MEDICAL DEVICES COMMITTEE’S NEWSLETTER

June 16, 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

“More FDA Inspection Troubles for Hospira, Inc.” Hospira’s regulatory woes are continuing. In October 2012, FDA inspected a facility in India, noting serious troubles with workplace sanitation, product sterility, and processing violations. The depth of violation resulted in adulterated products. More recently, FDA has determined that the company’s same facility still significantly violates good manufacturing practices regulations, according to Device Space. (June 10, 2013). [http://tinyurl.com/kxdlu39](http://tinyurl.com/kxdlu39)

“Meridian Biosciences, Inc. Receives FDA Clearance for New Molecular Amplification Test: illumigene® Mycoplasma.” FDA has cleared Meridian Bioscience, Inc.’s new molecular diagnostic test for use and sale in the US. Using its illumigene® platform, the company’s latest test is used to detect Mycoplasma pneumonia
(walking pneumonia). The test uses DNA amplification to detect the disease, providing a definitive result quickly, which is advantageous as compared with the current bacterial culturing method, which lacks sensitivity and can take up to six weeks to culture, according to Device Space. (June 10, 2013).

http://tinyurl.com/lzh4kpn

“Teleflex Incorporated ARROW NextStep Receives FDA 510(k) Clearance.” FDA has cleared Teleflex Incorporated’s ARROW NextStep® Retrograde Femoral Length Dialysis Catheter for sale and use in the US. The catheter is part of the company’s NextStep Hemodialysis Catheter portfolio, and features reversed port configuration, putting the venous port in the superior vena cava and the arterial port in the right atrium, which ultimately reduces recirculation and high flow rates, according to Device Space. (June 11, 2013).

http://tinyurl.com/k7xzvqq

“FDA Approves New St. Jude Medical Heart Devices that Address Previous Problems.” FDA has approved two of St. Jude Medical’s heart devices for sale in the US. The next-generation Ellipse™ and SIM Assura™ portfolio of implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators both use DynamicTx™ Over-Current Detection Algorithm. The new technology automatically calibrates shocking configurations to guarantee successful performance even if an electrical short occurs in one part of the system. The devices also feature a low-friction coating, reducing lead-to-can abrasion incidents, according to Device Space. (June 12, 2013).

http://tinyurl.com/ma2wcjv

“Regulators Down Under Issue a Hazard Alert on J&J’s Shoulder Surgery Guides.” One lot of Johnson & Johnson’s Glenosphere Orientation Guide, a surgical assist device, has been slapped with a hazard alert from Australian Department of Health. The alert stems from an arrow system on the orientation guides that is on the incorrect side, possibly leading to erroneous placement. The device is used with J&J’s Delta XTEND Reverse Shoulder System, and has been off the market since March, but since it is reusable, there are concerns that some of the faulty devices are still in use. The Department of Health did not recommend preventative removal of the devices, but did inform physicians that revision surgery may be necessary “if symptoms are evident and incorrect placement is suspected,” according to Mass Device. (June 12, 2013).

http://tinyurl.com/lvbtx9r

“Johnson & Johnson Unit, Cordis Corporation, Gets FDA OK for Advanced Guiding Catheter.” FDA has cleared Cordis Corporation’s ADROIT™ 6F Guiding Catheter for sale and use in the US. Cordis is a unit of Johnson & Johnson. The new catheter features the largest inner diameter available in the US as well as enhanced support and control for physicians using the device. The company asserts that these features will make it easier for physicians to treat complex lesions, according to Device Space. (June 13, 2013).

http://tinyurl.com/mfracoz

Intellectual Property and Innovations

“Texas A&M University Research Using Special Foams to Treat Aneurysms.” Researchers at Texas A&M University are exploring the use of foams to treat potentially fatal brain aneurysms. By using polyurethane-based shape memory polymer foams to fill aneurysms, the researchers are investigating an alternative to the traditional treatment of surgically cutting the aneurysm or implanting platinum coils to decrease vessel wall pressure and thus reduce the likelihood of rupture. The experimental technique essentially plugs the aneurysm while signaling healing factors, including endothelial cells, into the area, according to Device Space. (June 10, 2013).

