Medical Devices That Can Kill

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Defibrillators, stents, artificial hips—medical devices that should save lives can maim or even kill.

The ambulance crew gave the hospital staff at Corpus Christi Medical Center a fast rundown. Dennis Fegan, 48, had passed out at his home about 30 minutes earlier. Luckily, his parents were visiting, and they called for an ambulance after he fell from a dining chair to the floor. Then Fegan woke up, just as suddenly as he had collapsed. Three minutes later, he passed out again for less than a minute; then he came to. By the time the medics arrived, Fegan's parents had watched their son lose and regain consciousness at least eight times.

Fegan, a former oil rig worker and firefighter, fell unconscious yet again in the ER. This time he was hooked up to a heart monitor, and the emergency staff could see clearly what was happening: His heart had stopped. Fegan was flatlining at three-minute intervals, for 30 seconds each time.

His doctors soon realized that Fegan's repeated bouts of near death and resurrection coincided precisely with brief electrical jolts coming from a small device that had been implanted under his collarbone six years earlier to control his severe epilepsy. The Vagus Nerve Stimulation, or VNS, device sends electrical impulses to the vagus nerve, which controls many crucial body functions. Fegan's neurologist raced to the ER to turn off the device—and Fegan's heart began beating normally again.

That was four years ago, and while Fegan's heart has been doing fine, he worries that the VNS device could be harming other patients. His concern may be justified. In the 13 years since the device has been on the market, the U.S. Food and Drug Administration (FDA) has received reports of more than 900 deaths among people implanted with it. It's impossible to know whether any of those deaths are due to the device; its manufacturer, Cyberonics, says studies show it's safe. Still, some of the life-threatening incidents reported to the FDA are eerily similar to what happened to Fegan. Even more disturbing, problems with medical devices extend far beyond any single gadget, says Dr. William H. Maisel, MD, director of the Medical Device Safety Institute at Beth Israel Deaconess Medical Center, in Boston. Our system, say Dr. Maisel and other experts, doesn't adequately protect us from medical devices that can harm or kill.

Everyone is vulnerable. Though Fegan was being treated for the relatively rare condition of epilepsy, people have stumbled into disaster when they got a hip replacement, for instance, or had "better safe than sorry" treatment to prevent stroke, or asked for a fix for urinary incontinence. The FDA received more than 150,000 "adverse event reports" in 2007, and the true number of problems is almost certainly far higher. At one point, a government study found that less than 1 percent of device problems occurring in hospitals made their way into FDA files, and "the more serious the problem with a device, the less likely it was to be reported." Things have improved since then—but, experts say, not nearly enough.

How did we get to a point where we can't trust the equipment doctors use for—and in—our bodies? The FDA is both underfunded and too cozy with the device industry, say many critics, including some who work in the agency. In 2008 and 2009, a group of scientists and physicians wrote to members of Congress, charging that senior FDA officials had "ignored serious safety and effectiveness concerns of FDA experts" and had "ordered, intimidated, and coerced" them to change their decisions and approve devices. But that's not the worst of it. In 2009, a study by Congress's Government Accountability Office found that the safety and efficacy of many of the riskiest devices on the market have never been proved. Says Diana Zuckerman, PhD, president of the National Research Center for Women & Families, a group that analyzes research on medical products, "The FDA's oversight of these products is broken."

This sorry situation might finally be about to change: Even the FDA itself now says it needs help, and Congress is expected to take up the matter soon. But don't breathe a sigh of relief yet. Previous efforts at reform have ended up going nowhere. What follows, then, is a call to action: why you should care about the obscure topic of device regulation, what needs to happen, and how you can make your opinion heard.

In March 2005, 21-year-old Joshua Oukrop was mountain biking with his girlfriend in Moab, Utah, when he complained of fatigue. Seconds later, he collapsed to the ground, dead. Oukrop had a genetic heart condition and had gotten a defibrillator to control it. But it short-circuited, and when his heart started to beat irregularly, the device failed to deliver a shock. Oukrop's doctor says Guidant, the company that made the defibrillator, later told him that it had known of the defect for three years. Yet the company didn't alert physicians to the malfunction until May 2005, after the *New York Times* started investigating Oukrop's death.

No one expects the FDA to check the tendency of tongue depressors to warp or the seaworthiness of bedpans. But devices that shock our hearts or perform other critical tasks—so-called Class III devices—are supposed to be tested to see that they're safe. A quirk in the law, though, allows many Class III devices to skate through. Call it the "me too" loophole: All a company has to do is claim its device is similar to another of its products that went through safety testing or that it's "substantially equivalent" to a device that's been on the market for years.

