MEDICAL DEVICES COMMITTEE’S NEWSLETTER

August 11, 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

“Edwards Gains FDA’s Blessing to Test Next-Gen Sapien Valve.” Edwards’ Sapien transcatheter aortic heart valve (TAVI) is the only such device with FDA approval today. Consequently, American cardiologists have significantly fewer options for transcatheter aortic valve replacement than their European counterparts, since companies seek a fast approval there to gain capital before turning to the US. In response, FDA has begun its new modular approval program, which allows companies to report their study data incrementally, allowing clinical trials to proceed faster. In Edwards’ case, FDA has given a conditional investigational device exemption so that the company can test its Sapien 3 in patients with severe symptomatic aortic stenosis who are not otherwise candidates for surgery. The study will include a maximum of 500 patients and will explore three methods of implantation. The Sapien 3 features a “lower profile” as compared with earlier models, as well as a

“Hacking: FDA is Developing a ‘Cybersecurity Laboratory.’” FDA is soliciting bids from Codenomicon Defensics to help it build a “cybersecurity laboratory,” so the agency can examine potential software bugs and weaknesses in proposed systems. The “fuzz testing” will probe the software for defects or vulnerabilities that would leave it open to attack. Standardizing the review process will be beneficial, and device makers are beefing up their cybersecurity measures in preparation for the new testing, according to Mass Device. (August 6, 2013). [http://tinyurl.com/maatuHz]

“Labeling Glitch with Boston Scientific’s Promus Element Plus Prompts Recall in Australia.” Australia’s Therapeutic Goods Administration has issued a recall of Boston Scientific’s Promus Element Plus Monorail coronary stents following a labeling error. The company contacted cardiologists in Australia, giving them new instructions regarding the antiplatelet regimen to correct the error. The device has been approved in Canada for over a year, and gained CE mark approval last October, according to Mass Device. (August 7, 2013). [http://tinyurl.com/ld5spa2]

“CareFusion Saddled with Yet Another Class I Recall.” For the third time in a year, FDA has labeled a CareFusion Alaris infusion pump recall as Class I, the agency’s most serious recall classification. Class I designations are reserved for problems that could result in serious injury or death. In CareFusion’s latest recall, some of its infusion pumps were shipped with lower voltages than are required, which may result in a faulty communication between the processor and keyboard and ultimately, stop infusion, according to Fierce Medical Devices. (August 7, 2013). [http://tinyurl.com/mt2fb3m]

“FDA Rejects Wright’s Bone Graft.” BioMimetic Therapeutics is facing significant challenges following the company’s latest failure to obtain FDA approval for its bone graft implant. The latest rejection is based on the patients that BioMimetic selected for its Augment studies, claiming that the patients selected were low-risk, while the company was supposed to test its product against the standard of care. The agency is requiring a new study on a higher-risk population in order to reapply for approval. This is particularly problematic for Wright Medical, which bought the company for $190 million earlier this year, anticipating the Augment bone graft’s success. Wright is dealing with decreasing share prices on the announcement, and had to sell off its hip- and knee-replacement business in June in order to focus on its foot and ankle technologies, according to Fierce Medical Devices. (August 9, 2013). [http://tinyurl.com/k63qm7k]

“Alere Inc.’s HIV Test Grabs FDA Approval.” FDA has approved Alere’s Determine HIV-1/2 Ag/Ab Combo test for sale and use in the US. It is the first rapid Human Immunodeficiency Virus (HIV) test to simultaneously detect HIV-1 p24 antigen and antibodies to both HIV-1 and HIV-2 in human serum, plasma, and venous or finger stick whole blood specimens. It also differentiates between HIV-1 p24 antigen and HIV antibodies. The test is beneficial because it can be used in outreach locations, therefore expanding diagnosing power beyond traditional health care settings and possibly allowing individuals to start treatment earlier, according to Device Space. (August 9, 2013). [http://tinyurl.com/mx3tc5y]

