

Orthopedics • This Week

WEEK IN REVIEW

4 FDA Abused Power, ReGen Biologics Exonerated >> A U.S. Court of Appeals called the actions of the FDA unlawful and exonerated ReGen Biologics of accusations of misconduct. Short of misconduct, the FDA has no power to rescind the 510(k) clearance of the company's Menaflex collagen scaffold, said the Court. What does this all mean for your next encounter with the FDA? Read it here.

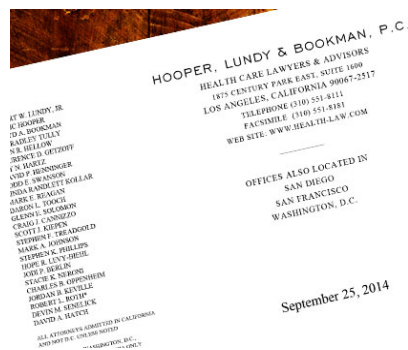
9 Myths and Facts About Orthopedic Surgeon Compensation >> Two announcements regarding orthopedic surgeon compensation—one on the last day of September and one a month earlier—offer startling new information about surgeon pay and how ineffective it is at delivering job satisfaction or even performance. For regulators, this article has a few inconvenient truths.

14 Three Reasons Surgeons Make Poor Decisions // New Study: Academic Medical Centers Discriminate Against Medicaid Patients // Massive New Study: These Popular New Devices DID NOT Improve Outcomes >> New study finds that doctors are stuck in their ways...despite evidence that they should change. Medicaid patients near academic medical centers are treated differently than private pay patients. And a massive new study from the Netherlands raises concerns about new devices. (Hint: they are no better after all.)



I'M GOING TO KICK YOUR ASS AND GET AWAY WITH IT.

18 POD Lawyer to Feds: "Show Us the Evidence" >> The legal battle over PODs is getting heated. The lawyers are starting to threaten sanctions and lecturing each other over ethics. Pat Hooper, the lawyer for the defense is demanding to see the evidence. We obtained the latest exchange between the combatants. No anonymous leaks, just a very public battle.



BREAKING NEWS

22 NASA and AlloSource Partner for Microbe Study

Free Joint Replacement Surgery for Needy

FDA Ortho Panel to Review VertiFlex Spine Device

Sunshine Act Disclosures Off to Cloudy Start

European Regulators Take Second Look at Zimmer/Biomet

Zimmer Acquires ETEX and Joint Preservation Products

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: This market, which is whipsawing investors with triple-digit days, both up and down, can't seem to ease into the final quarter of the year. King dollar is the biggest question mark. On the positive side jobs data is moving in the right direction—which for orthopedic companies is very good news. Workers have insurance, insurance companies have rising premiums and, with costs coming down, demand for orthopedic implants rises with conviction.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Symmetry Medical	6.55	10.64%	Most analysts think SMA will nearly double earnings for the 3rd quarter. And, of course, there is the OEM divestiture.
2	1	Stryker	11.52%	(1.20)	In the last 30 days, two analysts have lowered their EPS estimates. The market is nervous about SYK's future earnings reports.
3	5	NuVasive	8.01	1.01	Upgraded by Brean Capital and we're hearing great reports from Eurospine.
4	6	Medtronic	28.84	1.10	Somehow or other, despite all the sturm and drag over tax inversion, MDT is determined to merge with Covidien.
5	4	Zimmer	29.12	2.26	EU throws a snag into the Biomet acquisition. Probably a small delay. Likely a divestiture of a division.
6	3	Integra LifeSciences	12.57	0.58	While most analysts are expecting sales to rise a respectable 9.20%, earnings are not expected to keep pace. Implies down margins.
7	7	Globus Medical	29.68	7.28	Again, this quarter looks like another in a growing string of upside earnings surprises for GMED. Why? Analysts keep underestimating these guys.
8	8	Exactech	10.26	(1.98)	Sixth best value in orthopedics and, if past quarters are any indication, will likely show a 5% rate of YOY sales growth.
9	10	Johnson & Johnson	26.58	1.32	Investors sold JNJ off in the last couple of weeks and brought the stock closer in line with reasonable valuations.
10	9	ConMed	10.51	(5.54)	This quarter will be the first one with the new board and management team. Analysts are pretty much standing on the sidelines waiting for performance.

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Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	LDR Holding Corp.	LDRH	\$31.25	\$811	13.84%
2	Symmetry Medical	SMA	\$10.09	\$379	10.64%
3	Alphatec Holdings	ATEC	\$1.64	\$161	8.61%
4	Globus Medical	GMED	\$19.89	\$1,877	7.28%
5	Tornier N.V.	TRNX	\$24.00	\$1,174	7.14%
6	CryoLife	CRY	\$10.58	\$295	4.24%
7	MiMedx Group	MDXG	\$7.30	\$772	3.55%
8	Zimmer Holdings	ZMH	\$102.59	\$17,369	2.26%
9	Wright Medical	WMGI	\$30.80	\$1,553	1.78%
10	Johnson & Johnson	JNJ	\$105.13	\$296,497	1.32%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	\$0.16	\$8	-55.83%
2	Aurora Spine	ASG	\$1.38	\$22	-29.04%
3	MicroPort Scientific	853	\$0.48	\$689	-16.53%
4	TiGenix	TIG.BR	\$0.70	\$112	-13.34%
5	Bacterin Intl Holdings	BONE	\$4.44	\$30	-11.38%
6	RTI Biologics Inc	RTIX	\$4.87	\$277	-9.31%
7	K2M Group Holdings	KTWO	\$14.00	\$520	-6.42%
8	Orthofix	OFIX	\$30.82	\$568	-6.07%
9	ConMed	CNMD	\$37.68	\$1,030	-5.54%
10	Smith & Nephew	SNN	\$82.91	\$14,817	-4.23%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	\$65.02	\$63,688	16.71
2	Globus Medical	GMED	\$19.89	\$1,877	16.88
3	Johnson & Johnson	JNJ	\$105.13	\$296,497	17.91
4	Zimmer Holdings	ZMH	\$102.59	\$17,369	18.39
5	Exactech	EXAC	\$23.26	\$320	19.19

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	\$30.82	\$568	257.11
2	NuVasive	NUVA	\$35.87	\$1,685	69.47
3	Symmetry Medical	SMA	\$10.09	\$379	52.08
4	CryoLife	CRY	\$10.58	\$295	31.78
5	Smith & Nephew	SNN	\$82.91	\$14,817	28.33

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	\$10.58	\$295	1.06
2	Exactech	EXAC	\$23.26	\$320	1.07
3	Globus Medical	GMED	\$19.89	\$1,877	1.26
4	ConMed	CNMD	\$37.68	\$1,030	1.64
5	Zimmer Holdings	ZMH	\$102.59	\$17,369	2.15

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$30.82	\$568	13.97
2	NuVasive	NUVA	\$35.87	\$1,685	5.68
3	Symmetry Medical	SMA	\$10.09	\$379	4.34
4	Smith & Nephew	SNN	\$82.91	\$14,817	2.80
5	Medtronic	MDT	\$65.02	\$63,688	2.57

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	\$0.16	\$8	0.38
2	Alphatec Holdings	ATEC	\$1.64	\$161	0.78
3	Bacterin Intl Holdings	BONE	\$4.44	\$30	0.87
4	Symmetry Medical	SMA	\$10.09	\$379	0.94
5	RTI Biologics Inc	RTIX	\$4.87	\$277	1.14

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.70	\$112	19.58
2	MiMedx Group	MDXG	\$7.30	\$772	9.74
3	LDR Holding Corp.	LDRH	\$31.25	\$811	7.27
4	Wright Medical	WMGI	\$30.80	\$1,553	5.78
5	Globus Medical	GMED	\$19.89	\$1,877	4.17

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

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FDA Abused Power, ReGen Biologics Exonerated

BY WALTER EISNER

In the biggest case challenging FDA regulatory authority of this young century, the FDA's power has been narrowed and ReGen Biologics Inc. has been vindicated over allegations that the company used improper political pressure to influence the FDA's 510(k) clearance of Menaflex, the company's collagen scaffold.

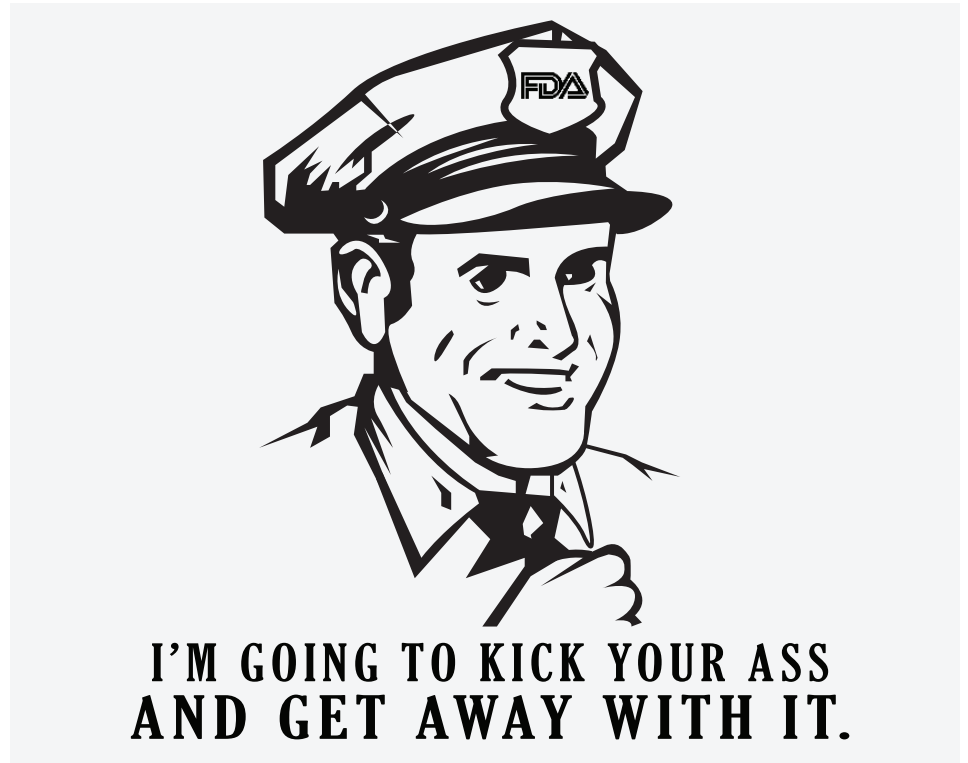
No Power of Rescission

On September 26, 2014, the U.S. Court of Appeals for the District of Columbia said the FDA cannot make up the power to rescind 510(k) clearances. They further said there is nothing wrong with asking congressional leaders to intervene on your behalf with government agencies. In fact, said the Court, it's the job of elected officials to advocate on behalf of their constituents.

