Warning! The medical "miracles" that may be hazardous to your health

From pacemakers to hip joints, implants keep millions of us healthy. Yet if a defective model is recalled, no one is required to tell you! A shocking report…and a call to action.

By Alexis Jetter

Kathy Hasenfus couldn't understand why she wasn't feeling well. At 54, the attractive Wisconsin businesswoman walked three miles a day, took kickboxing classes, and bicycled. Suddenly, climbing even a short flight of stairs left her breathless.

It wasn't her heart, Kathy was sure. Although she had been born with an abnormal heart valve, she'd just had it replaced with a new silver-coated device produced by St. Jude Medical, the world's leading manufacturer of such implants. So when her mother marched into Kathy's kitchen a month after the December 1999 operation, brandishing a newspaper article about the recall of a heart valve, Kathy didn't even want to read it. *It couldn't be mine,* she thought. *I couldn't be that unlucky.*

Her cardiologist wasn't aware of any recall. "I'm sure it's not your valve," he assured Kathy. "We have a good history with the company."

A few weeks later, though, Kathy called the St. Jude hotline—and learned she was indeed that unlucky. In some patients, the silver coating on St. Jude's Silzone valve was preventing surrounding tissue from healing properly, causing the device to leak and detach.

After an exam, Kathy's cardiologist confirmed that her valve was pulling loose; in a few more months, it might have killed her. Yet if her mother hadn't read the paper that day, Kathy might not have learned about the danger in time. Incredible as it sounds, in the United States, no one—not the manufacturer, not the Food and Drug Administration, not your surgeon—is required to tell you if your medical implant is defective. Even if your model is pulled from the shelves in a recall, you might never know.

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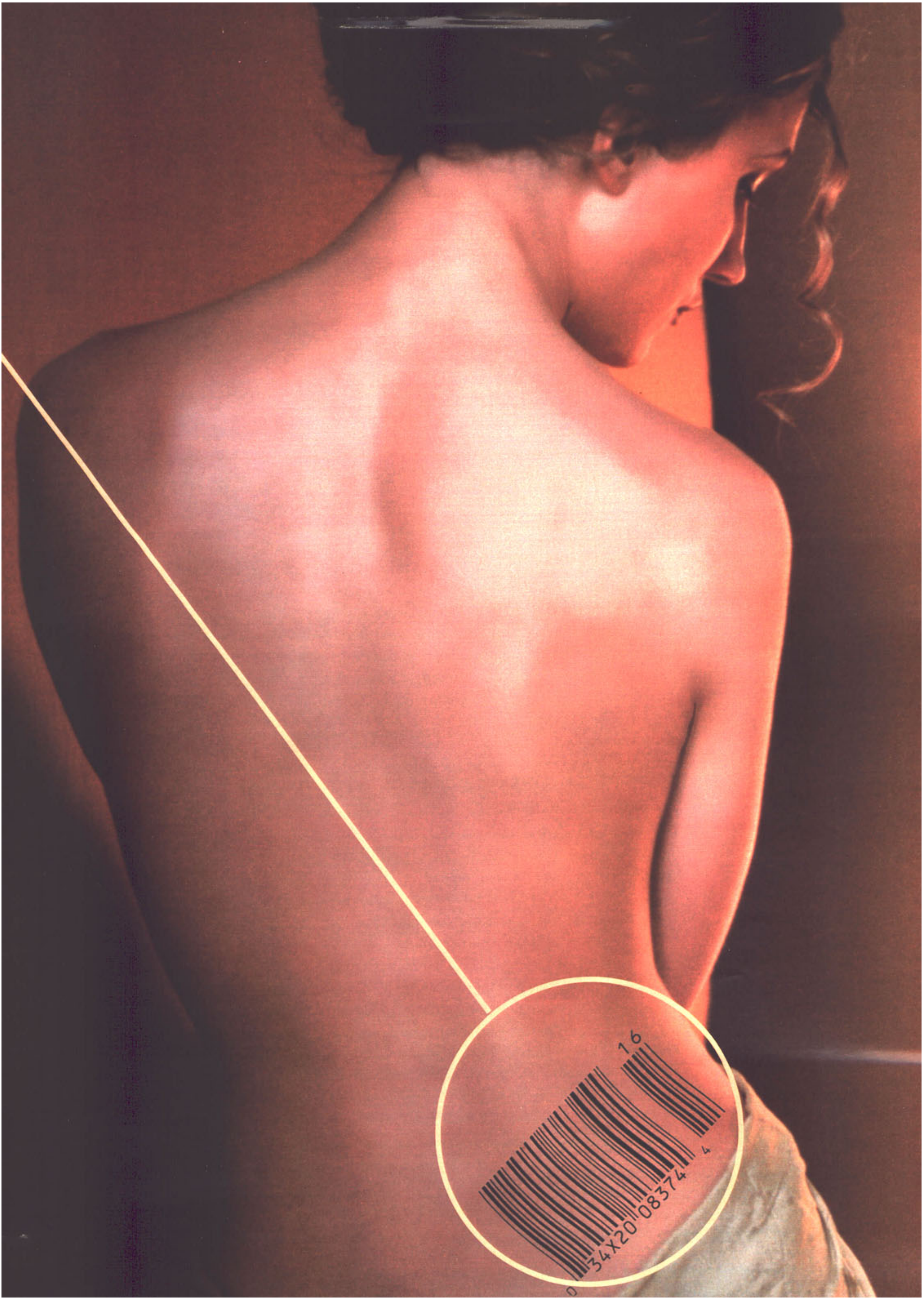
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Testing...testing?

