offered no evidence that Omega is even a POD.

PODs are highly controversial and deserve scrutiny. But physicians involved in PODs also deserve to be judged on facts, not smoking guns that only end up being smoke.

The kind of evidence and undocumented conclusion offered in the *Journal*

article would never fly in a clinical trial or pass peer-review in a medical journal. But apparently it's good enough for the *Wall Street Journal*.

—*WE (April 15, 2011)*

Feds Widening Infuse Inquiry

Infuse by Medtronic

The New York Times reported on April 11 that the U.S. Justice Department (DOJ) criminal investigation into Medtronic, Inc.'s off-label marketing of Infuse was "apparently widening." Medtronic received the first subpoena from the DOJ looking into off-label use of InFuse in October 2006.

According to the paper, a doctor, not part of the original group of physicians interviewed previously by the DOJ, said he had been contacted by Justice Department officials in the last few weeks. He asked not to be identified because the inquiry is under way. He also told the paper that it was his understanding that prosecutors had contacted other physicians in recent months.

The company responded, "Medtronic does not comment on what precise topics the government may or may not be examining at any point in the investigation."

Justice Department and Army officials have also been investigating the use of Infuse on dozens of soldiers at Walter Reed Army Medical Center in Washington. An Army report in 2008 found that a former military doctor, Timothy Kuklo, M.D., had overstated Infuse's benefit in a medical journal study that examined its use in the treatment of solders whose shin bones had been severely shattered by explosive devices in Iraq.

Kuklo, who became a Medtronic consultant, also forged the signatures of that study's co-authors in a journal submittal, the Army said. Medtronic later broke its ties to him and the medical journal retracted the article.

Wells Fargo Senior Analyst Larry Biegelsen wrote on April 12, "We think the timing of the *Times* article and the likely delay in Bill Hawkins' departure may be related. We also believe the article suggests that a resolution of the DOJ investigation could occur sooner rather than later and we would view this as a positive because it would remove uncertainty."

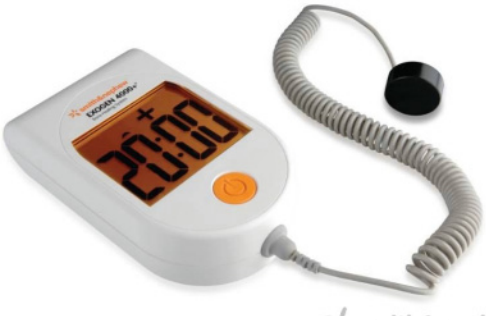
Biegelsen also wrote that he expects the company's biologic franchise to decline due to the chilling effect of the investigations on surgeons' off-label use of Infuse and the recent denial by the FDA of the company's Amplify approval request.

—*WE (April 13, 2011)*

large joints

S&N Launches EXOGEN CONNECTS

Reminding your bones to grow… Smith & Nephew has announced



Smith & Nephew

a new, free service that helps patients keep on track with their physician-prescribed EXOGEN Ultrasound Bone Healing System treatment plans. Via EXOGEN CONNECTS, patients can receive reminders and tips for healthy living.

Those who enroll in EXOGEN CONNECTS have on hand a personal wellness and support program that helps motivate and alert them so they can achieve better outcomes when using EXOGEN. (As indicated by the company, it is the only bone growth stimulator device approved to accelerate indicated fresh fracture healing.) Patients—who determine the frequency and method of contact—receive treatment reminders and tips for healthy living via text messages, emails or automated phone calls.

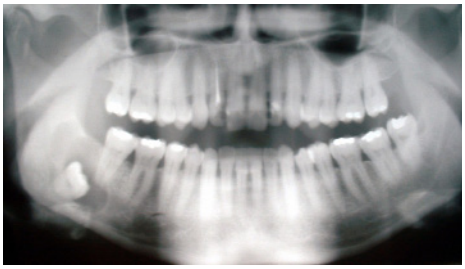
The EXOGEN Ultrasound Bone Healing System is an ultrasound device that emits a low-intensity pulsed ultrasound signal which has been shown in laboratory tests to stimulate genes and growth factors that are critical to the body's natural bone healing process. It is approved for the acceleration of healing of indicated recent fractures and also fractures that show no sign of healing (nonunion excluding skull and vertebra).

