Ten years ago, Kathleen Yaremchuk raced to the bedside of a patient inexplicably gasping for breath. Chair of the department of otorhinolaryngology (ear, nose and throat) at Henry Ford Hospital in Detroit, Yaremchuk performed an emergency tracheotomy on the woman, cutting a hole in her windpipe, inserting a breathing tube and saving her life. When Yaremchuk began getting more calls over the following months for mysterious cases of respiratory distress, she launched a study to figure out what was going on.

All these patients, it turned out, had a small device implanted in the top of their spines to relieve pain. The object, used to hold a protein that stimulates bone growth, was cleared for sale by the Food and Drug Administration in 2003 without clinical testing in humans. When Yaremchuk and her colleagues reviewed the records of all 260 patients implanted with the device at Henry Ford Hospital between 2004 and 2009, they found that a significant number developed airway obstruction, trouble swallowing and respiratory failure, in some cases leading to death.

The neck implant is just one of the products associated over the past decade with 1.7 million injuries and more than 80,000 deaths. A searing global investigation last year by the International Consortium of Investigative Journalists places much of the blame on significant failings in the FDA's oversight. The agency's laissez faire attitude has resulted in artificial hips that cause cobalt poisoning (which can damage the heart and brain); surgical mesh that cuts through flesh and organs, causing infections and hemorrhage; and defibrillators that repeatedly shock patients beyond human endurance. Safety problems have led to recalls of devices implanted in hundreds of thousands of people. And the devices can be difficult or impossible to remove if they go bad.
No wonder many patient advocates cheered when the FDA announced in November that it planned to make “transformative” changes in the way more than 80 percent of medical devices are cleared for sale in the United States. Some 32 million Americans walk around with such products in their bodies.

But the promised transformation is mere window dressing. Two key loopholes still exist, allowing most products to be approved for sale without clinical trials in humans. Although the FDA insists that high-risk devices undergo “stringent” testing to win approval, few actually do. A recent study, for example, found that only 5 percent of the highest-risk implantable cardiac devices were subjected to clinical trials on par with the testing required for drug approval.

In 1976, when medical devices first came under the regulatory control of the FDA, the agency simply grandfathered in all devices that were already on the market. Under this provision, known as the 510(k) pathway, new artificial joints, cataract lens implants and thousands of other devices developed after 1976 can win approval for sale (or “clearance” in FDA parlance) if the product is shown to have “substantial equivalence” to a previously cleared “predicate” device. Four out of five devices are cleared for sale this way. Of those, at least 95 percent were cleared without clinical studies, according to research by Diana Zuckerman and her colleagues at the National Center for Health Research.

For some devices, that makes sense. You don’t need a clinical trial to test a new tongue depressor or hospital stretcher. But the agency also lets higher-risk devices through based on predicate devices, some of which have been recalled for safety problems. A recent study by researchers at the University of Oxford discovered that 16 percent of surgical meshes cleared for sale in the United States between 2013 and 2015 were based on products previously removed from the market because of serious complications. When one of us asked the FDA how this could happen, officials answered that the agency doesn’t evaluate the performance of the predicate when clearing devices for sale, just that there is (or was) a predicate.
According to the FDA, the “most impactful” change it is considering is recommending (not mandating) that companies cite predicate devices no older than 10 years. Yet device-makers could still cite predicates that were themselves based on earlier devices that may date back well past 10 years, something the FDA acknowledged in an email to us, stating that “devices cleared under a 510(k), regardless of how long the predicate has been on the market, have met the 510(k) regulatory review standard.”

The second loophole is the supplement pathway, which applies to new versions of the highest-risk devices, such as artificial hips, deep brain stimulators and spine implants. This process allows manufacturers to inform the FDA that they want to market an updated version of a device with minor changes — once again, allowing them to circumvent clinical trials. Researchers at Harvard found that 99 percent (5,829 of 5,906) of implanted cardiac devices, such as pacemakers and defibrillators, were approved through the supplement pathway from 1979 to 2012.

The supplement pathway has led to a number of disasters, such as one involving Medtronic’s Sprint Fidelis defibrillators, which are implanted in the chest to shock the heart if it goes into a deadly rhythm known as ventricular fibrillation. The company told the FDA in 2003 that it had updated the device to use thinner electrical leads into the heart. But the new wires were prone to fracture, hitting some patients repeatedly with shocks when their hearts were fine, and not delivering shocks to others who needed them. Doctors put the Sprint Fidelis into Bridget Robb, a patient from Pennsylvania in her early 30s. It shocked her 31 times in a span of minutes in 2007. She said in congressional testimony that it felt like being shot in the chest by a cannon at close range.

