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Reusing Medical Devices

Fears overblown

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The fight over the reprocessing of certain medical devices is a classic example of why the public needs to be fully informed before drawing conclusions — and how difficult that often is.

A campaign has been under way in New Jersey for months trumpeting the dangers of reusing medical devices that were meant for one-time use. The Web site of a group with the consumer-friendly name of PatientGUARD asks New Jersey residents to sign a petition urging legislation that would require only new medical devices be used during surgery.

This is scary stuff. On its face, the situation sounds like a recipe for infections and instrument failures.

But those fears are overblown. The fact is, the Food and Drug Administration approves of reprocessing certain devices as long as those devices go through a rigorous process of sterilization and testing. In data going back to 2003, the FDA found no “clear, causative link” between an FDA-approved reprocessed device and a patient injury or death. In fact, Daniel Schultz, the director of the FDA’s Center for Devices and Radiological Health, told a congressional committee, “The safety of (reprocessed) devices is excellent. It’s in fact far better than the (original) out-of-the-box single-use device.”

So why is PatientGUARD so alarmed? The organization is primarily backed by the HealthCare Institute of New Jersey, or HINJ — a medical device and pharmaceutical industry group. In other words, these are the people who make the single-use devices and who are losing money when they are reprocessed and reused.

Lesson: Things are seldom what they seem in this complex, high-stakes, spin-driven world. As a voter and a consumer, you should know what group or industry is behind the warm-and-fuzzy name on the public-information ad. And you should get all the facts before drawing a conclusion or signing a petition.

On the other side of the issue is the Association of Medical Device Reprocessors (a refreshingly straightforward name, at least). That industry group obviously has a financial stake in this issue as well. Still, the safety of properly reprocessed devices is touted not only by the AMDR, but by the FDA.

Also backing the reuse of the devices is the New Jersey Hospital Association. Hospitals, of course, also have something to gain. They save about 50 percent of the cost by buying reprocessed rather than new equipment. But as long as patient safety isn't an issue, then that kind of savings can benefit the public by keeping down health-care costs and the cost of health insurance.

Federal and state officials need to keep an eye on this issue. More data collection is needed. The New Jersey Department of Health and Human Services — which says it hasn't seen any reliable data indicating that the devices are unsafe — is nonetheless asking hospitals to begin reporting any problems related to the use of reprocessed devices.

That's wise. If there is a real problem, then let's find it — with real, unbiased and science-driven

data. But until then, we urge consumers not to draw conclusions too quickly on this or any other complex issue.

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