Michael Truell, a company spokesperson, told *OTW*, "Following market research activities with surgeons, insurance companies and patients, we

uncovered some concerns that led us to the development of the EXOGEN CONNECTS program. The physicians were concerned that their patients may not remember to follow their treatment plan, while insurance companies liked the idea of having reminders keep patient treatments on track. Patients informed us that they needed to better understand their treatment and condition. EXOGEN CONNECTS was designed to meet all of these audiences' needs."

—EH (April 15, 2011)

Bisphosphonates and Teeth



Pidalka44/Wikimedia Commons

If going to the dentist isn't your favorite thing…bad news. According to a comparison study of women on and off bone-strengthening bisphosphonate therapies for osteoporosis, older women may need to need to see a dentist up to four times a year to control dental plaque. The study was performed by researchers at the Case Western Reserve University School of Dental Medicine and the Cleveland Clinic.

Leena Palomo, assistant professor of periodontics from the dental school, and Maria Clarinda Beunocamino-Francisco from the Center for Specialized Women's Health at the clinic, set out to study the long-term effects of bisphosphonate therapies on the jawbone, but came up with these new findings that impacts all women after undergoing menopause.

Twenty-eight postmenopausal women with normal bones were compared with 28 women who were on bisphosphonate therapies for at least two years or more. The participants (all between the ages of 51 and 80) received conebeam CT scans of their jaws and a complete periodontal check for dental plaque, bleeding, and loss of bone attachment and of the alveolar bone socket.

The findings for bone strength and other markers for osteoporosis were similar for both groups. But the researchers found both groups had increased dental plaque levels, which could endanger the jawbone of normal postmenopausal women and reverse any benefits gained in bone mass. While women from both groups had similar bone health results and women on the long-term oral bone-strengthening therapies showed no signs of bone death, they had abnormal dental plaque.

Plaque can trigger gum disease, an inflammatory reaction that produces the cytokines protein reaction. Palomo indicated that those cytokines also set in motion the process that weakens bones in osteoporosis.

Dr. Palomo told *OTW*, "It's not surprising to see that postmenopausal women accumulate plaque—they are just like everyone else. Nor is it a surprise that when plaque accumulates, the inflammation response to that plaque yields loss of the boney socket (hence the plaque bacterial biofilm should be removed often through professional cleanings). What is something of a surprise is that even though short term studies have shown that bisphosphonates have a beneficial effect on the boney socket, in our longer term study, the benefits to the bone are less robust than those seen in the shorter term. We hypothesize that this may be in part to plaque bacterial biofilm triggering inflammation and subsequent bone loss and washing out the benefits seen in short-term studies. We plan to test this hypothesis and since little is known about the subject we plan to continue our line of study."

—EH (April 12, 2011)

Osteoporosis? Green Tea + Tai Chi

Pair green tea with the gentle movements of tai chi and your bones could whisper "thank you." Dr. Chwan-Li (Leslie) Shen, an associate professor and a researcher at the Laura W. Bush Institute for Women's Health at the Texas Tech University Health Sciences

MASA/Wikimedia Commons

Center, has found that consumption of green tea polyphenols (GTP) and participation in tai chi independently enhanced markers of bone health.

Building on the existing studies that indicate that those who consume the highest levels of GTP tend to have lower risks of osteoporosis, Dr. Shen hypothesized that the mechanism behind this correlation may have to do with lowering chronic levels of inflammation. This double-blind, placebo-controlled, intervention trial, which was funded by the National Institutes of Health/National Center for Complementary and Alternative Medicine, involved 171 postmenopausal women who had weak bones but not full-fledged osteoporosis.

The results of the six month study show that consumption of GTP (at a level equivalent to about 4-6 cups of steeped green tea daily) and participation in tai chi independently enhanced markers of bone health by three and six months, respectively. A similar effect was found for muscle strength at the six-month mark.