The FDA had argued that because there was misconduct, they had a right to rescind. The Court didn't buy that saying, "FDA's inability or unwillingness to identify [any] wrongdoers is an indication that, in fact, no...misconduct occurred."

The Court ruled that the FDA went outside the law by rescinding the 510(k) clearance it had granted the company. If the FDA wants to change a device's classification, the agency should use its existing authority to reclassify a device and provide proper notice and opportunity for comment.

In short, the Court said the FDA can't grab power just because it's convenient and makes their job easier. "FDA obviously thinks notice and comment is unnecessary here, a not-uncommon



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sentiment among agencies that want to take action more promptly."

Safe and Effective?

While this is a big win for the industry, the fate of the company and patient access to the device is still in question. The FDA can still decide to reclassify the device and force the company to go through a PMA (pre-market approval) application process after already spending over \$30 million to get clearance.

That would be a shame because the Menaflex has already been through unprecedented two expert orthopedic panel meetings. Both panels agreed the device was as safe as its predicate, with one panel having some question over its effectiveness.

Industry Trade Group's "Potomac Syndrome"

Given that this is a big win for all medical device manufacturers we would expect the two industry trade groups, AdvaMed and MDMA (Medical Device Manufacturers Association), to cheer the decision. We contacted both trade groups for comment. AdvaMed said they would have no comment and the other didn't reply to us at all.

If the abuse of FDA's police powers in this case wasn't bad enough, both trade associations stood by as the FDA pummeled ReGen into bankruptcy. Clearly they did not see this as their fight or they saw no benefit in antagonizing the FDA with whom they need good relations to lobby on behalf of their



Courtesy of the associations

members. Maybe it's a kind of "Stockholm Syndrome" we should rename "Potomac Syndrome."

Failure to Protect and Promote

But back to the FDA's misdeeds.

It is the job of the agency to "protect" and "promote" public health. They failed on both accounts in this case by failing to get a safe device to patients who risk getting arthritis after a meniscectomy.

Kevin Stone, M.D., inventor of the device, filing the first patent in 1986, told us that the data is "overwhelming" that meniscectomy leads to arthritis. He added that repairing or regenerating the meniscus is the only method of restoring the normal mechanics of the knee.

He believes tens of thousands of patients were basically sentenced to years of arthritis pain because they did not have access to the device in the U.S. Patients in Europe and Asia have had access to the device ever since its introduction.

What does this all mean for getting new devices to patients?

Road to Redemption

Before we turn to Mark DuVal, a well-known private industry attorney, to answer that question, let's review the torturous road the FDA forced ReGen to travel for clearance as described in the Court's opinion. The story of that journey to clearance is a shameful tale of, at worst, willful abuse of power, and at best, bureaucratic ineptitude.

ReGen began commercialization efforts in 1993 for the device, a crescent shaped surgical mesh made of bovine collagen intended to reinforce and repair the knee cartilage remaining after knee surgery and to provide a scaffold on which new tissue could grow.



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In 2004, the company submitted a PMA. But then determining that the device was substantially equivalent to other meshes on the market, it quickly withdrew the PMA application in 2005 to seek 510(k) clearance.

FDA reviewers disagreed and issued a NSE (Not Substantially Equivalent) letter. The company came back in late 2006 with a revised label. Again the agency issued an NSE letter.

Substantial Equivalency Argument

The company ran out of administrative appeals and vehemently disagreed with staff that they believed were misapplying equivalency rules. (A later FDA report, co-authored by Jeff Shuren, M.D., JD, cited that its own lawyers agreed with the company.) So they went to their elected officials in Congress, who wrote to the FDA Commissioner

expressing concern over the procedure used by the agency.

The FDA, through Dan Schultz, M.D. the head of CDRH (Center for Devices and Radiological Health), then met with the company. He advised them to submit a new clearance request with additional revisions. The company did so in 2008. Again the review staff said, no.

At this point, Dr. Schultz decided to convene the agency's orthopedic panel of outside experts. The panel concluded in 2008 that the device was as safe and effective as the predicate. Dr. Schultz then issued a letter finding substantial equivalence.

FDA Goes Rogue

Then all hell broke loose. The Appeals Court noted that *The Wall Street Journal*

published an article alleging that political pressure had "skewed FDA's review process," and Senator Charles Grassley contacted the FDA raising concerns about ReGen's role in the process. Other members of Congress joined in.

Then, in April 2009, as ReGen was about to begin selling the device in the U.S., a group of FDA employees wrote a letter to President Obama accusing Dr. Schultz and the FDA Commissioner of improperly influencing the results of the agency's review.

Internal Investigation

The newly appointed Acting FDA Commissioner ordered an internal investigation and a report was issued on September 2009.

According to the Court, that FDA report identified "multiple departures

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*Burak M. Ozgur, MD FAANS, Eric Glaeckman, PA-C (2013) InFill® Lateral System: a novel technique for optimizing graft filling and endplate contact in lumbar interbody fusion surgery.

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from processes, procedures, and practices” that raised “serious questions about whether the integrity (as well as the quality) of the review process was compromised.”



Dr. Jeff Shuren

The report criticized ReGen’s access to high-level FDA officials, and those officials’ involvement in the decision making process; communications between members of Congress and the FDA

Commissioner; and ReGen’s level of involvement in the expert panel proceedings.

“Although the report stopped short of concluding that the review process had been compromised, it recommended reevaluation of Dr. Schultz’s decision to clear the Collagen Scaffold,” wrote the Court.

Shuren Replaces Schultz, Rescinds Clearance

Dr. Schultz suddenly resigned and a new team was appointed to review the device. Dr. Shuren took Schultz’s place as head of the CDRH.

Not surprisingly, the staff again concluded the device was not substantially equivalent and Dr. Shuren convened a second expert orthopedic panel. This

panel agreed with the first panel over the safety, but had some concerns about its effectiveness.

In October 2010, Dr. Shuren notified ReGen that the clearance “was in error” and an official rescission order followed in March 2011.

ReGen Fights Back

ReGen went bankrupt. However, institutional investors in the company kept the product alive and filed suit against the FDA, arguing the rescission was unlawful and that the FDA should have followed the reclassification route if it wanted to reclassify the device.

The U.S. District Court agreed with the FDA and ReGen, now called Ivy Sports Medicine, appealed. Ivy won the appeal on a 2-1 vote of the judges.

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Industry Impact

Mark DuVal says the FDA “again misjudged its strength and position... inventing its own rights is a common theme with this FDA Administration.”

He says the decision “provides a ray of hope that FDA cannot make-up-rules-as-they-go-along...just because the new administration has a differing scientific and regulatory opinion (and possibly another political agenda).”



Mark DuVal

The impact of this case, says DuVal, cannot be underestimated on a number of levels.

He says the FDA “not infrequently” exceeds its statutory and regulatory authority often granting to itself powers and interpretations of law and regulations well outside the scope of that actually given to them. “FDA has had its interpretations of law and regulations checked by such representative and famous cases as the Washington Legal Foundation case, the IMS Health case and the Caronia case, all First Amendment cases. “

It also lost the Utah Medical case as it relate to its authority to dictate specific CGMP/QSR requirements to a medical device manufacturer. In the Prevor case, DuVal says the court did not

agree with FDA’s interpretation of how to determine the definition of “primary mode of action” of a combination product. “And now we have the Ivy Sports/ReGen case.”

Keeping Vigilant

DuVal cites a number of current situations, including the agency’s attempt to introduce benefit-risk criteria into the 510(k) program in a July 15, 2014 proposed guidance. “The underlying benefit-risk of any device is presumed and has already been accepted in the decision to clear the predicate device. There is no need to make a benefit-risk determination in a 510(k), yet FDA has created it out of whole-cloth,” warns DuVal.

“We must continually keep the natural evolution of any bureaucracy in check because it will continually expand interpretations to grow its jurisdiction and authority and make the regulatory framework more complex and need more people to administer it. We often wonder if it is regulatory fiefdom-building or regulatory boredom, or both, that drives this need to create more, increasingly-complex rules. This in a great sense is what we fight when we fight these individual battles with FDA.”

Hopefully, says DuVal, the FDA will “rein in its thinking—but don’t count on it.” His pessimism is informed by the fact that going through the FDA appeals process can be futile because it typically upholds the decisions of its rank and file. The only

other alternative is to go to court, which is far too time-consuming and expensive.

“For that reason companies often take a more practical, yet painful, decision to roll over and acquiesce to the Agency’s (often incorrect or stretched) position,” added DuVal.

DuVal: “Return to Old-Fashioned Rulemaking”

He hopes that this is a clarion call for industry to request that Congress restricts the Agency’s “continued proliferation of guidance documents and return to old-fashioned, more thoughtful and deliberative rulemaking. At a minimum, we need to bolster the manner in which guidance documents are proposed and finalized. Otherwise industry simply falls victim to an agenda-driven agency that is drunk on its own perceived power.”

Hope for Patients

It’s bad enough when the cop on the beat whose sworn duty it is to “protect” and “promote” our welfare goes rogue and unlawfully beats up the smallest kid on the block, it’s equally bad when the bigger kids with a lot to gain and the ability to help, stand by and watch.