Some 25 million Americans rely on implanted medical devices, from brain stimulators to artificial knees. They help us live longer, more active lives. An estimated 750,000 people alone use pacemakers and implanted defibrillators, up nearly 50 percent since 1990.

But this high-tech gadgetry can mean high potential for trouble. Between 1990 and 2001, 689 recall notices, affecting more than two million implants, were issued for malfunctions or labeling or manufacturing errors. In general, heart devices get flagged most frequently: Within a one-year period, odds are one in 15 that a pacemaker will be recalled or become the focus of a safety alert; for defibrillators, the rate is one in six. In the case of a recall, firms remove a product from the market; a safety alert warns physicians to monitor a product that may pose a substantial risk. Either way, it doesn't necessarily mean your implant would have to be replaced.

With the stakes so high, you'd think there would be extensive testing before an implant could be marketed. Think again. The FDA does not run its own tests. Contrary to the popular image, there are no engineers in white coats hunched over products. "The FDA never sees the device," says Suzanne Parisian, M.D., a former chief medical officer at the agency. "All they see is the paperwork the manufacturer submits. They rely on those companies to be truthful."

That's how the system has always worked. But today, there may be more pressure to get products to market quickly. David Feigal, M.D., director of the FDA Center for Devices and Radiological Health, defends the agency's vigor in pursuing problems. But he also concedes that his division is understaffed, considering it must oversee 8,000 new medical devices every year.

If the FDA doesn't do its own testing, does it require manufacturers to run clinical trials involving large numbers of patients? Rarely. While a handful of high-risk devices must undergo testing, the vast majority do not. Some products escape extensive scrutiny because they're low risk (tongue depressors, for example). Others get through because they've been around for years. Until 1976, the FDA was not required by Congress to regulate medical devices before they went on the market. Items in use before 1976 were grandfathered in (though they might have been evaluated later).

Nor does the FDA typically call for a clinical trial if a manufacturer can claim that a new device is "substantially equivalent" to one already in use—the famous me-too clause.

That's how Kathy Hasenfus's new Silzone valve came to market. In 1998, the FDA approved the device based on studies of 38 people and 16 sheep; aside from its silver coating, the valve was considered substantially equivalent to an older St. Jude model that was widely used and trusted. Ultimately, an estimated 36,000 people worldwide, including 12,000 in the United States, received the new valve.

Signs of trouble with the Silzone model soon emerged. As is not uncommon with medical devices, the valve was marketed in Europe first, starting in 1997 (the approval time can be shorter in Europe). After a 1998 British study linked the valve to an increased risk of blood clots and stroke, Britain's top medical agency issued a safety warning. Authorities in Australia and New Zealand stopped the sale of Silzone valves in their countries.

The FDA, however, reviewed the British study and concluded that since other hospitals were not reporting the same problem, doctors did not need to be notified. Kathy Hasenfus's cardiologist seriously questions that decision. "If I had known in advance that other countries had stopped using this valve, I would not have allowed Kathy to have it," says Peter A. Fergus, M.D.

But by late 1999, a different complication was causing concern: Some of the valves were leaking. After the Silzone model was approved by the FDA, St. Jude voluntarily conducted an 800-patient study—the company hoped to confirm that the silver decreased heart infections. After initial findings showed that the device leaked more than other mechanical valves, the company

"We were guinea whose implant

Kathy Hasenfus learned about the recall of her heart valve from the newspaper.

PHOTOGRAPH BY JOHN NIENHUIS

halted the trial and issued a recall in January 2000.

