MEDICAL DEVICES COMMITTEE’S NEWSLETTER

August 18, 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

“Given Wins FDA Nod for Next-Gen PillCam Device.” FDA has granted FDA 510(k) clearance for Given Imaging’s next-generation PillCam SB 3. The device will be used to detect small bowel issues stemming from Crohn’s disease, gastrointestinal bleeding, and iron-deficiency anemia. The company plans to launch the new product in the US during the fourth quarter of 2013 in an effort to reverse its nationwide sales dip. The device has already been approved in other countries, and the company is reporting “very positive feedback” from physicians in Germany, Australia, and Canada, according to Fierce Medical Devices. (August 13, 2013).
http://tinyurl.com/l8r32fs
“Quantel’s Solutis Granted FDA Clearance.” FDA has cleared Quantel Medical’s Solutis for sale and use in the US. Solutis is a selective laser trabeculoplasty (SLT) glaucoma laser which is used to decrease intraocular pressure in glaucoma patients. It is non-invasive, sending laser energy to targeted regions where it promotes a regenerative response at the cellular level. The company has been waiting for a Massachusetts General Hospital patent to expire so that it can sell the technology within the US. It has been successfully selling the laser elsewhere since 2007, according to Device Space. (August 13, 2013). [http://tinyurl.com/m53zj23](http://tinyurl.com/m53zj23)

“FDA Sticks ‘Deadly’ Tag on Nova’s Glucose Test Strips.” Nova sent a letter to its customers, warning that 21 lots of Nova Max test strips should not be used because they may report high blood glucose levels in error. FDA has responded by deeming the recall to be Class I, meaning that the malfunction could cause serious injury or death. A faulty high reading could lead to incorrect insulin doses, resulting in hyperglycemia and potentially death. Nova is asking patients to return the affected strips to the company for free replacements, and FDA has asked that related adverse reports be identified through its MedWatch platform online, according to Fierce Medical Devices. (August 14, 2013). [http://tinyurl.com/monyc3j](http://tinyurl.com/monyc3j)

“Second Sight Gains CMS Coverage for Retinal Prosthesis.” Starting October 1, the Centers for Medicare and Medicaid Services will cover Second Sight Medical Products’ Argus II Retinal Prosthesis System. The retinal implant is used in adults with degenerative eye disease. The coverage is important because private insurers usually follow CMS in their coverage plans, so patients may avoid paying for the prosthesis out-of-pocket. The move also helps Second Sight, which will be able to reach a larger market and increase its revenue-generating potential, according to Fierce Medical Devices. (August 15, 2013). [http://tinyurl.com/n3nerwe](http://tinyurl.com/n3nerwe)

“Recall: FDA Sounds the Alarm on Hospira Blood Kits after 1 Patient Dies.” FDA has issued a Class I recall for blood kits made by Hospira following the death of a patient. Class I recalls are reserved for product malfunctions which may result in serious bodily harm or death. The patient’s death in this instance was due, in part, to a punctured blood bag, which resulted in a delayed treatment. Hospira warned its customers that the piercing pin component of its system can break through the bag’s outer wall, which could lead to blood leaks while exposing blood products to healthcare providers. However, the company did not recall the product, instead opting to distribute blunter piercing pins so that the bags can be safely used. The company also sent a letter recommending its customers properly follow its protocol when using the product, according to Mass Device. (August 15, 2013). [http://tinyurl.com/l3nkpuu](http://tinyurl.com/l3nkpuu)

**Intellectual Property and Innovations**

“New Antivirus System Could Protect Medical Devices from Infection.” Computer security experts at the University of Michigan are testing their latest technology which detects malware in hospital software. Malware is a potential problem, especially in hospitals, where software viruses may cause devices to malfunction. The system, WattsUpDoc, works by detecting abnormal power consumption and usage in devices. The group tested devices intentionally infected with viruses and found their malware successfully detected the abnormalities 94% of the time when known malware was used, and 84-91% of the time with previously unseen viruses. This technology is important because antivirus programs that work for home computer systems often do not work with medical device software and FDA recently identified cybersecurity as an increasingly prevalent concern, according to Fierce Medical Devices. (August 12, 2013). [http://tinyurl.com/knaqhqe](http://tinyurl.com/knaqhqe)