Let’s hope this is a clarion call for all involved. But more importantly, as Dr. Stone pointed out, let’s hope patients are given access to a device that can help them without leaving the country. ♦



Appeals Court decision

Myths and Facts About Orthopedic Surgeon Compensation

BY ROBIN YOUNG



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In medicine, one of the most divisive issues is compensation—not only its size but also its source.

Suppliers of medical devices, regulators and critics of surgeon compensation programs are all guilty of using compensation rates (and only compensation rates) to explain both good and bad physician behavior.

As if allowing physicians to earn fees for anything outside of patient care would adversely affect that care. No compensation for inventions. No compensation for administrative skills. No compensation for distribution skills.

How a physician earns a living is increasingly subject to regulatory and physician community review, criticism and even control.

Two announcements regarding orthopedic surgeon compensation—one on the last day of September and one a month

earlier—offer startling new information about orthopedic surgeon pay and how ineffective it is at delivering job satisfaction or even performance.

The first announcement was the release of the Medscape Physician Compensation Report for 2014 which looked at 25 physician specialties and ranked them in order of both compensation and job satisfaction.

The second announcement was CMS' (Centers for Medicare and Medicaid Services) release of the physician payment data base which had been collected as part of the Sunshine Act.

56% of Orthopedic Surgeons Would Not Go Back Into Medicine

Which physicians make the most money by specialty? Orthopedists. Which physicians are the second LEAST likely to choose medicine as a career? Orthopedists. (See the chart at the end of this article.)

Every year Medscape conducts a survey of 25 medical specialties and collects data regarding compensation and whether these top medical professionals would choose medicine as a career again.

The results are startling and unexpected.

At an average annual compensation of \$413,000, orthopedic surgeons beat out their colleagues in cardiology, urology, gastroenterology and 21 other specialties as the highest paid specialty physicians in medicine.

But, when it comes to who would choose medicine again, the internal medicine physicians are the most satisfied with their career choice (despite a “mere” \$188,000 average annual rate of pay).

Only plastic surgeons are less happy than orthopedic surgeons (at \$321,000 in annual pay). Out of 25 specialties, orthopedic surgeons rank 24th in terms of the percentage who would choose medicine again as a career.

Fifty-six percent of orthopedic doctors would not go back into medicine.

The survey by Medscape showed that doctors in seven of the ten lowest paid specialties were among the top ten MOST likely to select medicine as a career.

Why?

Perhaps one explanation for the counter-intuitive Medscape survey results is that the highest paid physicians are also

the group most targeted by regulators, watch-dog groups and even, more often than might be expected, their own colleagues.

Scientists who study human behavior and the effects of compensation on job performance, happiness or motivation have been saying for literally decades that money is a notably weak and flawed motivator of human behavior.

Scientific studies of pay and work behavior show unequivocally that the connection between pay rates and behavior is not cause and effect.

What the Scientists Say

Dr. Timothy Judge, business professor at the University of Florida and his

colleagues from Rollins College, University of Arizona, Jacksonville University and California State University San Marcos reviewed 120 years of research from 92 quantitative studies reviewing 15,000 individuals and 115 correlation coefficients found that the association between salary and job satisfaction is very weak.

The reported correlation ($r = .14$) indicated that there is **less than 2% overlap between pay and job satisfaction levels.**

Even worse, the correlation between pay and pay satisfaction was only marginally higher ($r = .22$ or 4.8% overlap), indicating that people's satisfaction with their salary is mostly independent of their actual salary.

When these same researchers looked at group-level (or between-sample) comparisons—similar to the Medscape survey—they found that “Employees earning salaries in the top half of our data range reported similar levels of job satisfaction to those employees earning salaries in the bottom-half of our data range” (p.162).

Another survey, this time from the Gallup Polling organization, reported no significant difference in employee engagement by pay level. These results were based on 1.4 million employees from 192 organizations across 49 industries and 34 nations.

The most famous study, now a classic piece of research in employment and labor science, was carried out by Dr.

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Edward Deci and his colleagues. The scientists analyzed results from 128 controlled experiments.

They found that pay type of incentives—whether marshmallows or dollars—reduced intrinsic motivation. The researchers found that for every standard deviation increase in reward, intrinsic motivation for interesting tasks *decreased* by about 25%.

When rewards are tangible and foreseeable (if subjects know in advance how much extra money they will receive) intrinsic motivation decreases by 36%!

Another recent study, this one by Yoon Jik Cho and James Perry (Yonsei University in Seoul and Indiana University in Bloomington) looked at over 200,000 U.S. public sector employees and documented that employee engagement levels were three times more strongly relat-

ed to intrinsic than extrinsic motives.

They also found that employees who are intrinsically motivated are three times more engaged than employees who are extrinsically motivated (such as by money).

The fact is: money is one of the least effective motivators for job performance and there is strong evidence that it will demotivate.

And here's the irony. Despite the abundance of research, companies, regulators and even physicians themselves still hold to this notion that compensation rates will affect physician behavior.

Not so. The keys to physician behavior—including device utilization, medical decision making and so forth—are such intrinsic factors as autonomy, respect and power—all of which are

under attack in this compensation debate.

\$3.5 Billion Paid to Surgeons

And then this headline came out on September 30, 2014.

As most medical device companies know, they are required to document all payments to physicians—even as little as \$10—and submit that data to CMS as part of the agency's ongoing effort to increase transparency and accountability in health care.

The data program, called Open Payments, was created by the Affordable Care Act. It collects consulting fees, research grants, travel reimbursements, and other payments which medical device manufacturers and pharmaceutical companies make to physicians and teaching hospitals.



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This first round of data was just released and it detailed 4.4 million payments from companies to 546,000 individual and almost 1,360 teaching hospitals and covered, essentially, 5 months of payments.

This data will be released on an annual basis and starting with the June 2015 report, will have 12 months of data.

“CMS is committed to transparency and this is an opportunity for the public to learn about the relationships among health care providers, and pharmaceutical and device companies,” CMS Administrator Marilyn Tavenner said. “This initial public posting of data is only the first phase of the Open Payments program. In coming weeks, we will be adding additional data and tools that

will give consumers, researchers, and others a detailed look into this industry and its financial arrangements.”

The agency was careful to say that these payments from medical manufacturers’ payments and health care providers do not necessarily signal wrongdoing. While the agency would like to discourage inappropriate relationships it does not want to harm beneficial ones.

So CMS is working closely with companies and physician groups to better understand the current scope of the interactions among physicians, teaching hospitals, and industry manufacturers. CMS encourages patients to discuss these relationships with their health care providers.

Manufacturers submitted data to CMS this summer and CMS performed initial matching to aggregate payments to a single physician or teaching hospital. After the data were collected and displayed, registered physicians and teaching hospitals had the opportunity to review payments reported about them and dispute information they believed inaccurate.

More than 26,000 physicians and 400 teaching hospitals registered in the Open Payments system to review payments attributed to them.

Because of questions about the accuracy of the data, about 40% of the records published were de-identified. The data, however, will be fully identifiable in 2015 after the reporting entity

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submits corrected data, and physicians and teaching hospitals have a chance to review and dispute.

Over time, CMS expects to make enhancements such as introducing new tools to allow for easier data searches. This improved search functionality will allow users to more easily review payments received by their personal physician, or search on criteria such as specialty, location, or types of payments received.

The data is available for public review at: <http://www.cms.gov/openpayments/index.html>

Beatings Will Continue Until Morale Improves

The divisiveness over physician compensation will continue as long as everyone at the “healthcare table,” except the physician, is expected to act in their own best financial interest.

We learned from CMS, \$3.5 billion has now been paid to physicians by companies over a 5 month period. The agency added charitably in their press release that the fact of a payment is not necessarily evidence of “wrongdoing.”

True.

In fact it isn’t evidence of anything... except possibly the fact that they just don’t get the role of compensation in the lives of today’s physician. ♦

Medscape’s Salary Review Table

Compensation by Specialty			Percentage Who Would Choose Medicine Again as a Career		
1	Orthopedics	\$413,000	1	Internal Medicine	68%
2	Cardiology	\$351,000	2	Family Medicine	67%
3	Urology	\$348,000	3	HIV/ID	67%
4	Gastroenterology	\$348,000	4	Pulmonary Medicine	63%
5	Radiology	\$340,000	5	Pediatrics	63%
6	Anesthesiology	\$338,000	6	Emergency Medicine	61%
7	Plastic Surgery	\$321,000	7	Rheumatology	61%
8	Dermatology	\$308,000	8	OB/GYN Women’s Health	60%
9	General Surgery	\$295,000	9	Psychiatry and mental health	60%
10	Ophthalmology	\$291,000	10	Nephrology	59%
11	Oncology	\$290,000	11	Oncology	58%
12	Critical Care	\$281,000	12	Critical Care	58%
13	Emergency Medicine	\$272,000	13	Diabetes and Endocrinology	57%
14	Pulmonary Medicine	\$258,000	14	Ophthalmology	56%
15	OB/GYN Women’s Health	\$243,000	15	Neurology	56%
16	Nephrology	\$242,000	16	Cardiology	55%
17	Pathology	\$239,000	17	Urology	55%
18	Neurology	\$219,000	18	Dermatology	53%
19	Rheumatology	\$214,000	19	Gastroenterology	51%
20	Psychiatry	\$197,000	20	Pathology	50%
21	Internal Medicine	\$188,000	21	General Surgery	48%
22	Diabetes, Endocrinology	\$184,000	22	Anesthesiology	47%
23	Pediatrics	\$181,000	23	Radiology	45%
24	Family Medicine	\$176,000	24	Orthopedics	44%
25	HIV/ID	\$174,000	25	Plastic Surgery	41%

Three Reasons Surgeons Make Poor Decisions // New Study: Academic Medical Centers Discriminate Against Medicaid Patients // Massive New Study: These Popular New Devices DID NOT Improve Outcomes

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Three Reasons Surgeons Make Poor Decisions James G. Wright, M.D., M.P.H., surgeon-in-chief at the Hospital for Sick Children in Toronto, is responsible for six surgical divisions. He has had ample opportunity to study and closely observe how surgeons come to a decision. His conclusion? There is a lot happening at the subconscious level. Dr. Wright, an orthopedic surgeon, tells *OTW*, “Most of us assume that because we are doing evidence-based medicine that the evidence will actually be used. This is not necessarily so, however, because the surgeon’s decision making process intervenes.”



