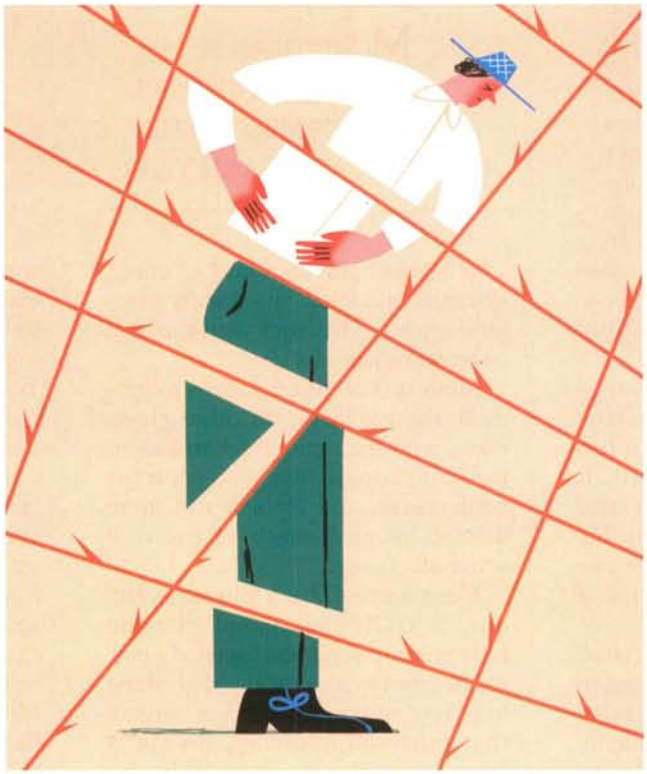
IN THE NET

The untold risks of hernia implants

By Trudy Lieberman



For years, Michael Ransford had known he would need surgery for his umbilical hernia. "People said if it ruptured, it could kill me," the sixty-year-old farmer told me. The pain from a second hernia, on his right testicle, sent him "through the roof." In 2016, shortly before Christmas, Ransford had an operation to repair both at Columbia Memorial Hospital, near his home in Ghent, New York.

In a postsurgical report, Ransford's doctor, Gary Pearlstein, noted that he had repaired both hernias with polypropylene mesh, a type of synthetic netting that is commonly used in such surgeries. Pearlstein used an oval mesh patch on the testicular hernia and a circular mesh patch on the umbilical hernia. The hospital's records identify the circular mesh as the Proceed Ventral Patch, a device consisting of multiple layers of material, produced by Ethicon, a subsidiary of Johnson and Johnson. The mesh provided "a nice solid repair," Pearlstein wrote.

Solid or not, the repair caused Ransford nothing but trouble. From the moment he got home, he suffered from a sharp, consistent pain. At first, he was able to get on his tractor and work his usual fourteen-hour days, but the discomfort eventually got so bad that he went back to Pearlstein. An ultrasound revealed that he needed a second surgery—just seven months after the first. This time Pearlstein found "multiple adhesions in the right groin area," which appeared to have developed on the surface of the mesh he had placed in Ransford's body—the mesh had stuck to his bowel. After the surgery, Ransford said, "The doctor left the impression he had removed some of the mesh but not all of it."

The pain continued, but it remained tolerable until an October 2018 hunting trip, when it suddenly worsened. "I said, 'Something is wrong,'" Ransford told me. When he got home, he called Pearlstein. Almost exactly two years after his first surgery, Ransford found himself on the operating table for a third time. Pearlstein opened him up and "found a lot of scar tissue and colonic adhesions pulling part of his colon into his groin."

"When I went in for the last surgery, the mesh had just about closed off the colon," Ransford said. "Pearlstein told me he got it in the nick of

Trudy Lieberman's most recent article for Harper's Magazine, *"Don't Touch My Medicare!," appeared in the November 2016 issue.*

Illustrations by Laura Liedo

time. He took out every single piece of the mesh he possibly could," amputating Ransford's spermatic cord and right testicle in the process.

