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The Medical Implants Loophole

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"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." This quote is at the heart of a lengthy article in the New York Times. The article explores in depth the approval process for medical devices such as the problematic hip implant manufactured by Dupuy Orthopaedics.

Other devices are also discussed, and the entire article provides great insight into the world of medical device manufacturers and the government agencies supposedly regulating them. Here are the opening paragraphs:

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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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.

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