"It's so easy to go through that process," says Thomas McGarity, JD, a professor of law at the University of Texas at Austin. "Quite frankly, there's flat-out abuse." In fact, a Class III device is more likely to get a me-too approval than to go through more rigorous scrutiny. But not all those fast-tracked devices are truly similar to the older product—and sometimes the difference is deadly.

Take the Sprint Fidelis, the subject of a 2007 recall. The Fidelis is a wire, called a lead, that was used for certain implantable heart defibrillators—it's the piece that transmits the electrical shock from the defibrillator to the heart. It was approved in 2004 after its manufacturer, Medtronic, said it was a simple modification of a lead that had gone through FDA review. But there was a crucial difference: The Sprint Fidelis was thinner, to help surgeons thread it through blood vessels. By December 2005, the company had already received 30 reports that the wire had fractured, leading some patients to receive unnecessary and painful shocks.

Medtronic didn't inform surgeons who might be using the device. But two Minneapolis cardiologists, Robert G. Hauser and Adrian K. Almquist, were tracking their patients' results in a database—and they noticed troubling problems. "We had one patient who got 55 shocks," says Dr. Hauser. "And a shock is a major event."

In February 2007, Drs. Hauser and Almquist confronted Medtronic executives with the pattern they'd seen. A month later, the company sent a warning letter to physicians.

By October, when Medtronic recalled the device, at least 13 people were dead, possibly because of the faulty lead or from surgery to remove it. More than 268,000 others faced a terrible choice: They could undergo a possibly fatal operation to have the wires removed, or take the risk that their defibrillator would fire unnecessarily or fail when their lives depended on it. (Medtronic has since instructed doctors on how to reprogram its defibrillators to send an alert that the lead is having problems.)

"We believe we acted responsibly," says David Steinhaus, MD, medical director of Medtronic's cardiac rhythm division. "When it appeared to be an issue, we pulled the Sprint Fidelis from the marketplace, and we informed physicians the whole way."

Dr. Hauser takes a different view. "The Sprint Fidelis should never have been approved without human safety data," he says.

Lana Keeton lives in pain because of a different hole in the regulatory safety net. In 2001, she was scheduled for a hysterectomy because fibroids—benign tumors in her uterus—were causing bleeding and cramping. A few days before the surgery, she mentioned to her surgeon that she leaked a small amount of urine when she coughed or sneezed. No problem, the doctor said; he could fix that at the same time. To do so, he'd use a sling made out of synthetic mesh to support her bladder. What the doctor did not tell Keeton (and probably did not know himself) was that the mesh he planned to use had been approved thanks to its similarity to an older product, Boston Scientific's ProtoGen—which was recalled in 1999.

Synthetic surgical mesh is used in thousands of surgeries each year to patch holes in the abdominal wall during a hernia repair, for example, or prop up sagging organs like the uterus or bladder. But it turns out that something about mesh can make it a hospitable environment for germs. Three days after Keeton's operation, she was rushed to the hospital with a life-threatening infection known as necrotizing fasciitis—flesh-eating bacteria.

Keeton needed emergency surgery to cut away infected tissue. She spent 16 harrowing days in the hospital and was bed-bound for another three months. Then, after her wound had closed, the mesh began eroding through the wall of her bladder like a grater through cheese. "The pain was so bad that it woke me up even when I was on a morphine drip," says Keeton, who has had 16 surgeries and procedures to repair the damage. Unable to work and facing a mountain of medical bills, she lost her home and was forced to declare bankruptcy. "Nobody should have to go through what I've had to," she says.

In 2008, the FDA issued an advisory: It had received more than 1,000 reports of infection, erosion, and other problems involving many brands of mesh. But the agency's action came years later than it should have, according to Diana Zuckerman. When ProtoGen mesh was recalled in 1999, Zuckerman says, the agency should have investigated all mesh products based on it, and doctors and patients should have been informed.

The consequences of the FDA's silence have been devastating. Published studies have reported problems that include bowel perforation, bleeding, and even death. Granted, those complications are rare. But, says Donald Ostergard, MD, past president of the American Urogynecologic Society, the FDA approval process for mesh "is inadequate to protect the public from what I consider to be a public health hazard."

Says Zuckerman, "You have all these women who started out with a relatively small problem with stress incontinence when they exercised or sneezed, and now they can't work, can't sit, can't have sex. When mesh goes bad, it's a disaster."

In an ideal world, manufacturers, hospitals, and doctors would quickly report any injury or death that might be linked to a device, and the FDA would act when it saw a worrisome pattern. But that's not how it works in the real world. Physicians frequently fail to let manufacturers know about problems. What's more, when a patient is harmed, the company gets to decide whether its product is responsible. Not our fault? Then no report necessary.

