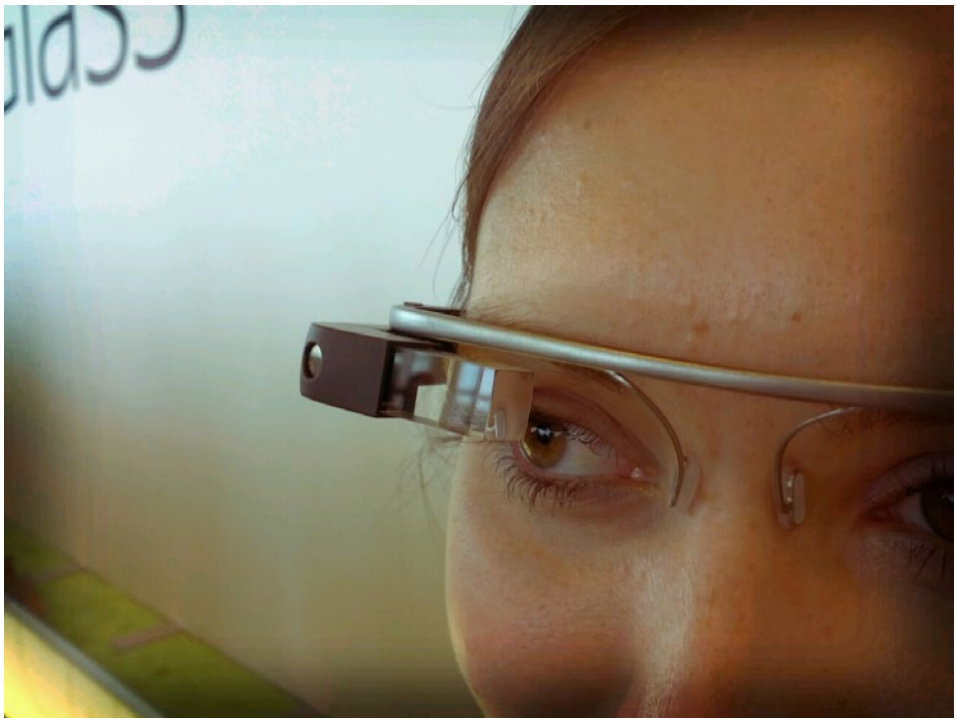
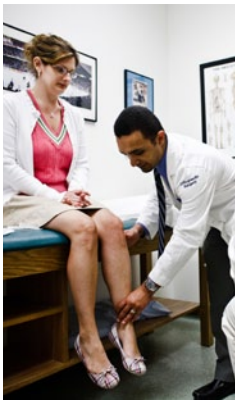
VOLUME 9, ISSUE 29 | SEPTEMBER 17, 2013

Orthopedics This Week

WEEK IN REVIEW





BREAKING NEWS

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Attention now turns back to the federal budget and its effect on CMS and Obamacare. The current continuing resolution to fund the government expires on September 30, and will need to be extended to avoid a government shutdown. Around the same time, we should also see if the Obama Administration is ready for the health reform law's open enrollment which begins on October 1.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	3	Stryker	18.71%	(0.44%)	Speaking to analysts a week ago, SYK acknowledged that M&A is likely the primary use of its $4.5b in cash. Up to #1 this week.
2	7	Zimmer	29.28	1.22	Why is ZMH so cheap? Now the least expensive ortho stock yet op margins are 29%. Purely due to valuation we move ZMH to #2.
3	6	Conmed	10.57	2.61	Investors have been buying CNMD on the basis of 2014 expectations. Consensus is that CNMD will report a much higher rate of earnings growth after this year.
4	10	Orthofix	16.25	3.82	This market basket of orthopedic assets is really under-priced. Consider: lowest P/E, 4th lowest PSR and 3rd lowest PEG.
5	1	Integra LifeSciences	11.77	6.89	Looking at all measures, only IART is cheaper than OFIX. Short stop at #1 due to good FDA news. Now comes the hard part, translating that into growth.
6	2	Globus Medical	28.53	(3.47)	On a relative basis, GMED is the 11th least expensive ortho equity. But those profit margins look sooo good.
7	5	NuVasive	6.30	4.02	And, interestingly enough, NUVA is more expensive than GMED. Most analysts are expecting 6-7% sales growth this quarter.
8	4	Smith & Nephew	20.78	0.80	What is so interesting is that most of SNN's press releases are NOT about orthopedic products. Also, SNN has missed estimates the last 2 quarters.
9	8	Medtronic	28.78	(2.93)	The attribute that Wall Street likes best about MDT is its dividend—which is growing at higher rates than inflation. Not innovation or sales growth.
10	9	Johnson & Johnson	26.68	(2.35)	JNJ is reportedly turning the fading ortho diagnostic unit into cash. Another strategic move by this management.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$16.22	$763	11.10%
2	Wright Medical	WMGI	$26.16	$1,231	7.48%
3	Integra LifeSciences	IART	$40.04	$1,125	6.89%
4	NuVasive	NUVA	$24.57	$1,095	4.02%
5	Orthofix	OFIX	$23.65	$460	3.82%
6	Conmed	CNMD	$33.00	$907	2.61%
7	RTI Biologics Inc	RTIX	$3.58	$202	1.42%
8	Zimmer Holdings	ZMH	$81.89	$13,884	1.22%
9	Smith & Nephew	SNN	$62.01	$11,140	0.80%
10	ArthroCare	ARTC	$34.34	$970	0.26%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$4.02	$387	-33.66%
2	Baxano Surgical Inc	BAXS	$1.70	$77	-11.92%
3	TiGenix	TIG.BR	$0.31	$39	-11.32%
4	Exactech	EXAC	$18.67	$252	-6.37%
5	CryoLife	CRY	$6.54	$181	-5.35%
6	Symmetry Medical	SMA	$8.31	$310	-3.71%
7	Globus Medical	GMED	$16.97	$1,576	-3.47%
8	Medtronic	MDT	$53.58	$53,444	-2.93%
9	Alphatec Holdings	ATEC	$1.99	$193	-2.93%
10	Johnson & Johnson	JNJ	$88.57	$249,597	-2.35%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$23.65	$460	9.20
2	Zimmer Holdings	ZMH	$81.89	$13,884	13.23
3	Medtronic	MDT	$53.58	$53,444	14.56
4	Globus Medical	GMED	$16.97	$1,576	15.05
5	Smith & Nephew	SNN	$62.01	$11,140	15.28

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$24.57	$1,095	87.75
2	Symmetry Medical	SMA	$8.31	$310	33.24
3	RTI Biologics Inc	RTIX	$3.58	$202	26.68
4	ArthroCare	ARTC	$34.34	$970	23.28
5	Integra LifeSciences	IART	$40.04	$1,125	19.68

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$16.97	$1,576	1.00
2	Exactech	EXAC	$18.67	$252	1.20
3	Orthofix	OFIX	$23.65	$460	1.31
4	Conmed	CNMD	$33.00	$907	1.36
5	Zimmer Holdings	ZMH	$81.89	$13,884	1.44

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$24.57	$1,095	9.24
2	CryoLife	CRY	$6.54	$181	4.67
3	Symmetry Medical	SMA	$8.31	$310	2.77
4	Johnson & Johnson	JNJ	$88.57	$249,597	2.70
5	Medtronic	MDT	$53.58	$53,444	2.26

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.31	$310	0.75
2	Bacterin Intl Holdings	BONE	$0.60	$31	0.91
3	Alphatec Holdings	ATEC	$1.99	$193	0.98
4	Orthofix	OFIX	$23.65	$460	1.00
5	Exactech	EXAC	$18.67	$252	1.12

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$4.02	$387	14.32
2	TiGenix	TIG.BR	$0.31	$39	9.45
3	MAKO Surgical	MAKO	$16.22	$763	7.43
4	Baxano Surgical Inc	BAXS	$1.70	$77	5.27
5	Globus Medical	GMED	$16.97	$1,576	4.08

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

Using Google Glass in Surgery

BY ROBIN YOUNG

In June of this year Dr. Rafael Grossmann of the Eastern Maine Medical Center performed surgery wearing Google Glass. Then in August, Dr. Christopher Keading of Ohio State University's Wexner Medical Center wore Google Glass while performing surgery on a 47-year-old patient's knee ligament.

