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The Implants Loophole

By BARRY MEIER

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A recently recalled artificial hip made by a unit of [Johnson & Johnson](#), designed to last 15 years or more, is failing worldwide at unusually high rates after just a few years.

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Andrew Testa for The New York Times

Two components of the A.S.R. device.

One of the most troubled orthopedic implants of the past decade, this artificial hip — known as the A.S.R., or Articular Surface Replacement — was originally promoted as a breakthrough in design that would last longer and provide patients more natural movement.

But many patients soon developed inexplicable pain, and surgeons, when replacing the implant, discovered mysterious masses of dead tissue near the thighs of some patients.

Until late summer, officials at the Johnson & Johnson unit, DePuy Orthopaedics, the largest maker of replacement hips worldwide, maintained that the A.S.R. was performing on a par with competing devices. But interviews with doctors indicate that DePuy received repeated warnings that the implant was failing and that surgeons were abandoning it.

The brief and troubled life of DePuy's A.S.R. hip points to a medical implant system that is piecemeal and broken on many fronts, critics say. Unlike new drugs, many of which go through a series of clinical trials before receiving approval from the [Food and Drug Administration](#), critical implants can be sold without such testing if a device, like an artificial hip, resembles an implant already approved and used on patients.

That way, manufacturers can rapidly make small changes to a device to improve it. But those simpler procedures have also effectively created a loophole, experts say, that lets

producers bundle a component from an unapproved implant into an existing design and sell a device with minimal testing. With the A.S.R., that process unfolded with devastating results.

“You are basically testing these devices in an uncontrolled way on a large number of people,” said Dr. [Sidney M. Wolfe](#), the director of the Public Citizen’s Health Research Group and a longtime F.D.A. critic.

Officials at DePuy declined to be interviewed for this article or to respond to specific written questions. In the past, they have said that the company moved promptly to take appropriate action on the A.S.R.

Late last year, DePuy announced that it was phasing the device out, but asserted at that time that the decision reflected lagging sales, not safety issues. And some doctors report good results with the implant.

“We believe we made the appropriate decision to recall at the appropriate time given the available information,” DePuy said in a recent statement.

The faulty DePuy device is one of a number of Johnson & Johnson products that have come under intense scrutiny in the last year, because of defects or manufacturing flaws that have prompted recalls of such household names as children’s Tylenol to Roloids.

DePuy officials cannot say how many patients in this country received an A.S.R. because the company, like other orthopedic makers, does not track such implants. The Johnson & Johnson unit sold two versions of the A.S.R. hip, one that the F.D.A. never cleared for sale in the United States and one that it did.

DePuy officials estimated that about one-third of some 93,000 patients worldwide who received some version of the implant were in the United States. Both versions of the A.S.R. shared a common component, a so-called cup, or the part of the joint that replaces a patient’s hip socket. It was that cup’s design, experts say, that would prove faulty.

As patients began complaining, doctors and regulators here remained largely unaware that the problem was widespread because no independent monitoring system exists in this country that tracks implant failures. Such a database, used in other countries, might have clued in American orthopedists to the problem. In addition, doctors who tried to sound an alert said they had been rebuffed by DePuy.

The director of Australia's orthopedic database said he believed that DePuy had been less than forthright about the A.S.R. Data in that country, he said, showed that in 2008 the A.S.R. was failing early at a rate higher than some competing devices.

"When it is clear to the orthopedic community that a company has not been honest, that is a problem," said Australia's registry's director, Dr. Stephen Graves. "I think that J.& J. has a major issue with DePuy."

Permanent Damage

For patients, the problems with the A.S.R. required additional painful operations in which the device was replaced with yet another artificial hip. For some, however, the damage to bone, muscles and nerves from the troubled device, which can shed tiny metallic particles, has left them permanently disabled. That damage can also complicate a replacement operation.

[Enlarge This Image](#)



Andrew Testa for The New York Times

Dr. Antoni Nargol, left, and Dr. David Langton said they expressed their concerns to DePuy Orthopaedics but were rebuffed.
[Selling an Untested Device](#)

One patient, Mary Ann Doornbos, a former [I.B.M.](#) employee in Illinois, remains on disability and still walks with a cane, one year after her A.S.R. was removed and replaced.

Ms. Doornbos, 56, said that she could not stand up long enough to cook a meal because the pain was constant. "I have been told that I have to be prepared that it will be like this for the rest of my life," she said.

