MEDICAL DEVICES COMMITTEE’S NEWSLETTER

June 30, 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,

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Regulatory/Legislative/Policy

“Medtronic, Inc. Recalls Surgical Breathing Tube.” FDA has classified Medtronic, Inc.’s recall of a breathing tube as Class I, meaning the malfunction could cause serious injury or death. The device, the NIM Trivantage EMG Endotracheal Tube, can collapse if used improperly, potentially inhibiting a patient’s breathing during surgical procedures. The company began its recall of the product in March, and asserted that no deaths or injuries resulted from the problem, according to Device Space. (June 24, 2013).
http://tinyurl.com/nmaz9p5

“DePuy Orthopaedics Wins FDA Approval for Customized Knee Implant System.” Johnson & Johnson’s DePuy Orthopaedics was granted FDA clearance to use its Trumatch Personalized Solutions system with its
already-approved Sigma RP knee implant. The company asserted that the system gives surgeons the greater positioning accuracy during implant procedures and more flexibility in accommodating different patients’ individual physiologies, according to Mass Device. (June 24, 2013). http://tinyurl.com/q5yafng

“FDA: Intuitive Surgical, Inc. Failed to Report Warning.” FDA is reporting that Intuitive Surgical, Inc. failed to report its customer warning to the agency. The company received 134 complaints and filed 83 medical device reports over a two year period concerning its da Vinci surgical robot. However, the company did not report a letter it sent to customers offering “suggestions and recommendations” regarding device use, according to Device Space. (June 26, 2013). http://tinyurl.com/ptwa367

“FDA Bars Medtronic, Inc. Catheter Imports amid ‘Serious’ Miscues.” FDA has blocked imports of two Medtronic, Inc. catheters, following “serious” miscues regarding the devices’ manufacturing facility. The agency cited microbial contamination failures, among other issues, in its letter to the company regarding an inspection from February, according to Device Space. (June 26, 2013). http://tinyurl.com/lb3nqn5

“Medtronic Warns over Pump Tied to 14 Deaths.” Medtronic, Inc. has issued four warnings regarding its SynchroMed infusion pumps. The company has received four Class I FDA recall warnings, one for each of the identified errors: an erroneous bolus, risk of electrical shorting, faulty connector catheter, and a potential deadly refill error. Since 1996, 14 patients have died using the pumps: 11 from improper infusion, two from blockages, and one from an electrical short. The company is actively seeking to correct the errors, recalling the catheter related to the blockages, while keeping the system on the market, according to Fierce Medical Devices. (June 27, 2013). http://tinyurl.com/omkhyee

**Intellectual Property and Innovations**

“J&J’s Animas Reveals Positive Artificial Pancreas Data.” Late last week, Johnson & Johnson’s Animas division revealed the positive results from the second phase of clinical trials for its artificial pancreas. The company’s Hypoglycemia-Hyperglycemia Minimizer System (HHM) merges an insulin pump and continuous glucose monitoring to act as a substitute pancreas. The group’s results showed the device maintained safe glucose levels overnight. The system’s automatic control algorithm successfully kept the 20 study patients within a healthy glucose range 90% of the time, and fewer than half the participants dropped below the designated level during the time period, according to Fierce Medical Devices. (June 21, 2013). http://tinyurl.com/ozlyy9m

“Dream of Regenerating Human Body Parts Gets a Little Closer.” Researchers in the US and Japan published an article in Nature detailing their findings regarding digit regeneration. The group revealed a signaling mechanism in the nail bed’s stem population that may be used to increase the amount of tissue that can be regenerated. The mechanism allowed the group to grow more of the mouse’s digit back, and may possibly be extrapolated to human fingers in the future. Furthermore, the researchers hope to further understand stem cell activation enhancement in a variety of tissues, with the goal of creating new regenerative therapies for various organs and limbs, according to Medical Xpress. (June 24, 2013). http://tinyurl.com/oeowgao

“Medtronic Kicks off Artificial Pancreas Study of its Own.” Following Johnson & Johnson’s positive artificial pancreas study results (see above), Medtronic has commenced an overnight study of its own artificial pancreas system. Medtronic’s version continuously monitors a patient’s glucose level with its MiniMed insulin pump and uses its own algorithm to predict blood glucose fluctuations and dispense insulin to maintain normal glucose levels. The company is recruiting US patients for its trial, which will also simulate system failures in
order to demonstrate the algorithm’s capabilities regarding over- or under-infusion, according to Fierce Medical Devices. (June 25, 2013). [http://tinyurl.com/ot7p7b9](http://tinyurl.com/ot7p7b9)

“New Palm-Sized Microarray Technique.” Scientists at the University of Texas at San Antonio and the US Army Institute of Surgical Research at Fort Sam Houston created a microarray platform to culture up to 1,200 individual cultures of fungi or bacteria. The researchers think the nano-scale platform technology may be eventually used for rapid drug discovery for the treatment of bacterial or fungal infections. It may even be used to identify antibiotics that would be most useful against a specific infection. The approach is automated which saves time, is more reliably reproducible, and prevents some forms of user error. The team showed that their nanoscale model provided similar results to larger macroscale techniques, indicating that it may be able to replace the current technique, according to Medical News Today. (June 27, 2013). [http://tinyurl.com/kadllah](http://tinyurl.com/kadllah)