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“There appear to be three issues which come to bear when surgeons are trying to make a decision. The first is that surgeons come to relatively firm decisions and aren’t good at integrating new information. We are rather entrenched in our ways of thinking and despite new information/variations on what we know, we have trouble changing mindsets. Let’s say someone comes up with a great answer to an issue—something that should solve a controversy. The researcher publishes his or her work and promotes it through talks. We still see a slow uptake in the actual use of that information. I am pleased with what we are doing with evidence based orthopedics, but I don’t think we have considered the logical outplay of that, which is behavior change.”

“The second issue involves decision making at work. We did a ‘secret shop-

per’ study where we sent blinded total knee replacement patients into surgeons and family physicians’ offices. The result? Both types of doctors were more likely to recommend knee replacement to men than to women. The most likely explanation is that doctors form unconscious biases. When we asked these physicians if they treat men and women differently, they answered ‘No!’ But we know from employment research that when people go to job interviews those who are tall, more physically attractive, etc., fare better. These ubiquitous biases subtly influence behavior...and this is highly underappreciated.”

“The unconscious thought process likely went something like this: ‘Women come to arthroplasty later in the course of the disease and people who have

arthroplasty later don’t bounce back to normal.’ Surely doctors would prefer having someone come in saying, ‘I feel fantastic’ versus, ‘I’m not sure that surgery helped so much.’”

“The third issue involves ‘confirmation bias’ wherein people grasp onto information that substantiates their views and discount any evidence that isn’t consistent with their views. For example, we looked at two forms of spinal instrumentation for idiopathic scoliosis. The surgeons had an explicit preference for one form of instrumentation (both before and after the trial). Afterwards we found no difference between the two forms of instrumentation in any aspect of what we thought should be affecting surgeons’ decision making. The surgeons found many reasons

to discount the information we shared with them and persisted in using the instrumentation despite the neutral finding.”

“In another study we surveyed orthopedic surgeons and asked, ‘How do you make decisions involving a total knee surgery?’ We found a significant difference between the surgeons; when we repeated the survey 10 years later we found *no difference* in the variations in opinions of orthopedic surgeons. The upshot is that they actually disagreed with themselves!”

“We really need strategies to minimize these variations. On the grand horizon is the issue of behavior change. For that, we will be working with psychologists.”

Study: Academic Medical Centers Put Medicaid Patients Behind Private Pay Patients Does it matter how crowded of an area a Medicaid patient lives in? Does the service they are ren-

dered differ if they are near an academic medical center? Reid Draeger, M.D. and colleagues set out to find answers to these questions. Dr. Draeger, an assistant professor at the University of North Carolina Chapel Hill School of Medicine, told *OTW*, “We conducted a series of research projects on this topic. Initially we looked at whether an appointment was offered to Medicaid versus privately-insured patients for acute rotator cuff tears, acute lumbar disk herniations, and flexor tendon lacerations. We found that Medicaid patients were less likely to get a timely appointment than privately insured patients for these scenarios.”

“In our latest study, just published in the *Journal of Bone and Joint Surgery*, we wanted to see the effect of geography and population density on whether or not a Medicaid patient was offered an outpatient orthopedic appointment. Our state, North Carolina, is similar in population density to many other

states; there are only a couple of academic medical centers and they are in high population density areas. Using the ‘secret shopper’ model from previous studies by our group, we called 203 orthopedic practices to see whether or not they would offer an appointment to a hypothetical patient using various patient scenarios—acute flexor tendon lacerations, acute rotator cuff tears, and acute lumbar disk herniations. We found that 119 practices offered the Medicaid patient an appointment within two weeks, and 160 offered the privately-insured patient an appointment within that same time period.”

“Patients with Medicaid were more likely to get an appointment if they were further away from an academic medical center or in a less-populated area. This result is in line with the literature coming out of the primary care field, but at odds with limited data that has been published in surgical subspecialty fields. We’re not entirely sure why we

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got this result, but we hypothesize that around these densely populated areas (where academic medical centers are located) there are more patients vying for appointments. So perhaps, the clinics can have stricter insurance profile guidelines as to whom they accept.”

“We were expecting the converse, i.e., that clinics further away from densely populated areas would have less expertise to care for some of these problems and would refer them to academic medical centers. There is likely an ethical issue here: are you going to make a patient drive four hours for something that could be done in their neighborhood simply based on insurance status?”

“Going forward we would like to look at this issue after the full implementation of the Affordable Care Act and compare our current results to those obtained in a similar fashion in five years. That would allow us to see if the patterns

of appointment offerings change. My guess is that with a much larger patient volume being insured by Medicaid through its expansion by the Affordable Care Act, more practices will offer Medicaid patients appointments in the future.”

“Studies like ours are important to hopefully help to establish baseline data on access to orthopedic care for Medicaid patients. These data could be used on a policy level to help ensure that future policies do not further impede access to orthopedic care for these patients.”

Most New Devices Not Better After All?

In reviewing 118 studies and 15,384 implants, researchers from the Netherlands found that none of five new devices reviewed improved functional or patient reported outcomes and that existing devices may be safer to use. What are we doing wrong as a field? Marc Nieuwenhuijse, M.D., an orthopedic resident at the Leiden University

Medical Center and ICOR research fellow, tells *OTW*, “Changes in the way of introduction of new orthopedic implants into the commercial market are necessary. The introduction of new orthopedic implants and related technologies has been the focus of major scientific and policy discussions since the failures of articular surface replacement and large head size metal-on-metal articulations in total hip replacement were brought to light. However, scientists and policy makers seem to ‘run out of steam,’ and the momentum for change generated by these recent high profile failures is waning.”

“The consequences of uncontrolled device introduction worldwide may not be fully recognized by the scientific community and there is a high likelihood that current practice regarding device innovations will not change much. As such, there is a need to investigate whether the problems associated with the articular surface replacement

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and large head size metal-on-metal articulation are isolated events or if there is a systemic problem affecting the introduction of a much wider range of implantable devices.”

“In this study, we evaluate the evidence concerning the introduction of five substantial, innovative, relatively recent, and already widely implemented device technologies used in major total joint replacement to determine the evidence of effectiveness and safety for introduction of five recent and ostensibly high value implantable devices in major joint replacement to illustrate the need for change and inform guidance on evidence-based introduction of new implants into healthcare.”

“I was surprised at the widespread usage of these innovations without either substantial research or convincing evidence of their benefit over existing alternative device solutions for the same conditions. Recent large scale failures of the articular surface replacement and large head size metal-on-metal articulations in total hip replacement have taught us that incremental device innovations can have a large impact on implant survival and patient safety. Since none of the five selected device innovations were safer than earlier alternative devices, we believe improved regulation and professional society oversight are necessary to prevent patients from being further exposed to these and future innovations introduced without proper evidence of improved clinical efficacy and safety. The clinical introduction of implants should follow a stepwise and controlled model preventing exposure of large numbers of patients to potentially inferior new devices.”

“Improved regulation and professional society oversight are necessary to prevent adverse events. We need to find a balance between being too careful and waiting until all of the results are available. The way to do this would be to

focus our research on new methods for early evaluation of implant performance. For example, I did research on radiostereometry that allowed for measurement with a high degree of accuracy (to a few tenths of a millimeter). This has predictive value for future loosening of implants. Additionally, improved surveillance through the International Consortium of Orthopedic Registries

should be undertaken. Their goal of combining all registries worldwide would lead to more accurate information. For now, we suggest adherence to the IDEAL recommendations and a critical point of view regarding evidence for efficacy and safety when considering adopting new implants.” ♦

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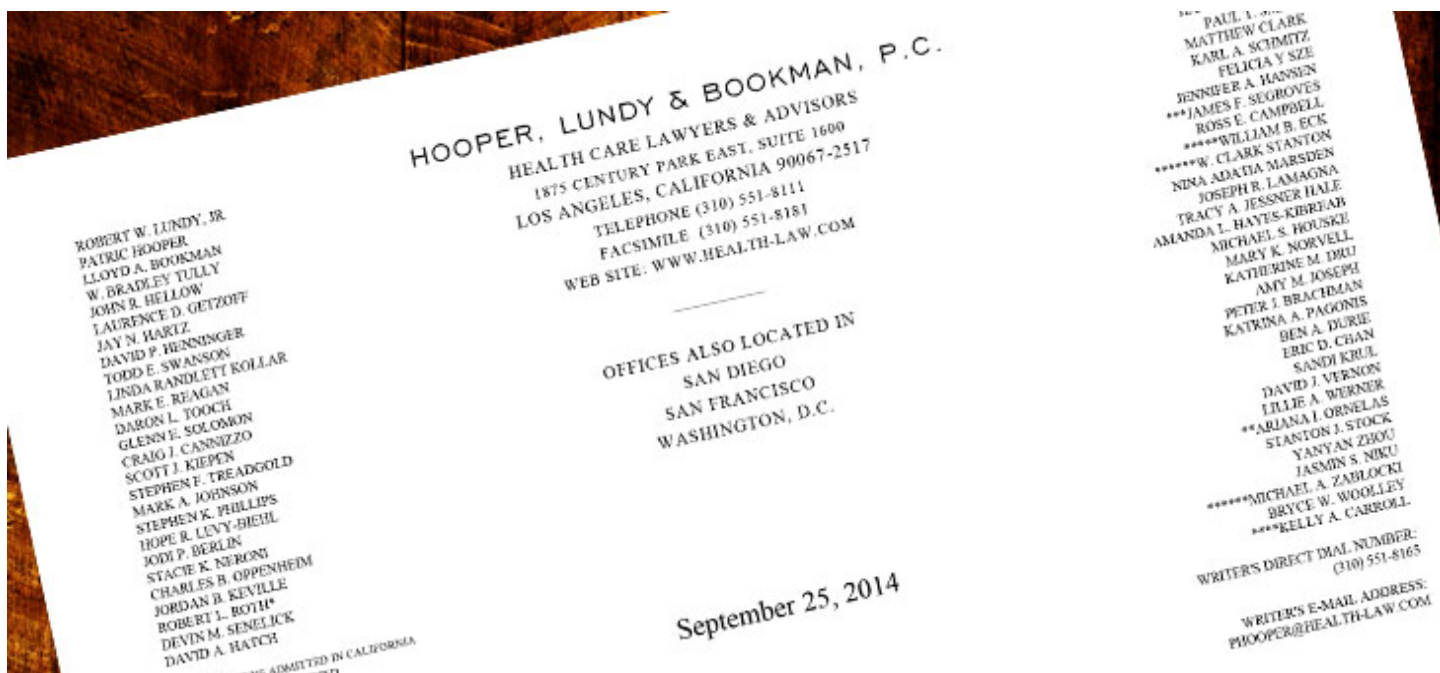
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POD Lawyer to Feds: “Show Us the Evidence”

BY WALTER EISNER



Patric Hooper – Hooper, Lundy and Bookman, P.C.