Like thousands of other patients, Ms. Doornbos did not know the hip component that caused her disability was a critical part of another device that the F.D.A. had never approved for sale.

Initially, DePuy developed the A.S.R. as a so-called resurfacing implant, a device comprising two components — the cup and a thigh component — that was used in a procedure in which

less of a patient's thigh bone was removed than in a standard hip replacement. And in 2003, DePuy started selling that version of the A.S.R. outside the United States.

But because resurfacing was a new procedure, the F.D.A. required DePuy to test the A.S.R. resurfacing implant in a clinical trial before it could sell it here. It was not until late 2007 that the company submitted that study data to the F.D.A. for review and possible approval, a process that was aborted last year when DePuy withdrew its application.

But back in 2005, the F.D.A. allowed DePuy to start selling the other version of the A.S.R., a modified standard hip replacement that used the same A.S.R. cup found in the company's unapproved resurfacing device. As a result, tens of thousands of patients here like Ms. Doornbos would get that version of the A.S.R.

Current rules do not require device producers to notify the F.D.A. when they bundle together components from approved and unapproved devices, Mark Melkerson, an agency official, acknowledged. New iterations of device designs already used on patients typically receive scant scrutiny from the F.D.A. before going to market.

An internal agency review released several months ago found numerous flaws with the process, and the F.D.A. is proposing changes to it. To win agency permission to market the A.S.R. in the United States, DePuy never had to perform any patient testing of it. Agency officials said the company cited clinical data it had used five years earlier to win F.D.A. approval to sell another all-metal hip implant called the Ultima. The Ultima, however, used a cup that had a totally different design than the one used with the A.S.R.

The F.D.A. also allowed another orthopedics company, [Zimmer Holdings](#), to sell a cup used in its unapproved hip resurfacing implant as part of a standard hip replacement. Hundreds of patients who got that component, which is known as the Durom, have also been forced to undergo early second operations after it failed not long after the first implant.

As for Ms. Doornbos, her surgeon simply told her in 2007 that he expected that she would not have to worry about a new hip for a long time.

"My doctor said that this was a new design that was particularly good for young people," she recalled.

Grave Concerns

It also was in 2007, the same year that Ms. Doornbos got her new hip, that an orthopedic surgeon in northeastern Britain, Dr. Antoni Nargol, would start seeing a few A.S.R. patients complaining of [groin pain](#). But two years later when Dr. Nargol and a colleague say they told DePuy officials they had found an explanation for why the A.S.R. was failing in patients, the company did not stop selling it or issue a warning.

Instead, the men said they were met with a response similar to one that other orthopedic surgeons who have tried to sound alarms encountered — a claim that the fault was not related to a particular device but to a doctor's surgical technique.

“They basically said that the problem was me,” said Dr. Nargol, who practices at a hospital in Stockton-on-Tees, a small industrial city south of Newcastle.

Dr. Nargol started as a believer in the A.S.R., not a critic; today both he and a colleague, Dr. David Langton, are consultants to lawyers suing the company.

Dr. Nargol's involvement with the A.S.R. started in 2004, he said, when DePuy asked him to be one of its investigators on the study of the A.S.R. resurfacing device it submitted in 2007 to the F.D.A. The 45-year-old surgeon said DePuy had shown him data to persuade him that the A.S.R. was superior to a competing resurfacing implant he was using called the Birmingham hip.

One DePuy video, he recalled, resembled a product face-off: An A.S.R. and a Birmingham were mounted on mechanical simulators that replicated years of use; soon, the oil used to lubricate the Birmingham turned black while the A.S.R.'s stayed clear.

“Their data indicated that the A.S.R. was going to last longer than the Birmingham,” he said recently. [Smith & Nephew](#), the Birmingham's marketer, would later assert that DePuy had doctored that test; DePuy declined to comment.

Dr. Nargol said he was not overly concerned in 2007 when a few of his A.S.R. patients developed pain because he first thought the problem was related to his implant technique. For example, an improperly positioned hip cup can cause so-called edge-loading, a situation where the joint's ball strikes against the cup's edge, chiseling off debris. And tests of those patients showed that they had elevated levels of cobalt and chromium ions, the A.S.R.'s constituent metals, in their blood, a sign of edge-loading.

“At first, I blamed myself,” Dr. Nargol said.

