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Orthopedics This Week

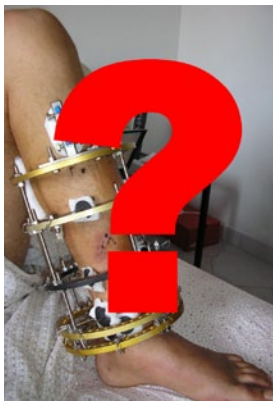
WEEK IN REVIEW

4 Landmark Ruling: Judge Orders Insurer to Pay for ADR >> Danica Dubaich was in agony. Her physician recommended an ADR. CIGNA repeatedly denied coverage. Never mind the evidence. So Dubaich sued…and won. In a July 31st landmark decision, a federal judge ordered CIGNA to pay. Could this be a trend? Lawyers Petti and Kantor are working on it.

8 China Squeezes Medical Products Suppliers >> China's regulatory oversight of business and health care is changing rapidly. New leaders have promised public examples of cleaning up corruption. Get ready to meet Xu Xinyu, a top regulator who will ask you to confess in return for leniency. Read what we learned about the new climate and laws.

12 Orthopedics Visionary, Lew Bennett, Dies at Age 87 >> Lew Bennett, one of the most beloved veterans of the orthopedic industry, passed away on August 15, 2013. In his wake he leaves a long trail of patients, coworkers and friends made better by his having passed through their lives.

14 Surprising Study Finding: Surgeons Don't Follow Disclosures + 35,000 Arthroplasties now in AAOS Registry + Stronger Implants Needed for Arthroscopic Biceps Tendonesis? >> New Rothman Survey finds that surgeon's don't use disclosures to interpret study results. Joint Registry: 180 hospitals and 35,000 arthroplasties. Has the move away from Ilizarov opened up new problems?



BREAKING NEWS

17 FDA Transfers Some Devices to Biologics Oversight

$3 Billion ASR Hip **Settlement Rumored**

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Pluristem: PLX Cells and Tendon Healing

China Investigating Device **Overuse for Profits**

Why People **Fall**

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: China giveth and China taketh away. China, whose medical market is not only rapidly growing but destined to become the second or third largest in the world, is clamping down on what regulatory authorities see as unfair business practices. GlaxoSmithKline was hit earlier this year. SNN, MDT and SYK all have major investments in the Chinese market. Walter Eisner has a key piece on China's changing mood this week

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Globus Medical	28.53%	4.03%	Nearly 30% operating margin means that GMED has the resources to grow at sustained double-digit rates.
2	3	Integra LifeSciences	11.77	11.41	Double good news from FDA for IART. Plainsboro facility good to go and Titan Reverse Shoulder cleared. Up one spot.
3	6	Stryker	18.71	(3.59)	China news is unsettling. But SYK's China investment is in Trausan. Solid firm. And SYK has the balance sheet to continue diversifying via M&A.
4	4	Zimmer	29.28	(4.19)	Zimmer's new Patient Specific Shoulder is very cool. Complements the Trabecular Metal Reverse Shoulder system.
5	5	Smith & Nephew	20.78	0.99	12% of SNN revenues come out of China. Good long-term strategic move but near term SNN needs to watch events there carefully.
6	7	Johnson & Johnson	26.68	(4.28)	After rising for two month, JNJ seems to have run out of steam. At current prices, JNJ is the 10th best value in ortho.
7	1	Medtronic	28.78	(4.27)	MDT's purchase of Kanghui, one of China's largest orthopedic companies, makes the recent Chinese regulatory news worrisome.
8	8	Symmetry	7.49	(1.42)	SMA is now trading at the lowest Price-to-Sales ratio of any orthopedic company.
9	9	Conmed	10.57	(3.95)	New Conmed director, Dirk Kuyper, bought stock at $31.63 per share. There are many reasons to sell stock, but only one reason to buy.
10	10	NuVasive	6.30	(11.86)	Oversold on the OIG news. And, insiders are buying—specifically Director Treharne for about $46,000.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$14.67	$690	19.66%
2	MiMedx Group	MDXG	$6.23	$600	12.86%
3	Integra LifeSciences	IART	$41.78	$1,174	11.41%
4	Tornier N.V.	TRNX	$19.73	$943	10.04%
5	Globus Medical	GMED	$18.06	$1,677	4.03%
6	Smith & Nephew	SNN	$61.21	$11,011	0.99%
7	Symmetry Medical	SMA	$8.36	$311	-1.42%
8	Stryker	SYK	$68.29	$25,823	-3.59%
9	Conmed	CNMD	$31.62	$869	-3.95%
10	Zimmer Holdings	ZMH	$80.52	$13,652	-4.19%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$22.60	$440	-19.89%
2	TiGenix	TIG.BR	$0.29	$37	-17.40%
3	CryoLife	CRY	$6.41	$177	-16.10%
4	RTI Biologics Inc	RTIX	$3.53	$199	-15.95%
5	Alphatec Holdings	ATEC	$2.03	$197	-14.71%
6	Wright Medical	WMGI	$24.15	$1,136	-12.31%
7	NuVasive	NUVA	$23.79	$1,060	-11.86%
8	ArthroCare	ARTC	$32.85	$928	-10.07%
9	Exactech	EXAC	$19.90	$268	-9.46%
10	Bacterin Intl Holdings	BONE	$0.60	$31	-7.83%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$22.60	$440	8.79
2	Zimmer Holdings	ZMH	$80.52	$13,652	13.01
3	Medtronic	MDT	$52.74	$53,131	14.02
4	Smith & Nephew	SNN	$61.21	$11,011	15.10
5	Globus Medical	GMED	$18.06	$1,677	16.02

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$23.79	$1,060	84.96
2	Symmetry Medical	SMA	$8.36	$311	33.44
3	RTI Biologics Inc	RTIX	$3.53	$199	26.30
4	ArthroCare	ARTC	$32.85	$928	22.27
5	Integra LifeSciences	IART	$41.78	$1,174	19.99

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$18.06	$1,677	1.07
2	Orthofix	OFIX	$22.60	$440	1.26
3	Exactech	EXAC	$19.90	$268	1.28
4	Conmed	CNMD	$31.62	$869	1.31
5	Zimmer Holdings	ZMH	$80.52	$13,652	1.42

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$23.79	$1,060	7.43
2	CryoLife	CRY	$6.41	$177	4.58
3	Symmetry Medical	SMA	$8.36	$311	2.79
4	Johnson & Johnson	JNJ	$88.41	$249,146	2.69
5	Medtronic	MDT	$52.74	$53,131	2.17

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.36	$311	0.76
2	Bacterin Intl Holdings	BONE	$0.60	$31	0.91
3	Orthofix	OFIX	$22.60	$440	0.95
4	Alphatec Holdings	ATEC	$2.03	$197	1.00
5	RTI Biologics Inc	RTIX	$3.53	$199	1.12

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$6.23	$600	22.19
2	TiGenix	TIG.BR	$0.29	$37	9.11
3	MAKO Surgical	MAKO	$14.67	$690	6.72
4	Baxano Surgical Inc	BAXS	$1.86	$84	5.77
5	Globus Medical	GMED	$18.06	$1,677	4.34

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

Landmark Ruling: Judge Orders Insurer to Pay for ADR

BY ROBIN YOUNG

Image created by RRY Publications, LLC / Source: Cigna Logo and Wikimedia

"The Court concludes that CIGNA has failed to prove that two-level ADR is an experimental procedure excluded from the Plan's coverage." – U.S. District Court Judge Dolly M. Gee on July 31, 2013

Danica Dubaich was in agony. She had bilateral foot pain, low back pain, left arm and hand weakness, right thigh numbness, right hip pain and headaches. Her physician, Brian Rudin, M.D., diagnosed degenerative disc disease at L5-S1.

To confirm his diagnosis Dr. Rudin performed a discogram of Ms. Dubaich's spine which clearly showed an annular tear at L5-S1. The discogram was consistent with an earlier MRI image which also indicated that pain was emanating from L5-S1.

