Editorial

The Lessons of Vioxx®

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On September 30, 2004, Merck & Co., Inc., announced a voluntary worldwide withdrawal of Vioxx (rofecoxib).[1] The company's decision was based on new 3-year data from a prospective, randomized, placebo-controlled clinical trial that was designed to evaluate the efficacy of the drug in preventing recurrence of colorectal polyps in patients with a history of colorectal adenomas. In this study, there was an increased relative risk for confirmed cardiovascular events, such as heart attack and stroke, beginning after 18 months of treatment in the patients taking the drug compared with those taking placebo.[1]

Rofecoxib was launched in the United States in 1999 and has been marketed in more than 80 countries.[1] Worldwide sales of the drug in 2003 were $2.5 billion.[1] Twenty million Americans, and millions more worldwide, had used the drug since its approval.[2]

So what is the relevance of this development to dermatologists? It shows us that we should never take any of our therapies for granted, no matter how long we have used them and how innocuous they appear. Rofecoxib was approved through the vigorous standards of the US Food and Drug Administration and was subsequently used in millions of individuals. It was only through the study described above that the potential dangers of the drug became evident.

In this era of biotechnology and advances in drug development, we are fortunate to have an ever-expanding armamentarium of dermatologic therapies. But with all of these new treatments, we have an important responsibility. We have to monitor our patients closely for any and all adverse or unusual effects. Many encountered adverse events may be coincidence and have no causal relationship with therapy, but they must be noted nonetheless. I think it is important to adopt the following practices to monitor our therapies:

1. Report any unexpected event to the manufacturer of the product. If no other similar observations are noted over a long period, it is most likely unrelated. However, an accumulation of sporadic similar reports may point to a potential side effect of a medication. If each individual physician does not take the time to communicate these observations, we might never be aware of potential problems.

2. Write and publish case reports of potential adverse events. Although a case report does not establish causality, it does inform the medical community of that possibility. Multiple reports of the same entity provide stronger evidence. Whenever I suspect an adverse event of therapy, the first thing I do is to perform a MEDLINE search for any similar occurrences.

3. Encourage your patients to tell you of any adverse or unusual events following initiation of therapy.

The rofecoxib experience teaches us important lessons about the potential pitfalls of medical care. However, I do not think this situation should make us afraid of our therapies but, rather, cautiously optimistic.

REFERENCES

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