The lawyers on opposite sides of the federal POD (physician-owned distributor) prosecution are getting fired up and going public.

Orthopedics This Week obtained the latest salvo of fire from Patric Hooper, the defense attorney for Reliance Medical and its PODs, to the feds over his “threat” to seek sanctions against the government over their refusal to turn over an alleged secretly conversation recorded in July 2011 between his clients and potential physician investors for their PODs.

Hooper beat the U.S. Department of Justice Department (DOJ) in 1995 when the agency tried to impose the Medicare

“Death Penalty” on physicians referring patients to labs they owned. The DOJ has been looking for a case ever since to get even. They found it in PODs, and once again Hooper is the attorney for the defense.

Hooper’s latest fight with the feds over physician ownership in the business of health went public and viral on September 25, 2014, when *CBS Morning News* sensationalized the death of a patient who had received spinal implants from a POD in which the surgeon had an ownership interest.

Click here to see the CBS Program: <http://www.cbsnews.com/news/federal-prosecutors-target-physician->

[owned-companies-that-profit-from-unnecessary-procedures/](#)

Hooper, citing a famous terrorist case, says even “enemy combatants” are entitled to due process rights. He says the government has been “persecuting” his clients ever since details of their investigation were leaked anonymously to the press. The former Deputy Attorney General of the State of California reminded the federal lawyers that, “we are required to do justice as opposed to trying to win a case at any cost.”

Get deep inside this latest fight over PODs.



September 25, 2014

VIA EMAIL

David M. Finkelstein
Arthur S. Di Dio
United States Department of Justice
601 D Street, NW
Washington D.C. 20004

Re: United States v. Reliance Medical Systems, et al.

Dear David and Arthur:

Thank you for your letter today in response to my email of September 22 that you characterize as being a “[threat] to seek sanctions against the United States.” You further state “this threat is part of a pattern of troubling conduct that began almost immediately after” I was retained in July 2014. You then discuss what you believe to be “a pattern of baseless accusations” by me. Before responding to these charges, let me please provide some context once again to the current situation.

Perhaps you had the opportunity to view today’s episode of “CBS This Morning” in which DOJ’s lawsuit against my clients is highlighted to a national TV audience. This publication and many others,

Letter continued on page 20...

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including articles in the Wall Street Journal and health industry media, and radio broadcasts, completely demonize my clients based in large part, if not wholly, on the allegations published by DOJ in its recent press release and in the body of the complaint in this case. The alleged tape recorded conversations of July 2011 and your characterization of their contents provide the primary fodder for the media's woefully inaccurate "description" of my clients and their conduct.

As you know, the media crusade against my clients did not begin with the filing of your lawsuit. Rather, the persecution began once your investigation started and was fueled by leaks to the media regarding the investigation. Moreover, as you obviously know, the conducting of the investigation, itself, was extremely detrimental to the reputation of my clients and their ability to earn a living and pursue an occupation. It requires no speculation to conclude that when a hospital or a doctor learns that DOJ is investigating someone who is engaged in doing business with the hospital or doctor, the hospital or doctor will be inclined to terminate the relationship to avoid being tainted by the investigation. This is especially so when counsel for DOJ essentially tell the hospitals that my clients' activities are illegal.

Here, since the filing of the action and well before then, hospitals and doctors have stopped doing business with my clients for fear of retribution and retaliation by DOJ and damage to their own reputations. Not surprisingly, my clients' competitors and some self-proclaimed medical "ethicists" are quite pleased by this result. The bad facts being bantered about also sell more newspapers than a more nuanced and truthful story. My clients have become pariahs in the health care industry due solely to your investigation and the charges you have made against them.

As you know, I am very familiar with the Federal Rules of Civil Procedure to which you refer in your letter regarding discovery and other procedural aspects of False Claims Act cases and are obviously prepared to proceed pursuant to such rules. However, as lawyers, especially government lawyers (and I was one many years ago), we are required to do justice as opposed to trying to win a case at any costs. Also, as you know, Constitutional provisions trump the Federal Rules of Procedure.

Here, fundamental fairness and due process of the law require that my clients be given timely notice of the evidence against them. DOJ has now possessed and selectively used the July 2011 tape recordings against my clients for more than three years. In fact, you used your characterization of their content to question my clients extensively about them under oath in March 2013 without ever giving them copies or even a transcript to review before, during, or after their testimony.

Now, your one-sided and agenda-driven characterization of their content is included in the juiciest parts of your complaint – the parts that were obviously intended primarily for the media's consumption and publication. Yet, you still refuse to make the recordings available to me under any circumstances and instead argue that I will get them in due course under the Federal Rules of Civil Procedure – i.e., months from now – even though my clients' liberty and property interests are continuing to be damaged and have been damaged for some time now.

I am certain you must know that Due Process of the Law prohibits the government from depriving a person of property or liberty absent timely notice and an opportunity to be heard regarding charges of the type here. DOJ's contentions based on the tapes have been destroying my clients' businesses and reputations for a long time now without the content being made known to my clients. Even "enemy combatants" are entitled to due process rights greater than that which have been given my clients under the circumstances here. See *Hamdi v. Rumsfeld*, 542 U.S. 507 (2004) where the Court determined the

rights of enemy combatants under Due Process Clause of the Fifth Amendment, among other laws. We once again demand to see the tapes immediately.¹

As to my “baseless accusations,” please let me remind you that my earlier speculation was correct about the pendency of a *qui tam* action even though I was mistaken about the relator. Moreover, it is apparent that you did not need any further information from my clients in July 2014 to complete your investigation confirming that my position rejecting your request for information (in addition to the 168,000 pages of documents already produced) was correct.

As to the allegations in paragraph 91 of the complaint, please produce the evidence in your possession that you contend supports them since my clients deny the truth of the allegations. I am trying to avoid filing a Rule 11 motion. Finally, I continue to stand by my other “accusations.”²

Very truly yours,

Patric Hooper

PH/PH

Jonathan Frank (via email)

¹As you know, under California Law, Penal Code Section 632 and others, tape recording a confidential conversation without the consent of all parties is a crime, and the content of such a recording is inadmissible in any court proceeding. We know there is an exception for law enforcement and assume that there was duly authorized involvement of law enforcement here but are beginning to question that assumption in light of your continued withholding of the tape recordings.

²I abide by the Central District’s “Civility and Professionalism Guidelines.” In my opinion ex parte discussions with other counsel in this case, such as your recent discussion with Mr. Frank, and your refusal to disclose the tape recordings until the federal rules purportedly require them to be disclosed are inconsistent with these guidelines.

COMPANY

Zimmer Acquires ETEX and Joint Preservation Products

Zimmer Holdings, Inc. has gotten its hands on breakthrough technology in biomimetic calcium phosphate, which mimics the chemical and structural features of human bone, promotes natural bone regeneration.

On October 1, 2014, the company announced it was acquiring Cambridge, Massachusetts-based ETEX Holdings, Incorporated. ETEX was founded in 1989 by Harvard Dental School researcher Dosuk Lee.

According to our friends at *Mass Device*, ETEX has not disclosed outside funding since 2005, when it booked nearly \$5 million. That year, an arbitrator ordered Medtronic, Inc. to pay ETEX \$50.2 million, ruling that Medtronic improperly canceled a deal following an assessment of a bone graft product ETEX had been developing.

ETEX Products

The financial terms of the transaction were not disclosed. According to a company press release, the acquisition “enhances Zimmer’s Biologics portfolio of differentiated treatments through the addition of ETEX’s Beta-bsm (injectable), CarriGen, EquivaBone (including DBM[demineralized bone matrix]), and Gamma-bsm (putty) bone void filler products.”

Joseph Cucolo, president of Zimmer Americas, said Zimmer is committed to developing the most comprehensive range of biologic

therapies in musculoskeletal care. As proof, he cites intervention solutions like Gel-One cross-linked hyaluronate and joint preservation solutions like Zimmer Knee Creations Subchondroplasty Procedure, along with Zimmer’s Chondrofix Osteochondral Allograft and Denovo NT Natural Tissue Graft personalized cartilage solutions.

Joint Preservation Business

More and more it looks like Zimmer is in the joint preservation business, as the former company’s Chief Science Office Cheryl Blanchard, Ph.D. once told us. “ETEX’s innovative bone substitute material products add more depth to a growing portfolio of solutions for the early stages of joint disease,” added Cucolo.

It was reported in July 2010 that ETEX signed a distribution deal with Stryker Corp. for a pair of its private-label bone graft substitute products. The non-exclusive distribution deal was for Stryker’s spine division to market and sell ETEX’s Bio MatrX Structure and Bio MatrX Generate products. Both products incorporated ETEX’s nanocrystalline calcium phosphate bone putty. — WE



Zimmer

NuVasive Opens Center of Excellence in Amsterdam

In conjunction with its appearance at Eurospine 2014 in Lyon, France, NuVasive, Inc. is the opening of the company’s European Center of Excellence (COE) in Amsterdam.