Ransford doesn't know whether he'll ever fully recover. Doctors who perform explant surgery—removal of mesh that has degraded—say that 75 to 80 percent of patients see an improvement, but that some continue to experience intermittent pain. "There's still some sensitivity as far as having sex," Ransford told me six months after his third surgery. "Believe it or not, I'm still uncomfortable."

Hernia mesh was born in mid-century America, during an explosive era of product innovation, when cheap plastic was big business. In 1951, two research chemists at Phillips Petroleum, Paul Hogan and Robert Banks, were trying to synthesize the colorless fuel gas propylene. Instead, they discovered polypropylene, a polymer plastic that Phillips began to market under the name Marlex. In the Fifties, Marlex was used to make hula hoops; today, polypropylene can be found in everything from car batteries to yoga pants.

In 1958, the Texas doctor Francis Usher implanted polypropylene mesh into dogs to see whether it had potential as a surgical implant. It worked well enough, and Usher tried using it to treat groin hernias in humans, hoping it would lower the rate of hernia recurrence, a common risk of hernia repair surgery.

Hernias occur when soft tissue protrudes through an opening in the wall of the surrounding cavity. The most common type are abdominal and groin hernias, which can only be repaired surgically. More than a million hernia repairs are performed in the United States each year, making them among the most common surgical procedures. Until the late Seventies, surgeons repaired hernias mostly with sutures, a complicated and difficult procedure. This began to change in 1984, when the hernia specialist Irving Lichtenstein developed a technique that made it possible for surgeons to implant mesh *without much training*. Hernia surgeries could now be performed at outpatient centers, eliminating costly hospital stays. These savings, in addition to the lower recurrence rate, led to the widespread adoption of mesh implants in hernia repairs.

By the early Nineties, traditional hernia repairs were on the way out. Mesh was in. "Almost overnight," Dr. Kevin Petersen, a Las Vegas surgeon, recalled, "all my colleagues started using mesh." Product reps warned surgeons that without mesh patients had a 30 percent chance of hernia recurrence, Petersen said, "even though there were very few small-animal studies to support that." Prominent doctors and medical experts began promoting mesh as the standard of care. "Nobody goes against the standard of care," Petersen explained. "It's a scary place for surgeons. They stick with the herd to protect themselves."

MORE THAN A MILLION HERNIA REPAIRS ARE PERFORMED IN THE UNITED STATES EACH YEAR

Mesh makers hired doctors to promote the product with other physicians, who then published articles in medical journals, presented papers at conferences, and lobbied still more doctors to push mesh as the new standard of care.

Mesh seemed like a win for everyone. A 2001 study noted that the Lichtenstein repair had "opened a new era in groin hernia repair," describing his "very simple" method of surgery that promised minimal pain and a "very low recurrence rate." The authors mentioned "fears of complications related to mesh implantation," but concluded that the concerns "have proved to be without foundation."

But warnings about mesh were already circulating. Documents filed in a 2011 New Jersey Superior Court case revealed that Chevron Phillips—the company that resulted from Phillips Petroleum's merger with the Chevron Corporation—had internal concerns "about litigation and the association with the MARLEX name with a permanent medical implant" as early as 1997. In 2004, a Phillips subsidiary that made a resin used in hernia mesh issued a warning about its product:

> Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

It would be another fifteen years before the medical literature began to challenge the belief that hernia mesh repairs were safe. A study published in the *International Journal of Clinical Medicine* in 2014 found that the "ubiquitous use of synthetic materials in hernia surgery has brought about a new clinical syndrome: surreptitious, irreversible neuralgia." Researchers noted that the new syndrome came on slowly and was puzzling to doctors. "Pain is progressive, unrelenting and unresponsive to treatment," they wrote, concluding that "removal of the mesh does not guarantee pain relief."

