MEDICAL DEVICES COMMITTEE'S NEWSLETTER

September 22, 2013

Dear Readers,

Welcome to the ABA's Medical Devices Committee's newsletter! We strive to bring you the latest and most pertinent information on corporate, regulatory, intellectual property, product liability, and other legal issues in the field weekly. Please find the newsletter below and feel free to contact me with any contributions, questions, or suggestions. I highly encourage attorneys, industry professionals, and law students to submit medical devices-related stories of interest. Have a wonderful week!

Sincerely,

Jessica von Reyn
javonreyn@gmail.com

Afia K. Asamoah, JD	David J. Dykeman, JD	Jessica von Reyn
Committee Co-Chair	Committee Co-Chair	Student Editor
Associate	Shareholder & Patent Attorney	J.D. Candidate, 2013
Covington & Burling LLP	Greenberg Traurig, LLP	University of Wisconsin Law School
620 Eighth Avenue	One International Place	Intellectual Property and Health Law
New York, NY 10018-1405	Boston, MA 02110	B.Sc., Anatomy & Cell Biology
(212) 841-1083	(617) 310-6009	McGill University, 2008
aasamoah@cov.com	dykemand@gtlaw.com	javonreyn@gmail.com

Regulatory/Legislative/Policy

"Quidel Scores FDA Nods for Life Tech-Powered Tests." FDA has cleared two of Quidel's infectious disease tests for use and sale in the US. The assays use Life Technologies' diagnostics platform, and the companies have partnered up to distribute their products internationally, as both already have CE marks. Quidel's Influenza A+B assay, which detects the flu and the H7N7 subtype was cleared. The H7N7 strain has a mortality rate of approximately 30%. The agency also cleared Quidel's RSV + hMPV assay, which is used to diagnose two lung infections, respiratory syncytial virus and human metapneumovirus, according to Fierce Medical Devices. (September 16, 2013). **http://tinyurl.com/olrqlyx**

"Crosstrees Medical Gets FDA 510(k) Nod for Next Generation Device for Percutaneous Vertebral Augmentation." FDA has cleared Crosstrees Medical, Inc.'s PVA Pod System for percutaneous vertebral augmentation for sale and use in the US. The device's clearance was granted following an IDE study of 135 patients compared to literature controls including vertebroplasty and kyphoplasty. The device is notable due to its significant pain reduction and reduced new fracture rates. These benefits also decrease the chance of other adverse events associated with the procedure, including nerve root compression and pulmonary embolism, according to Device Space. (September 19, 2013). **http://tinyurl.com/l3sbu4n**

"GE Issues Another Imaging System Fall Warning after Discovering Missing Screws." After discovering some of its imaging systems were installed without certain screws that hold up the overhead video monitors, GE Healthcare has issued an imaging system fall warning. So far, there have been no reports of falling monitors, but the company acknowledged that the problem could increase the chance of an adverse event. The Advantx and Innova systems were affected, according to Mass Device. (September 19, 2013). **http://tinyurl.com/qjnx24e**

"FDA Lays down Final Device ID Rule with Nod to Industry." FDA has created its final rule on unique device IDs (UDI). Under the final rule, which was the result of a year of negotiations with industry, companies must assign each device a unique number and barcode with manufacturing and expiration dates. The unique identifiers will be registered with the FDA and made publicly available through its Global Unique Device Identification Database. The final rule represents a number of compromises, for example, the agency will not require manufacturers of implanted devices to label each individual device. High-risk, Class III devices will be required to comply with the new rule within a year, Class II devices have three years to begin labeling, and most Class I devices will be exempt from the requirement, according to Fierce Medical Devices. (September 20, 2013). **http://tinyurl.com/nhb27xs**

"Baxter Recalls Caps over Deadly Embolism Risk." Baxter has launched its own voluntary recall of its Dual Luer Lock Caps, which have been improperly packaged. FDA has deemed the recall to be Class I, warning that use of the caps can cause serious injury or death, since embolisms could result. The company is concerned that loose particulate matter may have fallen into the packaging, meaning that it could enter the device's system and the patient's bloodstream. Customers are directed to return the affected lots so that Baxter can replace them, according to Fierce Medical Devices. (September 20, 2013). **http://tinyurl.com/m3h8co2**