Danica Dubaich was 44 years when Dr. Rudin completed his diagnosis. Given her age and otherwise good health, Dr. Rudin thought Dubaich was a good candidate for a motion preserving implant—either Charité from DePuy or ProDisc-L from…well, DePuy/Synthes.

Of course, Dubaich's insurer (CIGNA) rejected Dr. Rudin's request for a preauthorization of the motion preservation implant as being "not medically necessary." Such rejections are so common that the appeal letters are now free on Internet gaming sites or the corner of 16th and Broadway from Nigerian street vendors. (That may be a slight exaggeration.)

CIGNA's medical coverage policy document says that fusion is the reimbursable course of treatment for patients with Dubaich's diagnosis.

But Dubaich did not want fusion. Neither did her doctor, Dr. Rudin.

So she fought back.

Here's how Dubaich and her lawyers beat one of the largest insurance companies in America.

The Road to Justice Act I: DENY the Surgery

CIGNA's Medical Coverage Policy states "CIGNA covers the surgical implantation of Charité or ProDisc-L…as medically necessary" when the medical criteria are met. In 2011, after exhausting all conservative treatment, Dr. Rudin submitted a pre-authorization for a two level ADR [artificial disc replacement] at L5-L5 and L5-S1.

CIGNA's pre-authorization nurse denied Dr. Rudin's request saying "documentation submitted does not confirm that disc degeneration has been confirmed on complex imaging studies such as magnetic resonance imaging or computerized tomography."

Then CIGNA assigned a urologist to review Dubaich's file. The good urologist then opined that the treatment should be denied as experimental.

Here's his quote:

> "Based upon current available information, coverage cannot be approved because there is insufficient scientific evidence to demonstrate the safety and/or effectiveness of any of the following in treating degenerative disc disease:
>
> Charité or ProDisc-L lumbosacral intervertebral disc prosthesis when any of the following apply:
> - the planned procedure includes the combined use of a prosthesis and spinal fusion
> - simultaneous multi-level implantation is planned
> - the implant will be inserted outside of the L4-S1 region (Charité) or outside of the L3-S 1 region (ProDisc-L-L) [sic]
> - the individual has osteopenia or osteoporosis (T-score less than -1.0) –the individual has a history of a prior lumbar fusion
> - there is evidence on imaging studies the spine [sic] of any of the following:
>   - degenerative spondylolisthesis of Grade 2 or greater
>   - infection
>   - multi-level degenerative disc disease
>   - nerve root compression or spinal stenosis
>   - pars interarticularis defect with either spondylolysis or spondylolisthesis
>   - scoliosis
>   - severe facet joint arthrosis
>   - spinal fracture
>   - tumor

- o A lumbosacral disc prosthesis other than Charité or ProDisc-L.

At the present time, each is considered non-standard therapy and falls under the category of experimental/investigational/unproven. Your benefit plan does not cover experimental/investigational/unproven services."

CIGNA issued its Initial Case Resolution Letter on July 11, 2011. Importantly, that letter did not state the reason for the denial nor anything about absence of medical necessity or lack of FDA approval.

The Road to Justice ACT II: DENY the Science

Two days after CIGNA's rejection, Dr. Rudin appealed. He told CIGNA that he'd personally performed more than 200 disc replacements. He also cited several recent studies including the 2011 study by Delamarter et al., (*The Journal of Bone and Joint Surgery*). Here it is:

"The full title of this study is *Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc-L Total Disc Replacement Compared with Circumferential Arthrodesis for the Treatment of Two-Level Lumbar Degenerative Disc Disease*. The study compared the efficacy of ProDisc-L ADR with that of spinal fusion for 'the treatment of degenerative disc disease at two contiguous vertebral levels from L3 to S1.' Using 'a composite regulatory FDA-guided end point consisting of ten criteria,' the study found that 58.8% of the two-level ADR patients 'met all ten criteria and were considered a study success,' as compared to 47.8% of the spinal fusion patients. It found that 'the mean improvement [in back pain, as measured by the Oswestry Disability Index (ODI)] from baseline was 52.4% in the [ADR] group compared with 40.9% in the [fusion] group.' According to the study, its 'results suggest that the ProDisc-L total disc replacement is an appropriate alternate treatment to lumbar arthrodesis in [the two-level degenerative disc disease] patient population.'"

Rudin also cited studies by Bertagnoli, Goldstein, Hannibal and others.

CIGNA kicked Rudin's appeal to another physician, an orthopedic surgeon named Dr. Mino. He upheld the urologist's decision adding that the quality and quantity of data in the current peer-reviewed scientific literature was inadequate to establish the clinical utility, safety and efficacy of the use of an intervertebral disk prosthesis in any of these clinical presentations.

(For other examples insurer bias, see "Lies, Damn Lies and Blue Cross Blue Shield of North Carolina" http://ryortho.com/2013/05/lies-damn-lies-and-blue-cross-blue-shield-of-north-carolina/.)

Road to Justice ACT III: APPEAL to a Higher Authority

Rudin appealed again. This time CIGNA's Benefit Appeals Committee responded saying that the matter had been previously reviewed and, relying solely on the urologist's original evaluation while simultaneously ignoring Rudin's studies, the committee ruled that ADR was experimental, investigational, etc. You know the drill.

So Danica Dubaich walked into the law offices of Russell Petti and Lisa Kantor and asked if they would help her appeal these CIGNA rulings in district court.

Fighting an insurer like CIGNA is expensive. If a patient can afford the litigation, they can afford the surgery—so no lawsuit. Petti and Kantor had to take the case on contingency. They get paid only if they win. At any point during the suit CIGNA can agree to reimburse, ending the suit, and Dubaich's lawyers get nothing.

Petti and Kantor decided to represent Danica Dubaich anyway and filed a lawsuit against CIGNA saying that CIGNA was violating the Employee Retirement Income Security Act (ERISA) of 1974.

Under ERISA, workers who have insurance are covered for medical expenses which are determined to be medically necessary by the Plan Administrator (ERISA).

To be considered "medically necessary" under ERISA a treatment must:

- Be consistent with the diagnosis
- Meet quality medical practice standards
- Be the most appropriate level of service (for example, in the case of hospital inpatient care, care that could not be appropriately provided on an outpatient basis)
- Be recognized as an accepted medical practice and have received the required federal approval
- Not be primarily for the comfort and convenience of the patient

The Plan excludes experimental and investigational treatments, listed under "General Medical Expenses Not Covered." The specific language is as follows:

Research, experimental, investigational and unproven procedures, supplies, drugs and devices (Federal Drug Administration [FDA] approval does not necessarily mean a procedure or supply has been removed from the experimental list), with the exception of pre-certified clinical trials.

The term "experimental" is defined as follows: Any medical procedure, equipment, treatment or course of treatment, or drugs or medicines that are:

- limited to research
- not proven in an objective manner to have therapeutic value or benefit
- restricted to use by medical facilities capable of carrying out scientific studies
- of questionable medical effectiveness or
- would be considered inappropriate medical treatment

The Road to Justice ACT IV: CIGNA Exits Stage Left

Petti and Kantor filed the case in mid-2012 and over the course of the ensuing year fought it out. On July 31, 2013, United States District Court Judge Dolly M. Gee ruled.

Here's what Judge Gee said:

"As a general matter, CIGNA has made no showing that multi-level ADR is experimental."

"CIGNA has not met its burden to show that multi-level ADR is limited to research. Dr. Rudin offered Dubaich the procedure and has personally performed approximately 200 multi-level disc replacements. Nothing in the record establishes that the procedure is limited to research. Therefore, on this record, it does not appear that multi-level ADR is limited to research."

"CIGNA has not met its burden to show that multi-level ADR lacks therapeutic benefit. The Delamarter Study found two-level ADR to have better reduced back pain than spinal fusion, and the Bertagnoli Study found that two-level ADR eliminated instances of severe back pain and improved ranges of motion."