In the mid-Seventies, a magazine ad for Marlex claimed that the product gave "patients a better chance of recovery" because "it interlaces with body tissue, strengthening it so incisions can heal faster." Years later, this interlacing of body tissue with mesh was found to be a source of harm for many patients. Once the mesh is implanted, tiny blood vessels and nerves grow through the plastic surface, causing an acute inflammatory reaction. Scar tissue forms, and as it contracts, the mesh squeezes the blood vessels and nerves that surround it. "All of this occurs at the microscopic level," Dr. John Morrison, a hernia surgeon in Chatham, Ontario, told me. "You'd be able to see the folding and the scar tissue growing through the fold but no blood vessels or nerves with the naked eye. We feel that combination causes the pain."

"It's very difficult to go back in and remove every single strand of mesh," Dr. Robert Bendavid, who performed hernia repairs without using mesh at the Shouldice Hernia Center outside Toronto, told me before he died in 2019. "It breaks up into fibrils. How do you remove it when the fibers spread out and erode into the adjacent tissues?"

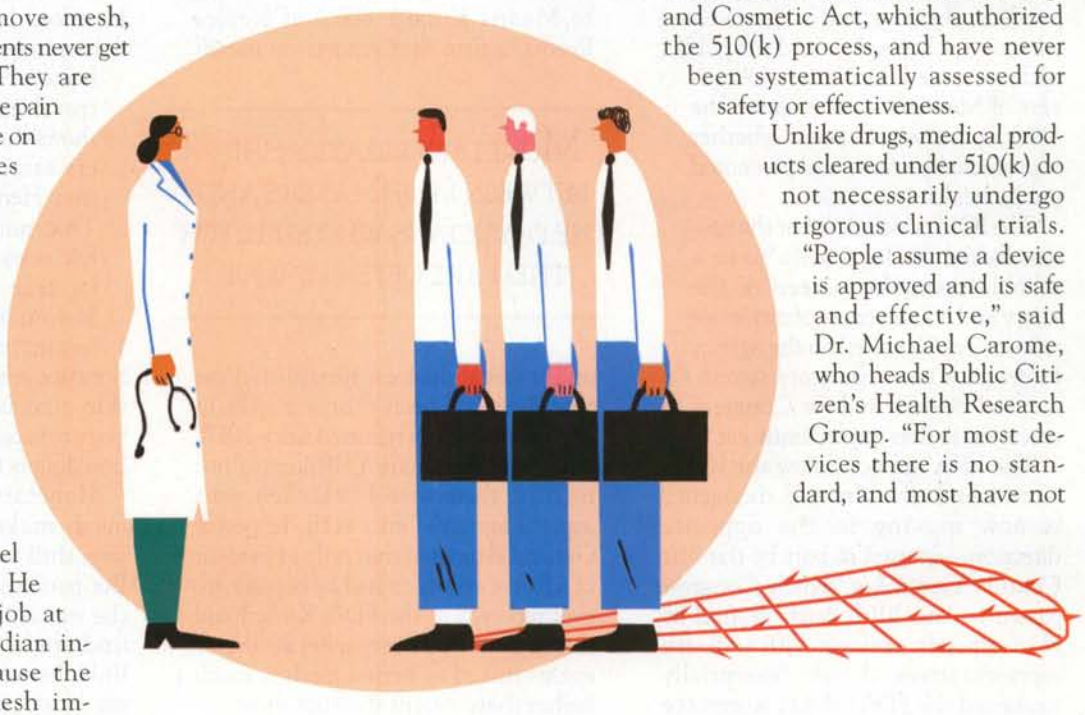
A 2018 research paper by Morrison, Bendavid, and others, published in the *Annals of Surgery*, noted that before the widespread use of mesh, chronic groin pain after hernia surgery was uncommon. Now, the researchers found, patients with mesh implants often suffered from testicular pain and dysejaculation, a burning sensation during sex. When hernias were repaired with tissue—the old-fashioned way—dysejaculation affects 0.04 percent of patients; with mesh it affects 3.1 percent.