Participants taking tai chi classes also reported significant beneficial effects in quality of life in terms of improving their emotional and mental health. Also, both GTP and tai chi had a profound effect on biological markers of oxidative stress. Because oxidative stress is a main precursor to inflammation, this finding suggests that green tea and tai chi may help reduce the underlying etiology of not only osteoporosis, but other inflammatory diseases as well.

Dr. Shen told *OTW,* "I was surprised that green tea intake and mind-body exercise such as tai chi can be easily adapted to every day life. Osteoporosis is a major public health threat for an estimated 44 million Americans, or 55% of the people 50 years of age and older. Long-term intake of green tea and daily tai chi exercise may be beneficial in mitigating the progression of degenerative bone disease such as osteoporosis."

—EH (April 11, 2011)

extremities

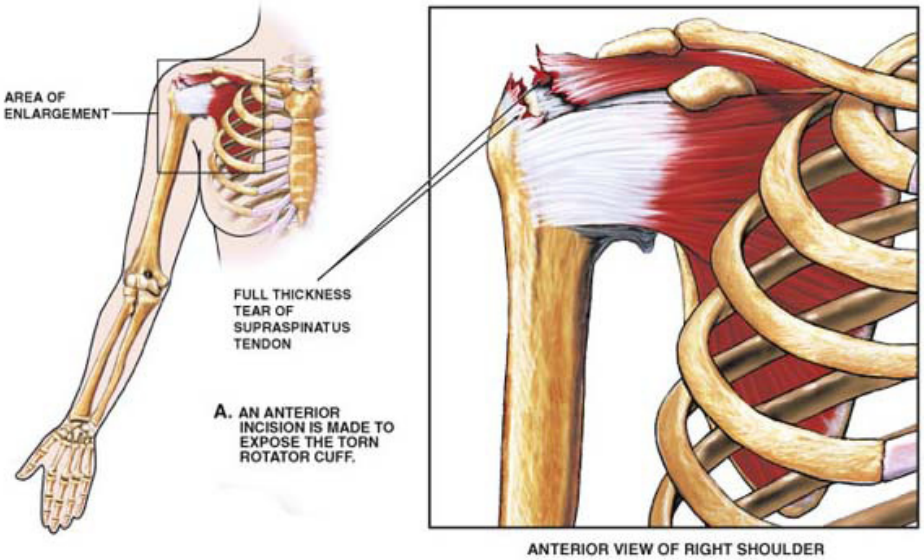
Left Untreated, Cuff Tears Grow

Rotator cuff tears are the most frequent tendon injury in the adult population. Half of the full-thickness rotator cuff tears, if they are not treated with surgery, get bigger, according to a study published in *The American Journal of Sports Medicine.*

Physicians at the Department of Orthopedics, Hadassah Hebrew University Medical Center, in Jerusalem, in light of the lack of precise knowledge of the evolution of tear size, decided to investigate. The authors prospectively followed 51 patients with 61 rotator cuff tears. The patients were 60 years old or younger and had a full-thickness rotator cuff tear equal to or larger than 5 mm, as diagnosed by bilateral shoulder ultrasound. All had been treated nonoperatively. At two to three years after the index ultrasound examination, a repeat ultrasound examination was performed by the same ultrasonographer.

At a follow-up of 25 to 39 months (mean, 29), 49% of the tears (30 tears) increased in size, 43% (26 tears) had not changed, and 8% (5 tears) decreased in size. For 25% (10 shoulders) of initially intact shoulders a new full-thickness rotator cuff tear was diagnosed. No correlation was found between the change in tear size and age of the patients, their gender, or the existence of prior traumas. There was a correlation between the existence of considerable pain at the time of the follow-up ultrasound and a clinically significant increase in tear size.

The authors conclude that full-thickness rotator cuff tears tend to increase in size in about half of patients aged



Nucleus Communications/Wikimedia Commons

60 years or younger. Therefore surgery should be initially considered in these patients to prevent a probable increase in size tear. Patients treated nonoperatively should be routinely monitored for tear size increase, especially if they remain symptomatic.