**Intellectual Property and Innovations**

“Ultrasound Patch Helps Accelerate Venous Wound Healing.” A recent clinical study by researchers at Drexel University has found that lower frequencies of ultrasound energy delivered directly to venous wounds are significantly more effective in healing. The team looked at chronic venous stasis ulcers, which are difficult to treat, usually located on the ankle, and have high recurrence rates after healing. In the study, patients who
were given low-frequency, low-intensity ultrasound treatment with standard compression therapy weekly had a net reduction in wound size after four weeks. The group that just received compression therapy, in contrast, had a net increase in wound size during the same period. The researchers also examined different frequencies and durations of treatment, and determined that the group receiving 15 minutes of 20 kHz ultrasound fared the best, although all the iterations resulted in wound reduction, according to Med Gadget. (August 5, 2013). [http://tinyurl.com/q2za682]

“Ohio State’s Wexner Medical Center Implants One of First MRI-Safe Devices for Pain.” Neurosurgeons at The Ohio State University Wexner Medical Center implanted the recently FDA-approved RestoreSensor SureScan MRI neurostimulation system. The system, made by Medtronic, is the first MRI-safe spinal cord stimulator to be approved in the US. The device is implanted near the spine, where it blocks pain signals to the brain, but unlike other stimulators on the market, it can safely be used with an MRI. Recent estimates project approximately 100 million Americans are living with chronic pain, many of who may become candidates for device use, according to Medical Xpress. (August 6, 2013). [http://tinyurl.com/krux8ro]

“Medtronic Implant Could Point to Future of Parkinson’s Treatment.” Medtronic’s Activa PC+S device may change the standard of care for neurological disorders, starting with Parkinson’s. The implant is novel, combining deep-brain stimulation and sensing technology, which records the patient’s electrical activity in specific regions of the brain. It behaves as a closed-loop device; it reads the patient’s brain signals and then administered stimulation as needed. The device already has a CE mark, so the company is distributing it to certain physicians in order to gather information from the sensors to hopefully better understand deep-brain stimulation. In the US, FDA has cleared the device for investigational use and the company plans to start trials in the coming months, according to Fierce Medical Devices. (August 7, 2013). [http://tinyurl.com/kq2lmlo]

“Micro-Machines for the Human Body: Researchers Adapt Microscopic Technology for Bionic Body Parts and Other Medical Devices.” Researchers at Tel Aviv University discovered a technique for printing biocompatible components for micro-machines in a way that makes them functional for medical devices, such as bionic arms. Microelectromechanical systems (MEMS) are typically made from silicon, but the new technique uses a highly flexible and non-toxic organic polymer, which can be safely and comfortably be used in the human body. The new method may allow bionic limbs to be safer and more efficient and could have other applications in the medical field, according to Science Daily. (August 7, 2013). [http://tinyurl.com/l3b2sy6]

“GE, U. of Wash. Team up to Make Paper-Based Diagnostic Device.” GE’s technology development division is working with the University of Washington under a $9.6 million grant from the Defense Advanced Research Projects Agency (DARPA) and $5.7 million grant from the NIH to create a paper-based diagnostic tool that detects infectious diseases with a simple nasal swab. The device is about the size of a deck of cards and diagnoses methicillin-resistant MRSA. The user applies the nasal swab sample to the device and the paper simply changes color to indicate a positive reading, according to Fierce Medical Devices. (August 8, 2013). [http://tinyurl.com/k2ppqt9]