Reports also may not appear in the FDA database, known as MAUDE (for Manufacturer and User Facility Device Experience), until long after a disturbing incident. For example, the database included no manufacturer's report about Dennis Fegan's episode of cardiac arrest until last year, even though Cyberonics, the maker of the VNS device, says it faxed a report to the FDA soon after it occurred. (In an internal document, Cyberonics suggests that a medicine Fegan was taking might have contributed to his heart problem. His medical records from the time of the attack, obtained by *Reader's Digest* with his permission, blame the device.)

Cyberonics says the VNS device is safe and effective, and in 2005, the FDA approved its use for another condition, treatment-resistant depression. That approval came over the strong objections of more than 20 FDA scientists and management staff.

Clearly, an overhaul is needed, say watchdog groups and government officials alike. But reform requires a balancing act, says Scott Gottlieb, MD, the deputy commissioner at the FDA until 2007: It's important that the new system continue to encourage innovation and allow manufacturers to quickly respond to feedback from surgeons. Tightening regulation too much could slow the pace of medical advances to a crawl.

But even Dr. Gottlieb agrees that the FDA needs a better system for tracking devices once they are on the market. Reform-minded experts have called for a national registry for the riskiest implantable devices. Just as every vehicle on the road bears an identification number, every device would have its own ID, perhaps in the form of a barcode; surgeons would register each device they implant, along with anonymous information about the patient. If the patient is harmed or dies, or needs more surgery to fix a problem caused by the device, the surgeon would be required to log that information into the registry too.

"If I get notified that my car or my child's car seat has a defect, why can't a person with a device implanted find out quickly and automatically when there's a problem?" says Dr. Maisel, of the Medical Device Safety Institute.

Short of a registry, experts want to:

- Require all cases in which a patient is seriously hurt by a Class III device to be reported to the FDA, not just those that the company decides are due to its product.

- Create an independent panel to routinely monitor the MAUDE data-base—and give the panel access to company data when there appears to be a problem with a device.

- Stop payments, often called kickbacks, from device makers to physicians and hospitals in exchange for using the company's device.

Some of these reforms may require legislation and will certainly take money. The Project on Government Oversight recommends doubling the FDA's current budget for device regulation by 2012. In the meantime, patients can protect themselves by questioning their doctors before consenting to being implanted with a device.

For Dennis Fegan, changes like mandatory reporting and the appointment of an independent panel can't come soon enough. His brush with death has left him worried.

"I can't help but wonder," he says. "How many patients with the VNS device went through the exact same thing I did and never lived to tell about it?"

7 Stay-Safe Questions

Jeffrey C. Lerner, PhD, makes his living tracking the safety of medical procedures, drugs, and devices—he is president of the nonprofit ECRI Institute, which works with the World Health Organization and federal agencies to improve patient care. If you're considering a device, here are the questions he says you should ask.

1. Are there nonsurgical ways to treat my condition?

2. Have any cases of serious harm associated with this device been reported to the FDA?

3. How many procedures have you performed using this device? (If it's only a handful, consider finding a more experienced surgeon, unless one will supervise your doctor.)

4. How long has this device been in use? Like the latest cell phone, a new device may be a little buggy. If you have a choice, go with one that's been on the market for several years.

5. What percentage of patients nationally have to go back into surgery to correct a problem with this device? What percentage of your patients each year have to go back into surgery to fix a problem with this device? (If your surgeon can't or won't answer, consider it a red flag.)

6. If there's a problem with the device—or if it's recalled—how does the manufacturer notify you? How do you notify me?

7. What are the danger signs that something is going wrong with my device?

Speak Up!

E-mail or call Senator Chuck Grassley (R-IA), a longtime FDA gadfly, and urge him to support a mandatory registry for implanted devices.

Take Extra Care!

Any implanted device carries risks, but some are more prone to problems than others. The following are in wide use—and either the type of device or some brands within the category have been linked to particularly serious, even life-threatening, complications.

Carotid artery stents are implanted to keep the neck's major vessel unobstructed, in hopes of preventing a stroke. But recent studies have shown that stents are roughly twice as likely to cause a stroke or heart attack as a Roto-Rooter-style surgery. (In some cases, treatment with drugs and changes in diet and behavior can be superior to either.)

Pedicle screws are used in spinal fusion surgery to stabilize the vertebrae. But studies comparing back surgery with and without pedicle screws found that patients who got the device were more likely than others to need more surgery, suffer more blood loss, and experience other complications.

Artificial spinal disks replace damaged or ruptured spinal disks between the vertebrae. But artificial disks can put enormous pressure on the spine, causing fractures in the vertebrae and leaving patients in pain.

Surgical mesh is used to repair hernias and treat gynecological conditions such as urinary incontinence and prolapsed uterus. Though many people flourish with it, studies show that mesh can result in nerve damage, incontinence, bleeding, infection, and intestinal obstruction.