"CIGNA has not met its burden to show that multi-level ADR is restricted to use by medical facilities capable of carrying out scientific studies."

"CIGNA has not met its burden to show that multi-level ADR is of questionable medical effectiveness. All the studies Dr. Rudin submitted found equal or better success in two-level ADR as single-level ADR. CIGNA does not dispute that single-level ADR is medically effective. CIGNA has not demonstrated that two-level ADR is not similarly effective."

"CIGNA has not met its burden to show that multi-level ADR would be considered inappropriate medical treatment. Dr. Rudin stated that Dubaich specifically is a good candidate for multi-level ADR. CIGNA has not rebutted Dr. Rudin's assessment."

"The Court concludes that CIGNA has failed to prove that two-level ADR is an experimental procedure excluded from the Plan's coverage. When confronted with Dr. Rudin's evidence that two-level ADR is not experimental, CIGNA merely stated that the quality and quantity of such evidence is inadequate."

With that, Judge Gee ruled that Danica Dubaich was entitled to coverage for a multi-level ADR.

She is now enjoying her two new ProDisc-Ls.

Curtain Call

Having persevered in this landmark case, Dubaich's lawyers are now preparing to challenge other cases of rejection of proper medical care by healthcare insurers including rulings based on Milliman guidelines. We look forward to reporting on more patient, physician and scientifically sound rulings. ♦

China Squeezes Medical Products Suppliers

BY WALTER EISNER

RRY Publications LLC

"Confess," Xu Xinyu, a division chief at the Chinese National Development and Reform Commission (NDRC), told executives of about 30 large foreign firms at a closed-door meeting on July 25, 2013 in a small hotel in Beijing.

Confess for Leniency

Xu reportedly told the attendees that half of the companies in the room were either being investigated or had been probed by the NDRC. Xu's message, according to an exclusive August 21, 2013 *Reuters* story, was that, "If you put up a fight, I could double or triple your fines."

The companies were being pressured to confess to antitrust violations and were warned against using external lawyers to fight accusations from regulators. Such brazen enforcement pressure might even make former U.S. Attorney Christopher Christie, of orthopedic deferred prosecution agreement fame, blush.

It was not reported whether among the companies attending the meeting were Medtronic, Inc., Johnson & Johnson, Zimmer Holdings, Inc. or Stryker Corp., who have all made acquisitions or formed joint ventures with Chinese orthopedic companies.

The meeting had been billed as a training session to mark the fifth anniversary of the anti-monopoly law. Officials from the Ministry of Commerce as well as the State Administration for Industry and Commerce (SAIC), a regulator in charge of market supervision, were also at the meeting.

According to the *Reuters* article, Xu's comments were perceived as threatening and consistent with the approach taken by other officials in private conversations with companies in recent months.

One lawyer reportedly asked a question about the anti-monopoly law. Xu asked the executive to elaborate on his company's practices so he could determine on the spot if it was in violation or not. The lawyer clammed up.

The NDRC is offering leniency for some companies in return for cooperation.

Price Fixing, Anti-Competitive Behavior

On August 7, 2013, the NDRC announced fines totaling a record $110 million against five foreign milk powder firms and one Chinese producer for price fixing and anti-competitive behavior. Three other milk powder makers were investigated but not fined because they carried out "self-rectification," the NDRC said at the time.

A Shanghai court recently ordered Johnson & Johnson to pay 530,000 yuan ($85,000) to a distributor who had

sued the company for setting a minimum price the distributor could charge for surgical sutures. The company was found guilty of "vertical monopoly." The court said the company caused the distributor to lose potential sales and made the award for lost profits.

"This case is a warning to companies that the Chinese government is increasing the intensity of anti-monopoly investigations," said Wang Xiang, a lawyer for the firm Orrick, Herrington & Sutcliffe.

Public Show

Chinese prosecutors, investigators and regulators have been on a very public reform tear lately in the shadow of the trial of ousted politician Bo Xilai. Bo, the 64-year-old former party chief of the southwestern city of Chongqing, has been charged with illegally receiving almost 27 million yuan ($4.41 million) and being guilty of corruption and abuse of power. Bo's trial was one of China's most political in decades.

The ruling party allowed almost real-time coverage of the trial to the population at large.

Weibo/Jinan intermediate court

Device Utilization Scrutiny

In addition to increased enforcement of the anti-monopoly law, the government is looking at the use of medical devices in Beijing after determining that over-utilization is taking place to increase profits.

John Tan, a lawyer with Reed Smith's Global Regulatory Enforcement Group based in Shanghai, wrote on August 15, 2013 that the local Beijing office of the Ministry of Health (MOH) announced that it has started a three-month review of the use of high-value medical devices in Beijing.

A previous investigation had found continuing problems at hospitals with the misuse and overuse of medical devices to increase profits. The investigation is intended to strengthen hospitals' management of the use of medical devices.

The MOH will also develop a database that will track the price and model of devices implanted in each patient, require hospitals to improve their purchasing management systems, and conduct periodic inspections of hospitals' purchasing and management of medical consumables.

Health Care Enforcement

In the last two months, there have been criminal and administrative enforcement actions by the NDRC targeting the pharmaceutical sector. Additionally, on August 14, 2013 the State Administration for Industry and Commerce (SAIC) announced a new three-month-long investigation into the pharmaceutical and medical services sectors, targeting bribery, fraud and anti-competitive practices.

The government has issued a new code of conduct for health care providers and a new guidance on strengthening anti-bribery controls in public medical institutions. Authorities also issued regulations on the centralized purchasing of medical consumables and large scale medical equipment containing provisions that would exclude companies found to have engaged in commercial bribery from participation in centralized purchasing.

A 2012 U.S. government publication stated, "Corruption remains endemic in China." In the health sector, bribery has become so common that the Ministry of Health has issued draft guidelines that may require both patients and doctors to sign a mutual non-bribery agreement before hospitalization.

New Leadership

Hansen Yuan, M.D., Ph.D. is the Past President of NASS (North American Spine Society) and ISASS (International Society for the Advancement of Spine Surgery), and currently the Editor-in-Chief of the *ISASS Journal*. Dr. Yuan, who has taught many Chinese spine surgeons, told *OTW* that this is a sign of changing Chinese leadership, starting with a new president.


Hansen Yuan, M.D., Ph.D.


Medtronic CEO Omar Ishrak

In Dr. Yuan's view, there is a new commitment to rid the system of fraud, abuse and improper payments to government and business leaders. Dr. Yuan also told *OTW* that the new commitment is beginning with leaders of hospitals and is changing the culture and the way that companies court doctors to use their products.

He doesn't expect to see individual doctors prosecuted, but expects health care system leaders to be held accountable. The corruption problem has been characterized in the press as being systemic and the new Chinese leadership wants to be very public about changing behavior from the top down, added Dr. Yuan.

Medtronic's Take

During a conference call with Wall Street analysts on August 20, 2013, Medtronic's CEO Omar Ishrak was asked what impact the government's actions are having on Medtronic's business.

Ishrak replied: "In our view most of that is directed around go-to-market models using distributors, which we are looking at very carefully. It's a market where we eventually have to have more direct presence with the customers themselves." He said the company has traditionally gone to market using distributors, whom he called, "extremely necessary."

"We are examining our distribution models very carefully. At the same time we're working very closely with the government to help put in the investment so that health care in China can be dramatically improved."

Legal Issues

Companies should be aware that success brings greater legal responsibilities.

According to a 50-page primer called, "Distribution in China – Legal Issues" from the law firm of McDermott Will & Emery, success in the China market leading to a "dominant market position" will immediately entail greater restrictions on the conduct of a company.

The McDermott paper outlines key legal issues for companies to consider when doing business in China. We've highlighted some of the current topics under the government's microscope.