NuVasive, Inc.

According to the October 1, 2014 news release, “The center will serve as NuVasive’s European commercial headquarters and function as the commercial hub for the European executive leadership and departments across marketing, surgeon education, sales, human resources, legal and other support functions. Meanwhile, the International Operations Center in Ireland, which was established in June, will remain the company’s international operational headquarters.”

Paul Kusters, senior vice president of the EMEA (Europe, the Middle East and Africa) branch said in the news release, “The opening of the COE is an important milestone for NuVasive and a key inflection point for our Company’s strategy to expand in EMEA. In the past year, we have expanded our footprint to include Spain and Poland. Additionally, we continued to build out our world-class leadership team in EMEA with the recent appointment of Phil Bradshaw as Managing Director for the United Kingdom. Phil brings nearly 20 years of experience in the medical device industry, including a decade with

DePuy Synthes and most recently with Stryker. Phil's extensive experience in various markets across Europe will be highly complementary as we continue to execute against our market share-taking strategy."

Kosters told *OTW*, "Our initiatives in both Spain and Poland are focused on expanding our footprint in these important markets and establishing a sales and distribution network."

Regarding the COE, Kosters commented, "The Center of Excellence in Amsterdam will function as a European management office for corporate functions and as a surgeon Education Center. The COE will better position us to realize our vision of serving the needs of patients and surgeons in Europe while also driving innovation in minimally disruptive surgical products and procedures throughout the region. We will also pursue our commitment to surgeon education and plan to train surgeons through workshops on Minimal Invasive (Maximal Access) surgery through cadaveric courses and workshops." — *EH*

NASA and AlloSource Partner for Microbe Study

The National Aeronautics and Space Administration (NASA) and a company providing bone and soft tissue allografts for use in surgical procedures would seem to be strange—if not incompatible—bedfellows. But that is not the case.

Thanks to match-making by the Colorado Association for Manufacturing and Technology (CAMT)—now called Manufacturer's Edge—AlloSource and NASA have become partners. AlloSource, one of the nation's largest pro-

viders of skin, bone and soft tissue allografts for use in surgical procedures, will leverage technologies developed by NASA for assembly and launch operations of various Mars missions—specifically focused on rapid molecular microbial burden measurement and genetic inventory cataloging.

"Working with NASA and the Jet Propulsion Laboratory (JPL) is an amazing achievement for AlloSource and we are grateful for Manufacturer's Edge's assistance in facilitating this relationship," said Thomas Cycyota, AlloSource president and CEO. "We are committed to researching and developing new processes that allow us to continue to maximize the gift of human tissue donation."

As AlloSource officials explain, in order for tissue to be safe and suitable for transplant, company technicians conduct a program of intense, specialized scientific testing. Tissue is subjected to microbiological testing at recovery and must be free of specific microorganisms and contaminants that would preclude tissue from processing or transplantation. They also conduct additional post-processing testing before the tissue is transplantable. This is similar to what NASA and JPL will also do.

JPL is a division of the California Institute of Technology, and is also the NASA

center that manages the Curiosity Rover mission. The work focuses on assessing a local region on the surface of Mars that could be a potential habitat for past life. The partnership will enable NASA, JPL and AlloSource to share ideas and processes related to microbiological testing methods and they will look for new ways to rapidly detect the presence of microorganisms.

The molecular microbial detection technology used in the rigorous pre- and post-mission testing of the Mars mission spacecraft components provides an opportunity for AlloSource to evolve its own microbial testing.

"This creative collaboration shows the value of connecting NASA's cutting-edge space program technology with AlloSource's tissue testing methods. We are delighted to help AlloSource connect with NASA and JPL and improve lives in this way," said Tom Bugnitz, CEO of Manufacturer's Edge (formerly CAMT). — *BY*



Courtesy of AlloSource



Courtesy NASA/JPL-Caltech

LEGAL

European Regulators Take Second Look at Zimmer/Biomet

European Union (EU) antitrust regulators are opening an in-depth investigation into the Zimmer Holdings, Inc. /Biomet, Inc. merger.

Reuters, quoting “unnamed people,” reported on October 2, 2014 that the European Commission, which has been reviewing the deal since August, will open the “in-depth investigation” because of concerns that the deal may reduce competition. The Commission had set a deadline of October 3, 2014 to make a decision about approving the merger or digging deeper.

Unicompartmental Knees and Shoulder Divestitures?

Wells Fargo analyst Larry Biegelsen said that if the report is true, then the review will extend into January 2015 according to his legal consultant, but is still likely to be resolved through divestitures in the consultant’s view. A second phase investigation, similar to issuance of the early July second request made by the U.S. Federal Trade Commission (FTC) would extend the review for 90 working days (18 weeks plus holidays).

The likely areas of divestiture, according to Biegelsen, are unicompartmental knees and shoulders, given the high combined market share.

Biegelsen points out that the EU anti-trust regulators also launched an in-depth investigation into the JNJ/Synthes merger on November 3, 2011, and that deal was cleared on April 19, 2012 after JNJ agreed to divest its trauma business to Biomet.



Staff Sgt. Alesia Goosic and wikimedia commons

EU/FTC Coordination

BofA Merrill Lynch analyst Bob Hopkins said that regarding the U.S. timelines, “based on past experience, generally if things go well,” a second request may only take three months to turn, but

that four to five months is more the norm.

“The possibility remains that the FTC could comment soon, but our conversations with FTC experts suggest FTC and EU regulators will likely coordinate the investigation to the extent permissible in order to reach agreement on any potential conditions placed on the deal. Coordination

between the U.S. and EU could potentially push out the FTC ruling into early next year,” writes Hopkins.

Both analysts believe the deal is still on track. — WE

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LARGE JOINTS

Free Joint Replacement Surgery for Needy

Christmas will arrive early for a few joint replacement patients who will get their surgery free of charge at Franklin Hospital in Valley Stream or Lenox Hill Hospital in Manhattan. The two hospitals will provide the operations for a few needy patients who are either uninsured or underinsured. Both hospitals are part of the North Shore-LIJ Health System. Giles Scuderi, M.D., vice president of North Shore-LIJ's orthopedic services, will perform surgeries at Franklin. He has been offering the free service since 2011.

The program, which is organized under the auspices of Operation Walk USA, is

an independent medical humanitarian organization that provides free hip or knee replacement surgeries to patients in the U.S. Operation Walk serves patients who do not qualify for government assistance programs and cannot afford surgery on their own.

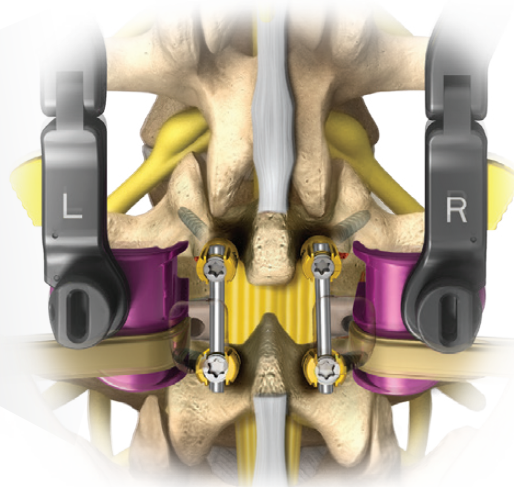
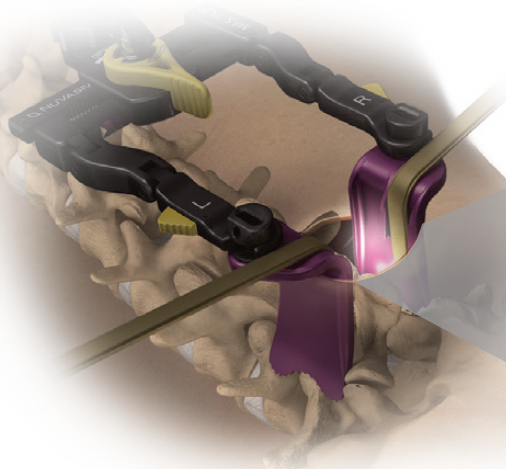
In just the three years since founding, this program has attracted the volunteer support of more than 140 dedicated orthopedic surgeons who, once a year during the first week of December, donate their time and skills to restoring the mobility, self-dignity and productivity for those among us who can't afford large joint surgery.

In 2010, when Operation Walk USA was

founded, only 9 hospitals in 9 states with 15 surgeons participated. The number of patients served that first year was 44. Which may sound small, but for each of those patients it was life-changing. In terms of the economic value of that gift, those physicians and hospitals donated an astounding \$1.2 million worth of time and expertise.



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Last year, the numbers literally exploded. In 2013, 32 states (triple in 3 years), 70 hospitals and 140 surgeons (10x !!) treated 203 patients.

Since 2010, Operation Walk USA has given back to the broader community an absolutely astonishing \$13.3 million dollars in pro-bono medical services and brought life and dignity back to 492 patients.

Rock on!

To volunteer—and we hope you will—please check this great organization out at www.opwalkusa.com. — *BY*

EXTREMITIES

Rotation Medical Commences Study on Rotator Cuff Tendon Tears

Rotation Medical has officially begun a multi-center post-market clinical study evaluating the use of the Rotation Medical rotator cuff system in treating

supraspinatus rotator cuff tendon tears. Involved in the study on this 510(k) cleared device are Ted Schlegel, M.D., from Steadman Hawkins Clinic, Jeffrey Abrams, M.D., from Princeton Orthopaedic Associates and Timothy Codd, M.D., from Towson Orthopaedic Associates/University of Maryland Medical System, among others.