M&A/Joint Ventures/Corporate News

“ConforMIS Plots New Moves after Pumping up Venture Round to $168M.” ConforMIS is reporting a successful Series E financing round of $167.7 million. Investors include “top tier” sovereign wealth funds, government investment funds, and private equity funds worldwide. The increased funding will be used to expand manufacturing for the company’s iTotal knee replacement system, marketing, and for several forthcoming “strategic initiatives,” according to Fierce Medical Devices. (August 2, 2013). [http://tinyurl.com/n2e8h26]
“Theragenics Agrees to $68M Buyout.” Juniper, a private equity firm, has entered into an agreement under which it will buy Theragenics for $68 million. Under the deal, the surgical device manufacturer can continue to solicit competing bids through September 6. If there are no competing offers, Juniper will close on the deal by the fourth quarter of 2013 and its Chief Financial Officer will become Theragenics’ new CEO, according to Fierce Medical Devices. (August 5, 2013). [http://tinyurl.com/k6f7b76]

“Freedom Meditech Completes $7 Million Series B Financing to Support the Launch of the ClearPath DS-120™ and Additional Product Development.” Freedom Meditech has successfully raised $7 million in its Series B financing round, money that will be used to support two of its products. First, the money will be used to aid the commercial launch of its ClearPath DS-120 Lens Fluorescence Biomicroscope which gained FDA approval earlier this year. The device measures the autofluorescence of the eye’s crystalline lens. Higher levels of autofluorescence indicate elevated levels of advanced glycosylated end products, which are present in systemic disease or from the aging process. Second, the funding will go toward the clinical development of the company’s I-SugarX, which is a small handheld device that people with diabetes can hold in front of their eyes to measure their glucose levels non-invasively, according to Device Space. (August 6, 2013). [http://tinyurl.com/l3ctnwg]

“Gene By Gene Grabs GE-Backed Diagnostics Startup.” Gene By Gene has purchased Arpeggi, a startup with DNA sequencing and data management technologies, under undisclosed financial terms. Arpeggi was selected as a part of the StartUp Health and GE Entrepreneurship Program earlier this year. Its technology is in line with Gene By Gene’s needs, and the acquiring company feels that the acquisition will help it to advance low-cost gene analysis, according to Fierce Medical Devices. (August 7, 2013). [http://tinyurl.com/m4m7fvy]

“SetPoint Snags $27M from GSK, Covidien.” SetPoint, a California startup, has raised $27 million in venture funding from GlaxoSmithKline, Covidien, and Boston Scientific. The company is working on a neuromodulation device that stimulates the vagus nerve in the brain, thereby signaling the body’s natural inflammatory reflex. The hope is to use the device as a potentially safer alternative to immunosuppressive drugs in the treatment of inflammatory diseases, like rheumatoid arthritis and Crohn’s disease. Last fall, the company’s first-in-human study showed a reduction in the severity of rheumatoid arthritis in six of the eight device users who did not respond to a traditional RA drug, according to Fierce Medical Devices. (August 8, 2013). [http://tinyurl.com/m9dahu3]

“Invacare Sells off Another Unit for $45M.” Invacare is selling off its Champion Manufacturing unit for $45 million in order to pay down debt stemming from its increasing losses and FDA scrutiny concerns. Champion manufactures medical chairs used in dialysis procedures. The division grew last year, but the company decided to sell it in order to take care of some of its debt and to further focus on the company’s core global product lines, according to Fierce Medical Devices. (August 8, 2013). [http://tinyurl.com/k4o8ll6]

Lawsuits/Settlements/Investigations

“China Fines Johnson & Johnson in Landmark Price-Fixing Case.” The Shanghai High People’s Court has fined Johnson & Johnson about $86,456 for price fixing in China. The Court found J&J created a minimum resale price for the products sold by Rainbow Medical, a Chinese distributor, and later penalized the distributor, ultimately refusing to renew its contract. The agreement resulted in a lack of competition in the medical instrument sector nationwide, harming consumer interests, according to Mass Device. (August 2, 2013). [http://tinyurl.com/ljujopu]
“Gore Beats Back St. Jude’s Patent Suit.” Gore has finally gained the upper hand after a three-year patent battle. AGA Medical brought suit against Gore in 2010, alleging the company’s Helex Septal Occluder infringed several of its patents. AGA Medical used the patented technology in its Amplatzer heart plug, which is used to treat atrial defects. Shortly after commencing the lawsuit, St. Jude Medical bought AGA Medical and continued the legal battle. A federal judge ruled against St. Jude though, and Gore may continue selling its product. St. Jude expressed disappointment with the result and may appeal the decision, according to Fierce Medical Devices. (August 5, 2013). [http://tinyurl.com/lo9k2df](http://tinyurl.com/lo9k2df)