Anti-Monopoly Law (AML)

The law went into effect in August 2008 and performs substantially the same role as the European Union's competition law and U.S. antitrust laws.

"Monopolistic conduct" is defined as including agreements, decisions or other concerted behavior that eliminates or restricts competition; abuse of a dominant market position; and concentrations such as mergers, acquisitions and joint ventures that may have the effect of eliminating or restricting competition.

The fines go up to 10% of a company's annual revenues, confiscation of illegal gains and private damage actions in the courts.

Anti-Unfair-Competition Law (AUCL)

The AUCL was enacted in 1993 to encourage and protect fair competition, discourage unfair competitive acts, and protect the lawful rights and interests of business operators and consumers

AUCL operates together with the AML, the Price Law and other laws to regulate the ways that businesses are allowed to compete with each other.

Price Law

The law was enacted in 1998 to standardize price behavior in order to encourage the rational disposition of resources, stabilize the general market price level, protect the rights and interests of consumers and business operators, and promote the healthy development of the socialist market economy.

Anti-Corruption Law

Under China's legal system, the laws governing commercial and governmental corruption fall under two categories:

- Administrative regulations, such as the AUCL and the Interim Provisions on Banning Commercial Bribery
- Criminal laws, mainly forbidding bribes to government officials

Foreign companies must also follow the anti-corruption laws of their home countries.

Dominant Suppliers and Dominant Distributors

Failure to comply with the additional legal duties to avoid abuse of a dominant market position can result in fines, confiscation of illegal gains and private damage claims for the abuse of dominance.

There is a presumption of dominance, and therefore additional legal duties, in the following situations:

- Market share is 10% or more, and the supplier and two other undertakings together have 75% or more of the market.
- Market share is 10% or more, and the supplier and one other undertaking together have 66.6% or more of the market.
- The supplier or distributor's market share is 50% or more.

Further, if a supplier or distributor declares publicly that it is dominant or has a market share in which the presumption of dominance arises, China courts will assume that the supplier or distributor is in fact dominant.

Corruption and Bribery

The giving of incidental gifts such as mooncakes, bottles of wine, dinners and other relatively small gifts is normally deemed legal if it is for promotional purposes. However, gifts of cash or anything of value for an improper purpose, such as obtaining or retaining business, will generally be regarded as bribery and considered illegal.

"Official" bribery is an offer of property to a state functionary in return for a benefit or assistance in obtaining an improper benefit. Significantly, "state functionary" includes doctors or medical workers in a state hospital

Click on this link for entire McDermott paper: http://www.mwe.com/files/Uploads/Documents/Pubs/Distribution%20in%20China%20-%20Legal%20Issues.pdf

The regulatory climate of China is changing rapidly. New leadership has promised changes and has been very public with examples of their actions to clean up corruption. If you see Xu Xinyu coming, get ready to confess. ♦

Orthopedics Visionary, Lew Bennett, Dies at Age 87

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

Lew Bennett, one of the founders of Howmet (later Howmedica Corporation, later part of Stryker Corporation) and a senior executive at Sofamor Danek (now Medtronic, Inc.), Smith &Nephew plc, NuVasive, Inc., SpineMedica Corp., Custom Spine, Inc., board member of HydroCision, Inc., and one of the most beloved veterans of the orthopedic industry, passed away on August 15, 2013. In his wake he leaves a long trail of patients, co-workers and friends made better by his having passed through their lives.

Lew Bennett (1926-2013)

Lew was born in Nashville, Tennessee on, December 17, 1926. Lew attended West High School and went on to marry his grade school sweetheart, Betty Gene Boone, in Nashville in 1947.

He was always driven to succeed, and early on bought a "house in an area that we couldn't afford." One Sunday Lew saw his neighbor drinking whiskey and grilling steaks. He strolled over and introduced himself. "What is your name? I'm Lew Bennett. He said, 'My name's Jim Thompson.' He told the man, "Jim, you don't look a lot different than I do, but you are living a lot better than I am." The man started laughing and Lew said, "What do you do?" This led to a Sunday phone call to a company called Ethicon, Inc.; that led to Lew getting an interview with Ethicon where he would soon be Salesman of the Year…the rest is orthopedic industry history.

In the more than 50 years that Lew Bennett shined in the orthopedic and spine worlds he never met a stranger and spoke to everyone with his signature, "Hi, How ya doing?" When they responded in kind, his answer was always "Like a million!" Lew held executive positions at multiple orthopedic and spine companies in the industry and developed long-term personal relationships with a number of surgeons.

As one of the founders of Howmet (which later became Howmedica Corporation), Lew helped position the company for an acquisition by Stryker. Lew also held executive positions at Sofamor Danek (now a division of Medtronic), Smith and Nephew, and NuVasive. His most recent positions included CEO of SpineMedica, president of Custom Spine and board member of Hydrocision. At some point, Lew got the public speaking bug, and he became a popular consultant and presenter, helping many people and surgeon practices. In all, he lectured at over 300 orthopedic and neurological resident programs. In addition, he consulted for over 550 orthopedic and neurological practices and universities.

As Lew told it, his wife had no interest in relocating to New York City during the Howmedica years. The result was that Lew logged a lot of frequent flyer miles, commuting between New York and Atlanta for ten years.

Randal R. Betz, M.D. of Shriners Hospitals in Philadelphia recalls Lew Bennett as one of his best friends. "One of the best years of my life was 1981, when I had the opportunity to meet Lew. At that time, he was giving a new residents program on practice management. Since then, Lew has done several hundred of these, and these were then refined and developed into a program for spine fellows and then into one for practicing physicians. During Lew's practice management session, there were several principles he liked to teach. One was "listening and learning," and there's a story that illustrates this. He was flying on an airplane (first class, of course). The lady sitting next to him had a young baby. When they started to descend from 35,000 feet, the woman began breastfeeding. Lew, trying not to stare too much, asked the woman why she was doing that, and she said, "Because it helps keep his ears from hurting." Lew's response was, "And to think all this time I've been chewing gum."

"In all seriousness, Lew is one of the most outstanding people persons I know. The key to his success was his wife, Betty Gene. She had to sit through all his jokes over all these years. If you ever watched Betty Gene when he's telling his jokes, she'd either hide her head in her hands or give you this cute little smirk and just nod."

Lew was known for being thorough. Everyone he interviewed could expect to sit there for two hours; on average he checked roughly 12 references. He often said to people, "Why the heck should I hire you?" When I (EH) spoke with him a few years ago he told me, "I want the whole story on a person, practically from when they were in diapers. Most distributors I know of don't take the time to thoroughly interview and vet the person. Weeks or months later they're wondering what went wrong."

His personality was golden, in part because not only did he teach, but he *lived* a positive attitude. "Look," said Lew, "a negative person is the kind who goes to an orgy and then complains about the cheese dip. Weed out these people." When attending trade shows, Lew was continually stopped by friends and well-wishers. One tradeshow observer commented, "Lew is like a rock star. He cannot walk two feet without someone stopping him to talk."

Jack Blair, former CEO of Smith & Nephew Richards, talks of his old friend: "How are you, Lew?" The answer was always the same…"Like a million." Lew grew up in and helped define the role of professional medical sales representative. From his earliest days with J&J, Lew quickly learned to develop personal relationships…not only with key hospital decision makers, but with their secretaries and assistants as well. "Lovable Lew" had his photo affixed to his business card, so everyone would remember him."

"Lew brought his experience and positive personality to Smith & Nephew Orthopedics (formerly Richards Medical) in 1980. He helped develop the company's sales organization, as well as organizing teaching seminars on how to manage successful physician practices (with a focus on patient satisfaction). Lew developed strong personal relationships with hundreds of orthopedic surgeons in the U.S. and overseas."

"Lew was a genial colleague. He always had time for his fellow employees…to mentor them, encourage them and to pass on his industry knowledge. He was never without a humorous story and he loved an appreciative audience. 'Lovable Lew' was one in a million!"