That doesn't satisfy Kathy Hasenfus, who was astonished to learn that the Silzone valve had received FDA approval with only limited trials. "We were guinea pigs," she says.

St. Jude insists it acted responsibly. "It's easy to say there should have been more patients and they should have been followed longer," says company spokesperson Peter Gove. "There's this assumption by some that there's something wrong with that [process]. There's nothing wrong.... That is the procedure the FDA required." He's right. There was nothing illegal or unusual about the Silzone approval or recall.

"Sorry, I thought you knew about this...."

In fact, St. Jude has been lauded for getting the word out quickly once its own study turned up problems. But even when the system works, there are too many loopholes. Recall notices go to hospitals and surgeons, not to the patients who are walking around with a possibly faulty device. Suppose the surgeon doesn't see the patient regularly after an operation? That was the case with Kathy Hasenfus. Her surgeon had learned of the recall even before it was announced in January 2000—the valves had been pulled from his hospital. But believing (wrongly, as it turned out) that the manufacturer would notify patients directly, he did not contact Kathy. Meanwhile, she was seeing her regular cardiologist, Dr. Fergus, frequently. But he didn't get a recall notice from St. Jude until late April, three months after the announcement. That letter urged him to make sure patients "keep scheduled appointments and report changes in symptoms," but said that the company was "not recommending additional follow-up procedures." If he had listened to that advice, Dr. Fergus insists, "Kathy could have continued to tear sutures away, which could have put her in danger of

pigs," says Hasenfus, could have claimed her life

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Recalls: cars vs. medical implants

Why your wheels get better protection than your body

	AUTOMOBILE	IMPLANT
Who issues recall	Manufacturer (rarely, the National Highway Traffic Safety Administration)	Manufacturer
Who must be notified	All car purchasers, current owners, dealers, and all 50 state Departments of Motor Vehicles	Hospitals and doctors only
How they find you	Every car has a vehicle identification number (VIN); because owners need a VIN to register their car and are required to notify the DMV if they move, the state can provide a current address for any car owner. The carmaker then sends the owner a first-class letter.	It's up to the surgeon to notify you.
Who pays	Under federal law, defective parts must be repaired or replaced at no cost to the car owner.	The patient pays for surgery to remove or repair a defective device. (Health insurer may lodge a claim against manufacturer.)

dying." He did send her for follow-up tests. The finding? One third of her heart valve had pulled away.

Kathy was relatively lucky—she heard about her device's recall shortly after it was announced. Some patients don't find out for years. LaDonna Dahl, 49, an advertising executive in Blaine, Minnesota, had a Teflon-coated jaw disc implanted in 1983 to relieve chewing pain. For 17 years, the corrosive Teflon on the Vitek implant ate away at the bone, carving a quarter-inch hole in her skull and causing severe headaches. LaDonna, however, thought her jaw disease, not the implant, was to blame.

Meanwhile, hundreds of other patients were reporting similar symptoms, as well as tumors and infections, with the Vitek jaw implant. Finally, in 1991, the FDA banned the device. By that time, the manufacturer had gone bankrupt, leaving the government to inform patients.

But the news never reached LaDonna Dahl. Nor did anyone ever contact her. She wasn't hard to find: Her medical records and address were on file at the University of Minnesota. Yet it was LaDonna herself, doing research on the Internet nine years after the recall, who discovered that the device was dangerous and should be extracted. In 2000, she had her implant removed. "Some of the Teflon was embedded in my jaw, so they had to scrape that off too," LaDonna reports.

Too little, too late

It was a highly unusual move for the FDA to pull the Vitek jaw implant. Normally, the manufacturer is the one to decide whether to issue a recall. As a result, warnings can be delayed for months, even years, while the company considers its decision—and doctors unknowingly implant faulty devices in still more patients.

Karen Riffe, 61, of Topeka, Kansas, can tell you about that. Sulzer Orthopedics knew in July 2000 that the Inter-Op shells, a component of the company's artificial hips, were failing. Throughout that summer and fall, orthopedic surgeons told Sulzer that something was wrong with the previously trusted device. It turned out that oil residue from machinery at Sulzer's assembly plant had coated the implants, preventing them from bonding to some patients' pelvic bones. But the company waited until December—when it identified the source of the problem—to recall the 40,000 joints it had sold. It was in November, just a month before, that Karen Riffe received her implant.

Four months later, the hip popped out, and Karen lay in the snow for two and a half hours before a neighbor found her and called an ambulance. When she arrived at the hospital, her doctor put in a second Sulzer hip. In Karen's case, that one turned out to be as bad as the first.