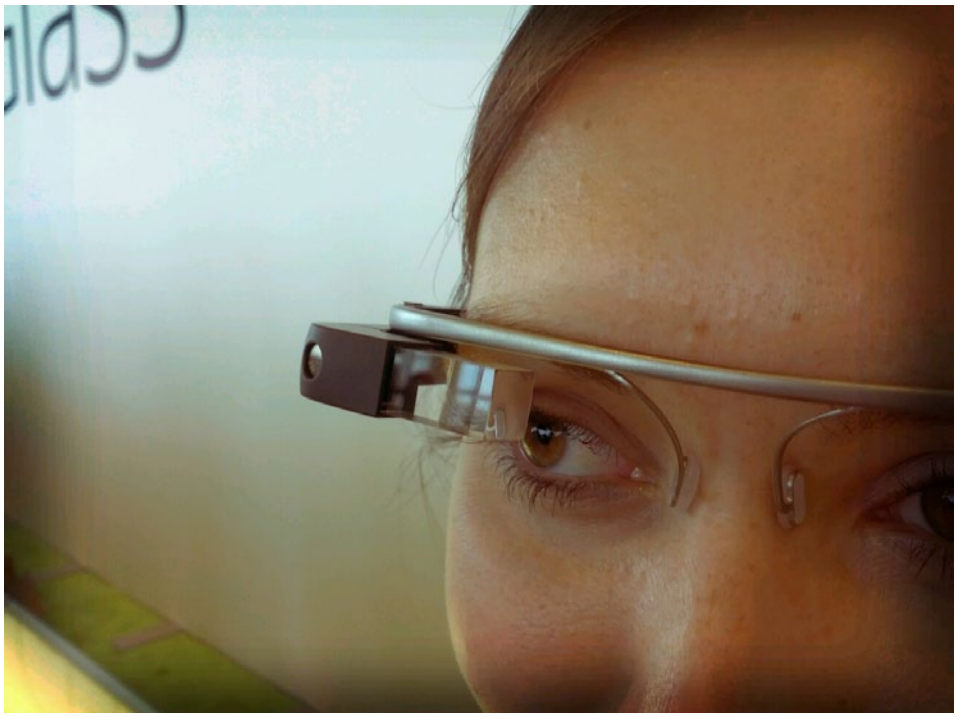
As far as we know, dozens of other surgeons have experimented with Google Glass in surgery since it first became available to developers in 2012.

Dr. Grossmann wrote about his experience in *PC Magazine*; "I wanted to show that this device and its platform are certainly intuitive tools that have great potential in healthcare and specifically for surgery, could allow better intra-operative consultations, surgical mentoring and potential remote medical education, in a very simple way."

Grossmann set up a Google + Hangout site where invitees could connect and watch a live-stream of what he was seeing through his Google Glass headset.

"I was able to show not just the patient's abdomen, but also the endoscopic view, in a very clever, simple and inexpensive way. I think that there should be ways to directly stream the endoscopic view thru Google Glass" continues Glassman.

What are the implications of a face mounted and wearable computer that will allow surgeons to stream a real-time point-of-view video of the surgery to anyone logged onto the Google + Hangout site?



Wikimedia Commons and Antonio Zugaldia

Since Google Glass is online, it can call up X-rays, MRI images and reference any other reports, materials or even hold a video consult, real time, with colleagues. And it is all controlled with natural language audio commands

Live streaming, consulting, surfing the internet—all while looking into the patient and performing surgery—using a heads up screen on the eye glasses themselves.

Is this cool or what?

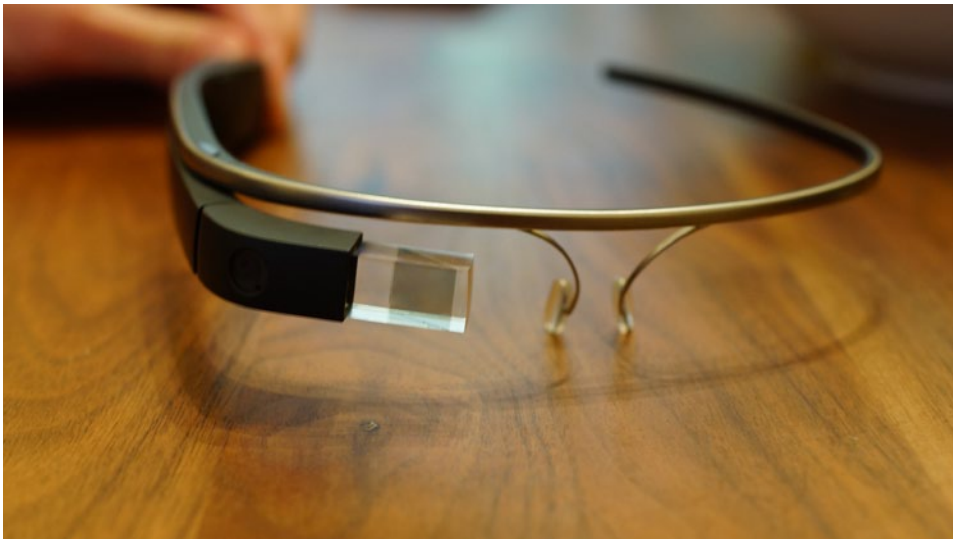
Google Glass

Glass (styled "GLΛSS") is a wearable computer with an optical head-mounted display (OHMD). Developed in Google's secret Lab X, the device displays information in a smartphone-like hands-free format that can communicate with the Internet via natural language voice commands.

Surgeons, or frankly anyone who wears Google Glass, can allow other people to see everything they see. From any computer (assuming they are logged into the right web site) other people can follow the surgeon throughout the surgery and—indeed, until the Google Glass is removed, around all day.

First Google Glass Surgery

Google Glass is lighter than the average pair of sunglasses and in the future, new designs will allow integration of the display into people's normal eyewear. In early 2013 Google delivered an Explorer Edition to testers and Google I/O developers in the U.S. for $1,500.



Courtesy Google, Inc.

A consumer version is on the way and should be available in 2014 for "significantly less" than the Explorer Edition.

Google Glass began testing in April 2012. In May 2012, Google demonstrated the 720p HD first-person video recording capabilities by giving the Glass to skydivers, abseilers (folks who rappel), and mountain bikers who then live-streamed their point of view to a Google+ Hangout.

On June 21, 2013, Spanish doctor Pedro Guillen, chief of trauma service of Clínica CEMTRO of Madrid, became the first physician in the world to broadcast a surgery through the use of Google Glass. Thanks to the Spanish company Droiders, rights holder of this system in Spain, a chondrocyte implantation in the knee of a 49-year-old patient, could be streamed worldwide over the Internet, while allowing another physician, Dr. Homero Rivas (director of innovative surgery, School of Medicine, Stanford University, California), an expert in telemedicine, to participate in the surgery.

One Writer's First Person Experience

Gary Shteyngart, writing in the August 5 edition of *The New Yorker*, described his experience with Google Glass as follows:

> "A pink rectangle above his field of vision, which looks like a twenty-five-inch television screen floating some eight feet away from him, is

replaced by another message: 'SVO Hav Su flight 150 225pm delayed.' The man has been Googling the N.S.A. leaker Edward Snowden on his computer, and now his glasses, which are synched to his Google Plus account, are informing him of a delay on the next Aeroflot (Su) flight to Havana out of SVO (Moscow's Sheremetyevo airport). Another flick of the index finger and a different screen clicks into place. Now it would appear that someone named Chris Brown is defending himself on Twitter and that a water bed for cows has been developed. The man has subscribed to all the news sources currently available for his spectacles: the *New York Times*, CNN, and *Elle* (hence news of the Forever 21 world traveler denim shorts, available at the flick of a finger). The man feels a tingle at the back of his ear, and a voice tells him his friend Christine Lee is ready to do a video call, also called a 'hangout.' The image of Christine at her desk beams above the man's right eye. He can see her and she, in turn, can see everything he sees through his glasses, the quiet green streetscape of East Eighty-Eighth Street streaming on her computer screen. He's going to go to the Guggenheim later and promises her that she will be able to watch the new James Turrell exhibition through his eyes."

Specifications: "OK Glass"

As of early 2013, Google is working on models that can be used with prescription lenses, which will be available to Explorers before the end of 2013.

The Explorer Edition receives data through Wi-Fi, or it can tether via Bluetooth to an Android device or iPhone, and use its 3G or 4G data; the Glass also has a GPS chip. Users issue voice commands by first saying "ok glass," followed by the command, or they can scroll through the options using a finger along the side of the device.

On April 15, 2013, Google released the Mirror API, allowing developers to start making apps for Glass. The terms of service, state that developers may not put ads in their apps or charge fees. Many developers and companies have built applications for Glass, including news apps, facial recognition, photo manipulation, and sharing to social networks, such as Facebook and Twitter.

On April 16, 2013, Google announced that production was complete for the initial Glass Explorer Edition units and the corporation would begin shipping immediately. On the same day, Google

also released a web-based setup page for Glass as well as the MyGlass companion app. Developers were also given first access to the Mirror API for Glass.

As of August 27, 2013, 10,000 people were selected as part of a contest to test the early version of the device.

Google Glass has the ability to take photos and record 720p HD video. While video is recording, the screen stays on.

A touchpad is located on the side of Google Glass, allowing users to control the device by swiping through a timeline-like interface displayed on the screen. Sliding backward shows current events, such as weather, and sliding forward shows past events, such as phone calls, photos, circle updates, etc.