John McClellan M.D. of the Nebraska Spine Center met Lew Bennett during his orthopedic residency training. He says, "Lew was a great mentor and a true friend. He taught the residents how to evaluate job opportunities to help us find the right position. I later met him when he visited our spine surgical practice. He taught the group how to better manage our practice and helped us run annual retreats."

"He taught us about marriage. He provided us with a book 'Like a Million' that taught me to have frequent discussions with my wife about our individual goals. It helped me build a stronger marriage. He taught life lessons on the golf course when at almost twice my age he could hit the golf ball straighter and shoot a lower score."

"Lew was the world's greatest mentor and a true friend. I will miss my friend."

Ron Pickard, former CEO of Sofamor Danek recalls time with his dear friend: "Lew was one in a million; someone you just enjoyed being around. As Lew would say, 'He wears well with people.' Lew, you certainly did." ♦

Those wishing to remember Lew Bennett with a donation are asked that in lieu of flowers please contribute Suncoast Hospice. They allowed Lew to stay home the entire time, which was his wish. http://www.thehospice.org/Donate

Surprising Study Finding: Surgeons Don't Follow Disclosures + 35,000 Arthroplasties now in AAOS Registry + Stronger Implants Needed for Arthroscopic Biceps Tendonesis?

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

Study Finds Most Surgeons Don't Use Disclosures Question to sports medicine specialists: Are conflict of interest disclosures important in interpreting data? Answer: Yes! Do you use them? No. Fotios Tjoumakaris, M.D., a sports medicine specialist at the Rothman Institute in Philadelphia, is the first researcher to delve into this topic. He tells *OTW*:

> "We sent 750 orthopedic surgeons a survey asking whether they used disclosure information to interpret study results; we received 522 responses. We presented participants with a hypothetical study on an OA [osteoarthritis] drug, along with the disclosure conflicts, namely, that the authors of the study received compensation to perform the study in question. We then changed the scenario of the study and the results (academic v. community setting, randomized study v. case series, and positive outcomes v. negative outcome of the drug) and asked how the respondents felt about the introduction of bias into the results.
>
> We found that only about 50% of participants used the disclosure information to interpret results at meetings. One surprise in our results was that people didn't care whether the study was occurring in an academic center or in a community center; I think people generally believe that orthopedic surgeons are ethical and trust the results that are reported. And the influence of the institution didn't matter. We initially thought that if the authors were from, say, Harvard then that might hold more cache, but in fact respondents seemed to feel that quality research could come from any corner.
>
> Interestingly, 20% of respondents felt that using disclosure information to interpret study results was not important. I was surprised it was this high, but I think with more surgeons being trained under the new rules of governance of reporting by the academy and other associations, that we will begin seeing disclosure as routine practice and will incorporate this information into how we interpret data.
>
> Going forward we want to formulate better questions and tease out each of the questions, such as the lack of reporting of negative results in journals. Our study clearly showed that when negative results were reported, it had the highest confidence factor among readers, even in the presence of obvious conflict among the researchers. We would like to know how many negative studies are reported, compare that to the positive results reporting, and see what people think of that conflict. I would also like to get more data driven analysis, i.e., look at studies where the author indicates having a conflict and have readers interpret them and see if that changes their perception of the study. Ultimately, it's important for all of us to know

Image by RRY Publications, LLC / Source: Wikimedia Commons

how we view data in the literature and how this data is used to drive clinical treatment decisions."

180 Hospitals and 35,000 Arthroplasties now In Joint Replacement Registry Benchmarks, report cards, quality improvement…all are a part of the now very active American Joint Replacement Registry (AJRR). David Lewallen, M.D. is an orthopedic surgeon with Mayo Clinic in Rochester, Minnesota, and is the medical director of this grand undertaking. Dr. Lewallen, past president of both The Hip Society and the American Association of Hip and Knee Surgeons, commented to *OTW*:

"We are excited that things are really accelerating now; we're adding hospitals rapidly and have 180 hospitals participating, 89 of which are submitting data. A total of over 2,200 procedures were downloaded into our system by hospitals in just the last week, which now contains information on over 35,000 arthroplasties. It's quite a prolonged process to get through the necessary legal work and IT security discussions…and then get the hospitals to begin submitting data. But we have exceeded our annual goal for 2013, and are just now bringing on a large group in New York with 17 hospitals.

A year from now we want to be collecting higher levels of data. Initially we are gathering level one data such as on the hospital, patient, surgeon, and implant. We will eventually come up with implant survivorship curves and can then look at data by category of hospital, size of hospital, and implant type. Then we will be able to provide data back to the surgeon, hospital, and manufacturers including information on how they 'score' relative to both an overall national benchmark and compared to hospitals or surgeons performing an equivalent volume.

We think that most surgeons will be pleased to get what is in essence a report card. Everyone involved in this work, whether it's a company, a hospital, or a surgeon, understands that there will be an increasing transparency of data with regard to these procedures over the years ahead. How nice it would be to get this information early on and have a chance to do something with it before it's more widely available. It would also be good if we could work together as a community to interpret the raw data. For example, let's say we get raw data on infection rates. We have no idea of whether a given hospital has especially tough cases and their revision rates or infection rates are better or worse than would be expected unless there is some sort of risk stratification. Otherwise it is possible for a facility seeing mainly younger, healthy patients to have an infection rate twice that expected and still appear at or below the overall national average, and vice versa for those seeing more complex, older patients with multiple comorbidities.

We also have an active public advisory board that includes patients who have had the surgery and representatives from patient advocacy groups like the Arthritis Foundation, AARP, and the Joint Commission. They provide great input to our governing board, which includes representation from the AAOS [American Academy of Orthopaedic Surgeons], the Hip Society, the Knee Society AAHKS, the insurance industry, orthopedic manufacturers and hospitals. Orthopedic manufacturers have been especially supportive via their organization—AdvaMED [Advanced Medical Technology Association]—because of the benefits provided by early detection of the occasional problem implants and equally important benefits of confirming the efficacy of those many implants which work well. Orthopedic surgeons can help support this effort by being local 'surgeon champions' at their hospital or institution. This person meets with the hospital CEO and others in administration to help explain the importance of this initiative and can provide an ongoing local contact for our AJRR staff. This effort will only gain in strength. In fact, in the future participation by surgeons may help fulfill quality improvement requirements such as the practice improvement portion of Maintenance of Certification through the ABOS [American Board of Orthopaedic Surgery]. There is another important discussion underway at present in Washington regarding the potential for financial incentives from government payors for surgeons and even hospitals for participation in 'qualified' registries which could quickly drive interest and participation rates even higher over the coming years."

Stronger Implants Needed for Arthroscopic Biceps Tendonesis Arthroscopic biceps tendonesis is becoming increasingly popular for severe biceps tendonopathy, superior labral anterior posterior (SLAP) tears and other shoulder conditions. Mark D. Miller, M.D., the S. Ward Casscells Professor of Orthopaedic Surgery at the University of Virginia, tells *OTW*, "Biceps tendonesis, which can be done several ways, is exploding in popular-

ity. We are beginning to realize that the bicep tendon is more of a problem that previously thought. The concern is that we may be doing too many tenodesises. Additionally, it is important to realize that the learning curve is steep, especially for the arthroscopic version; it is difficult to identify the biceps tendon in the subacromial space and it bleeds easily, thus making it difficult. You can do labs, go to a bioskills lab, and observe other surgeons, but there is nothing like doing it yourself with a live patient. We need stronger implants as well. I am hoping that companies recognize the importance and popularity of this technique and that they begin developing more tools for us. The implants we have at present pose some concerns about their pullout strength and ease of insertion, so there is definitely room for improvement."