"Even when you remove mesh, twenty-five percent of patients never get better," said Petersen. "They are doomed to live with horrible pain the rest of their lives or live on medication that makes them nonfunctional."

"Many of my patients are not able to work," Morrison told me. "They develop psychological problems, lose their jobs and families, become divorced, declare bankruptcy. They have nothing. These poor people have a hell of a time."

Forty-year-old Michael Younger is one of them. He was forced to quit his job at Sun Life, a major Canadian insurance company, because the pain resulting from mesh implants he received in 2008 was so intense that it was impossible to spend all day crunching numbers. For the next eleven years, Younger went from doctor to doctor seeking relief. He got none until Morrison removed the offending mesh in November 2019. "I would tell the doctors that it's the mesh causing pain, and they'd say, 'You're crazy, you're a lunatic,' and recommend antidepressants," he told me. "Nobody believed the mesh could do this. What you're telling them, in their minds, can't happen." Since the removal surgery, the pain is "getting a little tiny bit better each day. If this is as good as it gets, I'm a happy customer."

Doctors who use mesh say it reduces the chance of hernia recurrence, but many think the difference is not especially significant. Dr. Bill Brown, a Bay Area surgeon who performed mesh procedures for a brief period in the Eighties, explained it this way: The chance of a recurrence after a mesh repair is probably about 3 percent; the chance after a non-mesh repair is about 4 percent. To achieve the 1 percentage-point decrease, around 15 percent of mesh patients are likely to experience long-lasting pain. "I said, this is really stupid," Brown told me, and he went back to doing traditional repairs. But unfortunately, he said, "Younger doctors don't know how to do it the classic way." Despite growing evidence of the problems with surgical mesh, Brown remains an outlier.



Michael Ransford, like most hernia patients, knew little about the mesh products being placed in his body. He trusted the American medical system to make him well.

As medical researchers began to question the use of mesh and its possible long-term side effects, it became clear that the Food and Drug Administration was an unreliable regulator. Why was the hernia mesh that had injured Ransford and countless others still on the market? The answer lies in how medical devices in the United States are cleared for use, and in the cozy relationships their manufacturers have developed with the governmental body that regulates them.

Both patches implanted in Ransford had been cleared by the FDA in 2006 under the agency's 510(k) process, which allows new medical implants to be sold as "safe and effective" if they are similar enough to preexisting devices, some of which may have been cleared decades earlier. Many of the predicates for hernia mesh went on the market before passage of the 1976 amendments to the Food, Drug, and Cosmetic Act, which authorized the 510(k) process, and have never been systematically assessed for safety or effectiveness.

Unlike drugs, medical products cleared under 510(k) do not necessarily undergo rigorous clinical trials. "People assume a device is approved and is safe and effective," said Dr. Michael Carome, who heads Public Citizen's Health Research Group. "For most devices there is no standard, and most have not undergone testing. That's the fundamental flaw in 510(k). Patients are human guinea pigs."

Two years ago, a study on mesh implants published by Oxford University researchers found that the "vast majority of devices" are descended from six types of mesh that were on the market before 1976, most of which "lack clinical data and scientific evidence." Sixteen percent of recently cleared devices are connected to three predicate meshes that have been recalled for material and design flaws.

The Proceed Surgical Mesh, which was implanted in Ransford, received its 510(k) clearance in May 2006 on the basis of a predicate device called the Proceed Trilaminate Mesh, which had been cleared in 2003 on the basis of still another

product, cleared in 2000. This device was in turn based on devices dating back to the Fifties and Sixties. The second type of mesh implanted in Ransford, the Proceed Ventral Patch, was cleared by the FDA in December 2006. That product was based on five predicate devices, which had their own predicates that were on the market long before the 1976 amendments went into effect.

