

May 2015



POINTS OF INTEREST

NEWS AND VIEWS OF THE SPANGENBERG LAW FIRM.

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FAST-TRACK APPROVAL OF MEDICAL DEVICES CALLED INTO QUESTION

The medical device market is big business. But the fast-track approval process is raising some questions



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Flushable wipes may be damaging your home's plumbing



MEMORIAL DAY

Monday, May 25, 2015. Check out our list of activities in and around Cleveland!

PASSWORD TIPS FOR OUR DIGITAL WORLD

Keeping track of all of your passwords is now a simple task. Your passwords, however, should be complex.

TEAM UPDATE 2015: CASES WE'RE WORKING ON

This newsletter is intended to provide information regarding this law firm, legal issues, and public events. It is not legal advice. Every case is unique. Do not rely on information in this newsletter to make decisions without consulting with an attorney. You may copy and distribute this newsletter only in its entirety.

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Alert: Fast-Track Approval of Medical Devices

BY: PETER J. BRODHEAD, ESQ.



The United States is the largest medical device market in the world, with sales expected to reach \$133 billion by 2016. In most cases, medical devices save and improve lives. Unfortunately, not all devices undergo the same rigorous review process before hitting the market.

A number of new medical devices can and do bypass scrutiny by the U.S. Food and Drug Administration (FDA) through a fast-track approval process called the 510(k) program. If a manufacturer can prove that its product is "substantially equivalent" to an existing product, it can avoid stringent premarket testing. While the 510(k) clearing process provides patients with quick access to new products, there is an unsettling consequence: medical devices can be implanted in patients without requiring manufacturers to prove safety and effectiveness. And in fact, a recent study published in JAMA Internal Medicine found that only eight of the 50 new devices cleared through the program from 2008 to 2012 included required scientific data.

Defective Medical Devices Raise Concerns

Here are just a few examples of more notable defective medical devices that have caused injury to patients:

Defective Knee and Hip Replacements –

Clinical evidence continues to show that the design of some knee and hip replacement implants is seriously flawed. Adverse results include failing to properly bond to the thigh bone, improper placement or loosening after surgery. Bone fractures can occur as well as dislocation of the joint. Symptoms patients may feel range from general pain to swelling to an inability to walk. In 2013, The New York Times reported that Johnson & Johnson knew an all-metal hip implant would fail within five years in nearly 40 percent of patients who had the surgery.

Transvaginal Mesh Complications –

Surgical mesh, composed of synthetic materials, is permanently implanted in patients to repair weak or damaged tissue. But in certain procedures it can cause life-changing health complications, including

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FAST TRACKED DEVICES (continued)

mesh erosion when the device migrates from its point of placement and cuts through the soft tissues of the vagina or or pelvic organs. In addition, patients have experienced pain, bleeding and urinary complications, which the product was designed to fix in the first place.

Defibrillator Leads – Defibrillator leads are implantable wires that connect the defibrillator to the heart. In the event of a heart attack, defibrillators automatically administer shocks to the heart. Over the past decade, there have been several high profile examples of defibrillators malfunctioning, causing the device to fire unexpectedly or fail to fire at all when a patient’s life is at risk.

Protect Yourself

These steps from Consumer Reports can help protect you or loved ones from the risk of defective medical devices:

- Consider the alternatives: If your doctor suggests an implant, simply ask what will happen if you don’t get it. Sometimes patients aren’t adequately informed about the alternatives. For example, women who received Transvaginal mesh for prolapse repair may not have needed surgery. But people ill enough to require an implantable defibrillator for their heart may not have a choice.
- Research the device: The Food and Drug Administration’s website, FDA.gov, contains information on device safety warnings, complaints and recalls, which are all accessible by searching the name of the device. Also look for patient forums and other information about the device by searching online.
- Write down the details: Ask for the brand name, model and serial number (if applicable) of your device so that if you learn of a warning or safety recall, you’ll know whether yours is one of the problem models.
- Don’t panic: If you learn there are problems with your device, don’t assume that it has to be removed. Contact your doctor’s office and try to educate yourself as to the possible negative side effects you may experience with your device.



Q & A WITH ATTORNEY DAN FRECH

Q: I read about a lawsuit alleging that “flushable” wipes are not really flushable and may damage my plumbing. What’s that about?

