POLITICS AND POLICY

FDA Advises Against Morcellator Use in Hysterectomies

Citing Cancer Risks, Overseer Discourages Use of Morcellators to Remove Uterine Growths

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Federal regulators advised doctors Thursday to stop using a surgical device used in tens of thousands of hysterectomies each year, citing its potential to spread cancer.

The move by the Food and Drug Administration could change the way many women are treated for common but often painful growths in the uterus known as symptomatic fibroids, which spur about 40% of the roughly half-million hysterectomies performed annually in the U.S., by some estimates.

The agency's safety alert follows a series of articles in The Wall Street Journal that reported on the risk of using the device and a campaign started earlier by two Boston-area physicians to halt the procedures.

The instrument, known as a power morcellator, typically uses a tube-shaped blade to slice up and remove fibroids or the entire uterus, avoiding the long surgical scars associated with traditional, open surgery. But it can also spread an often undetectable cancer known as a uterine sarcoma, according to the FDA.

In a rare safety alert for medical devices—addressed to doctors, medical associations, hospitals, women, device manufacturers and advocacy groups—the FDA cited estimates that this cancer affects one in 350 women undergoing such procedures and that power morcellation can significantly worsen the odds of long-term survival.

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"For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the FDA discourages the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids," the agency said in a communication posted on its website Thursday. Myomectomy is the removal of just fibroids.

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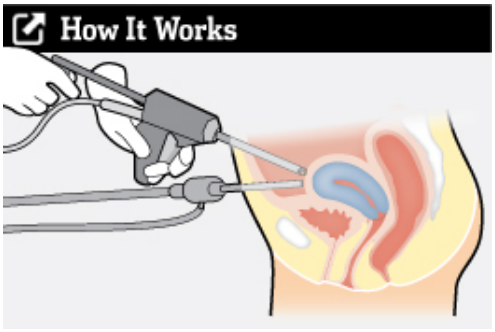

"In general, the procedure should not be performed," Dr. William Maisel, deputy director for science and chief scientist at the FDA's Center for Devices and Radiological Health, said at a media briefing.

If doctors do perform such procedures, the FDA said, they should advise patients of the cancer-spreading risk.

The concern is that using a powered device to slice undetected, cancerous tissue within the abdomen—and without any protective measures—raises the risk of malignant cancer cells embedding in other tissue and elevating the cancer to a more dangerous stage, studies have shown.

Because uterine sarcomas can't be reliably detected before they are removed, they can be mistaken for fibroids. The cancer is typically discovered only after the mass has been removed and tissue sent to a pathologist.

Amy Reed and her husband, Hooman Noorchashm, at home in February. *Gretchen Ertl for The Wall Street Journal*

This was the situation that ensnared Amy Reed, a 41-year-old mother of six and anesthesiologist at Boston's Beth Israel Deaconess Medical Center, who developed advanced uterine cancer shortly after a routine hysterectomy in October. The hospital where she was treated, Boston's Brigham and Women's Hospital, acknowledged that use of morcellation worsened her cancer.

The FDA began its review in December, "when some high-profile cases covered in the media came to our attention," Dr. Maisel said. The agency also noted there are many alternatives, including minimally

invasive surgery without morcellators, vaginal hysterectomies and open surgery. There are also nonsurgical options including drug therapy and ultrasound treatment.

The agency's alert prompted some to act immediately Thursday. Dr. Isaac Schiff, chief of the Department of Obstetrics & Gynecology at Massachusetts General Hospital, said, "I have asked our doctors to stop the procedure immediately until we have more information."

Robert Barbieri, obstetrics and gynecology chairman at Brigham and Women's Hospital, told surgeons Thursday that "we are immediately suspending use of this device in all cases until further notice," according to an emailed statement. Both hospitals had previously put tight restrictions on morcellators in response to cancer concerns.

Morcellators, introduced in the 1990s, have helped gynecologists perform about 50,000 fibroid-removal procedures each year through tiny holes, the FDA estimated, rather than longer incisions that can lead to bigger scars and a longer recovery.

The FDA doesn't directly regulate how doctors practice medicine, but advising against a procedure can significantly change practice by raising the risk of lawsuits for doctors who go against that advice, legal experts said.

"The fact that the FDA released this warning makes it more likely that a doctor who went against it will be held to have practiced in a way below the standard of care," said I. Glenn Cohen, a Harvard Law School professor who specializes in health-law policy and bioethics. "Second, this increases the chance that a patient may succeed in suing for a failure to get informed consent."

"Doctors have to act within a standard of care," Robert J. Gordon, a partner at law firm Weitz & Luxenberg in New York. "What the FDA says about a procedure goes a long way to establishing what the standard of care is for a jury."

Dr. Maisel said the clinical community has been aware of the risk of cancer since the advent of the procedure, although he said the rate of that risk is only now coming into focus. He also said it is conceivable that some patients may believe the risks of alternative procedures outweigh the risks of laparoscopic surgery with morcellation. They should be explicitly told of the risks, he said.

With the issue gathering steam since December, gynecological societies had already been doing their own reviews of power morcellation. Commenting on the FDA move, the American College of Obstetricians and Gynecologists said its own review, which includes an assessment of risks for various groups of patients, is ongoing. "We greatly appreciate the urgency behind the issue," the group said.

Dr. Maisel said older women have a higher risk of having a hidden sarcoma than younger women.

Some gynecologist have argued there are several ways to perform minimally invasive procedures without using morcellators, including cutting tissue manually inside protective bags. Gynecologists have said they seldom used these bags during hysterectomies and fibroid procedures previously.

A number of top hospitals have recently told their doctors only to morcellate inside bags. The FDA said it would convene a public advisory committee meeting this summer to discuss whether such bags can

enhance the effective use of morcellators, amid other issues. The FDA instructed morcellator manufacturers "to review their current product labeling for accurate risk information for patients and providers."

The FDA noted these changes, although Dr. Maisel also said bags have some downside, including obscuring surgeons' view during procedures, and are "not a panacea."

A spokesman for Johnson & Johnson's Ethicon subsidiary, the largest maker of power morcellators, said the company will review its product labeling as the FDA requested and supports plans for an advisory committee meeting. He noted that J&J's uterine morcellator instructions have always recommended doctors use protective bags when using the device on malignant or suspicious tissue.

"This is an important announcement by the FDA, and we support any measures that enhance patient safety, which is always our first priority," the spokesman said.

The FDA recommended "routine follow-up" with physicians for women who have already had hysterectomies or myomectomies, don't have symptoms and were told postsurgery tests were normal. Tissue is commonly checked for cancer afterward. But women with "persistent or recurrent symptoms or questions should consult their health-care provider," the agency said.

Diana Zuckerman, president of the nonprofit National Research Center for Women & Families, and an advocate for stiffer medical-device regulations, said the FDA's statement should have a major impact. "What surgeon is going to take the chance of using this device if the FDA has made such a strong warning?" she said. The FDA's action "is going to save a lot of lives."

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