PATIENT SAFETY BLOG

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DePuy Hip Recall Shows Need for Early Warning System on Defective Medical Devices, Drugs

Most consumers are shocked when they learn the reality of the early warning system for defective medical devices and drugs in the United States. Unlike Europe and most other advanced countries, there is no systematic, mandatory national registry of failures to provide an early warning system.

Manufacturers are required to send to the FDA reports of drug adverse reactions and device failures. But the manufacturers have no legal obligation to collect such data in the first place, except in the rare instances when the FDA uses its power to require

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such on a case-by-case basis.
The DePuy hip replacement recall in August 2010 repeats a familiar pattern. Hip replacement surgeons knew they were experiencing a lot of failures with the DePuy hips, but no one had systematic data, and everyone assumed the manufacturer knew what was up and would report promptly.

In March 2010, the company warned doctors there might be a high failure rate. Then in August, it issued the recall. Now many patients have hired lawyers to pursue lawsuits, but a better warning system might have prevented many of them from getting the defective device installed in the first place.

The New York Times has more here.

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