In 2011, the FDA asked the prestigious Institute of Medicine (IOM)—established in 1970 to provide independent, objective, and evidence-based advice to policymakers and the public, and now called the National Academy of Medicine—to evaluate the 510(k) process and assess whether it protected patients and promoted public health innovation.

The IOM concluded that the process lacked the legal basis "to be a reliable premarket screen of the safety and effectiveness of moderate risk devices." It called on the agency to design a new regulatory system for medical devices and for Congress to enact legislation implementing it.

The FDA did not follow the IOM's recommendations. Instead, the agency is now moving in the opposite direction—spurred in part by the 21st Century Cures Act, which Congress passed in late 2016. Partly crafted by FDA officials working with industry representatives, the act "essentially weakened the FDA's ability to enforce higher standards," Dr. Joseph Ross, a professor of medicine and public health at Yale, told me. "It lowered the bar, in my opinion. The FDA must impose the least burdensome standards."

When I asked the FDA for comment, a spokesperson told me that the IOM recommended replacing the 510(k) program but did not show that the program "was letting unsafe, ineffective devices on the market" or suggest a plan to replace it. The spokesperson acknowledged that 510(k) "could be improved" and that "that's what the agency has been doing for the past several years."

On its website, the FDA explains how the agency works with industry officials to apply those least burdensome standards. In effect, it's asking industry players how the agency can serve them better, tacitly acknowledging that medical device makers, not injured patients, are its customers. This is not surprising—the device industry paid the FDA some $289 million in user fees in fiscal year 2020.

Meanwhile, complaints about hernia mesh are stacking up in the FDA's MAUDE database, where device manufacturers are required to report malfunctions, serious injuries, and deaths. Doctors don't have an obligation to report such incidents, but many of them, along with patients' lawyers, are filing complaints, according to Madris Kinard, CEO of Device Events, a firm that reports on recalls and medical devices. Kinard told me that there had been a "drastic spike in hernia mesh cases reported since 2017." That year, there were 3,149 complaints; in 2020, there were 13,942. Ten years ago, the agency's Office of the Inspector General estimated that only 14 percent of adverse events caused by devices are ever reported to the FDA. Kinard said this suggests that the number of adverse events linked to hernia mesh is much higher than current statistics show.

MONETARY RELATIONSHIPS BETWEEN MESH MAKERS AND THE PHYSICIANS WHO SHILL FOR THEM ARE OFTEN OPAQUE

What does the FDA do with all the complaints that come in? The agency is supposed to look for patterns that might warrant legal action—warning letters to doctors or manufacturers, or a product recall. Since 2006, there have been four small recalls of Proceed mesh products, the latest a result of hair found in its packaging.

In the device industry, big money buys influence. Ninety-four percent of respondents in a 2020 survey of physicians who performed defibrillator implants had received payments from device manufacturers. Patients were substantially more likely to receive devices made by manufacturers that gave surgeons the largest payments.

According to data compiled by ProPublica, doctors and hospitals have received millions of dollars from mesh manufacturers in the past decade to support research and promote their products. Take the example of Dr. B. Todd Heniford, the chief of minimally invasive surgery at the Carolinas Hernia Institute in Charlotte, North Carolina: in 2013, Ethicon, the Johnson and Johnson subsidiary, paid Heniford close to $27,000, about 37 percent of the total he received from industry donors that year.

That sum was a mere trickle, however, before the floodgates opened—mesh companies went on to send Heniford hundreds of thousands of dollars in speaking and consulting fees, honoraria, research grants, and travel expenses. ProPublica data shows that in 2014 four manufacturers associated with hernia mesh gave Heniford a total of $300,000. That number grew over the next few years. Between 2014 and 2019, he received a little more than $1.4 million from LifeCell and Allergan, primarily for his work with Strattice, a biological mesh made of pig skin that is used to reinforce weak body tissues. He received nearly a million dollars from other companies.