What had gone wrong? After the recall, the manufacturer did not discard the oil-coated hips. Instead, according to company spokesperson Brad Bishop, it sent them to a factory to undergo a chemical wash, then returned them to hospitals. (The FDA was aware of this fix.)

Karen Riffe's second implant, one of those rewashed hips, popped out when she was at a highway rest stop. She had to crawl back to her car. "I was scared to death," says Karen, ➤

Most common implants

Latest annual numbers

Lens implants: 1.8 million

Heart stents: 456,000

Artificial knees: 331,000

Artificial hips: 192,000

Pacemakers: 152,000
(600,000 Americans have one)

Mechanical heart valves: 38,000

Defibrillators: 34,000 (150,000 Americans have one)

Bladder slings: 28,000

PROTECTING PATIENTS! Join the GH Campaign

Defective medical implants are causing scores of injuries, even deaths. But patients may be the last to know when a faulty product is recalled or put on safety alert. This must change! Good Housekeeping calls on federal authorities to protect the 25 million Americans who already have implants and the millions more who will get them in the future. We need a foolproof system to make sure patients are notified—immediately—when a medical device may be threatening their lives.

Your voice counts! Sign the coupon below. We will forward all coupons to federal leaders for action and report on our progress in a future issue of the magazine.

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who has had yet another hip replacement and a follow-up operation to correct the damage caused by the implants—and she's not likely to ever regain full use of her left leg.

Sulzer (now Zimmer) agreed to pay $1 billion to thousands of affected patients. Yet Karen only learned about the rewash problem through a TV ad placed by New York City law firm Weitz & Luxenberg, which has filed hundreds of lawsuits against Sulzer. "This happened three years ago," Brad Bishop says today. "Settlements were made where appropriate. All of the manufacturing processes have been changed since then."

Companies can't guarantee that every device is perfectly safe. But once a defect is discovered, they are required to get the word out quickly (although, again, not to the patient). Still, "there are times when we have issues with how rapidly companies report to us," acknowledges Dr. David Feigal of the FDA. He argues, however, that there would be more delays if the agency had to depend on hearing from doctors and patients. And while he sympathizes with implant recipients who want to be notified rapidly, Dr. Feigal stresses that the system works, because "there are many good reasons for manufacturers to get bad products off the market and replace them with things that work."

The FDA, in effect, depends on an honor code—and trickle-up reporting. If an implanted device is suspected of causing a death, hospitals are required to alert the manufacturer and the FDA. (Injuries need to be reported only to the company.) The manufacturer, in turn, must inform the FDA about defective products and recall existing supplies from hospital shelves.

Of course, companies may not be eager to disclose problems. A division of the Guidant Corporation, for example, produced a special kind of graft designed to strengthen a key abdominal artery without invasive surgery. But surgeons found the graft got stuck a third of the time, damaging the patient's artery and requiring an emergency operation to remove the graft.

What did Guidant report to the FDA? That the company had received 172 complaints. The real number was 2,800, out of only 7,632 units that were sold. Finally, company whistle-blowers alerted the FDA to what was going on. Last June, Guidant pleaded guilty to ten felonies and was fined $92.4 million, the largest penalty ever imposed against a U.S. medical-device maker for failing to report malfunctions to authorities. It was also one of the few felony convictions for such conduct. "We will not tolerate such threats to the public health," says FDA Commissioner Mark McClellan, M.D.

Better recall

After the Vitek jaw implant was pulled off the market, the inventor fled to Switzerland. The FDA then seized the company's remaining products, and a bulldozer buried them in a Houston dump.

Sadly, there's no easy way to ➤

Implant recalls: a brief, sad history

MARCH 2001–Aortic grafts
Guidant Corporation recalled a new aortic graft that endangered thousands and killed 12. In June 2003, the company pleaded guilty to ten felonies.

DECEMBER 2000–Artificial hips
Sulzer Orthopedics recalled 40,000 hip joints that were defective due to oil residue. Sulzer washed the joints and reissued them; some were still problematic.

JANUARY 2000–Mechanical heart valves
St. Jude Medical recalled 47,000 mechanical heart valves because their silver coating caused valves to leak and detach. About 12,000 people still have theirs.

JANUARY 1999–Bladder slings
Boston Scientific recalled 23,000 bladder slings, designed to control female urinary incontinence, after they were shown to erode vaginal walls and detach.

OCTOBER 1994–Pacemakers
Telectronics Pacing Systems recalled nearly 43,000 pacemaker wires, which could break away and perforate the aorta. At least two women died.