Leaving Ilizarov Method Raises New Issues Sanjeev Sabharwal, M.D., MPH is a pediatric orthopedic surgeon specializing in limb deformities. Dr. Sabharwal, president of the Limb Lengthening and Reconstruction Society, tells *OTW*:

> "The Ilizarov method of slowly pulling apart the bone ends and allowing new bone to form in the created gap remains a time tested and biologically sound method of treating a variety of congenital and acquired limb deformities and shortening among all age groups. About 15 years ago we transitioned to a more sophisticated computer assisted planning and execution method for treating such patients. While external fixators are still very useful and versatile, these devices can be associated with pin site drainage and be cumbersome for the patient. In the world of limb lengthening and deformity correction, there has been a push to transition from traditional surgical treatment relying solely on external fixation to using hybrid techniques with internal fixation, including intramedullary nails using a variety of ingenious methods for accomplishing controlled lengthening. However, there may be a new set of complications related to such emerging technologies and implants. Thus, while there is cautious optimism, these emerging techniques cannot be applied to all patients at this time. Furthermore, longer follow-up with greater number of patients treated at different centers would be necessary before these devices can be adopted universally.
>
> As the surgical techniques become easier, it is plausible that more surgeons may start implanting lengthening nails without fully comprehending the biology and potential complications associated with distraction osteogenesis. For example, patients with congenital shortening often have ligamentous laxity and potential instability at the knee and hip joints. If appropriate steps are not taken before and during limb lengthening in such individuals, the hip and knee joints can become unstable and dislocate over time. We, as surgeons and caregivers, have the responsibility to not only stay current with emerging technologies, but also remember the basic biologic principles of bone healing. We also need to look out for new and possibly different complications that may be associated with these emerging technologies. In the end, our goal is to deliver safe and efficient care and optimize functional outcome with the least amount of strain on the patient and the society." ♦

COMPANY

$3 Billion ASR Hip Settlement Rumored

Stephen Woods and Wikimedia Commons

Johnson & Johnson (J&J) is rumored to be considering a $3 billion settlement over the 11,000 or so DePuy ASR hip implant lawsuits.

In January, *Bloomberg* reported that five people familiar with the talks had said J&J officials were willing to pay about $2 billion to resolve the cases. Lawyers for plaintiffs rejected that amount as too little, the people said.

Two state court juries have returned verdicts. One $8.3 million verdict in favor of a patient and one in favor of the company.

$1 Billion and Counting

Company spokesperson Lorie Gawreluk told *Bloomberg* in an email that the company has already spent almost $1 billion on medical costs and informing patients and surgeons about the ASR recall. The company has set aside an undisclosed amount for litigation, which it increased before June 30, she said.

"The company also continues to support ASR patients with a reimbursement program to address recall-related testing and treatment costs," she said. "Reports about a possible resolution of the litigation are premature and speculative, including any estimates of resolution amounts."

Bloomberg reported on August 20, 2013, that lawyers for the company have discussed paying the $3 billion to settle the lawsuits and agreed to a roughly outlined "global settlement" with lawyers for the claimants. The math says that comes to roughly $300,000 per case.

$3 Billion Dwarfs Sulzer's $1 Billion

A $3 billion settlement would dwarf a 2001 accord Sulzer AG reached with patients who claimed that company's hip and knee implants were defective. Sulzer agreed to pay $1 billion to resolve those suits, then the largest settlement involving hip implants.

The rumored settlement amount, according to anonymous *Bloomberg* sources, is far from finalized, and any agreement will be affected by the seven product liability cases currently on J&J's legal docket. The cases are scheduled to go to trial between September and January.

Steven Skikos, a plaintiffs' lawyer in the lawsuits, told *Bloomberg* his group is preparing for jury trials, which include the first case in federal court.

"With the trials rapidly approaching, and our continuing efforts to obtain more information and data about the patients, it's easy to speculate about settlement," Skikos said in an e-mail. "However, any comment relating to settlement that does not come from the plaintiff's leadership, the court, or from the company itself remains premature, uninformed and a dangerous guess."

Bloomberg's people say several obstacles to a final settlement still must be overcome. One includes the number of years that J&J may potentially have to pay future claims. Another is whether the settlement would include reimbursing Medicare for claims paid. A third is the amount of compensation for extreme medical cases, which include dual hip surgeries or cases where infection prompted long hospital stays.

Seven Trials Scheduled

Seven other trials have been scheduled and will help lawyers for both sides frame questions over liability and damages. The first is scheduled to begin September 9 in federal court in Cleveland. U.S. District Judge David Katz is overseeing that lawsuit by Ann McCracken, a resident of Rochester, New York.

Judge Katz is overseeing about 8,000 federal cases consolidated before him for the pre-trial collection of evidence. About 2,000 cases are pending in the California Judicial Council Coordinated Proceeding before Judge Richard Kramer in San Francisco.

Trials also are scheduled in state courts in San Francisco in October; in Hackensack, New Jersey, in October and January; in West Palm Beach, Florida, in November; in Chicago in December; and in Los Angeles in January.

The McCracken DePuy case is McCracken v. DePuy, 11-dp-20485, U.S. District Court, Northern District of Ohio (Toledo). The consolidated federal case is In re DePuy Orthopedics Inc., ASR Hip Implant Products Liability Litigation, 10-MD-2197, U.S. District Court, Northern District of Ohio (Toledo).

—WE (August 22, 2013)

Medtronic Spine Continues Recovery

Medtronic, Inc.'s spine business reported $765 million in revenue for the company's first fiscal quarter of 2014. Revenue declined by 1% on a constant currency basis over the same quarter the previous year.

Core spine sales rose 1%, while biologics declined 11% on a constant currency basis.

Core Spine Growing

In a prepared statement on August 20, 2013, the company said the core spine business continues to show signs of stability, with growth driven by new products and procedures, as well as enabling technologies, including imaging, navigation, and powered surgical instruments.

Omar Ishrak, the company's president and CEO, said there were a number of positive highlights in their spine business. "Core spine outperformed a relatively stable market as our new products and enabling technologies continued to make a difference. Our U.S core spine business, excluding balloon kyphoplasty grew 1% this quarter. In BMP [bone morphogenetic protein] (Infuse), the decline appeared to be tapering and we saw relative sequential stability again this quarter. The independent reviews of Infuse commissioned by Yale University were completed in Q1, providing further evidence that for approved indications, Infuse is a safe and effective treatment option."

Medtronic, Inc. Spine 1Q14	Sales ($ in millions)	% Change*
Total Sales	**$765.0**	**down 1%**
Core Spinal	$641.0	1%
Biologics	$124.0	down 11%

Source: Medtronic, Inc.
** In constant currency*

Gary Ellis, the company's CFO said: excluding the kyphoplasty business, core spine grew by 3% globally. He added that the core spine market continues to see stability with a low single-digit price mix decline and flat procedure volumes. "Our new procedures and technologies, including our Solera posterior fixation system, Bryan Artificial Cervical Disk, Premium DBMs and AMT interbody devices are driving growth in our core spine business."

Ellis also told analysts that the company is differentiating its spine business from the competition through enabling technologies leveraged from their surgical technologies business, including O-arm imaging, StealthStation navigation and POWEREASE power surgical instruments. "Hospitals are investing in our capital equipment for spine surgery as they seek clear value from improved surgical precision and more efficient procedures. We are still early in realizing this large differentiated opportunity in spine which is resulting in increased revenue and

Memphis Daily News File Photo: Lance Murphey

share for our spinal implants as well as solid growth of our capital equipment in our surgical technologies business."

No Evidence of Cancer Risk for Infuse

Ishrak noted that later this fall, the company is expecting final publication of its retrospective analysis of a large, national payer database investigating the cancer incidents in the real world use of Infuse. "The manuscript of that study was recently published online, ahead of print by the journal *Spine*. The authors found no evidence that administration of BMP at the time of lumbar fusion surgery was associated with cancer risk. Looking ahead, if current trends continue, we expect our global FY'14 BMP revenue to be down in the mid single-digits which would be a significant improvement from the 15% decline last fiscal year."

