With Numerous Morcellator Lawsuits Filed, FDA Response To Cancer Crisis Underwhelms Critics, Tracey & Fox Reports

July 23, 2015

On April 17, 2014, the US Food & Drug Administration announced a major safety risk of power morcellators, medical devices frequently used to grind uterine fibroid tissue: morcellators can spread and worsen uterine cancer. In November of that year, the FDA would expand on its warning in an updated Safety Communication, warning surgeons to avoid using power morcellators in all but the rarest circumstances. Recommending that all morcellator manufacturers revise their devices’ labeling with a “Black Box” warning, notifying patients and surgeons that “laparoscopic power morcellators during fibroid surgery may spread cancer,” the regulatory agency said that it was “consider[ing] other steps that may further reduce such risk.”

Six days later, Johnson & Johnson initiated a “voluntary market withdrawal,” asking surgeons around the world to return their power morcellators immediately. While Johnson & Johnson’s decision effectively removed the world’s largest morcellator manufacturer from the market, smaller companies have yet to respond. Questioned by the Wall Street Journal on their own plans, Karl Storz, Richard Wolf, LiNA Medical and Olympus Corporation failed to respond.

Meanwhile, patients who believe that a morcellator spread their undetected cancers have begun to file lawsuits. Amid allegations that medical device manufacturers failed to warn the public of morcellation’s risks, more than 20 claims have been filed so far. The first of these morcellator lawsuits, filed by Scott Burkhart on March 14, 2014*, has now been settled for an undisclosed amount by LiNA Medical.

According to Sean Tracey, Esq., managing partner at Tracey & Fox, a growing number of critics say much more needs to be done than “warnings” and “recommendations.” Led by Amy Reed, an anesthesiologist whose undiagnosed uterine cancer was spread by a morcellator procedure in 2013, a vocal movement has formed around calls to ban power morcellators entirely. “Reed and her husband, Hooman Noorchashm, have bravely spearheaded several major changes already,” Tracey says.

Boston’s Brigham and Women’s Hospital restricted the use of morcellators in its own facilities after publicly acknowledging that Reed’s hysterectomy, performed at the hospital, had “upstaged” her cancer. Medical institutions across the country followed suit. Philadelphia’s Temple University Hospital announced that it would end the use of power morcellators completely, as did HCA Holdings Inc., a hospital network encompassing more than 270 facilities.

Tracey notes that several health insurance companies have also limited coverage for procedures involving the device, including UnitedHealth Group and Aetna, respectively the first- and third-largest insurers in the country. “But critics say changes from within the industry don’t go far enough. Reed and Noorchashm have called for regulatory action.” Tracey says that at least one legislator has heard
those calls: Mike Fitzpatrick, a Republican Congressman from Pennsylvania.

Inspired by the passion of activists like Amy Reed, Fitzpatrick drafted seven Amendments for inclusion in the 21st Century Cures Act, a sweeping healthcare reform bill passed mid-July 2015. Fitzpatrick’s legislation targeted the medical device approval process currently employed by the FDA, and included measures to strengthen the agency’s postmarket surveillance program for devices.

“Medical device approval has been surrounded by controversy for years,” says Tracey. He cites Section 510(k) of the Food, Drug & Cosmetic Act, which allows the FDA’s Center for Devices and Radiological Health to approve new devices without safety testing, as long as manufacturers can demonstrate that their products are “substantially equivalent” to one approved previously. “In the case of morcellators,” Tracey continues, “manufacturers weren’t required to provide new safety data after the first device was approved. That was more than 20 years ago.” Tracey notes that most morcellators use a spinning blade to grind fibroid and uterine tissue into small pieces. But Olympus Corporation, a Japanese company, introduced an entirely new design in [date]. “Olympus’ morcellator uses energy, rather than blades, to split apart tumors. But even with that significant difference, it was deemed ‘substantially equivalent’ and approved quickly through 510(k).”

Mike Fitzpatrick’s proposed legislation sought to change that process, and ensure that all devices are sufficiently tested in both safety and efficacy. But upon the 21st Century Cures Act’s passage, the House of Representatives had rejected all but one of his Amendments. Surgeons will now be required to include a medical device’s make and model on electronic health records. But this is only one small change to what many consider a hopelessly ineffective approval process.

Tracey & Fox continues to provide free consultations to patients who believe that a morcellator procedure spread or worsened an undetected uterine cancer. For a case eligibility evaluation at no cost, call 713.495.2333.


Source: http://www.pressadvantage.com/story/2996