Google Glass applications (Glassware) are free applications built by third-party developers. Glass also uses many existing Google applications, such as Google Now, Google Maps, Google+, and Gmail.

Medical Apps

One application in development is the MedRef for Glass app which is designed for hospital employees and uses facial-recognition technology to pull patient information. Also, we just saw an announcement from Palomar Health which is entering into a partnership with Qualcomm Life (a subsidiary of **Qualcomm**)) to launch Glassomics.

Glassomics is supposed to be an incubator and innovation lab aimed at exploring the applications of wearable technology in health care. By "wearable technology" Glassomics is referring to, of course, Google Glass but also smart watches and fitness bands.

Using Google Glass as a launching point, several developers, such as Augmedix, are working on a new generation of augmented reality Google Glass apps that promise to turn the device into a full-fledged next generation medical tool.

"Augmented reality" sounds a bit gamey or gamer—but it is effectively a cloud-based data engine that projects over (or overlays on top of) a real-time image. For example, the app would overlay a patient's medical record over the image of the surgery—or perhaps other data or images over the actual view of the surgery. In other words, "augment" a user's view of reality.

Non-Medical Apps

On May 16, 2013, Google announced the release of seven new apps, including reminders from Evernote, fashion news from *Elle*, and news alerts from CNN. Also noted was a "Glass Boutique," a store that will allow synchronization to Glass of Glassware and APKs.

Version XE8 made a debut for Google Glass on August 12, 2013. It brings an integrated video player with playback controls, the ability to post an update to Path, and lets users save notes to Evernote. Several other minute improvements include volume controls, improved voice recognition, and several new Google Now cards.

Other than the touchpad, Google Glass can be controlled using "voice actions." To activate Glass, wearers tilt their heads 30° upward (which can be altered for preference) or tap the touchpad, and say "OK Glass." Once Glass is activated, wearers can say an action, such as "take a picture," "record a video," "hangout with [person/Google+ circle]," "Google 'What year was Wikipedia founded?'," "Give me directions to the Eiffel Tower", and "Send a message to John" (many of these commands can be seen in a product video released in February 2013). http://www.youtube.com/watch?v=ErpNpR3XYUw.

For search results that are read back to the user, the voice response is relayed using bone conduction through a transducer that sits beside the ear, thereby rendering the sound almost inaudible to other people.

Google is also considering partnerships with sunglass retailers such as Ray-Ban or Warby Parker, and may also open retail stores to allow customers to try on the device.

If you have any experience with Google Glass, send us your story, to robin@ryortho.com. ♦

Fake Surgeries Alleged in Poughkeepsie

BY WALTER EISNER

Andrew Huth and RRY Publications LLC stock photo

Spyros N. Panos, M.D., surrendered his medical license to the New York State Board for Professional Medical Conduct on August 26, 2013. It's a license he's held since 1995.

image credit: Spyros N. Panos, M.D./Poughkeepsie Journal and Sarah Bradshaw

The Poughkeepsie, New York, orthopedic surgeon also faces over 250 lawsuits from former patients who accuse him of performing fake or negligent surgeries.

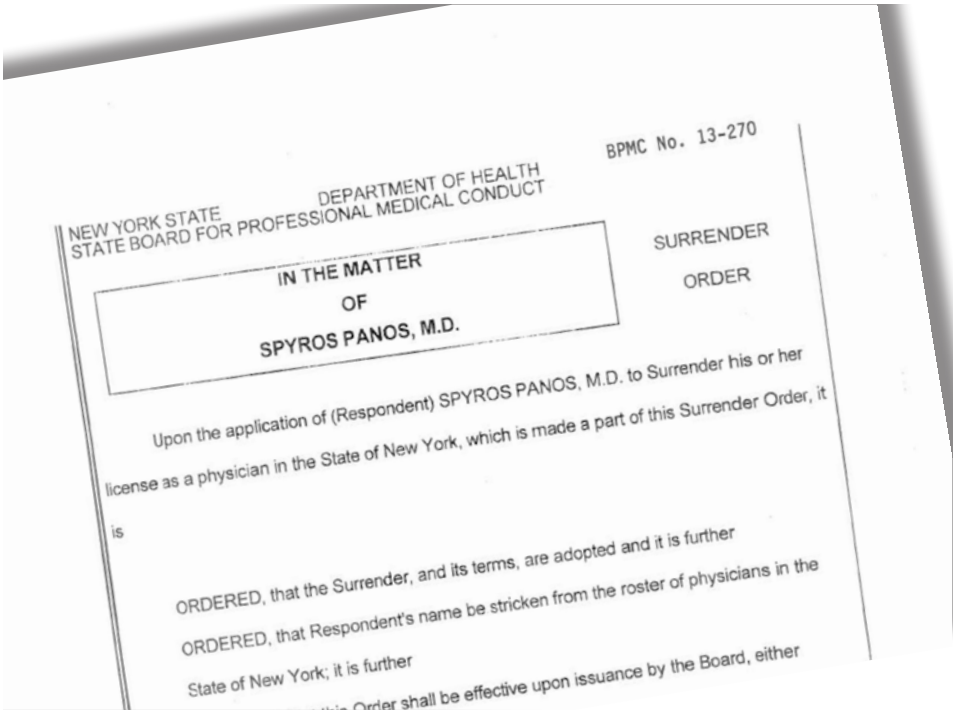
The Surrender Order No. 13-270 states that Dr. Panos said he applied for permission to surrender his license on the grounds that he cannot "successfully defend against at least one of the acts of misconduct" alleged in the charges against him. Dr. Panos said that receiving permission to surrender his license allows him "to resolve this matter without the various risks and burdens of a hearing on the merits."

Statement of Charges

In the Statement of Charges, the Factual Allegations assert that during a period of 2007 through 2010, Dr. Panos failed to "render appropriate care; maintain an adequate, complete and accurate medical record and submitted bills for payment for medical services when he was not in fact entitled to such payment."

The last charge caught the attention of federal accountants at the Department of Justice resulting in Dr. Panos and hospitals where he worked becoming targets of multiple federal criminal subpoenas. Neither Dr. Panos, nor any of the hospitals have been charged with any offense.

In addition to the civil and criminal legal issues facing him, Dr. Panos has endured intense public scrutiny in 19 investigative articles in the *Poughkeepsie Journal* by investigative reporter Sarah Bradshaw. National exposure came on September 5, 2013 with a



NEW YORK STATE
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT
DEPARTMENT OF HEALTH

BPMC No. 13-270

IN THE MATTER
OF
SPYROS PANOS, M.D.

SURRENDER
ORDER

Upon the application of (Respondent) SPYROS PANOS, M.D. to Surrender his or her license as a physician in the State of New York, which is made a part of this Surrender Order, it is

ORDERED, that the Surrender, and its terms, are adopted and it is further

ORDERED, that Respondent's name be stricken from the roster of physicians in the State of New York; it is further

Order shall be effective upon issuance by the Board, either

Panos Medical License Surrender

story on *ABC News* headlined "Surgeon Accused of Faking Operations Surrenders Medical License."

Attorneys representing former patients said that clients with potential cases against Dr. Panos began flooding their offices with calls immediately after Bradshaw wrote about the first few lawsuits in September 2010. Bradshaw said she was tipped off to the litigation from an anonymous source.

Dr. Panos and his attorneys have declined to comment to media.

Dr. Panos worked at the Mid-Hudson Medical Group in Poughkeepsie, New York, as an orthopedic surgeon from 1999 until he was fired in 2011 for not meeting the group's "professional standards."

Patient Allegations

Debra Cole, a retired telephone company technician is suing the surgeon for allegedly performing two faked knee surgeries.

JT Wisell and his law partner Nancy McGee, representing 153 plaintiffs, told us on September 6, 2013 that at least one-third of the firm's cases involve patients who had been told by a second physician, after surgeries by Dr. Panos, that the procedures were actually not performed.

One of their clients, Gary Flynn, according to Dr. Panos' surgical records, needed an acromioclavicular (AC) joint recession. Instead Dr. Panos allegedly performed a rotator cuff repair. Physicians have the right to practice medicine, but Wisell points out that the two procedures are different body parts.

"Phantom Knee Surgery"

Wisell also told us of a case where Panos claimed to have performed a full hip arthroplasty, when in fact, he had only performed a partial arthroplasty. Another former patient, Constance Nenni, died less than 24-hours after having an alleged "phantom" knee surgery.

The *Journal*'s Bradshaw reported that Chris Hanson filed a lawsuit against Dr. Panos because he says he never got better after two surgeries. He claims the doctor didn't actually operate on his knees and made him worse by improperly operating on his big toe.

Hanson gave the *Journal* a medical invoice showing that the Hudson Valley Center filled a claim with Medicare for $13,389 for a February 16, 2010, arthroscopic knee surgery.