Spine Market Growing

Piper Jaffray analyst Mike Miksic said that based on his estimates and the other companies that have reported, the total global spine market grew between 2.5 - 3.0%, recovering from a dip in the first quarter of 2013 driven in part by selling day differences and seasonality.

China and Lots of Cash

Management said their Kanghui orthopedics business in China continues to perform well with its revenue growing in excess of 20% and offsetting the lost revenue from their former Weigao joint venture.

Just to throw in a little extra for the analysts, Ishrak told them that over the next five years, the company expects to generate over $25 billion of free cash flow.

—WE (August 21, 2013)

LEGAL

China Investigating Device Overuse for Profits

The Chinese government is looking at the overuse of medical devices in Beijing after determining that over-utilization is taking place to increase profits.

John Tan, a lawyer with Reed Smith's Global Regulatory Enforcement Group based in Shanghai, wrote on August 15, 2013 that the local Beijing office of the Ministry of Health (MOH) of the People's Republic of China announced that it has started a three-month review of the use of high-value medical consumables and large-scale medical equipment in Beijing.

He continued that the Beijing MOH noted that prior inspections of hospitals had found continuing problems with the misuse and overuse of medical devices to increase profits. The investigation is intended to strengthen hospitals' management of the use of medical devices and to regulate the use of those high value medical consumables.

New Emphasis on Prosecution

This follows a declaration at the end of 2012 by China's Supreme People's Court, in conjunction with the Supreme People's Procuratorate, of a new judicial interpretation of China's criminal law prohibiting bribery. "This interpretation was widely viewed as signaling a new emphasis by Chinese authorities on prosecuting not just officials who accept bribes, but those who pay bribes as well," wrote Tan.

New Utilization Database

In addition to the new investigation, the MOH will also develop a database that will track the price and model of devices implanted in each patient, require hospitals to improve their purchasing management systems, and conduct periodic inspections of hospitals' purchasing and management of medical consumables.

Tan writes that this latest investigation follows on increased regulatory enforcement actions throughout China's life sciences industry.

In the last two months, there have been criminal and administrative enforcement actions targeting the pharma-

Xinhua/Xie Huanchi/Wang Qishan, China anti-corruption chief

ceutical sector and a pricing investigation by the National Development and Reform Commission (NDRC) into the infant formula sector that culminated in the largest fine in the history of China's enforcement of its anti-monopoly law.

Targeting Bribery, Fraud and Anti-Competitive Practices

The NDRC is also conducting an ongoing investigation of pharmaceutical industry pricing practices and considering systemic revisions to China's drug pricing system. Additionally, on August 14, 2013 the State Administration for Industry and Commerce (SAIC) announced a new three-month-long investigation into the pharmaceutical and medical services sectors, targeting bribery, fraud and anti-competitive practices.

Chinese authorities have also recently issued a number of administrative regulations targeting the life sciences industry, including a new code of conduct for health care providers, and new guidance on strengthening anti-bribery controls in public medical institutions.

Authorities also issued regulations on the centralized purchasing of medical consumables and large scale medical equipment containing provisions that would exclude companies found to have engaged in commercial bribery from participation in centralized purchasing. In the U.S., this is the "death penalty" when someone is excluded from government payment programs.

China doesn't kid around with Deferred Prosecution Agreements, settlements and exclusions. When one of the previous top regulators was convicted of corruption, he was executed. Now that's a death penalty.

—WE (August 19, 2013)

BIOLOGICS

FDA Transfers Some Devices to Biologics Oversight

Wound care products are regulated by the Food and Drug Administration (FDA) as a device. Effective immediately, certain products containing live cells will be regulated as a biologic product.

The FDA announced on August 14, 2013 that the agency is transferring oversight responsibilities for certain wound care products containing live cells from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER).

The agency says the move provides the opportunity to further develop and coordinate scientific and regulatory activities between CDRH and CBER. FDA believes that as more wound care products containing live cells are developed such consolidation is necessary for both efficient and consistent agency action.

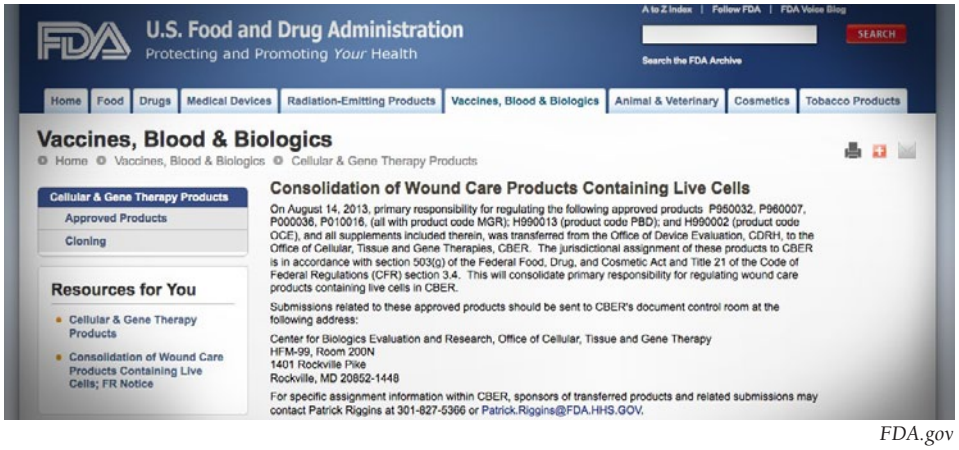
The agency has created a Web page listing the premarket approval applications and humanitarian device exemptions in CDRH that are being transferred to CBER. Sponsors of these products are encouraged to consult the Web page to find new contact information. The Web page address is: http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm356173.htm.

According to a notice in the *Federal Register*, some of the products transferred include the Apligraf diabetic foot and venous leg ulcer treatment from Organogenesis Inc. and the Dermagraft venous leg ulcer skin substitute by Shire subsidiary Advanced BioHealing (now called Shire Regenerative Medicine).

Specifically, the following approved products: P950032, P960007, P000036, P010016, (all with product code MGR); H990013 (product code PBD); and H990002 (product code OCE), and all supplements included therein, has been transferred from the Office of Device Evaluation, CDRH, to the Office of Cellular, Tissue and Gene Therapies, CBER.

For further information, contact: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5130, Silver Spring, MD 20993, 301-796-8930, john.weiner@fda.hhs.gov.

—WE (August 22, 2013)



FDA.gov

LARGE JOINTS

PKU Implants 3-D Printed Bones

Caption: Peking Third University, Beijing, China/Source: Courtesy of Peking Third University

The orthopedics department of Peking Third University, China, is printing bones with a 3-D printer and reporting good success when the bones are implanted into patients.

"We started the clinical trial to test those implants last year, and all the patients participating in the trial are recovering well," says Liu Zhongjun, director of the department.

In cooperation with a Beijing medical device company that owns an imported 3-D printer, the hospital has produced dozens of hip replacements and artificial vertebral bodies. To date, more than 50 volunteer patients have tried the implants.

Liu believes that these tests are the first time that 3-D printed artificial vertebral bodies have been used in humans, although artificial vertebral bodies have been used in orthopedic surgeries for years.

The hospital uses titanium powder to print the implants. The 3-D printer is able to print titanium powder into any shape, as long as the computer that controls the printer has a digital model to follow. "In another words," Liu explains, "the 3-D printed orthopedic implants can match better with the bones around them than can traditional ones. Besides, the tiny pores of the new implants, another feature of the 3-D device, enable bones to grow into the implants.