It’s true, there have been several lawsuits filed against various manufacturers, but the allegations in each case are essentially the same: the marketing and packaging for these wipes claim prominently that they are “flushable” when in fact they are not. If a product is represented to be “flushable,” that should mean that it will fully break apart and disperse within seconds of being submerged in water. Toilet paper is the traditional example of a “flushable” product.

Q: But I’ve flushed these wipes before and never had a problem, so they must be flushable, right?

Not really. You can flush a lot of things down a toilet – it doesn’t mean that they’re safe for your plumbing or the sewer system. So although the water in your toilet may whisk the wipes away, they don’t actually fully disintegrate. The problem is that these non-disintegrated wipes can and do accumulate - both in the plumbing in your home and in the municipal sewer system. The Plaintiffs in these cases are typically people who have suffered damage to their homes as a result of flushing these wipes as directed. Municipal sewer districts have also spent millions of dollars repairing and replacing equipment damaged by these wipes. Many municipal sewer districts are now actively advising their customers that that “flushable” wipes should not be flushed.

Q: What should I do if I have suffered plumbing damage as a result of using flushable wipes?

You can contact us to discuss your situation. Be aware that these wipes are also sold at a premium (meaning, at a higher cost) compared with regular wipes that aren’t marketed as flushable. So, since you probably shouldn’t be flushing the wipes anyway, you can and should just buy the non-flushable wipe - and not flush them!

Do you have a question that you would like to have answered in an upcoming issue of this *Points of Interest* newsletter? We would love to hear from you. Email us at ssl@spanglaw.com.





MEMORIAL DAY: MAY 25, 2015

A great day to get outside and enjoy events in around Cleveland with family and friends. Here are a few of our favorites:

Chagrin Falls Blossom Time Festival This annual Memorial Day celebration features a parade, carnival rides, a hot air balloon competition, lots of fair food, and more. yourhometownchagrinfalls.com/event/blossom-time-festival

Lakeview Cemetery Memorial Day Observance Includes a marching band, the Sons of the American Revolution Color Guard, and the James A. Garfield Camp #142 Sons of the Union Veterans in period grab. Bring a blanket and picnic; refreshments will be available for sale. May 25, 10:30 a.m. webcemeteries.com/lakeviewcemetery/events.asp

Bioblitz! Cleveland Metroparks Rocky River Nature Center. Join Naturalist Jen Brumfield for a fun nature hike. From birds to butterflies, plants, frogs and turtles, the race is on to find as many species of living things as possible. May 25, 10 – 11 a.m. clevelandmetroparks.com/Main/EventsProgramsCalendar/Bioblitz-6307.aspx

45th Annual Greek Heritage Festival, May 23-26, Church of the Annunciation, Tremont. Experience authentic Greek foods, drinks, dancing & shopping! TremontGreekFest.com

Great American Rib Cook Off and Music Festival, A four-day festival at Jacobs Pavilion at Nautica. Enjoy ribs prepared by chefs from around the country, live music, and more for the whole family. cleveland.about.com/od/springevents/p/ribfest.htm

Port Clinton Walleye Festival, May 21-25, An array of free live concerts, Kids Fishing Derby, Grande Parade, educational programs and activities, Walleye 5k Run & Walk, carnival rides, and more than 130 vendors. historicportclinton.com

Go Tribe! Cleveland Indians at Progressive Field, May 22-26. Head downtown to watch the Tribe take on the Cincinnati Reds or the Texas Rangers in what is sure to be a great weekend of baseball. cleveland.indians.mlb.com

PASSWORD TIPS FOR OUR DIGITAL WORLD

BY: BARBARA ANDELMAN, ESQ., Chief Operating Officer

Most of us provide a lot of personal information online every day. Our credit card number when we shop online. Our PIN when we do online banking. Family photos on Facebook. The reality is that we increasingly work and play in a digital world, and it's difficult to avoid sending and keeping sensitive info online. That's why strong passwords are critically important.

We typically log on to our computers using a username and password. And we often use the same or similar passwords for all of our accounts. It's tempting to select a very simple and easy-to-remember password - such as our birthday or mom's maiden name. Unfortunately, these simple passwords are also relatively easy for attackers to figure out. Bottom line: passwords should be complex to deter online hackers, phishing scams, spam and others hazards that unfortunately lurk on the Internet.