Monetary relationships between mesh makers and the physicians who shill for them are often opaque. But patients willing to wade through the morass of medical literature will find studies that disclose financial links between the sponsors and the medical personnel who conduct them. In Heniford's case, there were many. (A spokesperson for Heniford's practice acknowledged that he is in demand within the industry for consulting but noted that none of this income is tied to the use of mesh in particular surgeries.)

In 2005, Heniford appeared in a testimonial for a new lightweight mesh developed by Ethicon, the maker of the mesh that was implanted in Ransford, saying that the company was "on the brink of changing how hernias are performed in North America." He said that he had tested the new Ethicon mesh in an "unbiased manner" and had found it "plenty strong." He concluded by saying that "there is no use for a heavyweight mesh like Marlex at any time or anywhere in the human body." By then, thousands of patients had already got-

ten Marlex implants. In 2016, a new study of nearly a thousand patients revealed serious problems with lightweight mesh as well. Data from a large randomized trial published in the *Annals of Surgery* showed that lightweight mesh "has no significant benefit over heavyweight mesh for inguinal hernia repairs and was associated with greater pain and higher risk of recurrence." Johnson and Johnson had partly paid for the study.

In a 2019 interview with Drugwatch, a website that covers medical devices and lawsuits, Bendavid argued that the industry's financial largesse reached far beyond surgeons such as Heniford. Mesh makers, he said, also "buy research and hospitals," while doctors performing non-mesh repairs have no such support. Industry research budgets played a big role in shaping the practice guidelines issued by the HerniaSurge Group, an international group of hernia surgeons.

Two years ago, the group released guidelines recommending mesh repair as the first choice and advising that non-mesh options should be presented to patients only after discussing the benefits of using mesh. Thirty-five contributors to the guidelines disclosed that Johnson and Johnson and another manufacturer had given them grants for their work. (Johnson and Johnson did not respond to questions from *Harper's Magazine*.)

The guidelines did note, however, that "there is no polymer or mesh construction known that is free from the risk of migration placed in a setting with tensile forces," such as scar tissue, adding that "there are great concerns about the complications of chronic pain which still occurs in 10 to 12 percent of patients." (In response to my queries, the coordinator of HerniaSurge wrote that "there is a place for non-mesh in some cases" and that the guidelines are intended only "to aid surgeons and patients in decision-making.")

Hospitals are also complicit in the continued prevalence of hernia mesh. Many have teamed up with Intuitive Surgical, the leading seller of surgical robots. According to ProPublica, in 2018 Intuitive gave hospitals $3.3 million for "education" and another $1.3 million for "gifts."

It's not surprising, then, that many hospitals have now begun pushing robotic surgery as an essential element of hernia treatment. Morrison, the Canadian doctor, told me that robotic surgery may be useful for some procedures but has no place in repairing simple groin hernias. "They are extremely expensive to buy and to operate," he said, adding that a thirty-minute groin-hernia repair takes "much longer with a robot, with hugely increased costs and no benefit to the patient."

Many doctors agree that robots are an unnecessary expense. "It's an operation where the robot has no benefit and may introduce new risks," Dr. Marty Makary, a surgeon and professor of health policy at Johns Hopkins University, told me. To buy a robot, a hospital's capital budget must go up between $1.4 and $1.7 million. Once a hospital makes that kind of investment, it needs patients to make the monetary proposition work, charging them an additional thousand dollars or more per operation. One way hospitals prospect for patients is by offering free screenings at hernia fairs such as the one sponsored by the Cuyuna Regional Medical Center in Crosby, Minnesota, in the summer of 2019. Promotional materials promised that attendees would learn about diagnosing and treating hernias, "including minimally invasive robotic surgery," and said they could take the robot for a "test drive."