http://tinyurl.com/kuaelv2

“Magnets + Laser + Water = Promising Malaria Diagnostic.” Case Western Reserve University researchers are investigating the use of magnets to diagnose malaria. The device is a battery-powered box with a laser and
magnetic field. Malaria parasites are unable to digest the iron contained in the hemoglobin they eat, meaning they are iron rich, a characteristic the device uses to detect them. The researchers dilute the subject’s blood drop with water, create a magnetic field around the sample, and then illuminate it with a laser. Malaria parasites present will split in the blood and the remaining iron will line up in the magnetic field. The device would be significantly less costly than current models and is durable and well-suited to field use in Africa, but the group is currently seeking investors so they can test their device further, according to Fierce Medical Devices. (June 11, 2013). [http://tinyurl.com/mw6v5yt](http://tinyurl.com/mw6v5yt)

“Brain Stimulation Aims to Speed up Tinnitus Treatment.” Scientists at the University of Auckland’s Audiology section are showing that trans-cranial direct current stimulation (tCDS) may be more effective in a shorter time than traditional tinnitus treatments. Tinnitus, the sensation of hearing sound without auditory stimulus (such as a ringing in one’s ear), interferes with about 3% of the population’s quality of life. Current treatments include counseling and non-invasive hearing sound therapy (dampening the tinnitus signal through the use of hearing aids). Since tinnitus is not an ear disorder, but rather a brain disorder in which the brain misinterprets information, the researchers used tDCS to shape change the brain to train the individuals based on their specific types of tinnitus, according to Medical Xpress. (June 12, 2013). [http://tinyurl.com/muos7d4](http://tinyurl.com/muos7d4)

“Mystery Solved? Research Blames Ruptured Plaque for Stent Related Blood Clots.” South Korean scientists may have figured out the cause of very late stent thrombosis (blood clots) following drug-eluting or bare-metal stent implants. According to researchers at the University of Ulsan College of Medicine in Seoul, very late stent thrombosis occurs when plaque buildup in the stent ruptures. In drug-eluting stents, the ruptures probably occur inside the stents. If the researchers are correct, that plaque buildup is causing the thrombosis, the researchers have identified an important potential target for medical devices companies to address in future implant models, according to Fierce Medical Devices. (June 12, 2013). [http://tinyurl.com/mf4dg4m](http://tinyurl.com/mf4dg4m)

“Scan Predicts Whether Therapy or Meds will Best Lift Depression.” A team of scientists at Emory University have found that a pre-treatment brain scan can determine whether psychotherapy or antidepressant medication will better achieve remission for individuals with depression. The researchers are aiming to create reliable biomarkers to match optimal treatments for individual patients, as physicians currently use trial and error to make the decisions, which results in a remission rate of around 40%, according to Science Daily. (June 12, 2013). [http://tinyurl.com/mbacmmt](http://tinyurl.com/mbacmmt)

“MC10’s BioStamp: The New Frontier of Medical Diagnostics with Medtronic, Inc.” A startup in Cambridge, Massachusetts is making a manufacturing technology to create digital circuits to be embedded in fabric of flexible plastic. The idea is that individuals will be able to monitor their personal vitals unobtrusively. Current devices, such as wristbands from Nike, clip-on devices from FitBit, and eyewear from Google, all require that the user “wear” the technology, and MC10 is hoping their new technique will lead to less restrictive monitoring. Additionally, the technology may be used to monitor brain activity to determine whether the individual suffered a concussion or other adverse event, despite being asymptomatic, according to Device Space. (June 14, 2013). [http://tinyurl.com/mvlq9lu](http://tinyurl.com/mvlq9lu)

M&A/Joint Ventures/Corporate News

“St. Jude Pours $40M into Neuromod Outfit with Option to Buy.” St. Jude Medical has entered into an agreement to invest $40 million in Spinal Modulation, with the option to buy it outright for $300 million. The deal gives St. Jude the exclusive right to sell Spinal Modulation’s Axium Neurostimulator System, which currently has a CE mark and is being groomed for a large-scale clinical trial in the US later this year. The device is used to treat chronic spinal pain by targeting the dorsal root ganglion of the spine and uses 95% less energy
than other neuromodulation implants, according to Fierce Medical Devices. (June 10, 2013).
http://tinyurl.com/mnhmqxz

“TVA Medical Grabs $9.5M to Test Kidney-Failure Treatment Device.” TVA Medical raised $9.5 million in new venture funding. The five-year-old startup makes a device that allows patients in end-stage renal disease to undergo hemodialysis through arteriovenous fistula procedures (connecting an artery to a vein). The company will send its device through more clinical testing with the goal of expanding its global reach with the new funding, according to Fierce Medical Devices. (June 11, 2013). http://tinyurl.com/k9wt6ww