—BY (April 11, 2011)

spine

Strong Results for Cerapedics New Bone Putty

Cerapedics

A biologic bone graft material designed for patients undergoing posterior lumbar interbody fusion (PLIF) spine procedures produced a fusion rate of 97.7% compared to 59.1% for patients treated with autograft. The results of a randomized, controlled trial were presented at the Global Spine Congress, Barcelona, Spain, in March. Philippe Lauweryns, M.D., Ph.D. of the Department of Orthopaedic Surgery, Regionaal Ziekenhuis Sint Trudo Hospital, Sint Truiden, Belgium, was the principal investigator.

The purpose of the study was to evaluate the safety and efficacy of Cerapedics' i-Factor biologic bone graft material compared to autologous bone delivered via interbody fusion cages in single- and multi-level PLIF surgery.

End points were VAS for pain, Oswestry Disability Index (ODI) and radiographic images. The researchers took CT scans at six-month and one-year intervals, recorded adverse events and defined fusion as the presence of "bridging bone" as it was assessed by an independent board-certified radiologist.

At 6- and 12-months after treatment, data from 40 patients (45 levels) demonstrated that Cerapedic's i-Factor was superior to autologous bone when used as a bone graft material in spine fusion surgery. The radiological fusion rate for i-Factor was 97.7% while patients treated with autograft had a fusion rate of 59.1%. At one-year, i-Factor demonstrated a radiological fusion rate of 97.8% for patients in the study while 82.2% of the autograft patients achieved fusion. The study investigators reported that there were no wound problems, infection, hematoma nor ridiculer pain problems in either arm of the study.

Cerapedics' i-Factor biologic bone graft has been utilized clinically in more than 3,500 spine and trauma surgeries worldwide. It is currently being evaluated in the United States by the FDA as part of an Investigational Device Exemption Clinical Study in the cervical spine. i-Factor bone graft is not commercially available in the USA.

i-Factor is one of Cerapedic's platforms of novel osteobiologic products which incorporate the company's proprietary anorganic bone mineral and synthetic small peptide technology platform.

—BY (April 14, 2011)

Scoliosis: Good News for Teens

Stronger than expected…Researchers from Hospital for Special Surgery (HSS) have found that teens who undergo spine fusion for scoliosis using the newest surgical techniques can expect to be doing well ten years later. The research team had thought that the surgery would cause damage to the spine just below the fused discs, but the study showed that this was not the case.

"Fusion for adolescent idiopathic scoliosis using the newer generation spine implants appears to spare junctional disc degeneration and allows patients ten years out to have a relatively normal pain free lifestyle," said Daniel Green, M.D., in the news release. Dr. Green is the pediatric orthopedic surgeon at HSS in New York who led the study.

Scoliosis was for years treated with Harrington rods that were

Hospital for Special Surgery

implanted along the spinal column. Starting in the late 1990s, surgeons replaced this method with newer techniques to fuse the spinal column together. To evaluate these techniques, HSS investigators conducted a pre- and post-operative MRI in patients undergoing the surgery with modern techniques.

The investigators reviewed all spinal fusions performed by four senior scoliosis surgeons at HSS between 1991 and 1997. Thirty-three potential study participants were located and 20 agreed to participate.

"We wanted to see how the patients were doing ten years down the road, specifically focusing on the part of the spine that didn't have surgery. The standard belief was that the area of the spine just below the surgery would wear out, because of the increased stress that the surgery or the fusion would put on that part of the spine," Dr. Green added. "That isn't what we found. We found that the area of the spine adjacent to the fusion was pretty healthy and didn't show any major degeneration ten years later. While mild degenerative changes were noted in almost every patient, the severe changes that we were concerned that we might find were not there at all."

Dr. Green told *OTW*, "Other take home points of the study were that there were good functional scores and maintenance of correction over ten years post-fusion. Also, the most impressive degree of disc degeneration ten years after surgery was found remote to the lowest instrumented vertebra at L5-S1."

