In This Issue

Heart of the Matter

On Recalls–Drugs and Devices

BY SIDNEY GOLDSTEIN, M.D.

The recalls of Vioxx and implantable cardioverter defibrillators have beset the cardiology community with a cloud of uncertainty on how to advise our patients in a variety of areas.

Any patient who is the least bit aware of current events and has an ICD or has been taking Vioxx (rofecoxib) knows of the dangers they face. Some are grateful that they "dodged the bullet" before they stopped taking the pill. Others will have to make more complex decisions about the removal of an ICD.

Drug and device recalls are not new to cardiology. In the 1980s and 1990s, several "magic" antiarrhythmic drugs were recalled after they were shown to be proarrhythmic. Even now, there are patients with Björk-Shiley aortic valves in place who remain under radiologic surveillance to ensure the integrity of the faulty devices.

What has changed is the magnitude of the problem, as well as public awareness of the issues. Drugs advertised on television as a panacea for pain have now been shown to cause heart attacks, and devices presumed to prevent sudden cardiac death can fail.

People have been led to believe that there is no downside to therapy. Even though we have no data on the long-term benefits and safety of many devices or drugs, patients and doctors have ignored long-term risks. Those who raised caution flags were dismissed as "nattering nabobs" of nonconformity. The Food and Drug Administration has relied on the pharmaceutical manufacturers and device makers to disclose negative information about their products. Such naiveté hardly befits a governmental agency charged with such an important safety role.

What should we expect from regulatory agencies and the pharmaceutical and device industry to assure us that products are safe? Transparency, at the least. We should be able to see within the industrial databases in order to understand what is going on. We also need to have simpler surveillance procedures, so that we understand the issues. It is clear that, as reported widely in the press, Guidant erred greatly when it continued to sell a product it knew was defective and that Merck was less than forthcoming about Vioxx. It is also disingenuous of both physicians and industry to recommend that patients make their own decisions. It is equally mindless to suggest that physicians decide which of their patients—whom they have already defined as being at high risk of sudden death and in need of an ICD—are at the highest risk when advising device replacement.

It is just possible that patients and physicians will learn that there is no free lunch and that all devices and drugs carry some degree of risk. Beyond the immediate risks of implantation in high-risk patients, adverse effects may take years to emerge.

In the meantime, it is imperative that the FDA and the Centers for Medicare and Medicaid Services establish surveillance procedures and registries that will ensure the safety of the products being implanted and ingested. Clinical trials, on which we rely for safety and efficacy data, often are too short and frequently are conducted in populations too small and specific to determine safety in a larger and more heterogeneous population over a lifetime of therapy. ■

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