MedicalXpress

Patients seek US ban on fibroid removal devices

July 11 2014, by Matthew Perrone

More than a dozen Americans—including cancer patients, their family members and physicians—called on U.S. health regulators on Friday to block the use of electronic surgical tools used to remove fibroids, but which can inadvertently spread cancer throughout the body.

An expert panel of Food and Drug Administration advisers heard impassioned pleas from women with cancer and family members of deceased patients who said they were unaware of the cancer risks of the popular technique for treating fibroids by grinding the tissue and removing it through a small incision in the abdomen. The devices are also frequently used in hysterectomies, or removal of the uterus, a common approach for preventing the growth of future fibroids.

Surgeons developed the technique as an alternative to traditional surgery, which requires a larger incision that often results in more bleeding and longer hospital stays.

Doctors have long acknowledged the risk of accidentally spreading undetected cancer with the electronic devices, known as power morcellators. But the FDA has convened a two-day meeting after calculating that the problem may occur more often than previously thought. The agency said in April that as many as 1 in 351 women may have undetected uterine cancer that can be disturbed by the technique. Previous estimates put the rate closer to 1 in 7,000.

"Would you permit your wife or sister to undergo a procedure that has a

one in 351 chance of spreading cancer throughout the body?" Colleen Daley asked the FDA panel of obstetricians and gynecologists. Daley's sister, Patricia Marie Daley, died in 2011 of leiomyosarcoma, a uterine cancer that spread to her lungs after undergoing treatment with power morcellators.

Sarah Salem, who was diagnosed with the disease in 2012 after undergoing power morcellation, said surgeons should not be blamed for failing to detect cancers.

"But what we refuse to accept is the senseless and unethical risk that our surgeons took to allow the spread of our cancer," she said.

The FDA approved the first electronic morcellators in 1995 and about two dozen have been approved in U.S. since then. The devices were cleared through an abbreviated review process because they were deemed similar to manual surgical devices long on the market.

The panel of FDA advisers is scheduled to discuss a number of potential options for reducing the risks with the devices, including:

— identifying patients who may be at increased risk for uterine cancer

— adding new warnings to the morcellators' labeling about cancer spread

— using protective bags to collect uterine tissue so it doesn't spread into the abdomen.

— requirements for increased safety testing of the devices

Fibroids are non-cancerous growths in the uterus that can cause severe pain, heavy bleeding, and bladder and bowel dysfunction, mostly among women in their late 30s and 40s. It's unclear what causes the tumor-like

growths—which can grow as large as cantaloupes—but they account for an estimated 240,000 of the 600,000 annual hysterectomies in the U.S. At least 50,000 U.S. women undergo hysterectomy using the power morcellation technique.

Hysterectomy is a key treatment because it is the only way to ensure that fibroids do not return. Myomectomy, surgery that removes fibroids while leaving the uterus intact, is recommended for women who still want to become pregnant.