“We are pleased to conduct this important research with these well respected and accomplished thought leaders,” said Martha Shadan, CEO and president of Rotation Medical, in the September 15, 2014 news release. “The information that we gain from this post-market clinical trial will expand the body of evidence documenting the value of the Rotation Medical technology and advance our mission to provide relief for patients by reversing rotator cuff disease progression and restoring long-term shoulder function.”

Patients will be implanted with the company’s bioinductive implant and will be assessed as for tendon healing and growth of new tendinous tissue. Each participant will have an MRI to assess post-operative changes in ten-

don thickness, tendon quality, and tear size. According to the news release, “Researchers will also evaluate shoulder function using the American Shoulder & Elbow Surgeons’ (ASES) Survey and Constant Shoulder Score and analyze recovery outcomes including sling time, return to work, and physical rehabilitation. Study patients will be followed for two years after surgery.”

Dr. Schlegel commented to OTW, “With this post market study, we seek to build on the body of clinical evidence evaluating the use of the Rotation Medical rotator cuff system in humans. Studies have shown the ability of this technology to induce the growth of new tendinous tissue. This clinical study will enable us to further explore this and better understand the clinical outcomes implications associated with this technology. Within a year, we hope to have enrollment completed and plan to submit study results for publication. In addition, I expect that we will have significant experience using this technology in clinical practice to help patients suffering from rotator cuff disease.” — *EH*



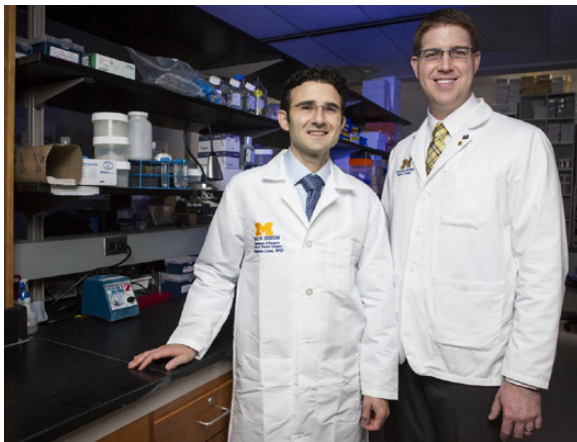
Rotation Medical Biomedical Implant, courtesy Rotation Medical

TRAUMA

Treatment for Burns That Cause Heterotopic Ossification

Researchers from the University of Michigan Health System have made progress in treating those in unusual situations: individuals burned by high-velocity explosive devices whose body turns on them and begins a process known as heterotopic ossification (HO) wherein bone begins growing where it should not be.

According to the September 25, 2014 news release, the research team made use of apyrase, a compound capable of breaking down ATP (adenosine triphosphate), and were able to reduce HO. “They confirmed the link between burn injury and activity of ATP, a primary energy source for cells that, when elevated, can make reactions normally impossible in biological conditions, possible—such as ectopic, or abnormal, bone. In addition to burn and trauma patients who are at risk for HO, more than one million patients a year undergo joint replacement in the United States and 20% of these patients will develop HO.”



Dr. Benjamin Levi and Jonathan Peterson
Courtesy University of Michigan Health System

Benjamin Levi, M.D., is director of the Burn/Wound and Regenerative Medicine Laboratory at the University of Michigan. He told *OTW*, “One of the most interesting results we saw was reduction of HO formation at a site distant from where we applied treatment. This was exciting in the context of one of the more difficult aspects of treating HO—not knowing where HO will form. For example, HO often develops in an uninjured joint following a major burn injury. By treating a burn wound on the dorsum of mice with apyrase we saw a reduction in the formation of HO at the distant Achilles tenotomy site. This effect on distant sites with local treatment speaks to the importance of the global inflammatory response to burn/trauma and its effect on osteogenicity of cells that form HO.”

He added, “HO is a common complication of joint replacements. We saw a reduction in HO following early treatment with anti-inflammatory apyrase in our model. A similar strategy may be useful in preventing HO following orthopedic procedures with early, targeted application of anti-inflammatory compounds.”

“The treatment of HO with surgery or radiation is very difficult and often has sub-optimal results including recurrence and need for further surgery. Like many complications of surgery and trauma, the best treatment strategy is prevention, especially because the location of HO cannot always be predicted. More research needs to be conducted to delineate the signaling pathway and cells involved in HO so that specific inhibitors can be developed. The role of anti-inflammatory treatment is also an important consideration.” — *EH*

New Osteoporosis Tx Could Avoid Infection, Cancer Risk

Working with a protein known as RANKL (receptor activator of nuclear factor kappa-B ligand), scientists at Washington University School of Medicine in St. Louis have created a new way to develop treatments for osteoporosis and autoimmune diseases. The key differentiator is that this treatment could avoid the risk of infection and cancer posed by some current medications.



Julia Warren and Steven Teitelbaum
Washington University School of Medicine in St. Louis

According to the September 24, 2014 news release, co-senior authors Steven Teitelbaum, M.D., and Daved Fremont, Ph.D., showed that copies of RANKL naturally come together in clusters of three. To send a signal, which triggers the development of bone-dismantling cells, each copy of RANKL in the cluster has to bind to a copy of a receptor, which passes on the signal. They mutated individual copies of the RANKL protein to make them better or worse at hooking up with the receptor. They then joined together two copies of the protein that were very good at attracting and holding onto the receptor with a third copy that did not bind to the receptor.

First author Julia Warren, an M.D./Ph.D. student, told *OTW*, “When

thinking about manipulating the region of RANKL that interacts with its receptor RANK to either enhance or abolish binding, we were met by a challenge shared across the tumor-necrosis factor superfamily that is in part a result of the homotrimeric nature of the protein. Specifically, the binding cleft that accommodates RANK receptor is actually formed by the interface between two RANKL monomers. Therefore, to individually alter each of the three RANK binding sites formed on a homotrimer of RANKL, we were limited by the requirement that our mutations all be on one side of the binding cleft. Further, we were hoping to identify mutations that limited the ability of RANKL to bind to its endogenous decoy receptor OPG (osteoprotegerin)."

"Luckily, we knew that this was a property we desired at all interfaces and therefore did not face precisely the same limitations. This unique difficulty was only overcome by using a screening approach called yeast surface display to randomly select for mutations in RANKL in combination with rational design of mutants based on established structural data. Ultimately, we identified a series of mutations that allowed us to selectively block or enhance RANKL binding to RANK while simultaneously preventing binding the decoy receptor OPG. When inserted in strategic combinations into our single-chain RANKL protein, we were able to individually manipulate each of the three receptor binding clefts to develop a highly potent inhibitor of RANKL/RANK signaling."

Asked about their future work, Warren commented, "Within the context of RANKL, we would like to assess our novel inhibitor of RANKL/RANK signaling in other in vivo models of human disease where osteoclast formation/activation plays a critical role.

Examples include breast cancer metastatic to bone and rheumatoid arthritis. Additionally, we envision generalizing this strategy of protein engineering to other members of the tumor necrosis factor superfamily which could have an impact on a wide range of human diseases." — EH

Concussion May Be Hidden Neck Injury

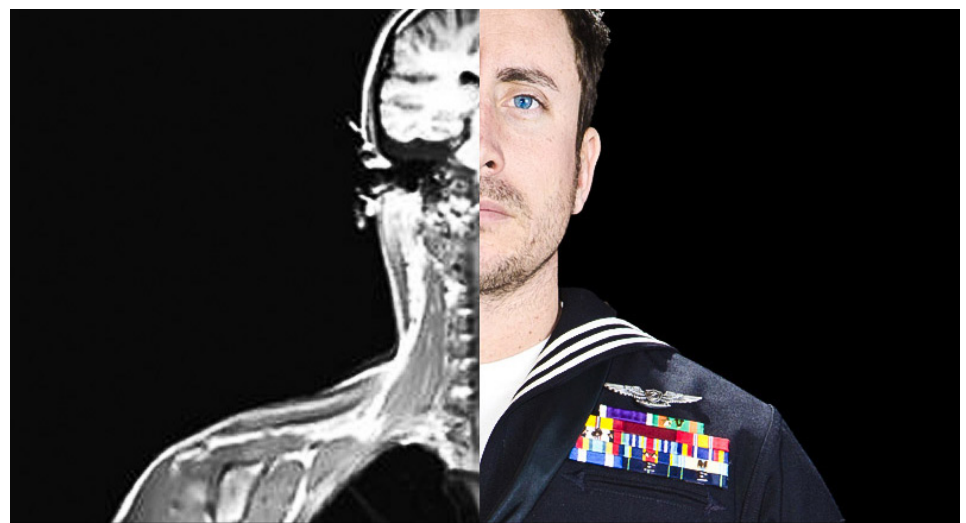
Is it a concussion or a neck injury? John J. Leddy, M.D., clinical professor of orthopedics at the University of Buffalo, has found that it is difficult to distinguish between concussion injuries and neck injuries based on symptoms alone.

"I think a lot of practitioners listen to the symptoms and just chalk it up to concussion, but if they also examine the neck in these patients, they might discover that a neck injury is involved—and that's a treatable problem," he said. Leddy, who is the senior author of a study on concussion, says that determining which condition a patient has experienced is critical because courses of treatment are very different.

He told a reporter for the School of Medicine and Biomedical Sciences, "Based on our research, we concluded that some patients who have been told they've suffered a concussion—and whose symptoms persisted for several months—may actually have suffered a neck injury rather than, or in addition to, a concussion."

"I'd seen enough patients in our clinic, some previously diagnosed with post-concussion syndrome, who continued to experience symptoms even after passing our treadmill test, which indicates full recovery from concussion. The symptoms for both conditions are so nonspecific that it's really hard to make a diagnosis based on them so we had to find another way to discriminate between them."

Leddy based his study on symptoms experienced by 128 patients treated at the University at Buffalo's Concussion Management Clinic, a joint effort between the Department of Orthopaedics and the Department of Psychiatry. To determine which patients had sustained a concussion and which were more likely to have had a neck injury, Leddy and co-author Barry S. Willer, Ph.D, professor psychiatry, evaluated



Wikimedia Commons and DARPA

them on a graded treadmill test developed by Leddy and Willer. They then correlated their patients' treadmill test results to their responses on a detailed questionnaire about symptoms.