“Your Eyes May Hold Clues to Stroke Risk.” Researchers at the National University of Singapore are reporting that retinal imaging may be used to assess a patient’s stroke risk. In a study published in *Hypertension*, the American Heart Association’s journal, the scientists looked at and rated patients’ hypertensive retinopathy (retinal blood vessels damaged by hypertension) to find a correlation between severity
of damage and stroke risk. They did caution that the results are preliminary; more studies need to be completed before clinical practice recommendations can be made, according to Science Daily. (August 12, 2013). [http://tinyurl.com/k3zb23f]

“Decellularized Mouse Heart Beats Again after Regenerating with Human Heart Precursor Cells.” Researchers at the University of Pittsburgh School of Medicine have successfully used human induced pluripotent stem (iPS) cells and a three-dimensional scaffold to create a beating mouse heart. To create the new heart, the researchers decellularized a mouse heart and then repopulated the resulting scaffold with multipotent cardiovascular progenitor (MCP) cells. The replacement cells came from reverse-engineered fibroblast cells which were induced to become iPS cells and treated further to differentiate into MCP cells. The repopulated cells eventually “rebuilt” the heart scaffold with human cells and even began to contract again, according to Science Daily. (August 13, 2013). [http://tinyurl.com/lplmfez]

“InSightec’s Surgery-Free Brain Tech Eases Tremor in Study.” In a study published in The New England Journal of Medicine, researchers reported that InSightec’s ExAblate Neuro, which provides MRI-guided spurts of ultrasound energy to ablate thalamic tissues, improved symptoms and the quality of life in the 15 patients tested. It almost halved the patients’ average tremor scores. The company is using the data to launch a larger, multicenter study of its device in pursuit of FDA approval so it can begin treating US patients with essential tremor, according to Fierce Medical Devices. (August 15, 2013). [http://tinyurl.com/lcr39lb]

“Two Teams Advance Artificial Pancreas Work in Quest for Better Diabetes Care.” Two separate projects are working to improve the development of a viable artificial pancreas system. Researchers at the University of Virginia’s Center for Diabetes Technology have found patients can better control their blood sugar with smartphone technology and are further developing their prototype system (Diabetes Assistant) which is linked to Dexcom monitors and Insulet OmniPod insulin pumps. Second, researchers at the Mayo Clinic and the University of Minnesota are using a grant to create a graphene-based wireless sensor that would be placed within blood vessels to constantly track blood glucose levels in real time, according to Fierce Medical Devices. (August 16, 2013). [http://tinyurl.com/md6cvmu]

**M&A/Joint Ventures/Corporate News**

“Medtronic Bags Telehealth Biz for $200M.” Medtronic has purchased Cardiocom in an all-cash deal worth $200 million. Cardiocom works in disease management technology, and the deal will give Medtronic an array of remote monitoring devices and telehealth platforms, all of which can be used to monitor patients’ conditions and report real time data back to healthcare providers. In its announcement, Medtronic asserted that the high-growth market is advantageous for the company, and that the technology has the power to reduce hospital readmissions, resulting in healthcare savings, according to Fierce Medical Devices. (August 12, 2013). [http://tinyurl.com/lp3vp7o]

“Boston Scientific Raising $1B as it Crawls out of Debt.” After “arguably the second-worst ever” deal in which Boston Scientific acquired Guidant, the company is working to pay down a significant portion of its resulting debt. The acquisition cost the company billions in damaged goodwill and harmed its growth overall. Under the plan, the company will sell about $1.1 billion in senior notes in two lots; $600 million of notes will be due in 2018, and the remaining $450 million will be due in 2023. The company has since restructured and gained a new CEO as well, according to Fierce Medical Devices. (August 12, 2013). [http://tinyurl.com/nx6yjk3]
“Baxter Wins Chinese OK for $4B Gambro Buyout.” Chinese regulators have approved Baxter’s deal to purchase Gambro for $4 billion, an acquisition that will solidify the company’s status as a global leader in kidney dialysis. In order to have the deal go through, Baxter must sell off its continuous renal replacement therapy segment, and extract itself from an outsourcing deal with Japan’s Nipro within the next three years. This latest acquisition will give Baxter greater holdings in Latin America and Asia, a move that may catapult the company over market leader Fresenius Medical, assuming it does not lose too many units in the process, according to Fierce Medical Devices. (August 13, 2013). http://tinyurl.com/m4rqavg

