MEDICAL DEVICES COMMITTEE’S NEWSLETTER

June 9, 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

“Scion Medical Technologies Receives FDA 510(k) Clearance for the Cassi™ Beacon™ Tissue Marker.”

FDA has cleared Scion Medical Technologies’ Cassi Beacon tissue marker for sale and use in the US. The marker continues the company’s line of Cassi breast biopsy products. The new tissue marker is placed in soft tissue during breast biopsies to radiographically mark the surgical site for the procedure while providing visualization under the major imaging instrumentalities, including ultrasound, x-ray, mammography, and MRI. Additionally, the device is notably the first breast biopsy marker to use polyetherketoneketone (PEKK) polymers, according to Device Space. (June 3, 2013). [http://tinyurl.com/le3xo3v](http://tinyurl.com/le3xo3v)
“Medtronic Wins FDA Nod, CE Mark for Angioplasty Balloon.” Medtronic received FDA clearance and a CE mark for its Pacific Plus balloon catheter, its next-generation vascular treatment, this week. The device is a percutaneous transluminal angioplasty catheter which is used to treat peripheral artery disease in renal, iliac, iliofemoral, femoral, popliteal, and infrapopliteal arteries, according to Fierce Medical Devices. (June 4, 2013). http://tinyurl.com/ldg6utd

“Cook Wins 510(k) Status for Next-Gen Biliary Stent.” FDA has cleared Cook’s metal biliary stent for use and sale in the US. The stent is used to correct bile duct obstructions while resisting migration, features the company asserts are more consistent than in competitor’s products. The device’s deliver system design permits the physician to install or remove the stent as necessary using a handle trigger, according to Fierce Medical Devices. (June 5, 2013). http://tinyurl.com/lgyhmpq

“Nephron Pharmaceuticals’ EZ Breathe Atomizer Tagged with Class I Recall.” FDA has deemed Nephron Pharmaceuticals’ recent recall to be Class I, meaning the malfunction could cause serious bodily injury or death. The device at issue is the company’s EZ Breathe Atomizer, and due to a manufacturing defect, one of the device’s washers can become dislodged from atomizer, potentially creating a choking hazard for the user, according to Device Space. (June 5, 2013). http://tinyurl.com/m5dp47k

“University of Washington Spinout Cardiac Insight Wins FDA OK for Heartbeat Monitor.” FDA has cleared Cardiac Insight’s Stealth™ body-worn ECG monitor. The device is lightweight, and features a low-power, disposable monitor, allowing it to be worn for an entire day. It will serve as the platform the company’s future devices and boats the potential to improve patients’ experiences as well as an easy-to-use system, according to Device Space. (June 7, 2013). http://tinyurl.com/k4e4j8r

Intellectual Property and Innovations

“Biodesix Touts Lung Cancer Dx’s Ability to Pick Better Treatment Option.” Biodesix is reporting positive results from its recently concluded Phase III trial examining the predictive power of its lung cancer blood diagnostic. The company’s PROSE trial, including 285 patients, looked at its VeriStrat test. VeriStrat is a blood-based protein diagnostic used to predict treatment outcomes between chemotherapy or the drug erlotinib (Roche/Astellas’ Tarceva). The treatments are used for advanced non-small-cell lung cancer, and the test is used to determine if the potential patient has an EGFR mutation, a mutation with which erlotinib works best. On the other hand, patients who are not found to have the mutation can be directed more quickly to chemotherapy, according to Fierce Medical Devices. (June 3, 2013). http://tinyurl.com/nxcqyp9

“Boston Scientific Pits Vaginal Mesh vs. Hysterectomy in Study.” Boston Scientific and the Pelvic Floor Disorders Network are pairing up to determine whether Boston Scientific’s Uphold LITE transvaginal mesh has better outcomes than traditional surgery for patients with uterine prolapse. Boston Scientific is contributing a $1 million research and education grant to study 180 patients with uterine prolapse. The patients will be evaluated twice a year regarding surgical success, patient safety, cost-effectiveness, quality of life and body image for up to five years during the study. The company hopes to conclude the study by 2017 and to use the data to help clinicians make more knowledgeable treatment decisions for those with pelvic floor disorders, according to Fierce Medical Devices. (June 3, 2013). http://tinyurl.com/laqzrtt

“Bard’s Drug-Coated Balloon Begins ‘Below-the-Knee’ PAD Trial.” C.R. Bard is seeking to demonstrate the versatility of its Lutonix drug-coated balloon in its Below the Knee trial which recently enrolled its first patient. The trial will enroll hundreds of patients to compare the Lutonix 014 drug-coated PTA dilatation catheter with a standard angioplasty balloon for patients with critical limb ischemia. People with critical limb
ischemia are at risk for amputation because their arteries are blocked to a great degree. The company hopes the study will provide the data to show the device’s safety and effectiveness so it can pursue FDA clearance, according to Fierce Medical Devices. (June 5, 2013). http://tinyurl.com/ltpfTk

“First Dual-Action Compound Kills Cancer Cells, Stops Them from Spreading.” Researchers have had some success in creating a potential drug that kills and stops the spread of melanoma skin cancer cells. Photodynamic therapy is currently used with specific drugs to kill cancer cells in a targeted manner. The new technology, which has been tested in mice, consists of a synthesized drug that kills melanoma cells and then prevents them from further metastasizing through inhibiting specific signals within the cells, according to Science Daily. (June 5, 2013). http://tinyurl.com/kzyv7pq

