MEDICAL DEVICES COMMITTEE’S NEWSLETTER

June 23, 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

“Endologix Inc. AFX Introducer System: Class 1 Recall – Reports of Dilator Breaking During Procedures.” Endologix, Inc. voluntarily recalled its AFX Introducer System in May, and FDA has declared the recall to be Class I, its most serious. The system is used to aid the introduction of catheters and other medical devices into blood vessels in a way that minimizes blood loss. However, there have been reports of the dilator breaking off during procedures, potentially causing serious injury or death, according to Device Space. (June 18, 2013). http://tinyurl.com/khj7jfv

“OrthoSensor Wins FDA Nod for Knee Tech.” FDA has cleared OrthoSensor’s Versasense knee system for use and sale in the US. The device is used in knee replacements to help surgeons align the limb. The company
asserts that the device removes the guesswork of the procedure, stating the surgeons generally have to rely on conventional instruments, personal judgment, and experience to assess soft tissue balance and limb alignment, but that the new device will eliminate the potential inconsistency. The device works with most knee replacement systems, although the company has been working specifically with Stryker, and has a co-marketing agreement with the company to use Stryker’s Triathlon knee system, according to Fierce Medical Devices. (June 19, 2013). http://tinyurl.com/jwtmb5a

“Fresenius Medical Care Receives FDA Warning Letter.” A year ago, FDA announced a Class I recall of Fresenius’ GranuFlo and NaturaLyte, two of its dialysis products. Now, the agency has sent the company a warning letter pertaining to its Optiflux Polysulfone Dialyzers (“artificial kidneys”) manufacturing plant in Utah. The warning letter stems from the agency’s inspection of the facility earlier this year, according to Device Space. (June 19, 2013). http://tinyurl.com/mx7xksj

“Abbott Wins FDA Nod for Hep C Gene Test.” FDA cleared Abbott Laboratories’ RealTime HCV Genotype II test for use and sale in the US. The approval marks the first FDA approval of a strain-identifying diagnostic for hepatitis C. The test discerns between seven genotypes of HCV from an infected patient’s blood, which permits physicians to improve their patients’ outcomes using personalized medicine. The test works with Abbott’s m2000 molecular diagnostic system, according to Fierce Medical Devices. (June 20, 2013). http://tinyurl.com/n49bx2f

“Philips’ Respironics Hit with Yet Another Ventilator Recall.” FDA has issued a Class I recall for Philips Healthcare’s Respironics’ ventilator. The ventilator has a potential software malfunction, which causes the device to cut off breathing support without sounding an alarm, a problem that could result in serious injury or death. Philips notified its customers of the problem earlier this month, and has sent engineers out to update the software and correct the error, according to Fierce Medical Devices. (June 21, 2013). http://tinyurl.com/n3ttmj3

**Intellectual Property and Innovations**

“Yale Study of Medtronic’s Infuse Shows it’s Equivalent to Bone Graft, but Studies were Biased.” Medtronic paid Yale $2.5 million to explore patient-level data from the company’s Infuse bone morphogenetic protein. Two independent research teams found the recombinant human bone morphogenetic protein-2 in Infuse is approximately equivalent to iliac crest bone grafts, the gold standard in spinal fusion procedures. The data used was from the company, and Medtronic was seeking to dispute a 2011 article that asserted a potential 50% risk of adverse events with Infuse. One of the independent groups found that Medtronic-sponsored early trials of the product were biased, underreporting adverse events, while the other group did not assess the reliability of the data. Physicians need to aware of the potential risks associated with Medtronic’s Infuse, and it seems likely that more trials will be conducted to obtain more definitive results, according to Mass Device. (June 17, 2013). http://tinyurl.com/k5gmy5r

“New Fluorescent Protein from Eel Revolutionizes Key Clinical Assay.” A Japanese research team from the RIKEN Brain Science Institute has discovered that Unagi (a freshwater eel) has a fluorescent protein which has the potential to serve in a clinical test for bilirubin. Bilirubin is an indicator of human liver function, hemolysis, and jaundice. Unagi is a culinary delicacy in Japan, where it is on the brink of extinction. The eel possesses Unagi Green protein (UnaG) which uses bilirubin to activate its green light emission, according to Medical News Today. (June 18, 2013). http://tinyurl.com/nvldlgv
“Fiber-Optic Pen Helps See Inside Brains of Children with Learning Disabilities.” Researchers at the University of Washington have created a computer-interfaced drawing pad that allows scientists to see inside the brains of children with learning disabilities while they read and write. The researchers used the device to study the brain patterns of children during functional magnetic resonance imaging (fMRI). They hope that continued study will correlate handwriting aspects, including stroke order, speed, and hesitations which a child’s brain pattern in order to better understand the neural connections involved in different disabilities, according to Science Daily. (June 18, 2013). [http://tinyurl.com/loklks59](http://tinyurl.com/loklks59)

