THIRTY-THREE YEARS before her death, Paulette Parr visited her doctor for a popular and relatively routine procedure. It was 1986, and Parr was 35, working in human resources at the local hospital in Sikeston, a 16,000-person Missouri enclave midway between St. Louis and Memphis.

A married mother of two young boys, she was interested in what plastic surgeons still call a “mommy makeover,” a catchall for the various procedures that nip, tuck, and lift women back to a pre-childbirth shape. For Parr, that meant getting her first set of breast implants.

For the next 15 years, through losing her first husband and remarrying and getting promoted to her hospital’s purchasing department, Parr was mostly happy with her implants, and with how they made her look and feel. But they were silicone-
Breast implants have long been a punch line, mocked as frivolous markers of female vanity. But that dismissive attitude overlooks a business with a serious and sometimes deadly impact on the health of its overwhelmingly female customer base. More than 8 million American women have undergone breast-related plastic surgeries since 2000; in 2018 alone, more than 400,000 women chose one for either cosmetic or reconstructive reasons. Breast augmentation is the most popular cosmetic procedure tracked by the American Society of Plastic Surgeons. Many women, especially those affected by breast cancer, say they are grateful to have implants as an option. “It’s a decision that’s personal,” says Lynn Jeffers, the society’s current president, a plastic surgeon, and a cancer survivor who’s getting ready to have her post-mastectomy reconstruction.

There are customers among who breast implants have caused injury, financial losses, and sometimes tragic crises for potentially millions of others. In 2018: 121,000 women chose one for either cosmetic or reconstructive reasons. Breast implant makers walk a fine line when it comes to creating a product that is both safe and “realistic.” Today’s implants are either filled with saline (more likely to break) or silicone (more natural looking and feeling but plagued by a history of safety concerns). Their exteriors can be either smooth or made of a “textured” silicone shell. Smooth implants are more popular in the U.S., but surgeons working with mastectomy patients sometimes prefer textured versions, because the products’ rougher surface enables tissue to grow onto the implant more easily.

All of these variations are prone to malfunctions or side effects, which can include ruptured implants; a buildup of scar tissue that can cause pain and tissue hardening; a large collection of symptoms often known as “breast implant illness,” which can include joint pain, migraines, and chronic fatigue; and, increasingly, a sometimes fatal cancer of the immune system known as BIA-ALCL, for “breast implant-associated anaplastic large cell lymphoma.”

“The breast implants that are on the market right now all have issues,” says Madrig Tomes, a former FDA manager who tracks reported medical device failures at her Device Events firm. “I wouldn’t recommend them to anyone that I care about.”

The causes of the various problems with breast implants are still poorly understood, which public health experts blame on a lack of testing or objective research. Industry studies that do not rely on manufacturer-provided data or funding. Device makers also have yet to fully report the data the FDA required as a condition of allowing silicone implants back on the market in 2006.

The cost of embracing such troubled devices became painfully clear last year, after a surge in cases of BIA-ALCL. More than 903 women have now been diagnosed with that once-rare lymphoma, and more than 31 have died. Hundreds of thousands of others are estimated to be at risk of developing the disease, which can take decades to surface and has been linked to textured implants in academic studies. Cases of the lymphoma have been reported in women with implants from various manufacturers, including Johnson & Johnson and Sientra. But Allergan’s Biocell implants have by far the worst record of affected patients. By the end of 2018, European regulators stopped Allergan from selling textured implants. The FDA was slower to respond, but in July 2019 it finally asked Allergan to recall those devices from the market, citing BIA-ALCL. The company complied and suspended future sales.

By May, Allergan was facing about 46 lawsuits, including some class action claims, related to BIA-ALCL and its recalled implants. Alleging that problems with Allergan Biocell implants have caused injury, financial losses, and wrongful death, these cases have now been consolidated in a multi-district litigation in the U.S. District of New Jersey.

An Allergan spokesperson told Fortune via email that the company does not comment on pending litigation, adding that it “has a demonstrated history of dedication to the health and safety of patients” and “has followed FDA regulatory reporting procedures and acted transparently with patients about textured breast implants.” In emailed statements to Fortune, Sientra did not address the linkages of BIA-ALCL with textured implants, while Johnson & Johnson acknowledged “a low number of BIA-ALCL cases” in Mentor textured implants. Both companies said they prioritized the safety of their patients. Bipin Achar, a general surgeon and director of the FDA’s Office of Surgical and Infection Control Devices in the Center for Devices and Radiological Health, also calls women’s safety a priority. “We know more about breast implants today than we did 10 years ago, and we continue to learn more,” she says. “We will not hesitate to take further action if necessary to protect patients.”
The breast implants that are on the market now all have issues. I wouldn’t recommend them to anyone I care about.

MADIBES TOWES, former FDA manager whose firm, Biotite Events, tracks medical device failures

A BRIEF HISTORY OF BREAST IMPLANTS
The devices are approaching a half-century of controversy

1976 Congress gives the FDA the authority to regulate medical devices. Silicone breast implants on the market since 1962, are grandfathers in.