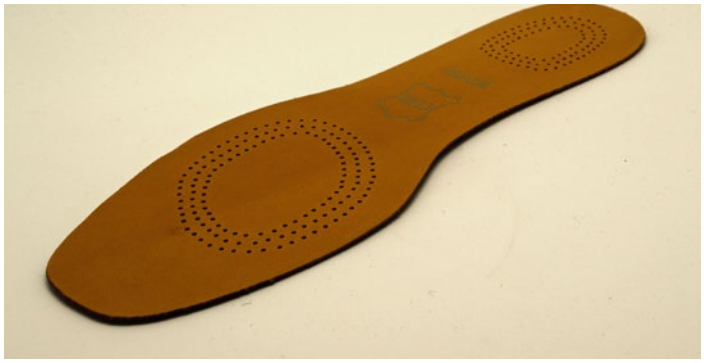
Liu's team launched the program in 2009. The hospital provided designing, and the medical device company digitalized the design. In mid-2010, the department started trials on sheep, and in 2012, the team got permission from health authorities for human trials. Liu believes that, "Producing medical devices through 3-D printing saves time and materials, and thus the cost will be lower than traditional methods."

—BY (August 19, 2013)

Insoles Not So Helpful With OA

Researchers from the UK have conducted a meta-analysis showing that wedge insoles may not go far in reducing knee pain. This work, published in the August 21, 2013 issue of the *Journal of the American Medical Association* found that among trials comparing wedge insoles with neutral insoles, there was no significant or clinically important association between use of wedge insoles and reduction in knee pain.

The study authors note: "The increase in rates of knee replacement for osteoarthritis [OA] has made the identification of effective nonsurgical treatments a high priority. Medial osteoarthritis is one of the most common subtypes of knee osteoarthritis. One type of treatment for medial knee osteoarthritis involves reducing medial (inner) loading to ease the physical stress applied to that compartment of the joint. The wedge is placed under the sole of the foot and angulated so that it is thicker over the lateral than the medial edge, transferring loading during weight bearing from the medial to the lateral knee compartment."



Wikimedia Commons and Clément Bucco-Lechat

Matthew J. Parkes, B.Sc., of the University of Manchester, England, and colleagues set out to assess the efficacy of lateral wedge treatments (shoes and

insoles designed to reduce medial knee compartment loading) in reducing knee pain in patients with medial knee osteoarthritis. The authors conducted a search of the medical literature to identify randomized trials that compared shoe-based treatments (lateral heel wedge insoles or shoes with variable stiffness soles) aimed at reducing medial knee load, with a neutral or no wedge control condition. The wedge needed to be of 5° to 15° of angulation, which is a level shown in previous studies to reduce external knee adduction moment (torque). Studies must have included patient-reported pain as an outcome. Twelve trials met inclusion criteria with a total of 885 participants of whom 502 received lateral wedge treatment.

The researchers found, when considering all 12 trials, the overall effect estimate was a standard mean difference in pain between interventions that showed a moderately significant effect of a lateral wedge on pain reduction. However, the findings were highly heterogeneous across studies. Larger trials with a lower risk of bias suggested a null association.

When trials were grouped according to the control group treatment, the authors found that compared with neutral inserts, lateral wedges had no association with knee pain and heterogeneity was much lower across trial findings.

Matt Parkes told *OTW*, "The fact that the flat vs. wedged insole trials were so consistent in showing no superiority of wedges over flat insoles was perhaps unexpected, given the wide-ranging opinions both in support of and against wedges. So, aside from a placebo effect, wedge insoles provide little arthritis pain relief."

—EH (August 22, 2013)

EXTREMITIES

Pluristem: PLX Cells and Tendon Healing

Pluristem Therapeutics, Inc., a developer of placenta-based cell therapies, announced August 14 the results of a pre-clinical trial using the company's PLacental eXpanded (PLX) cells in tendon injury. Scott Rodeo, M.D. and his orthopedic research team at New York's Hospital for Special Surgery (HSS) studied the effects of PLX cells on rat patellar tendons that had sustained collagenase-induced injuries.

"Cell-based approaches clearly have great potential for the augmentation of connective tissue healing, as well as for tissue regeneration. As an 'off the shelf' cell source, PLX cells could provide an effective option to improve tendon healing," stated Dr. Rodeo, in the news release. Dr. Rodeo is principal investigator for this study and professor of Orthopedic Surgery at Weill Cornell Medical College. Dr. Rodeo is co-chief of the Sports Medicine and Shoulder Service at Hospital for Special Surgery; associate team physician for the New York Giants Football Team; and physician for the U.S.A. Olympic Swimming Team.

"Pluristem is extremely pleased that the results of this pre-clinical trial validate our strategy to pursue the use of our PLX cells for tendon injuries and other orthopedic indications. We look forward to the results of our recently fully-dosed, Phase I/II clinical trial in

Pluristem Therapeutics, Inc.

Germany using our PLX cells in muscle injury," stated Zami Aberman, chairman and CEO of Pluristem.

PLX-treated tendons demonstrated better early structural properties at 2 and 4 weeks compared to saline-treated controls. This was evident based on statistically significant higher load-to-failure properties at 2 weeks following injection. Additionally, the demonstrated higher mean load-to-failure and stiffness properties were maintained at 4 weeks. These improved biomechanical properties may be related to the findings of a greater proteoglycan and collagen content seen at the tendon-bone interface of PLX-treated samples.

Aberman told *OTW*, "Pluristem is developing a pipeline of therapeutics for a variety of indications based on our patented PLX (PLacental eXpanded) cells. It is estimate that during 2014 we will have strong evidence that PLX cells have unique therapeutic effects for a variety of indications such as: muscle injuries, bone marrow failures and pre-eclampsia as well as having ongoing clinical studies in intermittent claudication (IC), critical limb ischemia (CLI), pulmonary hypertension (PAH) and tendon injuries."

He added, "We have completed the enrollment of all patients in the Phase I/II muscle injury study within about 6-months from the start of the study and it is estimated that the data from the 6-month follow-up could potentially be released during the first quarter of 2014. We strongly believe that the use of PLX cells following orthopedic injuries such as muscle and tendon injuries could potentially improve the quality of life of the patients in the U.S. and around the world."

—EH (August 20, 2013)

TRAUMA

Why People Fall

Researchers from the University of Michigan have delved into the question of why people—especially older individuals—fall. They now believe that the critical window of time between when the brain senses a fall and the muscles respond may help explain these falls.

The researchers, from the U-M School of Kinesiology, developed a novel way of looking at the electrical response in the brain before and during a fall by using an electroencephalogram (EEG). Their findings showed that many areas of the brain sense and respond to a fall, but that happens well before the muscles react. Lead researcher Daniel Ferris likened the study method to recording an orchestra with many microphones and then teasing out the sounds of specific instruments. In the study, researchers measured electrical activity in different regions of the brain.

"We're using an EEG in a way others don't, to look at what's going on inside the brain," said Ferris, a professor in kinesiology, in the August 14, 2013 news release. "We were able to determine what parts of the brain first identify when you are losing your balance during walking."

During the study, healthy young subjects with electrodes attached to their scalps walked on a balance beam mounted to a treadmill. When participants lost their balance and went off the beam, they simply continued walking on the moving treadmill, thus avoiding injury. The team then used a method called independent components analysis to separate and visualize the electrical activity in different parts of the brain. They found that people sense the start of a fall much better with both feet on the ground. Two grounded feet make it easier to determine where the ground is relative to the body.

Wikimedia Commons and Torsten Henning

The researchers were surprised that so many different parts of the brain activate during a fall. They also did not expect the brain to recognize a loss of balance as early as it does. Future studies comparing the elderly with younger subjects could determine if the elderly sense falls too late, in which case, pharmaceuticals might help them regain their balance. If it's a simple motor problem such as muscles not responding properly, strengthening exercises could help.

Dr. Ferris told *OTW*, "New mobile EEG technologies are making it possible to monitor people during a wide range of tasks. We can get information out of the EEG that includes when they sense they are going to fall. In the near future, it may be possible to determine if elderly individuals that fall have a problem with sensing they are losing their balance or is their problem limited to being strong and powerful enough to correct their balance."

Regarding future research, Dr. Ferris commented, "We have funding from the U.S. Army Research Laboratory that is designed to push the technology into more easily accessible and portable formats so that real-time brain monitoring can occur in activities of daily living."

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