“Court Upholds Life Technologies’ $48.6 Million Jury Award to Enzo Biochem.” A Federal Court Judge in New Haven, Connecticut has upheld a November 2012 jury verdict awarding Enzo Biochem $48.6 million. The verdict, entered against Applera Corporation (now Life Technologies, Inc.) resulted from the company’s infringement of Enzo’s patent of technologies using compounds in DNA sequencing systems to read the genetic code. The latest ruling means that Enzo can now seek prejudgment interest as well, an amount that may exceed $25 million, according to Device Space. (August 6, 2013). [http://tinyurl.com/mohxqfx](http://tinyurl.com/mohxqfx)

“Ambry Genetics Sues Myriad Genetics for Violating Federal Antitrust Laws.” Ambry Genetics has filed an antitrust counterclaim against Myriad Genetics. Myriad, along with other plaintiffs, initially filed suit against Ambry, alleging that the company was infringing Myriad’s patents with its hereditary cancer tests. Ambry is asserting that Myriad’s suit violates the Sherman Antitrust Act, in that the legal protection sought would further a wrongful monopoly on diagnostic testing of humans’ BRCA1 and BRCA2 genes in the US. The company went on to accuse Myriad of falsely representing the accuracy of Ambry’s tests to genetic counselors and payors, and claims that the alleged anticompetitive conduct results in significantly higher prices for consumers, according to Device Space. (August 6, 2013). [http://tinyurl.com/k3sxxd8](http://tinyurl.com/k3sxxd8)

“Alere Declares Victory in Proxy Challenge.” After months of challenges and an intense proxy fight, Alere has managed to have all four of its board nominees elected. Coppersmith Capital Management, a 7% shareholder, waged the challenge, urging the company to decrease and eliminate certain divisions in order to increase shareholder value and raise cash to pay down the company’s rising debt. Ultimately, Alere asserted that the victory solidifies the shareholders’ assent to its plan and tactical future strategy, according to Fierce Medical Devices. (August 8, 2013). [http://tinyurl.com/m8xrmpw](http://tinyurl.com/m8xrmpw)

“Zimmer Owes Stryker $228M in Patent Lawsuit.” In a patent lawsuit between Stryker and Zimmer, a Michigan jury found for Stryker back in February. The damages were set at $70 million, however; due to willful infringement, the district judge increased the penalty to $228 million. The three Stryker patents were infringed by Zimmer’s Pulsavac Plus, a vacuum-like device used during orthopedic surgery to clear the field of debris. The judge, in increasing the damages, cited the “flagrancy and scope of Zimmer’s infringement” as a deciding factor for his decision, according to Fierce Medical Devices. (August 9, 2013). [http://tinyurl.com/lajjza7](http://tinyurl.com/lajjza7)

“Boston Scientific Battles Whistleblowers in Spinal Stimulation Lawsuit.” Boston Scientific has been engaged in a years-long whistleblower suit alleging the company defrauded Medicare and Medicaid in addition to ignoring defects in its Precision Plus SCS spinal stimulation system. The company also allegedly concealed defects, denied replacement devices, participated in a kickback scheme, and retaliated against the employees who tried to halt the practices. Now, the company is trying to exclude evidence, asserting that the information came from confidential documents that employees obtained through breaching their employee contracts. The two employees filed a rebuttal, arguing that they handed over the documents in compliance with federal anti-fraud laws, according to Mass Device. (August 9, 2013). [http://tinyurl.com/lwytz5u](http://tinyurl.com/lwytz5u)

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