“SafeStitch Medical to Merge with TransEnterix, Raise $30M.” SafeStitch Medical and TransEnterix will merge during the next quarter under an agreement involving a private placement of approximately $30 million. Under the deal, SafeStitch will move from Miami to Research Triangle, North Carolina, keeping its name, stock symbol, and place on the OTC exchange. Each share of TransEnterix stock will be converted into 1.1723 shares of new SafeStitch as well, according to Mass Device. (August 14, 2013). http://tinyurl.com/myeemvx

Lawsuits/Settlements/Investigations

“Johnson & Johnson Can Exclude Recall Evidence in DePuy ASR Bellwether Lawsuit.” Johnson & Johnson’s DePuy Orthopaedics division is facing numerous personal injury lawsuits nationwide regarding its ASR device. The company recalled the device in 2010, but a federal judge has ruled that evidence of the device’s recall can be excluded from a leading trial over the device. The plaintiffs argued that the recall should not be excluded as a subsequent remedial measure, but the Court found that the recall occurred after the surgery at issue. Due to the like nature of the claims, many of the suits have been consolidated into multi-district litigation, such as in this case. The trial is scheduled to begin in September, according to Mass Device. (August 12, 2013). http://tinyurl.com/mcvvn4b

“CAS Medical Wins a Legal Round Against Covidien’s Nellcor.” A federal judge in Michigan has thrown out a breach-of-contract claim against CAS Medical. In 2011, Covidien’s Nellcor sued CasMed, claiming a breach-of-contract that resulted in a patent infringement lawsuit. The technology at issue measures brain oxygen levels. CasMed argued that it should be allowed to participate in the US Patent and Trademark Office’s re-examination of Nellcor’s patent, an assertion the court upheld when it found the re-examination is separate and apart from the patent itself, according to Mass Device. (August 12, 2013). http://tinyurl.com/lwbez62

“Spectranetics Takes Thermopeutix to Court over Distribution Deal.” Spectranetics and Thermopeutix are fighting over a distribution deal regarding the Tapas catheter, an infusion system. Thermopeutix owns the device’s trademark, but Spectranetics was to sell and market the device under the agreement. At the moment, Spectranetics is suing its former partner for trying to cancel the deal, while Thermopeutix is accusing Spectranetics of using its trademark wrongfully, voiding the deal. The case was filed in the 4th Judicial District of Colorado, Spectranetics’ home state, according to Mass Device. (August 13, 2013). http://tinyurl.com/m83khyy

“Bard Ordered to Pay $2M in Vaginal Mesh Trial Defeat.” The latest C.R. Bard case pertaining to its vaginal mesh implants has been returned, with the jury awarding the plaintiff $250,000 in basic compensation and $1.75 million in punitive damages. At issue was whether Bard knew the vaginal mesh implants it was selling were defective. In the particular case, the plaintiff asserted that her Avaulta Plus vaginal mesh implant caused bladder spasms, bleeding, and pelvic and rectal pain to the point it had to be removed. The plaintiff further alleged that the company knew the plastic used in the implant was unsafe for permanent use in humans, a claim the company is denied, arguing the device was properly designed and made. The suit is one of around 5,000 Bard faces regarding its vaginal mesh implants, which could cost the company hundreds of millions of
dollars in litigation charges, according to Fierce Medical Devices. (August 15, 2013). http://tinyurl.com/mbwovjt

“Gene By Gene Joins Ambry to Fight Myriad’s Dx ‘Monopoly.’” Following the Supreme Court’s decision nullifying five Myriad patents, Gene By Gene launched its own BRCA tests in an effort to garner some of the market. Myriad sued the company after it released its products, claiming infringement and in response, Gene By Gene as countersued, alleging Myriad is using an incorrect interpretation of the holding to create a monopoly over BRCA testing, in violation of the Federal Antitrust Act. This suit follows a parallel situation Myriad is facing with Ambry Genetics, a company that also launched its own test, was sued by Myriad for infringement, and then countersued. Neither company intends to take its BRCA tests off the market until a legal resolution is obtained, according to Fierce Medical Devices. (August 15, 2013). http://tinyurl.com/lor62tr

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