“Surgeons Implant Bioengineered Vein: Kidney Dialysis Patient First in US to Receive Lab-Grown Blood Vessel.” A team of doctors at Duke University Hospital have created and implanted a bioengineered blood vessel in a live patient, the first surgery of this type in the US. The vessel was created using donor human cells on a cylindrical scaffold and the cleansed of qualities that could trigger an immune response in the vessel’s recipient. Clinical trials of the veins started abroad in December. With the recent FDA approval, the study will enroll 20 kidney dialysis patients in the US, and then conduct a safety review. Kidney dialysis patients are good candidates because dialysis frequently requires a graft to connect an artery to a vein to increase blood flow during the procedure. Using bioengineered veins is potentially beneficial as compared with current methods, which include harvesting the patient’s own veins or using synthetic grafts, which are prone to clotting, according to Science Daily. (June 6, 2013). http://tinyurl.com/p27jg6l

M&A/Joint Ventures/Corporate News

“Zimmer Boosts Bone Biz with German Buyout.” Zimmer has purchased Normed Medizin-Technik, a German company that makes devices for bone reconstruction for undisclosed terms. Zimmer plans to use its acquisition to expand its extremities business, as Normed creates plates and screws for bone construction, fracture repair, fusion procedures, and external fixation, according to Fierce Medical Devices. (June 4, 2013). http://tinyurl.com/mlspqdp

“Indian Institute Concocts a Bargain-Priced, Ceramic-Coated Hip Implant.” India’s Central Glass and Ceramic Research Institute has created a ceramic-coated hip prototype which it projects to cost less than $530, just a tenth the cost of global medical device company models. Hip replacement surgery in the country is also less expensive; costing just one quarter of the going price in the US and elsewhere. India’s government is seeking to modernize its healthcare system and improve access to it, hoping to create more affordable options for its extensive population. Due to the size of the population, the less-expensive options may have far-reaching implications for multinational companies and the medical device sector at large, according to Fierce Medical Devices. (June 4, 2013). http://tinyurl.com/kkwk74p

“Baxter Raising $3.5B to Close Gambro Megadeal.” Baxter is shooting to become the global leader in dialysis devices through acquiring its competitor, Gambro, in a $4 billion deal. Baxter must find $3.5 billion to make the deal a reality and the company is selling five sets of senior notes to raise the necessary money. If the deal goes through, Baxter will leap ahead of current-industry leader Fresenius Medical in a growing market, according to Fierce Medical Devices. (June 5, 2013). http://tinyurl.com/mqamr4h

“Thermo Fisher Scientific Unveils $2.2 Billion Stock Sale to Fund Life Technologies Buy.” Thermo Fisher Scientific announced an underwritten public offering of $2.2 billion of its common stock in order to fund its acquisition of Life Technologies. The company also plans to give the underwriters a 30-day option to buy an
additional $330 million of common stock to cover any over-allotments. Ultimately, Thermo Fisher is projected to close the Life Technologies acquisition in early 2014, according to Device Space. (June 6, 2013). http://tinyurl.com/mo3pz4x

“Quest Allies with Hologic in Women’s Health Dx Deal.” Quest Diagnostics and Hologic have reached a five-year agreement, by which they will work together to create and promote new women’s health diagnostic products. The new deal expands on an existing contract between the two, with Quest increasing its APTIMA-related product offerings, while Hologic will create APTIMA tests for HPV, chlamydia, gonorrhea, and other infections, according to Fierce Medical Devices. (June 7, 2013). http://tinyurl.com/llxj7gc

**Lawsuits/Settlements/Investigations**

“Boston Scientific Can’t Escape New Jersey Whistleblower Lawsuit.” A lawsuit against Boston Scientific from 2011 has survived a motion to dismiss, following a ruling by a New Jersey judge. The plaintiffs allege that the company ran a scheme to defraud Medicare while promoting the off-label use of its Precision Plus spinal cord stimulation system, selling them without certificates of medical necessity and using false diagnostic codes for the devices. The company, in addition to seeking dismissal, also sought to disqualify lawyers working for the plaintiffs and to strike specific confidential information, but both were rejected by the court, according to Mass Device. (June 3, 2013). http://tinyurl.com/k39g259

“Intuitive Surgical Faces Shareholder Class Action Lawsuit.” Intuitive Surgical’s shareholders filed a class action lawsuit last month accusing the company and its executives of artificially inflating the stock’s price using misleading statements and “disreputable” sales practices. The suit alleges that the company posted “record financial results” which let the company’s executives cash in their personally held stock at the “fraud-inflated” prices. The company’s da Vinci surgical robot system is at the heart of the matter because its legal problems, currently the subject of a multitude of pending lawsuits have led shareholders to argue that the company knew or recklessly disregarded information about the system’s adverse events, possible FDA restrictions on sale, and that the company did not set aside money to cover potential liability, according to Mass Device. (June 3, 2013). http://tinyurl.com/lrlxwha

“Stryker Confronts Mounting Hip Recall Lawsuits.” Stryker is facing a host of lawsuits from its allegedly faulty ABG II and Rejuvenate hip replacements which it voluntarily recalled last year. An Illinois man is suing the company for $100 million, alleging that the company failed to properly warn patients of the implants risks, which resulted in soft tissue damage, pain, limping, metal poisoning, and additional surgeries. The company has already offered to reimburse patients for medical expenses incurred from the implants while lawyers are seeking to build and expand class action lawsuits relating to the devices, according to Fierce Medical Devices. (June 4, 2013). http://tinyurl.com/l9pwgqy

“Kentucky Cardiologist Confesses to Unnecessary Stenting.” This week, a Kentucky cardiologist admitted that he lied about a patient’s heart health to obtain Medicare reimbursement for a stent implant. The doctor is the third cardiologist in the nation to be federally prosecuted for the offense, according to Mass Device. (June 7, 2013). http://tinyurl.com/mfjoo7h

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