“RTI Biologics to Acquire Pioneer Surgical Technology for $130 Million in Cash.” RTI Biologics Inc. will acquire privately-held Pioneer® Surgical Technology for $130 million in cash. RTI Biologics provides orthopedics and other biological implants. Pioneer manufactures and distributes metal and synthetic products in orthopedics, biologics, spine, trauma, and cardiothoracic markets. RTI Biologics is hoping to use its new acquisition to improve its current implant portfolio into metals and synthetics, while expanding its direct distribution, according to Device Space. (June 12, 2013). http://tinyurl.com/nx48vq4

“Mindray Medical to Buy ZONARE Medical Systems, Inc. for $105 Million.” Mindray Medical International Limited, China’s largest medical devicemaker, will acquire ZONARE Medical Systems, Inc. for $105 million. Mindray Medical is hoping to use its new acquisition to expand its high-end ultrasound research and development as well as improve its US sales in its quest to become the leading global provider of high-quality imaging products, according to Device Space. (June 13, 2013). http://tinyurl.com/kwhwmw5

“Startup NeuroTronik Hauls in $13.1M for Heart Device.” North Carolina’s NeuroTronik closed a successful $13.1 million Series A financing round. The company spun out from Synecor 11 months ago, in order to work on a nerve-stimulating device that improves heart function without requiring the invasive defibrillator implant surgery. NeuroTronik asserts that the device may shorten hospital stays for those with acute heart failure, approximately 1.2 million US patients annually, according to Fierce Medical Devices. (June 13, 2013). http://tinyurl.com/ljv8cw5

“MVC Capital Invests $22.4 Million into Ohio Medical Corporation.” MVC Capital, Inc. completed its follow-on investment of $22.4 million in Ohio Medical Corporation this week, purchasing convertible preferred stock. MVC’s investment will substitute for equity financings in Ohio Medical that had deleveraged the company. MVC is reportedly pleased to have completed its obligation, and stands by Ohio Medical’s line of medical suction and oxygen therapy devices, according to Device Space. (June 14, 2013). http://tinyurl.com/lt2lyz4

Lawsuits/Settlements/Investigations

“Becton Dickinson AG Says Former Engineer Planned to Flee to India with Trade Secrets.” The FBI arrested a former Becton Dickinson engineer late last week at a hotel in New Jersey. The company alleges that the engineer was trying to flee to India to mass-produce one of its drug injection devices in violation of trade secret law. Becton Dickinson worked with the FBI to ultimately suspend his work visa and provided information about his company email, according to Device Space. (June 10, 2013).
http://tinyurl.com/ml7qvky

“NuVasive Ordered to Pay Medtronic Royalties in Spinal Implant Suit.” A US District Court has ordered NuVasive to pay royalties to settle a patent dispute with Medtronic. The patents at issue concern several spinal-related implant products, and the court ordered a 13.75% royalty on NuVasive’s CoRoent XL implants and an
8.25% royalty on MaXcess retractors. Medtronic sought much higher royalties, 26% and 22%, respectively. NuVasive plans to appeal the ruling, and the litigation royalty expense accruals will expire in February of 2015, when the patents expire, according to Fierce Medical Devices. (June 12, 2013). [http://tinyurl.com/n96kc7j]

“In a Blow to Myriad, SCOTUS Rules Human Genes as Unpatentable.” The US Supreme Court unanimously ruled that human genes, as products of nature, cannot be patented. Myriad had argued that its patents on isolated BRCA1 and BRCA2 genes were legitimate. The genes are an essential component of the company’s diagnostic test for hereditary breast and ovarian cancers. In an opinion written by Justice Clarence Thomas, the Court found that it was “an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.” However, the Court also found that complementary DNA (cDNA), a synthetic version of the gene, is patentable, according to Fierce Medical Devices. (June 13, 2013). [http://tinyurl.com/n5tytlk]

“Medtronic Notches Small Win in German TAVI War with Edwards Lifesciences.” A local court has denied one patent infringement claim brought by Edwards Lifesciences against Medtronic in the two companies’ fight for TAVI technology and market share in the country. The decision is just the first of three ongoing TAVI patent battles between the two companies and if Edwards ultimately wins, all of Medtronic’s CoreValue system would be removed from the German market. Edwards would still have to post a large bond, should reparations be necessary following an appeal, according to Mass Devices. (June 14, 2013). [http://tinyurl.com/l7dnm46]

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