MEDICAL DEVICES COMMITTEE’S NEWSLETTER

July 7, 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

“South Korea Revises Medical Device Regulations.” Medical device regulatory changes are afoot in South Korea. The country’s Ministry of Food and Drug Safety made three amendments to the nation’s Medical Devices Act. First, Class IV devices will require Summary Technical Documentation (STED), a requirement that will be voluntary for Class I, II, and III devices. Second, the country’s electronic safety compliance standards will stem from IEC 60601-1 Third Edition, and will have new standards phased in depending on classification levels. Finally, the country’s regulatory scheme is also changing its classification and grade regulations, according to Mass Device. (July 1, 2013). http://tinyurl.com/kz42g8c
“Integra LifeSciences Recall Affects Medtronic’s Infuse Kits.” Medtronic is recalling some of its Infuse spinal fusion surgery kits after receiving notification from Integra LifeSciences regarding potential endotoxin contamination of its absorbable collagen sponges. Some of the affected sponges were components of the Infuse/LT-Cage bone graft kits, and Medtronic is recalling those lots. In response, Australia’s Therapeutics Good Administration issued a “recall and hazard alert” despite no reported adverse events in that country stemming from the sponges, according to Mass Device. (July 2, 2013). http://tinyurl.com/lrgxbcp

**Intellectual Property and Innovations**

“High-Resolution Mapping Technique Uncovers Underlying Circuit Architecture of the Brain.” Researchers at the Salk Institute and Gladstone Institutes are using a sophisticated brain tracing technique to create detailed maps of neurons connecting to the basal ganglia. The researchers used the monosynaptic rabies virus system to map the neurons in mouse models. The implications of the sophisticated mapping could be significant: further understanding of the anatomy underlying the neurological region may direct research into Parkinson’s and Huntington’s diseases, as well as other disorders that appear to involve basal ganglia, according to Medical News Today. (July 1, 2013). http://tinyurl.com/n77u2wb

“NanoString Touts Positive Data after Middling IPO.” According to a recent study published in the *Journal of Clinical Oncology*, researchers found that NanoString’s Prosigna yielded better information than Genomic Health’s Oncotype DX. The devices are used to chart PAM50 gene expression in post-menopausal women, a predictor of cancer recurrence. NanoString is hopeful the results will help boost its sales and popularity nationwide after a neutral IPO, according to Fierce Medical Devices. (July 2, 2013). http://tinyurl.com/lferdqs

“Test can Accurately and Swiftly Detect Most Leading Causes of Bacterial Blood Stream Infections.” Scientists from the Medical College of Wisconsin have found that a new automated diagnostic test can quickly and accurately detect the main causes of Gram-positive bacterial blood stream infections, in addition to the presence of three antibiotic resistant genes. This is significant because it may lead to faster diagnosis and treatment of patients with sepsis, a life-threatening condition in which time is of the essence. The test, Verigene BC-GP, screens for the DNA of 12 species of Gram-positive bacteria and three antibiotic-resistant genes in a patient’s blood sample, according to Science Daily. (July 2, 2013). http://tinyurl.com/lfgv5ny

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

“Thoratec Buys Terumo’s Heart Tech for up to $56.5M.” Thoratec is looking to strengthen its hold on the left ventricular assist device market as it acquires Terumo’s investigational DuraHeart II. Pursuant to the agreement, Thoratec will pay $13 million upfront, with potentially $43.5 million in additional milestone payments. The device has not garnered regulatory approval anywhere, but the company hopes to speed the process. The two also have a distribution agreement under which Terumo will sell the device in Japan and other Asian countries after its successful regulatory approval. Thoratec also hopes to start a human study for the device in 2016, according to Fierce Medical Devices. (July 1, 2013). http://tinyurl.com/otz2t64

“Roche Buys Blood Diagnostics Outfit for $220M.” Roche Diagnostics has purchased Constitution Medical Investors for $220 million upfront. The company will pay additional amounts as designated milestones are reached. Its acquisition is a Boston-based hematology company, known for Bloodhound, a diagnostics platform used for blood disease detection which will expand Roche’s presence in the professional diagnostics sector, according to Fierce Medical Devices. (July 2, 2013). http://tinyurl.com/n7cuujn
“ArthroCare Forks over $45M for Sinus Surgical Tool Company.” ArthroCare has acquired San Antonio-based ENTrique for $45 million in cash. The move will give ArthroCare new implants, disposables, and surgical instruments for endoscopic sinus surgeries. ArthroCare points to the prevalence of sinusitis specifically, and ear, nose, and throat disorders generally in the population to support its purchase, according to Fierce Medical Devices. (July 2, 2013). [http://tinyurl.com/kqmswvg](http://tinyurl.com/kqmswvg)