"We did some sophisticated statistical analysis," said Leddy. "Even when we looked at the data in multiple ways, there was really no way to separate out the two groups based on their symptom patterns alone."

Because a concussion is a brain injury, the researchers thought that cognitive symptoms would be more likely associated with concussions. To their surprise that did not turn out to be the case. "People who have had neck injuries can also have problems with concentration and with memory. They feel like they're in a fog, which is exactly what people report after concussion," Leddy said. Both groups reported experiencing headache, dizziness, blurred vision, poor concentration and memory deficits.

Leddy says patients who think they've had a concussion—and whose symptoms have not diminished after several months—should be examined for neck and vestibular injury by a sports medicine physician, neurologist or a rehabilitation medicine specialist. —BY

REIMBURSEMENT

Sunshine Act Disclosures Off to Cloudy Start

Ready or not and 33% incomplete, RCMS (Centers for Medicare and Medicaid Services) released the first round of Open Payments data on September 30, 2014.

The big news?

Big Pharma Rules

We did a quick review of the 4.4 million payments for a total of \$3.5 billion paid to 546,000 individual physicians and almost 1,360 teaching hospitals for the last five months of 2013 and found most of it came from Big Pharma and heart device makers.

Companies like Eli Lilly & Company, Shire U.S. Holdings, Forest Laboratories, Amgen, St. Jude Medical, Astra Zeneca Pharmaceutical, Cordis, Ethicon and Johnson & Johnson (non-ortho) dominated the listings.

Seeking Alpha reported that Roche's Genentech unit led the way in the non-research category with \$135 million. Most of this (90%) went to a Southern California hospital network for royalties. Bristol-Myers Squibb was #1 in the research category with \$329 million which, according to the company, was largely the value of experimental medicines used in studies. Medtronic, Inc. paid one unidentified doctor approximately \$3 million who was among a group of six physicians paid at least \$500K by the device maker. The company's total outlay for the period was \$30.1 million. Johnson & Johnson paid \$68 million for non-research expenses.

Tom Sullivan of *Policy and Medicine* reported the following payments:

General Payments: \$976,743,814—This figure includes all meals (a huge portion of the data, many of which hover at or below \$10); speaker and consulting fees; travel and lodging; educational materials; entertainment; and gifts. There were

4,283,132 total payments in the general database.

- The identifiable general payment reports 2,720,099 payments for a total of \$669,561,563 in payments or transfers of value.
- The de-identified data reports 1,563,033 payments for a total of \$307,182,251.

Research Payments: \$1,486,242,674—Pharmaceutical companies spent vastly more on their research endeavors than on general payments. Notably, Sullivan says only about 10% of the research payments are identifiable on the covered recipient level in the Open Payments.

- The identifiable research payment spreadsheet has 23,226 lines of data equaling \$155,815,828.
- The de-identified data has 199,887 lines equaling \$1,330,426,846.

Sullivan added the best analysis of the data thus far is available at *ProPublica* which includes a break out of nature of payment categories.

Ortho Is Junior Partner

We had to look long and hard to find orthopedic companies like Smith & Nephew, Biomet, Inc., Medtronic Sofamor Danek and DePuy Synthes.

Future reports will be published annually and will include a full 12 months of



CMS and RRY Publications LLC

payment data, beginning in June 2015. According to CMS, more than 26,000 physicians and 400 teaching hospitals registered to review payments attributed to them.

The Clouds

Not all payments were noted because during the review and dispute period, CMS identified payment records that had inconsistent physician information, such as National Provider Identifier (NPI) for one doctor and a license number for another. In cases where CMS was unable to match the physician information or the record was not available for review and dispute but the company had attested that the payment had been made, the personally-identifiable information has been suppressed temporarily in the record.

After the reporting problems were discovered, the American Medical Association (AMA) recommended pushing back the site's launch to March 31, 2015. The AMA argued that site inaccuracies could unfairly harm physicians and that technical challenges had left doctors insufficient time to review and challenge the information included.

Robert Wah, president of the AMA, noted in an interview that the 26,000 physicians registered to review and dispute any claims was much smaller than the 546,000 physicians in the system, meaning most doctors have had little time to review information.

He cautioned consumers that "there is a high likelihood of inaccuracy when only 26,000 physicians had a chance to look at it."

De-Identification

About 40% of the records are de-identified. This data will be fully identi-

able in 2015 after the reporting entity submits corrected data, and physicians and teaching hospitals have a chance to review and dispute. In addition, data that were disputed and not resolved by the end of the September 11 review period have not been published and will be updated at a later date.

Because the data covers only five months, has no historical comparison, has so much "de-identified" data and 190,000 delayed reporting payments to researchers that were for the development of experimental products not yet for sale, the information will be "completely useless," said Michael Carome, the director of health research at Public Citizen.

Download at Your Own Risk

Downloading the information from CMS is not for the meek or old computers. The files are so big it takes a long time to download and instructions cover 51 pages.

CMS intends to unveil a second, more user-friendly site for consumers in October.

To view the Open Payments physician payment dataset, click here: www.cms.gov/openpayments — WE

SPINE

FDA Ortho Panel to Review VertiFlex Spine Device

The FDA's Orthopaedic & Rehabilitation Devices panel is planning to meet on December 12, 2014 to consider VertiFlex Inc.'s pre-market approval application (PMA) for the company's Superior ISS (interspinous spacer).

Compared to X-STOP

Company President and CEO Earl Fender says the panel is going to see evidence from the "largest and most rigorous FDA trial ever completed for spinal stenosis." The device is for the treatment of patients with lumbar spinal stenosis. The IDE (investigational device exemption) trial involved enrollments of 470 patients between June 2008 and December 2012 at 31 centers across the U.S. Patients were randomized 1:1 to either the Superior ISS or the commercially available X-STOP IPD.

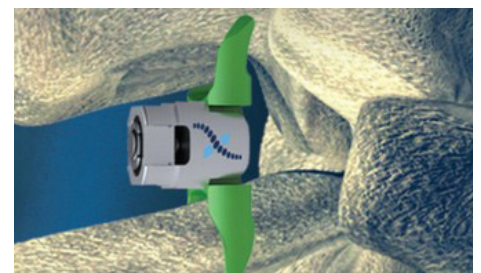
The company submitted its final module of the PMA this past April. The final module covers the clinical results from the Superior IDE trial evaluating the device's safety and effectiveness.

Design Goal

The device is designed to achieve indirect spinal decompression for patients suffering from neurogenic intermittent claudication due to moderate lumbar spinal stenosis. Superior is implanted minimally invasively through a cannula designed to be less traumatic to the patient. The Superior ISS can be implanted under general or local anesthesia.

Proposed Indications

The proposed "Indication for Use" for the device, as stated in the PMA, is as follows:



Superior Interspinous Spacer System/VertiFlex, Inc.

“Treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing.”

“Patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superior ISS may be implanted at one or two adjacent lumbar (L) levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.”

The panel will meet on December 12, 2014, from 8:00 a.m. to 6:00 p.m. at the Holiday Inn Washington-College Park, 10000 Baltimore Avenue, College Park, Maryland.

VertiFlex, Inc.

The company, founded in 2005 and headquartered in San Clemente, California, has developed proprietary, minimally invasive technologies for performing both indirect and direct decompressions of the lumbar spine. These procedures, according to the company, fill the gap in the stenosis treatment continuum between conservative care and traditional spine surgery, providing new options for interventional spine physicians and less invasive options for traditional spine surgeons.

The FDA cleared the company’s Totalis direct compression system and UniVise spinous process fixation device in January 2013. A year later, CMS granted cov-

PEOPLE

Kevin D. Cordell New President of U.S. Extremities at Wright

Kevin D. Cordell, formerly vice president of sales for the GI Solutions business at Covidien Ltd, has been appointed president of U.S. Extremities at Wright Medical Group, Inc. Cordell is managing Wright’s U.S. extremities and biologic business and reports directly to the chief operating officer.

Pascal Girin, Wright’s executive vice president and chief operating officer stated in the September 15, 2014 news release, “For over 20 years, Kevin has led the development, implementation and execution of successful commercial strategies and programs for global medical device, biotech and pharmaceutical companies. His proven track record of success and his passion for building high performing commercial organizations will serve us well as we continue to focus on accelerating revenue growth, driving sales rep productivity gains in our U.S. foot and ankle business, and launching new products, in particular our new INFINITY ankle.”

The news release indicates that while at Covidien, Cordell also served in the capacity of vice president of sales & global marketing for its Peripheral Vascular business. “He joined Covidien in July 2010 through the acquisition of ev3 Inc., where he served as vice president of U.S. sales from January 2009 to July 2010. Prior to ev3, Mr. Cordell served as vice president, global sales of FoxHollow Technologies, Inc. from March 2007 to October 2007. Earlier in his career, Mr. Cordell also held various positions of increasing responsibility for Johnson & Johnson’s Cordis Cardiology



Kevin D. Cordell, Wright Medical Group, Inc.

and Centocor companies. He received his bachelor’s degree in finance from the University of Oklahoma.”

Robert Palmisano, Wright’s president & chief executive officer commented, “Kevin is an accomplished senior executive with a demonstrated history of leading direct sales organizations and developing fast-growing, underpenetrated markets, and I’m delighted to welcome him to the Wright management team. His deep experience and strong capabilities will be instrumental as we continue to drive our success in our U.S. extremities and biologics markets.”

Cordell told *OTW*, “I’m delighted to join the Wright Medical team and support the continued growth of the U.S. Extremities business. My top near-term priorities will be to continue our focus on accelerating revenue growth, launching new products, including the new INFINITY total ankle system, and driving sales productivity gains in our U.S. foot and ankle sales organization. I am also looking forward to working with the rest of the Wright leadership team as we work to further extend our leadership position in Extremities and Biologics.” — *EH*



Orthopedics This Week

Orthopedics This Week | RRY Publications LLC

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