80,000 Deaths. 2 Million Injuries. It’s Time for a Reckoning on Medical Devices.

Patients suffer as the F.D.A. fails to adequately screen or monitor products.

By The New York Times Editorial Board
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When the Food and Drug Administration announced last month that it couldn’t guarantee the long-term safety and efficacy of vaginal mesh products — medical devices that have been on the market for decades — the collective response from tens of thousands of women harmed by the products sounded something like this: Duh.

The mesh, which is used to hold pelvic organs in place when muscles become too weak to do the job, has long been tied to life-altering injuries, including nearly 80 deaths as of 2018. In the past decade, seven companies have spent a collective $8 billion to resolve more than 100,000 patient claims — making litigation over vaginal mesh (or pelvic mesh, as it is sometimes called) one of the largest mass tort cases in United States history. As those lawsuits have made clear, most of these medical devices were approved for market with nearly no clinical data.

It seems incredible that products meant to reside inside the human body would be used on patients without any proof of safety or efficacy. But thanks to regulatory loopholes and lax oversight, most medical devices are poorly vetted before their release into the marketplace and poorly monitored after the fact.

Problems can take years to emerge and can be impossible to correct, in part because permanent implants are not easily extracted from the body. (Removing mesh from pelvic tissue has been likened to removing chewing gum from long, thick hair). When trouble does arise, device makers often equivocate, regulators dither and patients seeking redress are forced into lengthy and expensive court battles. In the end, faulty products can remain on the market for years.

The F.D.A. finally pulled the remaining vaginal mesh products off
the market last month (although most companies had already stopped selling them because of all those lawsuits). But on Thursday, the agency said it would not ban a breast implant linked to a rare form of cancer and so many other side effects that doctors have coined a new term — “breast-implant illness.” Like mesh, the breast implant was approved years back, based on meager safety evidence. Regulators now say there is not enough proof of harm to justify reversing that decision.

The risks of waiting loom large: In the past decade, nearly two million injuries and more than 80,000 deaths have been linked to faulty medical devices, many approved with little to no clinical testing, according to a global investigation by the International Consortium of Investigative Journalists.

Women are particularly well acquainted with this cycle. Essure, a permanent birth control device consisting of two metal coils injected into the fallopian tubes, has been linked to autoimmune disorders and more than 800 pregnancy losses. The product was pulled from the market last year — by the device maker, which cited declining sales, not by the F.D.A. And the power morcellator — a spinning blade that shreds uterine tissue so it can be more easily extracted from the body — has proved deadly for some women, whose cancer was spread by the device. As The Times has reported, the morcellator was widely used for 20 years before regulators realized there was a problem.

But that’s not to suggest that only women are affected: There have been metal hips that released poisonous debris into the body, implantable defibrillators that shock people at random (causing indescribable terror) and artificial heart valves with questionable shelf lives. In operating rooms, there have been staplers that misfire; temperature control machines that spray bacteria into open chest cavities; and robotic surgeons that slap, burn and, in some cases, maim patients.

In every one of these cases, a combination of dubious regulatory approvals, skimpy post-market surveillance, and faltering responses from regulators caused irrevocable harm that might have been avoided.

After searing investigations by journalists and patient advocates, the F.D.A. has promised to make “transformative” changes to medical device regulation. But so far, the agency’s suggestions...
have been meager at best. And in the meantime, regulators have accelerated the device approval process, not slowed it down. Dr. Jeffrey Shuren, head of the agency office in charge of device regulation, has suggested that the benefits of bringing innovative products to market quickly are worth the increased risks.

It’s true that devices have restored hearing, vision and the ability to walk and have provided many other benefits to millions of people. But the drive to innovate does not justify the growing catalog of medical device disasters. Patients should not have to wonder whether devices will save their lives or destroy them. Reasonable changes could greatly improve the current system.

**TIGHTEN APPROVAL STANDARDS:** Regulatory loopholes — some of which date to the dawn of device regulation and were not meant to be permanent — enable companies to bring new or “updated” medical devices to market without testing them in human trials first. Companies need only to convince regulators that their products are similar to ones that are already approved, even if the other products are decades old or were subsequently pulled from the market. Eight years ago the Institute of Medicine advised the F.D.A. to abolish at least one of these loopholes, what’s known as the 510(k) pathway. It’s past time for the agency to heed that advice, and to ensure that no medical device intended for permanent residence inside a human body is used on patients without first being rigorously tested.

**FIX POST-MARKET SURVEILLANCE:** Industry proponents say that medical devices can be brought to market quickly and safely by having companies conduct rigorous testing after products go to market instead of beforehand. But companies often fail to complete such studies, even when they’re ordered by regulators. What’s more, device makers frequently skirt rules requiring them to report publicly all incidents of malfunction, injury or illness — often through mechanisms that the F.D.A. itself created. And after years of wrangling, the industry and its regulators have still not fully put a system in place to better notify patients of product recalls and other safety issues.

The F.D.A. has vowed to fix some of these lapses. They’ve promised to abolish reporting exemptions — as detailed by Kaiser Health News — that keep safety issues hidden from the public and to promote breast implant registries that monitor patient outcomes.
That’s a good start, but more can be done. An industry that prides itself on innovation, and earns some $400 billion in annual revenue, should be well equipped to build a global medical device registry where patient outcomes for all medical devices are openly monitored, and where doctors and patients can log concerns and obtain information.

**LOosen Industry’s Grip:** Dr. Shuren reportedly referred to device makers, not consumers, as his office’s main customers at a recent industry gathering. As misguided as that statement may sound, he’s not wrong: The medical device industry funds 35 percent of the office’s work, and by law, that funding is contingent upon the agency’s approving devices quickly, and through the least restrictive pathway possible.

It’s not solely those laws that give medical device makers influence over regulators. The industry maintains a well-oiled revolving door with the F.D.A. — as The Associated Press has noted, the last four people to hold Dr. Shuren’s position have gone on to lucrative industry gigs. Device makers also spent more than $300 million lobbying Congress in the decade ending in 2017, according to the Center for Responsive Politics. What’s more, they pay doctors and hospitals hundreds of millions in consulting fees every year, according to the National Center for Health Research. None of this violates any rule, but all of it contributes to the current crisis.

Medical institutions and professional societies should establish, or amplify, guidelines discouraging such payments. Stronger laws that provide more funding for the work of device regulation — so that the F.D.A. is not as reliant on industry dollars — would also help the agency to fulfill its mission.

That mission is to protect patients.