“Early Brain Stimulation May Help Stroke Survivors Recover Language Function.” Researchers at McGill University have found that transcranial magnetic stimulation (TMS) and speech and language therapy following stroke can decrease a patient’s aphasia (inhibited speech and language skills). The TMS device was placed over the subjects’ language region and low intensity stimulation was achieved. Essentially, the researchers shut down the working part of the brain, in order to force the stroke-affected component to relearn language. As compared with sham patients, who received TMS outside the language-related brain region, TMS patients experienced improvements three times that of their sham counterparts, according to Science Daily. (June 27, 2013). [http://tinyurl.com/lr3s7tt](http://tinyurl.com/lr3s7tt)

M&A/Joint Ventures/Corporate News

“Lombard Medical Technologies’ $32 Million Funding to Roll out Newly Approved Aorfix.” Following its successful $32 million funding round, Lombard Medical Technologies gained FDA approval for its Aorflex delivery system. The system is used in conjunction with the company’s Aorfix stent graft for abdominal aortic aneurysms. The company will use the remaining funds to launch its device in the US, according to Device Space. (June 24, 2013). [http://tinyurl.com/ov5t27e](http://tinyurl.com/ov5t27e)

“Mevion Raises $55M for Cancer-Fighting Device.” Mevion Medical has raised $55 million in equity investments and debt financing. The company plans to commercialize S250 Proton Therapy System, which received FDA clearance a year ago. The system is used to specifically target tumors and lesions while preserving healthy surrounding tissues. It is more precise than x-ray treatments and more compact than similar proton therapies, two characteristics the company hopes to capitalize on during commercialization, according to Fierce Medical Devices. (June 25, 2013). [http://tinyurl.com/owun67m](http://tinyurl.com/owun67m)

“NanoString Technologies Inc. to Raise $54 Million in IPO.” NanoString Technologies, Inc. announced the details of its initial public offering. The company will offer 5.4 million shares of common stock to the public for $10.00 a share, a proposal that could raise $54 million. The company also is giving underwriters a 30-day option to buy up to 810,000 shares to cover any overallotments. NanoString Technologies proves life science tools for translational research and molecular diagnostic products, according to Device Space. (June 26, 2013). [http://tinyurl.com/omc8oqs](http://tinyurl.com/omc8oqs)

“Philips Healthcare Strikes $300M Deal with US Hospital.” Royal Philips and Georgia Regents Medical Center (the state’s public academic health center) have entered into a 15-year alliance to improve patient-centered approaches to care while creating a novel business model. Pursuant to the agreement, the company will provide the hospital system with a comprehensive range of consulting services, advanced medical technologies, and operational performance, planning, and maintenance services in exchange for pre-determined monthly
operational costs. The alliance will serve all areas of care, including the hospital’s extensive network of outpatient clinics. Philips is seeking to work closely with healthcare providers to find innovative solutions to the financial and logistical complexities of health care delivery, according to Device Space. (June 28, 2013).  
http://tinyurl.com/p7fbq7l

“Boston Scientific Buying Bard’s Electrophysiology Biz for $275M.” Pursuant to a deal expected to close later this year, Boston Scientific will pay $275 million for C.R. Bard’s electrophysiology business. Boston Scientific will acquire Bard’s cardiac catheter ablation devices, recording systems, and mapping tools in a market that is growing about 10% annually. Coupled with its recent acquisition of Rhythmia Medical, Boston Scientific is looking to capitalize on a recent demand for new heart treatments, according to Fierce Medical Devices. (June 28, 2013).  
http://tinyurl.com/opnkk3t

**Lawsuits/Settlements/Investigations**

“Minnesota Feds Probe Medtronic over Trade Agreements Act.” The US Attorney’s office for Minnesota is looking into Medtronic’s compliance with the Trade Agreements Act. The Act applies to acquisitions of more than $193,000 by the US government. Under the statute, the products must be made either from the US or from a “designated country” to comply with the statute’s “rule of origin.” “Designated” countries are those that have specific trade agreements with the US, and do not include China, India, Malaysia, Taiwan, and Thailand currently. The company stated that it is complying fully with the inquiry, according to Mass Device. (June 25, 2013).  
http://tinyurl.com/kquqjad

“Internal Bard Memo Shows Medical Device Company Knew Mesh was Unfit for Humans.” C.R. Bard is facing a number of personal injury lawsuits pertaining to its transvaginal mesh implants, and a recently unsealed memo is not going to help its case. The memo shows that the company ignored warnings that the plastic it was using for the device was not suitable for implantation and attempted to hide the use of the particular type of plastic from its manufacturer, according to Fierce Medical Devices. (June 26, 2013).  
http://tinyurl.com/qxu6efl

“SEC Hammers Imaging Company, CEO with Fraud Charges.” The SEC has filed charges against Imaging3, a California company, and its CEO, for fraud stemming from the company’s alleged misrepresentations to FDA. The company declared bankruptcy in May, after creating a three-dimensional scanner that failed to garner FDA clearance after three attempts. FDA determined the device was unsafe and yielded “scientifically invalid and useless” images, determinations the company’s CEO did not disclose to investors when asked. The SEC is seeking a court order to prohibit future violations, penalize the company with fines, and prohibit the CEO from serving at a public company in the future, according to Fierce Medical Devices. (June 27, 2013).  
http://tinyurl.com/q627hou

“Federal Circuit Again Invalidates Cordis Patent Claims Against Medtronic, Abbott, Boston Scientific.” A three-member panel of judges for the Federal Circuit ruled Cordis’ (Johnson &Johnson’s subsidiary) and Wyeth Pharmaceuticals’ (a subsidiary of Pfizer, Inc.) stent patents invalid. The finding is a win for Abbott, Boston Scientific, and Medtronic who were on the other side of the long-standing battle over drug-eluting stent technology and a coating drug, rapamycin, according to Mass Device. (June 28, 2013).  
http://tinyurl.com/or9m84z

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