Personal injury attorney Luis Solimano, said he received "four or five" complaints from Dr. Panos' former patients. Without identifying a complainant, Solimano reportedly said that one patient went in for a surgery, but when the pain continued and the patient went for a second opinion, the new doctor said the surgery hadn't been performed.

Michael S. Kelton, a medical malpractice defense director at a large New York law firm with no ties to any plaintiffs in this case, told Bradshaw that he couldn't recall a malpractice claim against an orthopedic surgeon in which the surgeon said he or she performed surgery and the patient underwent anesthesia, but the surgery wasn't actually performed.

Brian Brown, Nenni's attorney, accuses Dr. Panos of using patients like human cash registers, scheduling as many as 22 surgeries a day. The average orthopedic surgeon typically schedules no more than 32 procedures a month, according to American Academy of Orthopaedic Surgeons statistics.

Billing Practices

Arthur Caplin, the director of medical ethics at NYU Langone Medical Center and a former non-M.D. representative with the New York State medical licensing board, said he found it troubling that others besides Dr. Panos aren't under investigation.

He told Bradshaw, "You can't perform this many suspect surgeries without the cooperation of many other people."

This is where the plot thickens. Lawyers for the plaintiffs are also suing Dr. Panos' former employer, the Mid-Hudson Medical Group, as well as other defendants including Vassar Brothers Medical Center and Saint Francis Hospital and Health Centers in Poughkeepsie, claiming they didn't supervise Dr. Panos properly and billed payers for the surgeries.

Because of the federal subpoenas issued to Dr. Panos and the medical group, there is a legal stay in place that prevents plaintiffs' attorneys from taking sworn statements from any employee and former employee of the medical group or any hospital where Dr. Panos practiced, according to Wisell.

The group wanted to put on hold the multiple civil cases filed against the group and Dr. Panos, a former shareholder and board member, until after the federal criminal investigation is complete, according to the motion.

The stay was put in place for Dr. Panos to avoid self-incrimination in the federal cases of fraud and billing irregularities, Wisell told Bradshaw. Mid-Hudson and the various hospitals and surgical centers where Dr. Panos practiced have submitted billing records, surgical records and surgical schedule logs to plaintiffs' lawyers, but under the stay, are not yet required to directly respond to civil actions, Wisell added.

False Claims

The group's motion said the criminal investigation appears to focus on alleged fraud, including seeking payments for false representations of procedures.

According to Bradshaw, Panos' lawyer said Mid-Hudson Medical billed for medical services, not Dr. Panos, and the money went directly to the group.

Plaintiffs argue that the hospitals where Dr. Panos performed their surgeries should have been able to tell from surgical records that he was an outlier in the number of procedures he was performing.

High Volumes

On July 21, 2013, Bradshaw reported that Dr. Panos' surgical records show he performed half as many operations in one day as the typical orthopedic surgeon averages in one month raising questions about administrative oversight and patient safety.

She reported that Dr. Panos was in nearly back-to-back surgeries over the course of sometimes 12-hour-long surgery days, often with two patients under anesthesia at the same time, according to records kept by the City of Poughkeepsie hospital where he had privileges. In three cases, he was in two surgeries at the same time, according to the records. He frequently performed short operations—one was only seven minutes—according to his surgical schedules at Vassar Brothers Medical Center. The logs are for four days between December 31, 2009, and December 16, 2010.

Plaintiffs' attorneys allege that Dr. Panos couldn't have done legitimate surgeries during the times given on the surgical records involving their clients.

The *Journal* obtained Dr. Panos' surgical records for December 12, 2009, May 20, 2010, July 29, 2010, and December 16, 2010. Operation times are tracked by the start and end of anesthesia.

According to a *Journal* analysis, the logs show:

- For those four days, Dr. Panos performed 69 surgeries, or an average of 17 per day.
- In three cases, Dr. Panos was supposedly in surgery with two different patients at the same time: On December 16, 2010, he was supposedly in surgery with one patient from 9:15 a.m. to 10:25 a.m. and with another patient from 9:57 a.m. to 10:27 a.m. On the same day, he supposedly finished a surgery at 2:40 p.m. but had started another surgery at 2:28 p.m. that also ended at 2:40 p.m.
- Dr. Panos' highest-volume day was 19 surgeries in 10-1/2 hours. His volume of surgeries ranged from 10 in 6-1/2 hours to 20 in 12 hours.

Plaintiffs' attorney Brown said he has seen a dozen Vassar Brothers surgical logs for days ranging from April 24, 2008, to December 16, 2010, which show the same pattern—Dr. Panos performed between 15 and 22 surgeries each day.

Brian Brown of Manhattan said the surgical logs are "irrefutable evidence" that others knew Dr. Panos was putting people under anesthesia and, in some cases, doing nothing at all, and billing for multiple procedures.

A Safe Exit?

In the midst of the legal proceedings, Mid-Hudson, with about 120 physicians, announced in April that the group was planning to transfer its assets to the Mount Kisco Medical Group, with about 285 physicians.

McGee, the attorney for 153 plaintiffs told Bradshaw she found it "interesting that it's not a merger, a buyout, that the employees of Mid-Hudson Medical Group will just become employees of Mount Kisco Medical Group. That is very curious to me."

Brown said Mid-Hudson shareholders are being allowed to "walk away from taking any responsibility for the heinous acts committed against so many of their former patients."

That asset shift was challenged in court by attorneys for the plaintiffs in the Panos lawsuits.

On June 26, 2013, Bradshaw reported that a judge ruled that the civil cases were not a reason to block any transferring of assets to Mount Kisco.

The strange case of Dr. Panos gets even weirder as the *Journal* ran further reports documenting that he was doing individual medical evaluations for Fiduciary Insurance Company of America and then was arrested in Maryland for allegedly shoplifting baseball cards from a local Wal-Mart.

There has been no news from the Justice Department and no civil trials have started. Dr. Panos is innocent until proven guilty, but he has already paid the price.

To read Bradshaw's investigative reports from the *Poughkeepsie Journal*, click here: http://www.poughkeepsiejournal.com/section/panos?template=odytheme&theme=panos

♦

The Article I've Always Wanted to Write

BY ROBIN YOUNG

Do you have a story to tell? We want to publish it. Consider *OTW* your venue to publish case reports, appeals for volunteer work, new technology assessments, payer battles and even fund raisers. You name it, if it is all about the world of orthopedics and you are passionate about it—then you have an outlet at *OTW.*

This week, we are proud to offer two personal stories from two fathers who are talking about their sons. In both cases, the appeal is to you, our reader, to support two programs—one is a very important research program and the other is an existing adaptive sports program. Through the examples of these two sons we see why such vitally important programs require your generous support.

Left to right: Dr. Richard Guyer, Jeff Guyer, and Shelly Guyer

Jeff Guyer

It's been two years since Jeff Guyer, a talented biomedical engineer with Alphatec Spine and the son of Texas Back Institute (TBI) co-founder and former NASS President Dr. Richard Guyer, passed away at the age of 30 from rare form of cancer called myxoid liposarcoma.

Every parent's heart breaks when they hear of a child—even an adult child—who's passed too early. Jeff Guyer's life was an extraordinary one and if there is any comfort, it is in his life well lived.

Dr. Guyer and his wife Shelly sent me an appeal last week to contribute to a fund dedicated to raising research money for sarcoma. Very little money is actually raised each year for this particular type of cancer.

The money is going to Massachusetts General Hospital. This is the fourth year of fund raising. This year the funding got a jump start of $50,000 from some wonderful friends of the Guyer family and we're going to our best at *OTW* to keep the momentum going.

Join me by going to this website: https://give.massgeneral.org/spinspiration/ and putting a few bucks on the September 29 Beyond Pedaling Ride in Snider Plaza. We're going to be backing Rick and Shelly Guyer. Come join us.

Finally, Texas Back is sponsoring a third silent auction on Friday September 27 where everyone can bid on wonderful and creative baskets created by all the different departments and other friends either by visiting TBI at 6020 West Parker Road, Plano or by going online at www.32auctions.com/texasback

My Son

As I grow older, I come to understand more thoroughly the often silent challenges people go through with their families and loved ones. We normally don't see that part of people's lives. I've been fortunate, frankly. My son, who was born with a pretty severe form of cerebral palsy, has grown up to be an independent and terrific adult.

Raising a child with a disability is a learning experience—for everyone. In my own experience I know one thing absolutely. It is that the human spirit is the most powerful force in the world.

In my son's case, his spirit carried him through multiple surgeries and difficult life challenges. Scott's grit was especially on display when was playing adaptive hockey in school. He was the

"We Love to Play" Organization

team goalie. Wheelchairs would come barreling at him, sticks waving and the puck flying. He would literally launch his body at the coming mass of metal and rubber to block the plastic disc. No player treated any other player gently. Full-body contact. And we'd bring him home bruised, bloody and thoroughly happy.