Intellectual Property and Innovations

"Study: Bypass Safer than Stents for Diabetics." A team of researchers at St. Michael's Hospital in Canada published the results of their study, finding that the mortality rate is 30% less for diabetics with heart disease treated with bypass as opposed to those treated with stents. The researchers looked at clinical data from over 30 years of trials, encompassing 3,612 patients. While stenting procedures are shorter and less invasive than bypasses, the researchers assert that their work represents a call to action. They stated that doctors must disclose that "long-term mortality reduction is best achieved with bypass surgery," in order to provide true informed consent, according to Fierce Medical Devices. (September 16, 2013). **http://tinyurl.com/p48pxag**

"Robotic Surgery: Intuitive Surgical Touts Independent Prostatectomy Study." A study published in *Urology* has found that minimally invasive prostatectomies, such as those performed by surgical robots, are safer than traditional, open surgical techniques. Looking at data from 5,319 radial prostatectomies, the researchers found that, even though the minimally invasive procedures take longer, patients had significantly fewer perioperative blood transfusions as well as a shorter average length of stay. The minimally invasive group had surgery either laparoscopically or using a surgical robot. This study is important for Intuitive, makers of the

da Vinci surgical robot, as the company has faced significant criticism stemming from its robotic surgery line, according to Mass Device. (September 16, 2013). **http://tinyurl.com/mtszaev**

"Copper Bracelets, Magnetic Wrist Straps Fail to Help Rheumatoid Arthritis." A study conducted at the University of York determined that copper bracelets and magnetic wrist straps do not impact pain, swelling, or disease progression in rheumatoid arthritis. The randomized controlled trial followed 70 patients with active symptoms for a five-month period. Patients wore four different devices for the duration of the study and reported on their pain, disability, and medication use. The researchers found that the standard magnetic wrist strap and the copper bracelet did not improve patients' symptoms beyond the placebo level. The scientists hypothesized that individuals using the devices probably feel they are working due to the placebo effect and also because users generally start wearing the devices during flare ups, which subside naturally, according to Science Daily. (September 16, 2013). **http://tinyurl.com/k3qah57**

"Fluorescent Compounds Allow Clinicians to Visualize Alzheimer's Disease as it Progresses." Researchers have created a new class of imaging agents that allow them to visualize tau protein aggregates in living patients. Tau protein aggregates indicate Alzheimer's disease and neurodegenerative disorders, and the researchers hope that their work can be used to study the progression of the disease and effectiveness of different treatments on an individual level. The work is notable because tau accumulation is a better indicator of neuronal loss than senile plaques, better understood proteins that also accumulate during Alzheimer's, according to Science Daily. (September 18, 2013). **http://tinyurl.com/ls7tpes**

M&A/Joint Ventures/Corporate News

"IMRIS Grabs $25 Million in Financing." IMRIS Inc. has received $25 million in financing. The company is obtaining the funding through a secured loan facility agreement with Deerfield Management Company L.P. IMRIS features several FDA-cleared devices, as well as development-stage products, giving the company a foundation for future growth. The company will use the capital to further development of its latest innovations while improving its balance sheet, according to Device Space. (September 16, 2013).
http://tinyurl.com/jwrbkml

"VisionCare Snags up to $15M to Market AMD Device." VisionCare has solidified up to $15 million in debt financing from Life Sciences Alternative Funding. The company has received FDA clearance for its Implantable Miniature Telescope, the only FDA-approved implant for end-stage age-related macular degeneration. The implant is inserted during an outpatient procedure and can improve vision for patients with severe to profound impairment, and is nearing permanent reimbursement status from the Centers for Medicare and Medicaid Services. With its increased support, the company is hoping to improve its revenue while increasing the use of its implant nationwide, according to Fierce Medical Devices. (September 17, 2013).
http://tinyurl.com/nx6hqlr

"Atossa Seals Another Big Deal to Advance Breast Health Dx Test." Atossa Genetics has made an agreement to have McKesson Medical-Surgical to sell and distribute its MASCT device nationwide. MASCT extracts breast fluid in a non-invasive procedure. The sample is then compared to the company's National Reference Laboratory for Breast Health using ForeCYTE, which determines the patient's future breast cancer risk. The device is also distributed by Thermo Fisher, so the testing kits will be sold to large clinics and hospitals, as well as physician offices, according to Fierce Medical Devices. (September 18, 2013).
http://tinyurl.com/mzpn5de

