PATIENT SAFETY BLOG

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Defective DePuy Hip Implant Shows Big Hole in Regulatory System

Patients naturally assume that when a sophisticated metal implant like a hip replacement is surgically placed into their bodies, it must have been thoroughly tested before wide use. The now-recalled DePuy ASR hip replacement shows how wrong that assumption is.

A medical device manufacturer in the United States can cobble together new components into an old, already-approved device, and the new hybrid device is

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essentially grandfathered into government approval since it in theory closely resembles the old device.

As explained by New York Times reporter Barry Meier in a long outtake:

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.

Read more here.

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