That was forty years ago.

Looking back, it is crystal clear how much sports helped not only my son but every child who participated. Playing in a team taught competitiveness, spirit and self-reliance. It also created a lifelong group of close friends.

Scott still plays hockey. His friends and a younger generation of teens and 20-year-olds also play in his league. These guys and gals have spina bifida, cerebral palsy, MS, amputations, spinal cord injuries, cognitive issues and other forms of disabilities.

In 1995 Scott and his friends organized their program into a non-profit 501(c)(3) organization to manage four seasonal sports activities—floor hockey, softball, football and soccer—for adults with physical disabilities in and around the Twin Cities.

The name of the group is: "We love to Play."

I'm telling this story in order help Scott and Charlie Brose, the president of "We Love to Play" raise a little bit of money—about $4,000—to pay for equipment and admin expenses (printing, mailing, promotions). Everything else is donated—coaches, referees and gymnasiums

So, in addition to helping support myxoid liposarcoma research at Mass General, join us also in supporting adaptive sports for adults with various forms of disability. Please send a few bucks to: www.welovetoplay.org/donate.

Or make your check payable to "We Love to Play" and mail to:

We Love to Play
6537 Riverwood Lane
Brooklyn Center, MN 55430
♦

Doctor Attacks Arthritis With Joint Distraction // Professor Creates New Arthroscopy Skills Simulator // New Single Portal Arthroscopy Technique Announced

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

Doctor Attacks Arthritis With Joint Distraction Sanjeev Sabharwal, M.D., M.P.H. is a pediatric orthopedic surgeon specializing in limb deformities. Dr. Sabharwal, president of the Limb Lengthening and Reconstruction Society (LLRS), tells *OTW*,

> "We are seeing some reports of initial success with controlled joint distraction, primarily for early ankle arthritis in young adults, and certain cases of severe Perthes disease, affecting the femoral head in adolescents. The procedure, known as arthrodiatasis, may be indicated in certain younger patients with early arthritis or those at a high risk for developing premature arthritis who may not be ideal candidates for undergoing a fusion or joint arthroplasty.
>
> The technique of arthrodiatasis involves placing an external fixator across the involved joint and distracting it a few millimeters to recreate a joint space. This procedure is mostly done using an articulated hinge so that the joint can still move while it is in the fixator (about three months). The treatment concept is based on unloading the arthritic joint by distraction while still allowing motion for joint lubrication and healing of the weight bearing areas. Thus far there are anecdotal reports indicating positive results in the short to medium term follow-up. We still need long term follow-up, as well as greater number of patients in order to further refine the indications for this procedure. It would be ideal to have multicenter comparative studies or analysis based on patient registries so that such emerging techniques can be more thoroughly investigated and compared with the more traditional treatment options. By having such pooled analysis one can perform a more in-depth analysis using robust methodology. Well done research studies in this field can help sort out which subgroup(s) of patients

Andrew Huth and RRY Publications LLC.

may be more likely to benefit from arthrodiatasis."

Professor Creates New Arthroscopy Skills Simulator Wouldn't it be nice to know that the residents joining you in the OR for arthroscopy were properly trained? Now there is a way. Jonathan Braman, M.D. is an assistant professor in the Department of Orthopaedic Surgery at the University of Minnesota. He tells *OTW,*

> "We have created an arthroscopic skills simulator that is different from any other on the market. We are not trying to simulate the inside of the joint with virtual reality. Instead, our simulator breaks down the skills needed to be a competent arthroscopist; and, the modules for those skills will be available in a low cost, self-directed way.
>
> The modules, which are primarily geared toward PGY1 [post graduate year 1] interns, involve three main skills. The first is visualization, or the ability to see something on the screen and hold it. The second skill is triangulation or the manipulation of something in space. The third skill is object manipulation, or moving things around with your non camera hand.
>
> We are now doing a pilot study where we are trying to demonstrate that the simulator can differentiate between expert arthroscopists and novices (construct validity). Then there is face validity where an expert arthroscopist says, 'Yes, this is similar to what we do.' In several weeks we will be embarking on a multicenter trial where learners are randomized into those who were exposed to the curriculum and those who were not. The three month study will involve benchmarks and will be similar to what is currently done with 'open skills.'"

New Single Portal Arthroscopy Technique Announced Daniel Cooper, M.D. is a sports medicine specialist at The Carrell Clinic in Dallas, Texas. Dr. Cooper, who is the developer of this new technique, told *OTW*,

> "Forty years ago, in the early days of knee arthroscopy, surgeons were using a bulky device that didn't allow them to visualize the pathology. Then modern arthroscopy was developed, which involved using a separate portal for the arthroscope and another portal for the working instrumentation. The following two decades we used three/four portal approaches; then in the early '90s industry developed the

modern arthroscopy fluid pumps, which made management more efficient. This was very helpful to patients because most people who do lot of this recognize the morbidity involved in putting an extra cannula up through the quadriceps. Many studies—and my experience—show that eliminating the third portal helps patients recover quicker.

In 2008 I had an infected patient; one portal healed and the other drained, meaning that it needed to be washed out. I washed it out through just one portal by inserting both the arthroscope and shaver at the same time into the draining portal. This experience made me realize how much I could do and see, so I thought that if we could reduce the size of the instrumentation then we could get a lot done through the same sized portal. I approached Stryker Endoscopy executives with the concept of making a new instrumentation system for single portal arthroscopy. This was perfect timing in the industry due to recent improvements in fiberoptic and shaver design that allowed for a smaller arthroscope and instruments that could get the job done through a single portal and still retain excellent optics. The new instrumentation has just been released in the last two weeks.

We undertook a prospective study comparing 100 patients in a row who had a knee scope with two portal technique and 50 patients who underwent a single portal procedure. On average, the single portal patients reported improved activity scores and less pain at one month postop as compared to the two portal technique. Of those who underwent the single portal technique, 42 % never took a pain pill after discharge, a finding that was highly significant. We will soon be presenting all of our clinical results and have recently submitted this work for publication. I would like to note that this process was done in an extremely ethical manner; many products in orthopedics are brought to market after being used extensively (then someone reports on their experience retrospectively). Before we released this, however, we did a prospective study in the hands of the same surgeon."

Danger: Don't Wait to Treat Shoulder Instability A veteran sports medicine doctor tells *OTW,*

> "We really need to get the word out that shoulder instability in younger athletes must be treated early on. We are seeing more and more of these injuries and the old theory of, 'We'll just treat it later' is not an option. Letting an unstable shoulder go on to multiple recurrences will have a negative effect on the athlete. Why? Because then they can't have a simple operation to solve the problem.
>
> Orthopedic surgeons must be more aggressive about early treatment of these injuries. I know of a case where a professional athlete's shoulder popped out and he was told by the medical staff that he would be 'fine.' Once the scope went in, however, it was evident that the shoulder was blown apart. I am amazed that people are still debating this…it's inappropriate because the data is the data. If you treat this injury conservatively the patients will have recurrences… and you will have done more damage in the long run." ♦

COMPANY

FlowerCubes Promise to Cut Orthopedic Costs

Flower Orthopedics Corporation/FlowerCube

By only providing the tools needed, the FlowerCube will challenge the orthopedic status quo and cut implant and instrument costs by as much as 30%.

That's the promise Oliver Burckhardt made as he came roaring back into orthopedics with a September 4, 2013 announcement that his new company, Flower Orthopedics Corporation, had just made a deal with McKesson Medical-Surgical to provide implants and instruments to the supply manager's surgery center customers.

No Reps – Mobile App

The Cube is sold in a rep-less model to eliminate the need to have an implant rep in the room during surgery. Surgeons can pick their preferences using a mobile tablet app which streamlines the ordering/replenishment process and minimizes inventory levels. Reps are now apps.

Burckhardt is no rookie having had stints as president of Orthofix, Inc. and CEO of Scient'x Corp.

FlowerCube

The product is a standardized, single-use bone fixation package that provides, according to the company, "significant operation and operational efficiencies." Each cube is indication-tailored and contains all of the necessary implants, trials and instruments needed to perform a procedure.

The company says the cube concept provides surgery-specific applications in individual sterile packaging, which eliminates the need for pre-op sterilization and, "considerably" reduces the number of implants and instruments brought into the operating room (OR). All instruments in the cube are single-use and disposable, removing the need to reprocess surgical tools post-op. The disposable feature helps minimize the risk of infection potentially associated with reusable devices and expedite OR turnaround time. With these efficiencies, the company believes hospitals and ambulatory surgical centers (ASCs) could save as much as 30% of the combined implant and instrument costs currently spent on each surgical case.

Burckhardt, president and CEO of the company, said the number of items brought into the procedure room for each orthopedic case today is unnecessarily excessive. "It's confusing, time-consuming and inefficient. If providers are going to compete in this environment of declining reimbursements, they need better solutions. We developed our FlowerCubes to simplify the process of preparing for and conducting bone fixation surgery while ensuring clinical excellence. What you get is consistent, reliable quality with faster patient turnaround time likely."