1984 Maria Stern, who claims her Dow Corning silicone implants made her sick, wins $1.5 million in punitive damages.

1992 After more lawsuits and congressional hearings, the FDA calls for a moratorium on most silicone implants.

1999 Dow Corning, facing more than 20,000 lawsuits, files for Chapter 11 (it would later agree to a $2.3 billion settlement). Separately, manufacturers Bristol-Myers Squibb, Baxter Healthcare, and 3M establish a settlement fund for women with damaged silicone implants.

2006 The FDA allows silicone breast implants back on the U.S. market.

2010 A government raid uncovers French implant maker Poly Implant Prothése’s use of an unapproved industrial-grade silicone; its shutters and its founder is jailed.

2018 Europe halts sales of Allergan’s textured implants.

2019 July The FDA asks Allergan to recall the devices.

breast implant products have been and continues to be the subject of a significant number of product liability claims,” the company warned in its February report.

The risks of the breast implant business haven’t dented the company’s prospects. In April 2019, Allergan and 3M established a settlement fund for women with damaged silicone implants. Allergan’s shares closed in early May at $380 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.

But in 2018, the FDA still didn’t see Allergan’s operations. And the company hasn’t been able to trade publicly since one in 500,000 in 2011 to one in 3,800 in 2019. Peter Cordeiro, a Memorial Sloan Kettering plastic surgeon who followed his patients for 27 years and almost exclusively used Allergan implants, estimates that his patients now have one in 35 chance of developing the cancer.
To lose all the women in my family to cancer, to make this decision that is supposed to save my life—and then, just kidding! This put me at a whole other risk.

MIA KARGEN, who had a mastectomy and reconstructive surgery in 2016.

FORTUNE FIVE HUNDRED

PROBLEMS WITH IMPLANTS have increasingly complicated the health of one particularly vulnerable community: women who seek high risk of developing breast cancer.

Every year, more than 100,000 women—a quarter of breast-related plastic surgery patients—have “reconstructive” procedures, mostly after mastectomies. They don’t all have the disease; many of these women, who don’t want to lose their breasts, choose implants for cosmetic reasons.

“Her legs got so big that she couldn’t even put them together, her arms swelled up … and then we were just sitting and waiting for the end,” says Calvin Parr, her husband.

More than a year ago, Paulette Parr, 68, was diagnosed with BIA-ALCL. Her long blond hair started to fall out, and eventually she asked Calvin to cut it all off with his barber clippers.

In May, the FDA was convening hearings to discuss the disease and the overall safety of breast implants. “Cases of BIA-ALCL have been reported in patients with an implant history that includes textured implants,” Dr. Stephanie Mansson Brown, Allergan’s VP of clinical development for devices, testified. “What is important is that the FDA has cleared implants specifically when identified early and treated appropriately.”

But in May, as the FDA said it would not ban textured breast implants, Parr’s tests showed that her lymphoma had metastasized. In June, as AbbVie announced its plans to buy Allergan, she spent the month hospitalized and undergoing more treatments. Eventually, her doctors told her that her health was too poor for her to qualify for an experimental treatment that seems to be effective for other patients with BIA-ALCL.

“She suffered an awful lot,” Calvin says, his Southern drawl thickening. “Her legs got so big that she couldn’t even put them together, her arms swelled up … and then we were just sitting and waiting for the end.”

Finally, on July 24, the FDA asked Allergan to recall its Biocell textured implants. The agency would later upgrade the recall to its most serious “Class I” designation, warning that “use of these devices may cause serious injuries or death.”

But in the last week for Paulette Parr. Twenty-nine days after the recall, after spending her 68th birthday in a St. Louis hospital bed, she died.

To the plaintiffs’ lawyers acknowledge that lawsuits against medical device manufacturers are difficult to pursue, because individual claims filed are often preempted by the FDA’s preexisting approval of the products. “Every case is something wrong with this product, you are not entitled to bring this action, because it has already gone through this strict federal approval process,” is how Jennifer Leuze, a lawyer representing the plaintiffs in the Allergan litigation, describes the preemption argument.

Whatever the eventual legal outcome, the problems with breast implants are clearly affecting their sales. Even before the COVID-19 pandemic shut down elective procedures, plast-ic surgeons were reporting a drop in demand. But even the plaintiffs’ lawyers say it’s too early to estimate AbbVie’s potential exposure, but “it’s definitely an issue we’re watching,” says Mizuho Parr. Twenty-nine days after Paulette’s death, the problems with Breast implants have been amplified by the pandemic and resulting economic downturn. Breast augmentations fell after the last recession, as consumers cut back on nonessential spending. During AbbVie’s May earnings call, CEO Richard Gonzalez acknowledged that he expects the contraction to have a “pronounced” if “transient” impact on Allergan’s medical aesthetics business.

For Calvin Parr, the pandemic meant that he was no longer able to share with Paulette and trying to get used to a more permanent sort of life. He still spending hours across the street, so he’s able to break up the days with visits from his grandchildren. But sometimes he wakes up and realizes that Paulette, before remembering she is gone. “I’ve got nobody to hang on to,” he says. A year ago, he and Paulette were still planning the rest of their retire-ment together. “All of our life, I was the one making arrangements to make sure Paulette would be taken care of. We knew I’d be going first,” he says. “But then they killed her. The dumb implants killed her.”