By the time Medtronic recalled the defibrillator in 2007, about a quarter-million were in circulation worldwide. Individuals implanted with it live under a sword of Damocles: They risk electrocution and possible death if they leave the Sprint Fidelis alone — and they risk death if their heart stops and the product fails. If they choose to have it removed, they face a 12 to 16 percent rate of serious complications or death from the surgery, according to a study published in 2010 in the journal Circulation.
Cases like these have received widespread coverage in the press but have had virtually no effect on FDA policy. Even a damning 2011 report by the Institute of Medicine (requested by the FDA), which deemed the agency’s 501(k) pathway so flawed it should be thrown out, fell on deaf ears.

Part of the problem lies in whom the agency believes it serves. At a recent meeting in Utah, the FDA’s device director repeatedly referred to manufacturers as the agency’s “customers” and showed a slide proclaiming “90 percent customer satisfaction.” Another slide documented the agency’s shorter and shorter approval times over the past eight years. These might not be the priorities of patients and taxpayers if they knew how often devices go on to harm people.

The FDA has become a captive agency. In 2007, Congress passed the Medical Device User Fee Amendments (MDUFA), which requires manufacturers to pay for device approvals. (Similar legislation, the Prescription Drug User Fee Act, directs money from drug companies to the FDA.) By 2018, 35 percent of the FDA’s budget for regulating devices came directly from the companies that make them. Zuckerman says that to continue collecting user fees under the MDUFA, the agency has to meet “performance goals” for faster approvals — leaving less time to evaluate products before they go on the market. It’s an inherent conflict of interest exacerbated by the revolving door of directors and commissioners who come from industry to the FDA and then go back. Before being appointed by President Trump to head the agency, Scott Gottlieb was paid millions of dollars for consultancies, directorships and other ties with some 20 health-care companies. He is a vocal supporter of Trump’s deregulation drive, arguing in 2013 that “the FDA’s caution is hazardous to our health.”

This is not a new problem. Before Gottlieb, President Barack Obama appointed Margaret Hamburg, who was then a director of Henry Schein, a leading medical-device distributor, to head the FDA. And in 2005, President George W. Bush named Lester Crawford, who abruptly resigned after just two months and came under criminal investigation for making false statements to Congress concealing his ties to companies the FDA regulates.

The relationship between the agency and the device industry is so cozy that in 2015, Rob Califf, then the FDA commissioner,
met secretly with the Advanced Medical Technology Association (AdvaMed), the industry trade organization, to help craft the 21st Century Cures Act, which lowered the bar of evidence needed to approve devices even further.

Last fall, the FDA and AdvaMed were aware of the planned release of the Implant Files, the report by the investigative journalists’ consortium. AdvaMed executives were so concerned that they held a meeting to discuss strategies for dealing with the anticipated stories, which made headlines around the world in November. The executives promised their member companies that they would “hit back and hit back hard.” One day after the first reports were published, the FDA issued its “transformative” changes to the 510(k) pathway.

If Americans want devices that are safe and effective, they’ll need a new kind of regulation. First, the FDA should recategorize any implanted device as a high-risk or Class III product, which would subject it to rigorous clinical trials. Data from these studies should be made publicly available, or the manufacturer would forfeit the right to sell its product. And implanted devices should be entered into registries that track outcomes; patients should be given access to a website where they can immediately report problems and receive updates.

Lawmakers should also revive the congressional Office of Technology Assessment, which the House of Representatives killed in 1995, during a fit of anti-regulation insanity inspired by Newt Gingrich’s Contract With America. The office provided an invaluable service by independently assessing evidence for a wide range of technologies.

Finally, the FDA commissioner should be a civil servant without financial conflicts, not a political appointee (a practice started under Richard Nixon).

To do all of this, the FDA needs to overcome the constant threat of losing funding if it goes against the wishes of the industry it is supposed to regulate. Congress should repeal the MDUFA (and the prescription-drug equivalent) and fully fund the agency. Until the FDA requires clinical testing of implanted devices, as it does for drug approval, we simply won’t have the evidence to prove that a device is safe or effective.