These are everyday moms, sisters, daughters and aunts from around the country who by virtue of a faulty medical device, have had their worlds turned upside-down.

Device Fast-Tracked.

The laparoscopic power morcellator is used to treat uterine fibriods and hysterectomies. It does so by grinding tissue and removing it through the abdominal cavity.It was approved through the Food and Drug Administration's fast-track approval process known as 510(k). The device never underwent safety evaluations before being being used on thousands of women every year.

Harm goes unreported.

For two decades it was branded as a safe, routine procedure. However, if a uterine fibroid is harboring an undetectable cancer, the morcellation of that cancerous tissue and its removal through the abdominal cavity can spread that cancer throughout a woman's body.

This device can take a Stage 1 treatable cancer immediately to a Stage 4 terminal cancer. Studies have shown the risk of this device spreading cancer in a woman is as high as one-in-350 cases. Currently, there is no sure way to distinguish between a benign fibroid and a cancer prior to using the device.

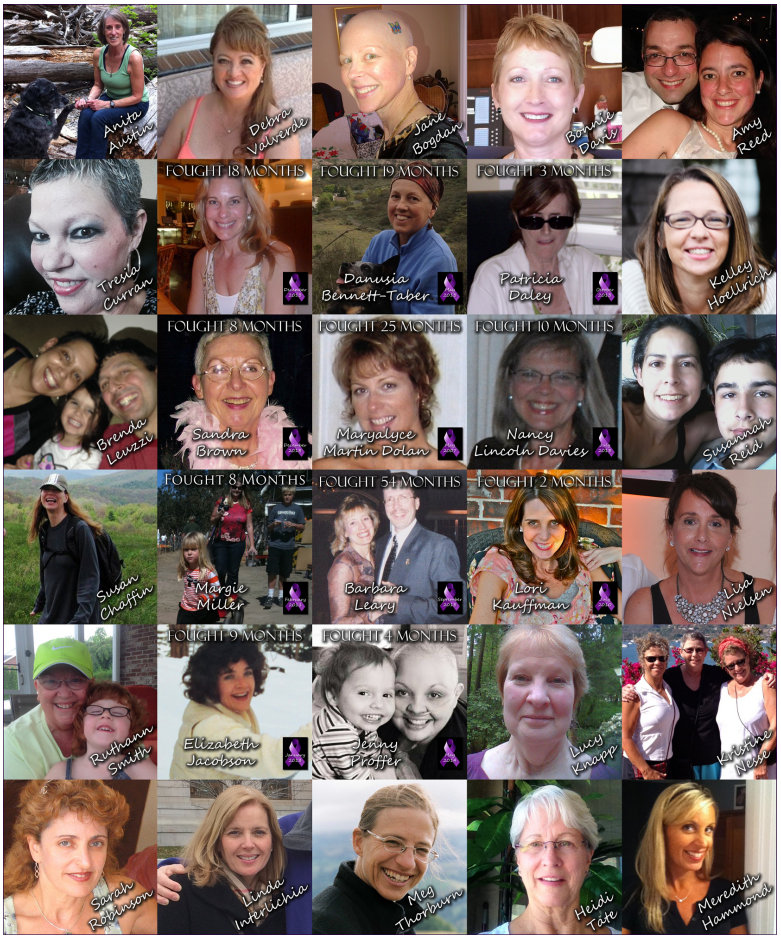
Despite the spread of cancer by the blades of this device, no one ever reported it to the FDA...

Until Amy and Hooman.

That is until Amy Reed, a mother of six and a doctor, underwent morcellation and had cancer spread throughout her body. Her patient report to the FDA was the first adverse event report ever received by the FDA regarding morcellators, despite her same hospital having had a patient harmed by a morcellator one year earlier.

After the initial report from Amy, hundreds of other reports began to flow into the FDA about morcellators. Those reports ultimately led FDA to issue its strictest safety warning on the device. Manufacturers stopped marketing morcellators and insurers stopped coverage.

But it should not have fallen on patients to get the FDA's attention. Everyone in the chain of care should have a responsibility to inform the FDA of death and serious injury caused by devices--from the manufacturer who creates the device, to the hospital who oversees the procedure, to the doctor who ultimately uses the device.



THE GUARDIANS

While many medical devices prove to be lifesaving, we know that some can cause harm and devastating consequences on patient health. But it is the responsibility of the medical community to recognize unsafe devices and report them to the Food and Drug Administration.

The Medical Device Guardians Act (MDGA) will help protect women from suffering the same fate as those harmed by morcellation.

First, this bill simply codifies existing medical ethics which recognizes that physicians are in the best position to identify and report unsafe devices: Physicians who prescribe and monitor the use of drugs and medical devices constitute the group best able to observe and communicate information about resulting adverse events.(AMA Opinion 9.032 - Reporting Adverse Drug or Device Events). Today, reporting unsafe devices to the FDA is as easy as downloading an App.

Second, the bill adds physicians reports in the list of groups, like hospitals, that are already protected from having their reports to the FDA used against them in a civil case. Doctors should be incentivized to report safety issues without the fear of those reports being thrown back at them by trial lawyers.

This is a reasonable fix that, while too late to protect those harmed and killed by morcellators, we can help protect thousands of other patients around the country by incorporating doctors into the medical device safety reporting system.