—EH (April 13, 2011)

Innovative Solus Cleared by FDA

Federal regulators have cleared, for sale in the U.S., an innovative interbody spacer from Alphatec Spine, Inc. called the Solus anterior interbody fusion system. The Solus is an interbody implant with a unique added feature—counter rotating blades which provide 4 points of fixation. Or, as the company stated in its press release, the Solus has a "patented fixation technology which allows for enhanced segmental stability with a simplified surgical technique, while providing for substantial spacing to add bone graft."

The Solus comes pre-assembled and there are no screws or anchoring plates required to be passed into and out of the wound area in order to achieve fixation. The implants fixation blades rotate on a central axis, which greatly reduces the required retraction of soft-tissue, further reducing potential complications. Finally, the Solus has a zero-profile construct which, according to Alphatec, should reduce the risk of scar tissue build up, and vascular complications.

Alphatec is offering the Solus in multiple footprints and lordotic angles to accommodate every spine surgeons' requirements.

The 510(k) clearance by the Food and Drug Administration means that the Solus device has been judged to be as safe and effective as a similar product already on the market.

Alphatec has been selling the Solus device in Europe for some time. Company President and CEO Dirk Kuyper said that the device will be available on a limited basis in the United States until a full commercial launch occurs in the second half of the year.

Alphatec Spine, Inc.

Alphatec Spine, Inc.

"In order to optimize the success of this revolutionary product, the controlled launch will be a tiered release, with an emphasis on both clinician and sale training," he said.

—BY (April 11, 2011)

people

Alpert "Retires" From Medtronic

Susan Alpert, M.D., Ph.D., a former director of the FDA's Office of Device Evaluation and, since 2005, the Senior Vice President and Chief Regulatory Officer at Medtronic, Inc. is retiring at the end of April.

Dr. Alpert told *OTW* at the 10th University of Minnesota Design of Medical Devices Conference, that senior executives at Medtronic are mandated to "retire" when they reach age of 65. But as was clear from our conversation and her vibrant enthusiasm for medical devices, she is not going to retire. She will be looking to find ways to stay active in medical devices through consulting activities. There are probably no more than four or five individuals in the U.S. with the length and depth of experience at both the FDA and private industry.

Susan Alpert, M.D., Ph.D./Courtesy of Medtronic

A Medtronic spokesperson confirmed the company's regulatory affairs. Vice President Patricia Shrader will be replacing Alpert. Shrader is a former regulatory SVP at Becton, Dickinson & Co.

Prior to joining Medtronic, Alpert was Vice President of Regulatory Sciences at C.R. Bard, Inc. At the FDA, Alpert held a variety of positions in the Centers dealing with drugs, devices and radiological health, and foods, including six years as the Director of the Office of Device Evaluation. She is a microbiologist and pediatrician with a specialty in infectious diseases and has practical experience in laboratory research and clinical trials.

Public Policy Activist

Alpert has also been active in various public policy efforts, including a stint on the board of the Food Drug Law

Institute (FDLI), a forum for the FDA and the legal, business, academic and consumer communities to exchange perspectives on public policy, law and regulation relating to products subject to FDA jurisdiction. She serves on the board of advisors for the Medical Technology Leadership Forum (MTLF), an educational organization focused on policy makers, the general public, and the media regarding critical issues affecting the development and adoption of advanced medical technology. In addition, she is on the board of the Women Business Leaders (WBL), an organization of women leaders in the health care sector. She is also a past Chair of the Regulatory Affairs Professional Society and a Fellow in that society. Alpert also serves on the Executive Committee of the Clinical Trials Transformation Initiative (CTTI), one of the public/private partnerships working with the FDA to streamline the development of medical products.

She earned her undergraduate degree at Barnard College, Columbia University in New York City and holds a master's degree and Ph.D. in biomedical sciences from New York University. She received her medical degree from the University of Miami (Florida) and completed her clinical training at Montefiore Medical Center in the Bronx, New York, and at Children's National Medical Center in Washington, D.C.