"Nanosphere Snags $30.2M in Stock Sale." Nanosphere raised $30.2 million in an over-allotted stock sale, money it will use to further commercialize its FDA-cleared Verigene gram-positive blood culture test. The company will also seek agency approval for its other tests, including a gram-negative blood stream infection panel and a gastrointestinal enteric test. Its Verigene system maps bacterial genomes using gold nanoparticles for greater specificity, according to Fierce Medical Devices. (September 19, 2013). **http://tinyurl.com/k8t58c6**

Lawsuits/Settlements/Investigations

"Bard Resolves New Jersey Vaginal Mesh Suit." C.R. Bard has reportedly settled a pending suit regarding its vaginal mesh implant, one of over 8,000 upcoming lawsuits stemming from the device. The case at issue was scheduled to proceed to trial on the 23rd of this month. This is one of several cases the company has resolved; last month, the company settled a case, and it plans to appeal the two cases it lost earlier. Settling may become the norm for this line of cases, as the company is crunching the numbers to determine whether litigation is financially reasonable, according to Fierce Medical Devices. (September 16, 2013).
http://tinyurl.com/o7qmt75

"Boston Scientific, OrbusNeich Call Cease-Fire in Stent Fight." Boston Scientific and OrbusNeich have reached a settlement in their longstanding patent stent feud. The original suit, filed over a year ago, contained OrbusNeich's claim that Boston Scientific violated its patents with many of its stents. The suit was first filed in Germany, but OrbusNeich ultimately filed suit in other nations, including Ireland, Holland, the UK, and the US. The financials of the agreement were not disclosed, but Boston Scientific will pay a certain amount in order to have OrbusNeich give up all stent-related suits. The settlement does not cover "future financial obligations," according to Fierce Medical Devices. (September 17, 2013). **http://tinyurl.com/kow9emv**

"Medtronic Wins a Round in Patent Spat with Edwards Lifesciences." A federal judge in California denied Edward Lifescience's invitation to declare two Medtronic patents invalid. Medtronic accused Edwards of patent infringement regarding its Sapien transcatheter aortic valve implantation system and is looking to obtain damages and a permanent injunction. The two patents at issue explain techniques to control heart rhythm during the implantation of transcatheter aortic valves, according to Mass Device. (September 18, 2013).
http://tinyurl.com/n8hwg8g

"Covidien Slapped with Patent Suit." Ivera Medical is accusing Covidien of willfully infringing its patents. Ivera argues that Covidien's Kendall Disinfectant Cap infringes three of its patents, while competing with the company's own Curos Disinfecting Port Protector. Ivera is seeking a permanent injunction as well as compensatory damages in its suit. Covidien does not comment on pending litigation, and Ivera expressed disbelief at Covidien's actions, asserting "the exposure [Covidien has], including treble damages and the potential to disgorge all profits, for them is quite large," according to Fierce Medical Devices. (September 18, 2013). **http://tinyurl.com/o9kka23**

"Edwards Hit with Shareholder Suit over 'Misleading' Sapien Claims." Edwards Lifesciences is facing a class-action lawsuit from its shareholders regarding its Sapien device. In the complaint, the investors contend that the company knew physician adoption of Sapien valve would be sluggish, but still predicted huge sales in an effort to boost its share price. The share prices dropped 41% after the outlook was corrected. Edwards does not discuss pending litigation, according to Fierce Medical Devices. (September 19, 2013).
http://tinyurl.com/mutapv5

"Whistleblowers Accuse Masimo of Concealing Evidence." Whistleblowers who filed a False Claims Act lawsuit against Masimo are asking a federal judge to sanction the company for allegedly concealing evidence

and interfering with its subpoenas. The suit started in October of 2010 when former sales reps alleged the company was promoting off-label uses of its devices and billing government insurance programs incorrectly, according to Mass Device. (September 19, 2013). **http://tinyurl.com/qbrkrct**

"BD Ordered to Fork over $113.5M in Antitrust Verdict." Becton Dickinson has been ordered to pay over $113 million in compensation to Retractable Technologies, temporarily resolving a six-year antitrust battle. Becton Dickinson plans to appeal the jury verdict as soon as possible. The company may be on the hook for three times the ordered amount due to the federal antitrust statute. Retractable Technologies, for its part, asserted that the verdict "vindicates" its claims of a monopoly in the safety syringe market through false advertising, according to Fierce Medical Devices. (September 20, 2013). **http://tinyurl.com/l8s4hqg**

Click here to join the Section of Science & Technology Law's Medical Devices Committee to receive this newsletter weekly.