“Wireless Subretinal Prostheses Allows Blind Mice to See Light.” A team of scientists from the US and Scotland have created a novel retinal prosthesis that sends signals directly to the neurons behind damaged photoreceptor cells. The prosthesis is placed below the surface of the retina, where it connects directly to the brain via the intact neurons. Data from a mounted camera is sent to a small computer which forwards a signal to a wireless infrared laser device than shines on the retinal implant. The implant then sends electrical signals directly to the brain. The technology is scalable, so more pixels can be added to provide a better image for the brain to interpret. The researchers have tried their technology in mouse models and reported that light exposure to light resulted in similar visual cortex activity as compared with mice without damaged retinas, according to Medical Xpress. (June 19, 2013). [http://tinyurl.com/kk6yqov](http://tinyurl.com/kk6yqov)

“New Algorithm Measures Heart Rate by Head Movements.” Researchers from MIT’s Computer Science and Artificial Intelligence Laboratory created an algorithm that approximates the time of intervals between heartbeats based on small head movements caused by a rush of blood from a heart contraction. The pulse calculations using this method were consistently within a few beats per minute of those made by electrocardiograms. The video-based pulse measurement system may be useful for seniors and newborns, who have sensitive skin which could be harmed by the repeated attachment and removal of EKG leads, according to Medical News Today. (June 21, 2013). [http://tinyurl.com/llxyb9y](http://tinyurl.com/llxyb9y)

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

“Siemens Inks Companion Diagnostics Deal with J&J.” Siemens has signed a deal with Johnson & Johnson’s Janssen Pharmaceutica to design, develop, and commercialize companion diagnostics. J&J’s unit is creating a compound to identify human β1-adrenergic receptors, biomarkers linked with heart failure. Pursuant to the deal, Siemens will produce a lab test to identify potential clinical trial enrollees, and then it will create an in vitro system which will be commercialized with the therapy, according to Fierce Medical Devices. (June 17, 2013). [http://tinyurl.com/ktk5erd](http://tinyurl.com/ktk5erd)

“Amaranth’s Dissolving Cardiac Stent Drives $25M Fundraising Round.” Amaranth Medical is well on its way to raising $25 million of Series B funding for its bioresorbable cardiovascular stent. The latest round follows the company’s successful $7.5 million round in 2006. While the company’s stent is still in its early stages (so far, it has had 11 patients in its South American clinical trial), it hopes to attain a CE mark, and ultimately, FDA clearance. The bioresorbable stent is poised to become huge in the stent market, as their ability to dissolve could remove the risk of stroke and other complications stemming from stents remaining in vessels, according to Fierce Medical Devices. (June 17, 2013). [http://tinyurl.com/knexxta](http://tinyurl.com/knexxta)

“BD, JDRF Team up for Artificial Pancreas.” The Juvenile Diabetes Research Foundation (JDRF) will be working with Becton Dickinson to develop an artificial pancreas. The two groups have a three year partnership to develop a single device which will combine treatment and monitoring of diabetes. Current treatment usually involves catheter-equipped insulin pumps and invasive continuous glucose monitors, a two-part solution that presents risks of infection, error, and technological failure. The hope is that combining the two technologies
would eliminate or at least minimize some of the risks, while making diabetes management easier, according to Fierce Medical Devices. (June 18, 2013). [http://tinyurl.com/ny8tnft]

“Techne Corp. Agrees to Purchase Bionostics for $104 Million.” Techne Corporation has acquired Bionostics, Inc. for $104 million. Bionostics creates, manufactures, and distributes control solutions used in the verification of proper operation of in vitro diagnostic devices, including blood gas and blood glucose testing. Under the agreement, Techne’s Hematology Division will operate with Bionostics as a new Clinical Controls Division of R&D Systems. Techne hopes to capitalize on Bionostics’ potential, as diagnostics move from the lab to the operating room and home points of care, as well as the increasing prevalence of diabetes and other diseases, according to Device Space. (June 18, 2013). [http://tinyurl.com/k89hdja]