Unfettered from government and corporate restraints, Alpert has agreed to provide *OTW* readers with her perspective on regulatory affairs and upcoming changes in the FDA's 510(k) clearance program.

—*WE (April 13, 2011)*

THE PICTURE OF SUCCESS

Dr. Victor Goldberg

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

Dr. Victor Goldberg

Although he eventually rose in his career to become Department Chair, years ago Victor Goldberg, now an internationally respected joint replacement expert, often occupied a different kind of chair…the one outside the principal's office.

Dr. Goldberg, a professor and former chair of orthopedics at Case Western Reserve University (CWRU), is also a past-president of the Orthopaedic Research Society and of The Knee Society. He has gained much in his life…but first there were heavy losses.

Young Victor lost his father at the age of five, battled his own illness at the age of seven, and then lost his mother when he was seventeen. With his life virtually turned upside down, Victor Goldberg's future could have gone either way. "We lived in Brooklyn; I was the youngest of three boys and although my mom and I spent numerous afternoons in the principal's office, I was actually interested in school. Because my dad was an optometrist I had some feeling for what healthcare involves. It was the pediatrician who treated me one summer, however, that really led me to consider a career in medicine. I had rheumatic fever and was put on bed rest and penicillin. This doctor spent a lot of time with me, and impressed me with his kindness. I became enamored with the idea of being a doctor, a quest that my mom supported."

His plans for a white coat ceremony were periodically interrupted by schoolyard altercations, however…until, that is, a strong teacher and mentor got hold of him. "In 7th grade my teacher was Mr. Moses, a faculty advisor who also ran the safety monitor activities. He took control of me and put me on the safety squad and gave me a badge. All of a sudden I felt a sense of authority and I stopped acting out. I could tell that he took more of an interest in me than just wanting to control my behavior… and that meant something…he had my attention."

Those early fits and starts of growth set the foundation for greatness. Much later on, Victor Goldberg would lead Case Western's department of orthopedics to the ranking of #1 in NIH grant funding in the country. "Although my mom was not able to see the results of her caring and determination, it was indeed her messages about the importance of being focused, working hard, and achieving great things that brought me where I am today. All these losses, including the death of one of my brothers, showed me that I didn't want to waste what my parents had taught me."

So it wasn't a beaten down Victor Goldberg who entered college, but one somehow strengthened by the unexpected growth that can often occur during grief. "I adhered to my goal and did not waver. I knew I had to be a part of medicine because of the empathy that is an inherent part of the field. My early interactions with those in the medical world, as well as my substantial personal losses, set the stage for me…I wanted

"The most meaningful award I have ever received was the 2009 Distinguished Alumnus Award from HSS."

"As a young orthopedic surgeon I struggled to get an NIH grant, and in fact I went to the 'trough' three times before I had any success. Not only did this teach me to be persistent, but I learned to utilize the built-in educational process (i.e., I paid close attention to the critique of the grant application that the reviewers returned to me). Ever since my fourth NIH grant application in 1976 I have received continual funding from the agency."

to have a lifetime of treating people in a compassionate manner."

Once a playground scrapper, Victor Goldberg was now on track, having garnered a full scholarship to New York University and meeting his wife at the age of 19. "Medical School at Downstate was tough, but it was a standout program where I found talented mentors such as Dr. Stan Aronson—a pathologist who taught me the value of critical thinking. I was interested in neurosurgery, and I went to Case Western for an internship in surgery. I was depressed to see that there was little that neurosurgery could do for people. On my next rotation, orthopedics, I encountered Dr. Charles Herndon, the prominent chair and just a wonderful man. It was striking to me how happy the people working in orthopedics were—and that the patients tended to do very well."

Soon after, his number was up…the draft board came calling. And although the military is not known for its flexibility, Dr. Goldberg had quite a bit of freedom. "Increasingly drawn to orthopedics, I dropped out of my neurosurgery residency and immediately received a notification from the draft board. I was able to get a deferment for a year and then I joined the Air Force as a partially trained surgeon, a role that took me to bases in New Mexico and Arkansas. I performed a wide variety of surgeries on my own and in general was accorded a great deal of independence by the military. I read a lot about orthopedics during that time, and my commitment to the field was soon complete."