JANUARY 1991–Jaw implants
The FDA recalled the Vitek Teflon jaw disc, implanted in about 26,000 patients, mostly young women. The Teflon ate into bones and caused tumors. Vitek had gone bankrupt, so the FDA publicized the recall itself, but only a fraction of patients were reached.

NOVEMBER 1986–Heart valves
Pfizer Corporation recalled the Bjork-Shiley heart valve. The metal struts that held the valve in place tended to fracture, causing an estimated 248 deaths. Despite attempts by the company to inform patients, only about 14,000 of the estimated 23,000 to 40,000 patients were ever located.

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clean up the mess in LaDonna Dahl's jaw. But some experts say there is a way to alert future patients to problems: a national registry. As of now, makers of only 12 types of life-supporting implants are required to track the patients and surgeons who use their devices. But that doesn't mean they *must* notify patients—it means the contact info is available.

Why not track everyone? asks Robert E. Baier, Ph.D., director of the biomaterials graduate program at the State University of New York at Buffalo. He envisions a state-run implant registry modeled on the automotive industry. "If you're the third owner of a used Chevy, and the brake discs are tearing on that model, you'd get a notice to come in and have them looked at. Wouldn't it be just as reasonable that, if we discovered that the plastic in your artificial hip is too brittle, you'd be called in and inspected and told whether you should have that part replaced?"

All that's needed, says Baier, are bar code stickers for each implant—one for the medical chart, another scanned in with the code on the patient's wristband. That way, any future safety alerts about the implant would be attached to patients' contact information and could be mailed directly to their home. "None of this is hard to do," he says. "It's like scanning a bag of potato chips at the supermarket counter."

If we were to track patients nationally, we might also know sooner when a problem is emerging, says Mehmet Oz, M.D., vice chairman of the Department of Surgery at NewYork-Presbyterian Hospital/Columbia Presbyterian Medical Center. "We're finding out too late in the game." Some European countries already have implant databases. But in the United States, they've been blocked for a variety of reasons. Tracking patients is costly because people often move or change doctors; companies are unlikely to voluntarily shoulder the expense of finding them. And, according to Dr. Feigal, the registries could not be mandatory: Ironically, new medical privacy laws prevent the agency and manufacturers from contacting patients without permission. And patients themselves may worry about confidentiality.

But Kathy Hasenfus is ready to sign up. "Anyone can go on the Internet and find out everything they want about me in a second: my credit rating, how many toes I've got," she says. "I want to know if my heart device is working."

In May 2000, five months after her first open-heart surgery, Kathy was prepped for her second. "Weren't you just here?" the nurses asked. The second operation was more complicated than the first—and riskier. In a "redo" operation to replace a defective prosthetic valve, there's a 5 to 6 percent chance the patient will die, according to Kathy's cardiologist, Dr. Peter Fergus.

But the surgery went smoothly. And Kathy was back on her feet—and back to her active life—in just a few weeks. Not that she isn't still angry at what happened to her and fearful about what could happen to others. "Recalls are something that should happen to cars or window blinds," says Kathy, "not to heart valves." ■

This article is the first in a series on recalls of dangerous products.

How to protect yourself

All products carry some risk, which patients need to weigh against the benefits. If surgery is not an emergency, you should also research pros and cons of similar medical products made by different manufacturers and get recommendations from more than one doctor. Once you have an implant, experts advise these steps to minimize potential problems:

Know your device. Find out exactly what it is and what it's supposed to do. Don't leave the hospital until you've written down the company name and the product name, model, and serial number. Ask that this information be put in your medical chart as well; incredibly, such record keeping is not routine, according to Jeffrey Lerner, Ph.D., president of ECRI, a health services research agency.

Be sure your doctor is in the loop. It's amazing how many patients neglect to tell their personal physicians that they have an implant. It's important: Even if a device is functioning well, patients may need to avoid certain machines, like an MRI scanner, for example.

Keep informed. Check out the manufacturer's Web site if you have a question. Also, the FDA Web site (www.recalls.gov) will tell you whether there's ever been a recall for your product or model.

Keep others informed. You can and should report your own problems to the FDA (called "adverse events" in the agency's lingo). You can do so at the same Web site (see above). But the form you need to fill out is complicated; you may need your doctor to help. Also, your M.D. can add relevant medical info. Just make sure the form actually gets sent in.

Stay in touch with your surgeon. Your follow-up care may be handled by another doctor, but your surgeon or his hospital would be the one most likely to hear of a recall or safety alert. Let that office know if you move or if you change your phone number.