Tips for Creating Strong Passwords:

- Passwords should be 8 to 24 characters long
- Include at least one letter and one number and special characters if allowed (!@#%&^&*())
- Passwords are case sensitive, so "SaMplE4!" is different and stronger than "sample4!"
- Passwords should not include any form of your account User ID or the word "password"
- Don't use your name, your spouse's name, your child's name, or your pet's name
- Change your passwords at least every 45 days.
- Do not post your password any place where it can be seen.

Your Passwords Should Be Complex - But Keeping Track Of Them Is Easy

Keeping track of complex, secure passwords used to be tricky. The good news is that there are two easy-to-use, free products for handling this task: **DASHLANE** and **FASTPASS**. All you have to remember is one master password for the whole thing - these password managers do the rest. Download LASTPASS at lastpass.com. DASHLANE is available for download at dashlane.com.



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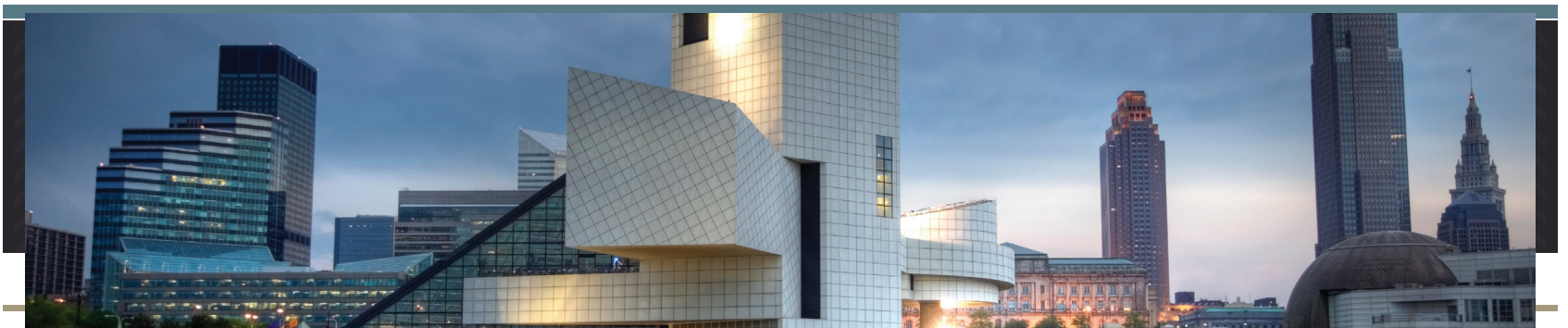
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A referral from a client or friend is the greatest compliment our firm can receive.

We are grateful for every one of these gestures and for the confidence you place in us by doing so.

From all of us at Spangenberg Shibley & Liber, we express our sincere appreciation. Thank you!

TEAM UPDATE: WHAT WE'RE WORKING ON.

Phone Lineman Struck and Killed by Falling Utility Pole

An experienced telephone utility lineman was out in the field training new hires when a 20-foot utility pole snapped and fell on top of him. He collapsed and was taken by ambulance to the hospital, where he was pronounced dead as a result of blunt force trauma to his chest. On behalf of his family, The Spangenberg Law Firm recently filed a wrongful death lawsuit against the company that was responsible for inspecting the pole. An investigation showed the pole to be rotten, causing it to break. The lineman, who was 43 years old at the time of his death, is survived by his wife, three young children, and his parents.

Trucking Company's Failure to Maintain Vehicle Results in Permanent Injuries to Young Father

Our client, a 31-year-old father of two young children, was

injured when a heavy truck - driving the opposite direction from our client on a two-lane state route - lost both of its back passenger-side wheels. One of those heavy truck wheels crossed the centerline and struck our client's pickup truck head-on. The company that owns the heavy truck had no preventative maintenance and inspection program - in violation of Federal regulations. As a result of this collision, our client suffers from permanent Myofascial Pain Syndrome, meaning he endures daily bouts with migraine-type headaches and is permanently medicated. He has undergone physical therapy, chiropractic treatment, nerve-block injections, and nerve-freezing procedures, among others, to try to relieve or at least control his symptoms. He is affected every day by the crash, which was caused by the company's reckless failure to properly maintain its trucks.