The winner of three Kappa Delta Awards for Excellence in Research in Orthopaedic Surgery, Dr. Goldberg to a great extent credits his time at Hospital for Special Surgery (HSS) for laying the foundation for his career. "The most meaningful award I have ever received was the 2009 Distinguished Alumnus Award from HSS. I applied to this program because Dr. Herndon was an alumnus, and strongly encouraged me to pursue this residency. I could not have achieved all that I have without the wonderful program at HSS."

Indeed, when asked about his most life-altering experience, Dr. Goldberg states, "Getting to work alongside Eugene Lance, M.D., Ph.D. at HSS was tremendous. He had a brilliant scientific mind, and gave me insight into research and the specifics of how to approach it. His mantra was, 'Ask the *right* questions and develop the methodology to answer those questions.' I worked on two bone transplantation projects with him, something which further allowed me to observe his laser thought process. The result of all this was that I made a commitment to become a researcher and then spent a year with Dr. Lance in England."

Once he returned to the U.S., Dr. Goldberg would have a work environment envied by many. "I accepted an offer from Dr. Herndon to join Case Western, in part because he was able to provide not only generous funding, but protected time for research. Then as now, such a situation is rare and valuable."

While critical, funding and keys to a lab were only the beginning. "Doing the balancing act between my clinical work and research was really demanding. There were great lessons, however. I learned the importance of organizing my work so that I could spend time doing academic work; I also came to see that clinician-researchers won't get very

far if they don't have sufficient support and infrastructure."

When asked how a young clinician-researcher can present a good argument to the Chair, Dr. Goldberg advises, "Let them know that your research will be making a contribution toward the mission of the department. When you approach the Chair, be sure to have an organized program of research prepared. Don't walk in and say, 'I have an idea for a project.' Leaders in academia bet on people—not projects—so you have to convince the Chair that the goals are attainable and that you are the one for the job."

Dr. Goldberg, who as Chair led his department to the coveted #1 NIH funding slot, did a lot of convincing and a lot of research. An example: Since 1986 he has been the Principal Investigator on a controlled cartilage repair study. "We are developing new biomatrices that are completely unique. They are more structured, more biologically active, and more capable of interfacing with the host and providing the host with the necessary drivers of healing."