But Dr. Langton, an orthopedic resident working with Dr. Nargol, was not so sure because Dr. Nargol’s patients with the Birmingham hip seemed to be doing fine. So he began to take blood samples from Birmingham patients as well as A.S.R. patients not experiencing pain.

That study, which was presented in mid-2008 to a medical meeting, showed that many A.S.R. patients had elevated blood levels of cobalt and chromium. It also soon became apparent to Dr. Nargol that well-positioned cups were failing.

By 2008, the Australian registry was also showing that the A.S.R. was failing early at a fast growing rate. And as doctors operated on patients to remove and replace the device, they discovered that the metallic debris shed by the device had set off a reaction that was destroying muscle and bone.

Working with an engineer at Newcastle University, Dr. Nargol and Dr. Langton concluded by early 2009 that the design of the A.S.R. cup — the very component that the F.D.A. had allowed to be sold without clinical testing — was at the heart of the problem. Its interior surface was so shallow, the researchers asserted, that it was particularly vulnerable to edge-loading and shedding debris. In February 2009, the two British physicians met with DePuy officials at a company facility in Leeds, where the A.S.R. was then being produced.

Dr. Nargol said he expressed his grave concerns to the company about the A.S.R.’s safety. He said DePuy officials told him that they had confidence in the device because many other doctors had used it successfully and that they were not aware of similar complaints.

“I told them I was done,” he said.

Device Recall

In April 2009, not long after that meeting, Betty Jane Haak, a 74-year-old grandmother, got an A.S.R. cup as part of a new hip. These days, Ms. Haak has pain on that side and highly elevated levels of cobalt ions in her blood.

A specialist has urged her to have the device replaced, but because she had a [heart attack](#) this spring, she delayed doing so. Ms. Haak said at one point that she feared she might not be able to withstand surgery.

“Do I risk a heart attack, or do I risk poisoning myself?” she said.

The case of the A.S.R. is not the first time in recent years that problems with orthopedic implants emerged in registries elsewhere well before doctors in the United States stopped using that device. And the absence of such a system also means that device companies like DePuy — not doctors, patients or even regulators — determine when safety alerts about implants are issued or products are withdrawn from the market.

It was in March, a year after Dr. Nargol's meeting, that DePuy issued a safety alert about the A.S.R. But even before that, the company had decided to drop the A.S.R., even as it was still being used on patients.

Late last year, DePuy publicly announced that it would phase out A.S.R. sales and close the British plant that produced it. It also withdrew its F.D.A. application to sell the A.S.R. resurfacing implant in the United States and halted sales of the device in Australia. It cited declining sales, not safety concerns, for all those actions.

“When they said they were doing it for commercial reasons, I had to laugh,” said Dr. Graves, the head of the Australian registry.

In August, when DePuy recalled the A.S.R., the company said it would pay for operations to replace the device if needed and also urged patients who were experiencing pain to see their doctors. DePuy said in a recent statement that it was working with health authorities in several countries to address patient needs.

“We have an extensive team in place to handle the clinical, reimbursement and communications needs associated with this recall,” the company said.

Not surprisingly, the A.S.R. episode has touched off a wave of litigation both here and abroad against DePuy from patients like Ms. Doornbos and Ms. Haak. Johnson & Johnson has said it was currently unable to predict what the A.S.R.'s problems might cost the company over time.

Some officials have renewed efforts to begin an orthopedic registry in the United States. But an expert involved in that, Dr. Kevin Bozic, questioned how successful it would become because so far only 15 medical centers nationwide were voluntarily reporting data.

To make such a system effective, some experts believe that the federal government would need to mandate such reporting as a condition of payment through taxpayer-financed programs like [Medicare](#). It is estimated that hundreds of millions of dollars in public funds are spent unnecessarily every year on premature device replacement procedures.

The F.D.A has also recently proposed rules that, if adopted, could require implanted devices like artificial hips to undergo more thorough testing before they were approved for sale. However, the fate of those proposals is unclear and the device industry is questioning the need for broad changes. Meanwhile, surgeons like Dr. Nargol continue to witness the fallout. At several [hospitals](#) in Britain, he said, the earlier replacement rate for the A.S.R. now exceeded 20 percent and might soon reach 30 percent.

The impact on individual patients also continues to be profound. Recently, Dr. Nargol said he had met with a woman who now used two canes to walk because of the hip tissue damage she suffered from an A.S.R.

He said the woman became inconsolable when he told her that little could be done to ease her condition.

“It really brought it home,” he said. “The destruction this situation has caused.”