Hospitals also run promotions on local TV stations, offering free hernia screenings; newscasters deliver subtle pitches for robotic surgery and hernia specialists explain how robots are used. (These screenings have been put on hold during the pandemic.) After one such segment in Amarillo, Texas, in which a doctor said would-be patients could "play" with a robot, a delighted TV anchor gushed, "That makes it so nice." There was no mention, of course, of the cost.

The website Health News Review summed up the marriage of hernias and product marketing:

> There is almost robotic repetition in the themes you hear consistently in these robotic surgery promotions … It's free. If you must have surgery, the outcomes from robotic surgery are fantastic. And

if you don't have surgery for the hernias, we might find you're asking for big trouble.

Over the past few years, many wealthy Americans have journeyed to the Shouldice Hernia Center for non-mesh hernia repairs, which the hospital has long specialized in. The procedure is covered under Ontario's universal health insurance. Foreigners can pay privately.

The hospital has rigorous criteria for accepting patients, and uses a technique developed in the Forties that is considered the best option among non-mesh repairs. Surgeons at Shouldice rarely use general anesthesia, and patients stay in the hospital for several days after surgery for monitoring.

The consumer advocate Ralph Nader has had two hernia surgeries at Shouldice. Sidney Wolfe, who headed Public Citizen's Health Research Group for forty-four years, and the Kentucky senator Rand Paul, a conservative Republican who is no fan of Canada's national health insurance system, have also had surgeries there. Nader told me that he learned about the clinic from Canadian relatives, and chose Shouldice because "it's the gold standard" for a lower price. Paul, an ophthalmologist by trade, told the Louisville *Courier-Journal* that although there were hernia centers in the United States, they didn't specialize in the surgery he needed.

Where can the public get an unbiased assessment of available hernia treatments? There are around seventy brands of hernia mesh on the market, and hospitals usually make the choice on behalf of their patients in accordance with bulk-purchasing agreements with manufacturers. Doctors occasionally have some input, but patients are rarely told which brand will be implanted in their bodies.

What patients do see on hospital websites are promotions for hernia surgeries and the doctors who perform them. In a non-scientific survey of the websites of sixteen hospitals and two physician practices, I found very little useful information about the risks of hernia mesh. In my sample, only the Cleveland Clinic provided an honest, straightforward warning, listing the possible side effects of mesh implants, such as chronic groin pain and pain during sex. Noting that managing such pain can be "challenging," the site also described a number of remedies, including partial or complete removal of mesh from previous surgeries.

Other institutions either avoided mention of the long-term risks or wrote around them. The Wexner Medical Center at the Ohio State University, for instance, noted that mesh repairs "account for the low rate of hernia recurrence," but did not mention the possibility of long-term pain. In a section about "possible complications," Johns Hopkins Medicine advised that "chronic pain is also a risk," adding that most pain would go away with conservative management, although "in rare cases" further surgery could be necessary. Stamford Health, a physician group affiliated with Stamford Hospital in Connecticut, acknowledged that while there were "concerns" about the devices, they were related to "reported complications with mesh products that have since been recalled."

Michael Ransford is now suing Johnson and Johnson for failing to disclose the risks of its implants. He is one of more than a thousand plaintiffs in a suit pending in a New Jersey state court.

Ransford is not the only former patient to turn to the courts. Brett Vaughn, a lawyer with the Hollis Law Firm outside Kansas City, says that roughly thirty thousand people have filed cases involving hernia mesh in federal and state courts since 2018. According to Kelsey Stokes, an attorney with the Houston firm Fleming, Nolen, and Jez, about one hundred new cases are being filed a week.

But even if their lawyers prevail in court, settlements to individual injured plaintiffs may be small. Miller and Zois, a Maryland law firm that specializes in hernia cases, tells prospective clients on its website that hernia-mesh litigation in 2011 resulted in a $184 million settlement. But those with less severe injuries "probably received some nominal amount or nothing at all." ■