Products and Roll-Out

Through an exclusive distribution agreement with McKesson, the company will immediately begin the roll-out of its hand and wrist cubes. Foot cubes will be launched over the course of the fourth quarter 2013. The goal is in 2014 to have cubes addressing all commonly occurring fractures.

The company currently offers a broad range of bone-fixation implants. More than 200 plate options are manufactured in partnership with ZRINSKI AG, a German manufacturer and supplier of implants, medical products and technical solutions.

"Providing surgeons with only the tools they need in a more efficient way, without compromising patient care, is the right type of change we need for the future of orthopedics," concluded Burckhardt.

—WE (September 10, 2013)

Active Implants Secures Funding for Trial

Active Implants LLC has closed the first tranche of $8.7 million in new funding for its knee repair technology.

A total of $26 million has been committed by View Capital RIA, L.P. in Dallas, Texas and River Street Management in Memphis, Tennessee.

The proceeds will be used to fund a multi-center trial on the company's NUsurface Meniscus Implant and initiate a randomized clinical trial to support applications for U.S. regulatory approval. Patients are currently being enrolled in Europe and Israel.

According to Elliot Hershman, M.D., the implant is a "novel, composite polymer implant which is used to treat knee patients who have pain and disability arising from osteoarthritis caused by a previous meniscectomy, meniscus dysfunction or insufficiency. The NUsurface Meniscus Implant was designed to meet the needs of patients too old for meniscus repair and too young for a total knee replacement." Hershman is chairman of the Department of Orthopaedics at Lenox Hill Hospital in New York and Active Implants' chief medical officer.

Active Implants LLC/NUsurface Meniscus Implant

"Demonstrated Superiority"

Henry Klyce, the company's chairman and CEO said clinical studies outside the U.S. have "demonstrated the superiority of the implant over current standard-of-care treatments." The implant, added Klyce, "is designed to fill a significant treatment gap between non-operative care and knee replacement surgery." Company management estimates the potential worldwide market for the product to be in excess of $2.0 billion annually.

The company has been working with leading knee sports medicine surgeons in Europe and Israel on a prospective controlled, multi-center trial of the device. Peter Verdonk, M.D., Ph.D., from Orthopaedic Center Monica Hospitals Antwerp and the University of Ghent, Belgium, has enrolled patients in the study for two years. He said, "I am impressed with the results observed to date and believe this technology could represent a new method of treating patients with meniscus problems who are often on a long and painful progression to knee replacement."

The company was founded in 2004 to develop and commercialize a new platform technology made from medical grade polycarbonate urethane. The founders were Amiram Steinberg, who previously founded Implant Ltd. (former DISCure), and Limber Ltd., and Steven Bradshaw, a U.S. medical device executive. The headquarters are in Memphis, Tennessee with its research and development center in Netanya, Israel. Half of the company's workforce is employed at the R&D center.

The company's other product is the TriboFit hip system with a "Buffer" acetabular component which "snap-fits" either directly into the acetabulum or inserted into a HA metal shell which is "press-fit" into acetabulum.

Neither product is available in the U.S.

—WE (September 15, 2013)

LEGAL

Is the FDA Rearranging?

On Friday, September 6, 2013, FDA Commissioner Margaret Hamburg, M.D., announced in an internal email that she was forming a "Program Alignment Group" charged with identifying and developing plans to modify FDA's functions, processes, and possibly its structure in order to best achieve mission-critical Agency objectives."

"Significant strides in scientific innovation and increased biomedical discovery, the globalization of the food system and medical supply chains, as well as the expansion in FDA's regulatory authorities via many new forms of legislation, require the Agency to continue to find ways to ensure that we are meeting our critical public health and regulatory mission," she wrote.

The Commissioner is asking senior leaders to report back in three months on their ideas.

Scott Gottlieb, a contributor for *Forbes* wrote on September 8, 2013 that there will be a lot of internal resistance. "A major re-organization will create a lot of dislocation. Big bureaucracies don't respond well to this sort of dramatic change."

He wrote that the best proxy was the unexpected merger of FDA's drug and biologics center in 2002. By 2004, he continued, that re-organization was largely rolled back after internal resistance to the change mounted.

Gottlieb speculated that the most likely result of the effort will "result in FDA creating a few model programs that cut across its existing centers—and some mandates for better alignment. The focus is likely to fall on FDA's post-market regime and its inspection resources, which right now reside across the different centers. I'd expect those to be better integrated after any reorganization."

According to Hamburg's memo, the group will look at "what changes may be necessary from an operational standpoint to transform the Agency from a domestic Agency operating in a globalized world to a truly global Agency fully prepared for a regulatory environment in which product safety and quality know no borders."

Image created by RRY Publications, LLC / Source: FDA and Zibbett.com

"We need to transition to distinct commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, well-designed and coordinated implementation, and a de-layered management structure," stated the memo.

—WE (September 13, 2013)

DePuy Hip Trial Postponed, Settlement Rumored

The first federal DePuy ASR metal-on-metal hip trial that was supposed to start on September 9, 2013, has been postponed to September 24, 2013. The case is Ann McCracken vs. DePuy Orthopaedics, Inc., et al.

Image created by RRY Publications, LLC. Source: Morguefile and alvimann

On September 6, U.S. Federal District Judge David Katz ordered the postponement after conferring with the parties. He determined that because of the delayed designation of the trial, which occurred in July 2013, additional discovery and consideration of additional legal matters requires a two week continuation.

The trial, originally scheduled to begin in July 2013, was first adjourned to September 9, according to court documents (In re: DePuy Orthopaedics Inc., ASR Hip Implant Products Liability Litigation; MDL-2197, U.S District Court for the Northern District of Ohio).

There have been two prior trials in state courts. One in California this spring resulted in an $8 million award for the injured hip patient and a verdict for zero this summer in Chicago. DePuy has not paid the $8 million award and

is appealing to a higher court to try to reverse that judgment.

The federal trial is the first of eleven thousand federal lawsuits involving the ASR metal hip implant. This first case is designated as a "bellwether" case by the court to test the value of these cases. "Obviously, DePuy cannot have eleven thousand jury trials to determine the payment on these cases. There will have to be some kind of settlement of most of them. Since DePuy does not want to pay what the lawyers for the injured hip patients think DePuy should pay the judge has scheduled some trials to 'test the waters'," wrote Joseph Saunders, a personal injury lawyer from Florida on his blog.

The cases selected for trial were selected as average cases to be representative of most of the cases in the litigation so that the jury verdicts will be helpful in trying to value the rest of the cases.

Settlement Rumors

"If this first federal ASR trial is going to take place, then it is in everyone's best interest that the parties be fully prepared to present their proofs, in which case the additional preparation time is a good thing," said Rochelle Rottenstein, an attorney representing some of the plaintiffs. "There is also the possibility that the parties will settle the matter out of court in the two weeks. We've heard that Johnson & Johnson wants to settle the DePuy ASR cases, and if that's true, then it almost certainly will want to settle them all before even one goes to trial. If the first plaintiff wins, it could make it more difficult—or more expensive, anyway—for J&J to settle the pending cases."

A rumored $3 billion dollar settlement has been reported by *Bloomberg*.

—WE (September 15, 2013)

BIOLOGICS

FDA Trips Up High Flying MiMedx

On August 28, 2013, the FDA sent an unwelcome and surprising letter to Georgia-based allograft supplier MiMedx Group, Inc., informing them that one of their allograft products, EpiFix, did not meet the requirements for an allograft and therefore was being sold without the required FDA clearance or approval.

The letter, otherwise known as an "Untitled Letter", said the following:

> "The FDA is contacting these other distributors under separate cover. These products include: AmnioFix™ Injectable, AccelShield™ Injectable (Accel Spine), --- (b)(4) ----------, and EpiFix ™ Injectable, all of which are intended for use, among other things, in reducing inflammation and scar tissue formation, as well as for enhancing wound healing of soft tissues. These micronized amniotic/chorionic-based products are manufactured by --- (b) (4) ---- --- dehydrated composite amnion and chorion tissue, and then having the end user re-suspend them in normal saline for injection into soft tissues. Injectable amniotic/chorionic-based products are human cells, tissues, and cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d). However, these products are HCT/Ps that do not meet all of the criteria in 21 CFR 1271.10(a) and therefore are not regulated solely under section 361 of the Public Health Service Act (PHS Act) and the regulations in 21 CFR Part 1271. Specifically, the products do not meet the minimal manipulation criterion set forth in 21 CFR 1271.3(f) (1) due to the micronization process which alters the original relevant characteristics of the structural tissue, relating to the tissue's utility for reconstruction, repair or replacement. As a result, your HCT/Ps are drugs as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)] and biological products as defined in section 351(i) of the PHS Act [42 U.S.C. 262(i)]."