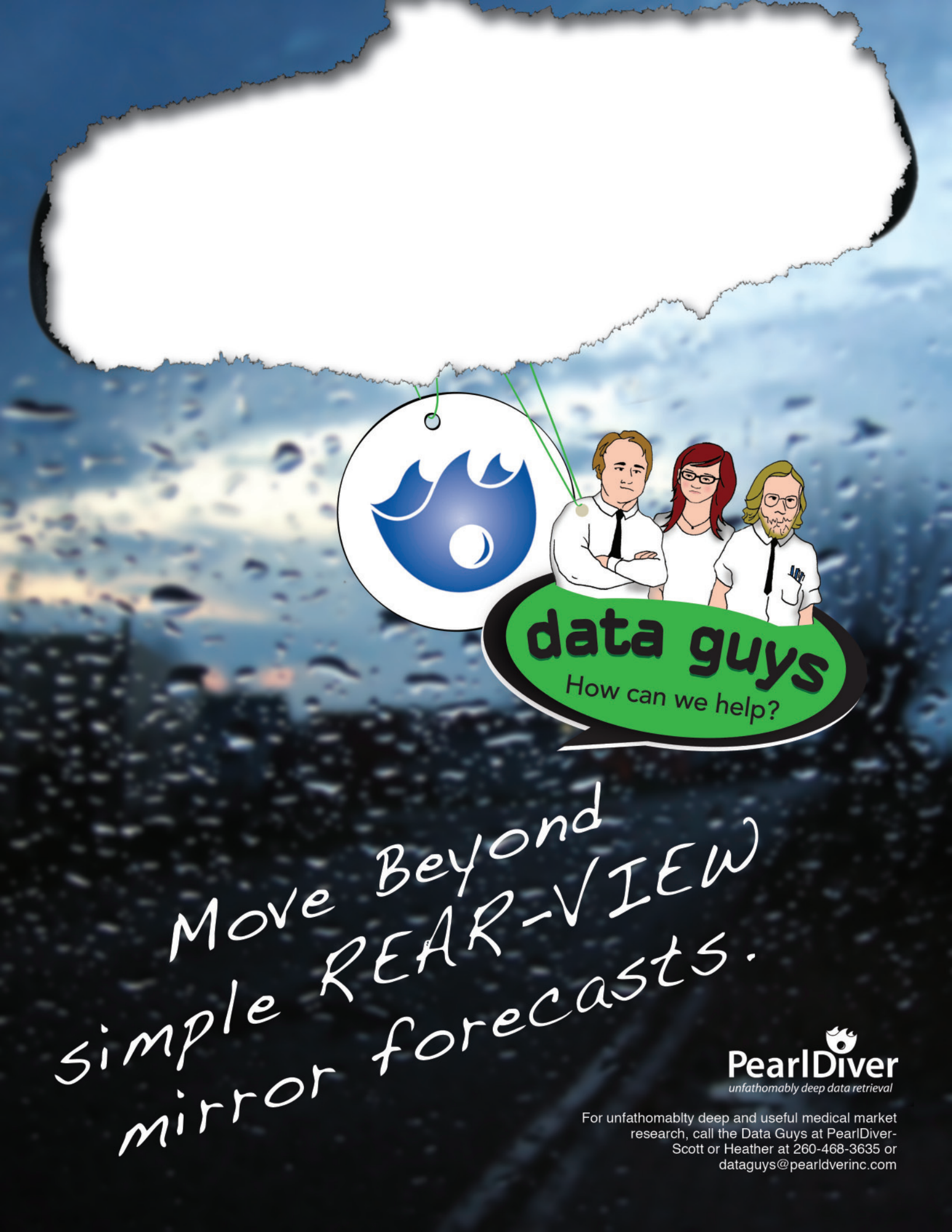
"As for being honored with the incredible Kappa Delta Awards, two of those recognized our work on bone transplantation. The other I shared with Dr. Ed Greenfield; together we developed a program on how to understand bone integration with implants, why they fail, and the role of infection. We learned that what is important with regard to integration is to have an environment that is mechanically stable and free of infection."

"The running theme of my clinical research is the regeneration of musculoskeletal tissue. My work has evolved from looking at the simple issue of bone transplantation and now to the stem cell aspects of musculoskeletal tissue. The most interesting thing that has emanated from my stem cell research is exploring the capability of getting cells to express a specific phenotype to understanding how they develop into cartilage or bone."

Show up, be focused, get it done, and bring your enthusiasm…those, says Dr. Goldberg, are the elements of his success. Even if you do all of this, however, there will be times when things don't go your way. "As a young orthopedic surgeon I struggled to get an NIH grant, and in fact I went to the 'trough' three times before I had any success. Not only did this teach me to be persistent, but I learned to utilize the built-in educational process (i.e., I paid close attention to the critique of the grant application that the reviewers returned to me). Ever since my fourth NIH grant application in 1976 I have received continual funding from the agency."

A beacon not only for young clinician-scientists, Dr. Goldberg's steady, wise presence has been heartening to those closest to him…his wife and three children. "My wife has been my loving companion for more than 50 years. She is insightful, bright, and always tells me the truth. We are incredibly proud of our children. Our son is a dedicated cardiologist, one of our daughters is a socially conscious attorney, and our youngest daughter works for Cedars Sinai Hospital in L.A. where she runs an outreach program for children. As for me and my free time, I haven't yet found anything else that I love as much as orthopedics."

Dr. Victor Goldberg…from a rocky start has come a boulder of strength. ◆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