

## Integrity Matters Broadcast – By Jim Bracher

### "Patients must also be smart consumers"

#### Question:

How can Guidant Health Systems remain in business while delivering pacemakers that kill people? What can I do to make sure I don't die because of a faulty product?

#### Response:

Guidant has a history of irresponsible leadership and inconsistent product quality. This column addressed their malfeasance in July, 2003 when I wrote: ***Greed, whether for power or money (or both), is at the heart of this problem. Compromising health and life cannot be tolerated. Fortunately, such reckless endangerment seems to be the exception. Most manufacturers and, especially the ones associated with health care, test and monitor each product to guarantee both quality and safety. Our society safeguards us with many agencies responsible for testing products that affect our lives. Organizations that we have created and support test, on our behalf, what we drive, wear, eat and utilize in all aspects of our lives, specifically in areas related to health care. These processes are overwhelmingly effective.***

Problems with Guidant's popular heart defibrillator have led federal regulators to start an inquiry into whether the company violated a corporate integrity agreement it signed in 2003. Indianapolis-based Guidant had signed the integrity agreement after a former Guidant, subsidiary, Endovascular Technologies Inc., pleaded guilty to 10 felonies and paid \$92.4 million to settle criminal and civil charges in a case involving a device meant to treat abdominal aortic aneurysms. The Justice Department contended that Guidant covered up thousands of Ancure incidents in which the delivery system of the device had malfunctioned, including 12 deaths.

More recently, Guidant reported yet another malfunction to the Food and Drug Administration, but it did not inform patients and doctors for three years until physicians at Abbott Northwestern Hospital in Minneapolis, publicly questioned the company's conduct. Guidant maintains that the device is highly reliable. Under federal law, a company must report any incident to the FDA in which its medical device might have caused or contributed to a death or serious injury, or if the malfunction is likely to recur. Guidant's reputation erodes confidence in the integrity of health care. This cannot be allowed.

So, before accepting potentially-risky health treatment recommendations:

- Ask questions. Get second opinions.
- Demand current information that confirms the quality and reliability of any treatments, including technologies, you elect.
- Utilize this toll-free hotline: 888-463-6332; which will connect you with the Food and Drug Administration. The FDA can also be reached online at: <http://www.fda.gov/comments.html>. The FDA addresses many concerns about technology, toxicology and health safety.
- Research current news regarding issues related to medical devices and radiological health. Learn what products and services are working well and which ones are causing problems: <http://www.fda.gov/cdrh/consumer/>

Forward additional health hotline suggestions directly to us - ([info@brachercenter.com](mailto:info@brachercenter.com)) - so that we might pass along helpful resources and strengthen the integrity of health care delivery.

**Restoring confidence in health care's integrity is a must.**

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James F. Bracher is the Founder of Bracher Center for Integrity in Leadership - [www.brachercenter.com](http://www.brachercenter.com)