MiMedx Group, Inc.

In other words, MiMedx's micronized and injectable versions of its allograft placental tissues which are sold under several brand names including AmnioFix, AccelShield and EpiFix, did not meet the requirement of minimal manipulation because, during processing, MiMedx had "micronized" the tissues. Micronizing the tissue, said the FDA, altered their original structural characteristics enough to push them from the allograft designation into a drug and biologics regulatory category.

MiMedx, a public company, was literally crushed in the marketplace when the letter was disclosed. Its stock, which had been trading at $6.06 per share (about $600 million market value) before the letter, collapsed to an intra-day trading low of $1.81 before closing at $3.85 per share ($370 million market value).

CEO Pete Petit and President Bill Taylor immediately scheduled a conference call to explain the FDA letter and to reassure investors. They came out swinging. The letter was a surprise, they said. Based on guidance from their internal FDA experts they believed they were in full compliance.

Furthermore, said Petit, MiMedx is the market leader and is trying to set the highest standard with respect to FDA regulations—as opposed to other suppliers of amniotic tissue forms. "We have seen some violations of the 361 regulations [by other firms] and my years in healthcare have made it clear to me that those types of continued violations will and should cause the FDA to direct individual cases. And if concerns are significant, to then take broader steps and ensure that the regulations are being followed."

Importantly, Petit noted, the letter did not meet the threshold of regulatory significance in the manner of a Warning Letter.

According the FDA, the agency uses Warning Letters for violations that may lead to enforcement action if they are not promptly and adequately corrected. FDA uses Untitled Letters for violations that are not as significant as those that trigger Warning Letters. Unlike a Warning Letter, an Untitled Letter does not include a statement warning that failure to promptly correct a violation may result in an enforcement action.

Finally, Bill Taylor mentioned that he and his staff would be meeting with the FDA and working to find a resolution. In the final analysis, he said, it may all be resolved with labeling changes.

Doubts Persist

Petit and Taylor are long-time healthcare company executives, but first time human tissue processors. Indeed, Pete Petit is known for both his exemplary management skills and his aggressive style.

Will the FDA see "micronizing" in the same manner as Petit and Taylor? As Taylor pointed out in his conference call with Wall Street, other products are "micronized" including human skin (Cymetra) and bone. Although in the case of Cymetra, the micronized allograft skin is injected into skin so the homologous requirement seems to be met. In the case of allograft bone, the material is typically used to augment bone in the recipient.

In addition, management made it clear that the products affected by this FDA letter were a minor part of their business (about 15% of sales) and even if they had to stop commercializing them, it would not change their sales and earnings guidance for 2013.

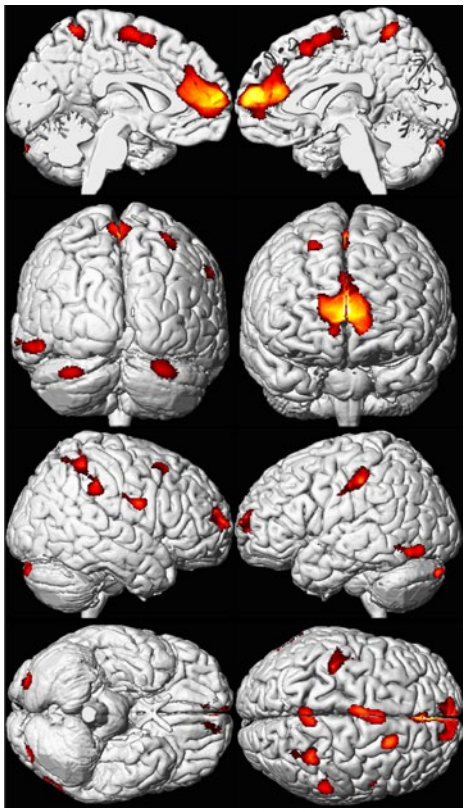
The market, however, remains skeptical. At last count, the number of law firms soliciting plaintiffs to sue MiMedx was about eight, although the final number may well hit double digits.

From our perspective, we would not want to bet against Petit and Taylor. Eventually and sooner than later, they will get these issues resolved and put to bed.

—OTW Staff (September 10, 2013)

Stem Cells Assemble Early Stage Human Brain

The internet and media that cover medical news have been buzzing about a story, published in the peer-reviewed journal *Nature*, reporting that researchers using stem cells have created a "mini-brain." Researchers found that stem cells were able to assemble themselves into tiny clumps of complex neural tissue that they termed "cerebral



Wikimedia Commons and Cecil KM, Brubaker CJ, Dietrich KN, Altaye M

organoids." These structures resembled developing regions of the brain and were able to interact.

Researchers from the Austrian Academy of Sciences, the University of Edinburgh, the Wellcome Trust Sanger Institute and St. George's University, London

carried out the study. What they were trying to do was create a model of the human brain at its very early stages.

The researchers took human stem cells, derived from either embryonic stem cells or adult skin, and supplied them with nutrients and oxygen to support their development into brain tissue and structures. They were able to identify tissues similar to several developing brain structures, including the:

- cerebral cortex – the outer layer of the brain, which plays an important role in higher brain functioning
- choroid plexus – a structure ultimately responsible for the production of cerebrospinal fluid that surrounds and supports the brain
- retina – the light-sensitive tissue at the back of the eyes
- meninges – the membranes that surround the brain and spinal cord

The researchers also found that the cerebral organoids displayed key features of human brain development including patterns of cell organization expected to be seen during the early stages of development.

The tissues grew for approximately two months with the organoids reaching a maximum size of approximately 4mm in diameter. Although growth stopped, the tissue continued to survive up to ten months when the study ended. The researchers think that the lack of continuous growth is likely because of the lack of a circulatory system. They believe that their study represents "a novel approach for studying human neuro developmental processes"—how the human brain develops.

—BY (September 7, 2013)

LARGE JOINTS

StelKast's EXp Cleared for Knees

StelKast, Inc., a privately held manufacturer and distributor of orthopedic implants for knee and hip replacement, has received 510(k) clearance from the FDA to market its product Ex*p* for the company's Proven Gen-Flex Total Knee System. EX*p* is a blend of the antioxidant vitamin E (a-tocopherol) and a cross-linked polyethylene technology that, StelKast affirms, preserves mechanical properties to ensure lasting implant performance.

According to the news release, StelKast was the first company to introduce this technology in the U.S. in 2011 as an alternate bearing material in hip replacements.

"Incorporating our unique EX*p* polyethylene technology with our Proven Gen-Flex Total Knee System allows our knee patients to benefit from the extraordinary success currently offered by our hip products," said John Reyher, senior vice president and general manager of StelKast. "EX*p* will further enhance the durability of our knee devices providing orthopedic surgeons with more advanced, cost-effective solutions for their patients."

Full commercial launch of the EX*p* knee products is planned for September 2013.

—BY (September 13, 2013)

Courtesy of StelKast, Inc.

EXTREMITIES

NO Anesthesia During Ankle Surgery—and It's OK?

The surgeon was half-way through a two hour ankle replacement procedure when the patient suddenly asked, "How's it going?" Later the patient commented on the noise made by the saw as it was cutting through his bone. What was going on?

What was going on was hypnosis. The patient,66-year-old Alex Lenkei, of Worthig, West Sussex, Ireland, chose to forgo traditional anesthetic and instead sedated himself for the surgery with hypnosis.

Lenkei explained, "I asked them if I could do the operation with hypnosis. They agreed because they realized I've got a track record and I'm capable of doing it. I'm not averse to anesthetic—it's just that my pain control is a hell of a lot better than the medical profession's and I heal a lot quicker because my body doesn't have to get rid of all of the chemicals. I have been using self-hypnosis since the age of 16 or 17."

Dominic Nielsen, M.D., who performed the operation at Epsom Hospital in Surrey, said it was "nerve-wracking" making the first incision "not being sure whether he would be able to feel it, but once we got through that bit it became very much like doing any other ankle replacement."

According to Nielsen, Lenkei hypnotized himself in a very short period of time and told the surgeon when he was ready for him to proceed. "He seemed to just put himself into a trance if you like and just lay there and did not have any problems at all. The whole set-up was exactly the same as it would have been for somebody under a general anesthetic," he said.

Nielsen did say that an anesthesiologist was on hand in case the hypnosis failed during the operation. "If it became painful, or something about his heart rate or blood pressure became unsafe, then he would have been in a position to have anesthetic within a split second." he said.