“GI Dynamics Hauls in $52.2M to get Obesity Tech through FDA.” GI Dynamics successfully raised around $52.2 million through a private placement, money that will help it obtain FDA approval for its obesity device. The company’s device, EndoBarrier, is currently undergoing a pivotal trial for safety and effectiveness in 500 obese individuals with diabetes. The company reports that the device is performing ahead of expectations, and that it hopes to file with the FDA by 2015, according to Fierce Medical Devices. (July 3, 2013). [http://tinyurl.com/m246vpm](http://tinyurl.com/m246vpm)

“Theragenics Inks International Deal as Buyout Looms.” Theragenics has signed an agreement under which Accelyon will distribute its AgX100 sees in Europe, Australia, and New Zealand. The three-year deal is predicted to generate about $1 million of revenue annually, and the company is hoping to grow its international presence through the agreement. The brachytherapy seeds will be packaged into needles, custom strands, and other configurations. Interestingly, Theragenics is also being pursued by Juniper, a private equity firm, and is negotiating, although it resolutely denied that the talks represent a final decision to sell, according to Fierce Medical Devices. (July 5, 2013). [http://tinyurl.com/keejh6m](http://tinyurl.com/keejh6m)

**Lawsuits/Settlements/Investigations**

“Covidien Could be on the Hook for Nearly $450M in Back Taxes.” A “notice of deficiency” issued by the IRS shows that Covidien may end up paying around $450 million in back taxes for tax deductions it took from 1997 to 2000. The IRS is claiming that Tyco International, Covidien’s parent company, made loans among its three divisions, loans that IRS says do not count as debt. The company disagrees, and plans to file a petition in the US Tax Court to contest the assessment, according to Mass Device. (July 2, 2013). [http://tinyurl.com/mfnzjxf](http://tinyurl.com/mfnzjxf)

“More Hospitals Settle Medtronic’s Kyphon Medicare Fraud Cases.” In the latest round of settlements stemming from a US Justice Department case relating to Medicare overcharges, 55 US hospitals have agreed to pay a total of $34 million. The overcharges come from Medtronic’s kyphoplasty spine procedure, which the company acquired back in 2007, for $3.9 billion when it bought out Kyphon. Most of the hospitals are involved in a whistleblower suit from former Kyphon employees, who are looking to take about $5.5 million of the settlement. With the latest round, the settlement now includes over 100 hospitals and $75 million, according to Mass Device. (July 2, 2013). [http://tinyurl.com/mljkae6](http://tinyurl.com/mljkae6)

“Clock Ticking on Vaginal Mesh Lawsuits against J&J, Others.” While thousands of women have filed lawsuits against Johnson & Johnson and other companies regarding injuries from vaginal mesh implants, the numbers may steadied as the statute of limitations approaches. In many states, the statute of limitations is two years after a warning. The prominent warning was FDA’s 2011 publication disclosing safety problems with the devices, meaning that the statute of limitations could soon run on the claims. Early verdicts have borne out predictions that the vaginal mesh suits will be costly, for example, Endo Health Solutions settled some of its pending suits for $54.5 million, according to Fierce Medical Devices. (July 3, 2013). [http://tinyurl.com/kxw4t9z](http://tinyurl.com/kxw4t9z)
“Medtronic Prevails in Bone Mill Antitrust Suit Filed by Lenox MacLaren Surgical.” Medtronic won an antitrust lawsuit against Lenox MacLaren Surgical regarding a bone mill. Bone mills are used to grind patients’ bone samples into uniform pieces so that they can then be packed into a bone void or fracture during spinal fusion procedures. Lenox had a distribution deal with Medtronic for the bone mill, but the company ultimately purchased only 500 mills it was contractually obligated to, while developing its own mill to overtake the Lenox model, according to the allegations. The court, however, found that Lenox misrepresented the size of the bone mill market and that the company simply failed to adequately market its own device, according to Mass Device. (July 3, 2013). [http://tinyurl.com/k4kugyl](http://tinyurl.com/k4kugyl)

“Stryker Sued Again over Allegedly Faulty Metal Hip Implant.” Yet another patient is suing Stryker, alleging a faulty metal hip implant. The suit was filed in a US District Court in Kentucky regarding the company’s Rejuvenate hip implant, a device that the patient alleges caused pain and discomfort, symptoms that failed to diminish, even with a second surgery to replace it. The plaintiff is seeking actual damages (as his medical, pharmaceutical, and rehabilitation bills have added up) and punitive damages in his suit. The company voluntarily recalled the particular hip implant model in July 2012, two years after the plaintiff’s initial surgery, according to Fierce Medical Devices. (July 5, 2013). [http://tinyurl.com/m75vc7s](http://tinyurl.com/m75vc7s)

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