“Vertos Hauls in $23M for Spinal Device.” Vertos Medical closed $23 million in financing this week. The money comes mainly from Pitango Venture Capital, and the devicemaker will use the funding to increase the market for its pain-reducing spinal surgery device. Mild, the company’s surgical kit, was created to aid lumbar spinal stenosis patients, allowing them to walk farther and stand longer without pain. The procedure involves one incision and does not require a hospital stay, sutures, or implants. It has been FDA-cleared since 2008, and the company hopes the latest round of financing will allow it to commercialize the device further, according to Fierce Medical Devices. (June 19, 2013). [http://tinyurl.com/lzg35p8]

“Wright Selling Off Hip and Knee Biz for $290M.” Wright Medical is selling its hip and knee implants business (OrthoRecon) to MicroPort Medical for $290 million. The deal will allow Wright to focus more strongly on its extremities (foot and ankle) and biologics divisions. The companies hope close the deal by the end of this year. Wright’s divestiture comes after years of restructuring since its 2010 admission of anti-kickback laws, according to Fierce Medical Device. (June 20, 2013). [http://tinyurl.com/lszl4aq]

“Mayo Joins Sanovas to Develop Lung-Clearing Asthma Treatment.” Sanovas has teamed up with the Mayo Clinic to market the company’s outpatient treatment for asthma. The treatment, bronchial thermoplasty, uses heat to reduce smooth muscle in the bronchus, decreasing airway constriction. The two groups will further develop the technology, while Sanovas will maintain its exclusive worldwide license of Mayo’s patent, according to Fierce Medical Devices. (June 20, 2013). [http://tinyurl.com/mumotej]

“ALung Pulls in $9.5M, Aims for $7.5M More.” ALung Technologies has drummed up $9.5 million of its aspirational $17 million in its latest funding round. The company is looking to use the money for its Hemolung respiratory assist system, which the company is aiming to commercialize both in the US and in China. The device is already cleared for sale in Europe and Canada. With its latest funding, the company will probably seek a US trial, since the company is meeting with FDA later this month to discuss the parameters of a proposed three-year trial, slated to being next year, according to Mass Device. (June 21, 2013). [http://tinyurl.com/m97skaw]

**Lawsuits/Settlements/Investigations**

“Delcath Hit with Investor Lawsuit after FDA Harangue.” In New York, Delcath’s investors filed a class action lawsuit, accusing the company of withholding safety information about the company’s Melblez system in order to artificially inflate its share price. The Melblez system is a drug-device combination, used to treat eye cancer that has spread to the liver using a collection of filters and pumps to isolate the liver and saturate it with chemotherapy without impacting surrounding tissue. FDA later found the filters leaked the chemical into the bloodstream, an error that lead to about 7% of the patients dying from adverse events after the treatment. An
FDA panel unanimously found that the device’s benefits do not outweigh its risks, and consequently, the company’s shares fell 40%, according to Fierce Medical Devices. (June 17, 2013). [http://tinyurl.com/lwfgssk](http://tinyurl.com/lwfgssk)

“Globus Owes $16M in J&J Patent Suit.” A Delaware jury has found Globus Medical infringed three Johnson & Johnson patents, and awarded $16 million in damages. Specifically, the jury found three discontinued Globus products violated J&J’s DePuy Synthes patents. Globus has stated it will be trying to reverse the judgment, and notes that the court has not yet entered a formal judgment, according to Fierce Medical Devices. (June 17, 2013). [http://tinyurl.com/k5ad2we](http://tinyurl.com/k5ad2we)

“Endo’s AMS Owes $54.5M in Vaginal Mesh Lawsuit.” In a settlement of some of its vaginal mesh lawsuits, Endo Health Solutions’ American Medical Systems will pay over $54.5 million. Over 5,000 product liability claims have been filed since 2008, and it is unclear how many cases were resolved in this settlement. The cases stem from 2008, three years before Endo bought AMS, when patients started alleging the company’s vaginal mesh devices caused pain, incontinence, and organ damage. Many of the suits have been consolidated, and Endo’s first court appearance concerning the product is scheduled for December, in a federal court in West Virginia, according to Fierce Medical Devices. (June 21, 2013). [http://tinyurl.com/m76x4ts](http://tinyurl.com/m76x4ts)

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