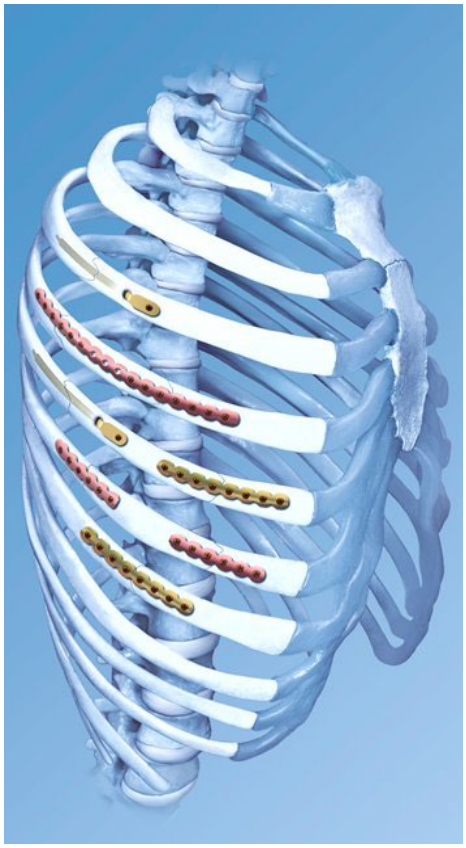
—BY (September 7, 2013)

Wikimedia Commons and Dashaundamon

TRAUMA

New Rib Fracture Instrumentation From DePuy Synthes

Over 350,000 people suffer rib fractures every year in the U.S. DePuy Synthes CMF has launched new instrumentation that enables less invasive surgical fixation and stabilization of those rib fractures.



DePuy Synthes CMF/MatrixRIB System

According to a September 12, 2013 announcement, the MatrixRIB system is precontoured with low-profile titanium plates, locking screws and intramedullary splints.

The company says the MatrixRIB Minimally Invasive Plate Osteosynthesis

(MIPO) system was designed to provide surgeons with improved access, through small incisions, to rib fractures including difficult to reach sub-scapula rib fractures. The new instruments include a Trocar, Threaded Reduction Tool (TRT) with self-drilling tip and a 90 degree screwdriver with drilling capability.

Adam Shiroff, M.D., FACS, chief of trauma at the Jersey Shore University Medical System, said surgical fixation and stabilization of painful rib fractures is a growing procedure. "The introduction of new MIPO instrumentation should help make it an even more attractive option for both surgeons and patients. The instrumentation facilitates a less invasive rib fixation procedure, and a less invasive procedure may result in less pain, quicker recovery and reduced hospitalization."

According to research cited by the company, potential benefits of surgical stabilization (osteosynthesis) of severe rib fractures over non-surgical treatments include reduced duration of mechanical ventilation support, shortened ICU stays and hospitalization, better secretion management through efficient cough, and minimized chest wall deformities resulting from trauma.

Rib fractures are associated with respiratory complications, prolonged hospitalization, prolonged pain, long-term disability and mortality.

Since its launch in 2009, more than 5,000 patients worldwide have received the system implants. The system is the only rib fixation system that is approved by the AO Foundation.

—WE (September 12, 2013)

SPINE

Second FDA Clearance Since April for Abyrx, Inc.

Although founded just five months ago, privately held Abyrx already has its second FDA clearance.

Abyrx, Inc., a privately-held therapeutic device company, reports that the United States Food and Drug Administration has cleared a new resorbable hemostatic bone putty, called Hemasorb Plus, for clinical use in the United States.

The firm's release states that Hemasorb Plus complements Abyrx's existing surgical hemostat product offerings which currently include AHBP, a synthetic hemostatic bone putty that absorbs within days following surgery, and Hemasorb, a synthetic resorbable hemostatic bone putty that is available with a custom spatula or in a syringe-like applicator.

David J. Hart, Abyrx's chief operating officer, is leading Abyrx's market introduction of Hemasorb Plus. He stated, "The bone hemostasis market is undergoing a significant transformation as surgeons seek improved solutions to address bone bleeding. "

Abyrx's surgical hemostat products are used by cardiothoracic, craniomaxillofacial, spine, orthopedic, neurological, and trauma surgeons. The company estimates that over 3.5 million patients undergoing surgical procedures each year could benefit from the intraoperative use of its products.

John J. Pacifico, Abyrx's president and chief executive officer, commented, "Since 2006, our organization has been primarily focused on research and development. With the addition of Hemasorb Plus to our product portfolio, we will increase efforts toward expanding the availability of our products to surgeons and hospitals throughout the world. As part of this process, we will evaluate opportunities to further enhance our commercial infrastructure and manage the growth of our distribution channels."

Hemasorb Plus is the second new product clearance Abyrx has announced since the company was established in April of this year.

—BY (September 13, 2013)

Abyrx, Inc.

Wenzel Spine Product Receives Patent

The United States patent office has granted a patent to Wenzel Spine, Inc. of Austin, Texas, for a product with one of the longest names in the industry. It is Wenzel Spine's Zero-Profile VariLift® Stand-Alone Expandable Interbody Fusion System.

Courtesy of Wenzel Spine, Inc

Chad Neely, CEO of Wenzel Spine, said, "With the issuance of this new patent, the Patent Office has confirmed Wenzel Spine's innovative stance in this fast-paced technological arena. We have numerous additional patent applications under review and will continue to work to expand the Wenzel Spine patent portfolio as we continue to innovate and develop new products."

The VariLift family of devices features zero-profile interbody designs, which allow for stand-alone use of the VariLift system for lumbar and cervical fusion procedures. Wenzel Spine's Cervical and Lumbar VariLift Stand-Alone Expandable Interbody Fusion Systems are commercially available in the U.S. and Europe. The company offers minimally invasive solutions for stand-alone treatment of disc herniations, spinal stenosis, and spondylolisthesis.

—BY (September 9, 2013)

Mazor Robotics Performs 1st Deep Brain Stimulation

A patient at Celebration Health hospital, Orlando, Florida, was the world's first to receive deep brain stimulation (DBS) using Mazor Robotics Renaissance Guidance System. Nizam Razack, M.D. performed the procedure in August and later performed a similar operation on two more patients with positive results.

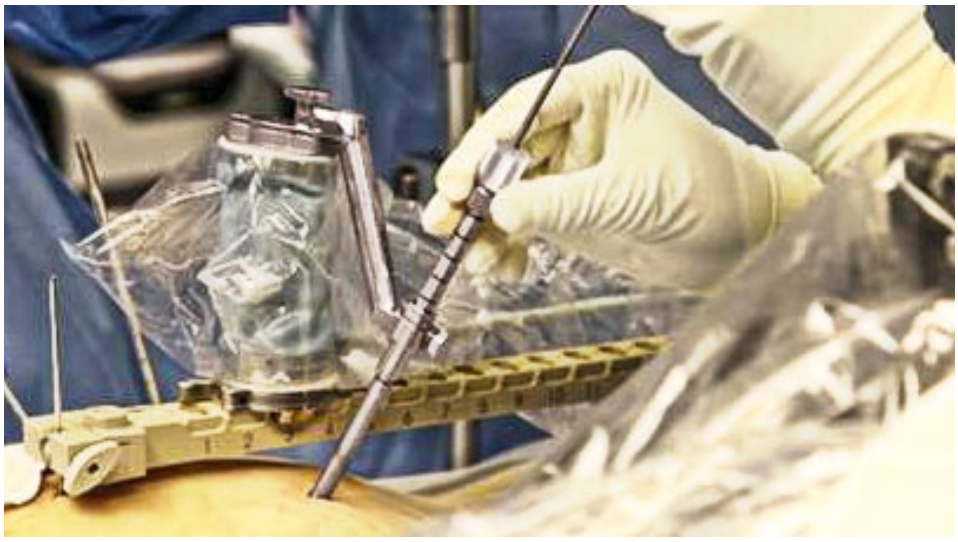
DBS is a procedure to implant a battery-operated medical device in the brain to deliver electrical stimulation to block abnormal nerve signals that cause the debilitating neurological symptoms of Parkinson's disease and essential tremor.

The use of Renaissance's proprietary pre-operative planning software allows surgeons to determine the optimal trajectory for implanting the electrodes before beginning the surgery and then use the guidance unit to execute the implantation with precision. In Razack's three cases, he used Alpha Omega's micro drive, NeuroDrive, in conjunction with Renaissance to carefully position the electrode in the appropriate area of the patients' brains.

"Mazor Robotics Renaissance increases guidance accuracy during the procedure and adds an extra element of safety for patients undergoing this major operation," said Razack. "The technology also allows for less time in the operating room. I've performed over a thousand DBS procedures and I was eager to be a part of introducing this revolutionary technology into the neurosurgical field."

Surgeons have successfully utilized Renaissance in 36 brain biopsy procedures in Germany. Mazor Robotics officials believe this could be a major application for Mazor Robotics technology as there are 180,000 new diagnoses of brain tumors each year. In addition, according to the Parkinson's Disease Foundation, more than 30,000 patients with Parkinson's have undergone DBS treatment and doctors diagnose 8,000 to 10,000 new cases worldwide each year.

—BY (September 9, 2013)



Courtesy of Mazor Robotics Ltd.

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