Post Marketing Studies of New Medications: 

Implications for Patient Safety

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Abstract

The public assumes that once the Food & Drug Administration (FDA) approves a drug it is safe to use, but this is not always the case. Although the development and approval of new drugs is complex and lengthy, safety and efficacy concerns make it necessary to determine whether the FDA should require all new drugs to undergo post-marketing studies.

Adverse drug reactions (ADRs) are one of the leading causes of serious health problems in the United States, killing more than 100,000 people every year and injuring more than two million. There have been several instances of delayed discoveries of adverse reactions from drugs which have been approved and marketed. Avandia (a diabetic medication) caused heart attacks when used on a long-term basis. Redux (dexfenfluramine) an obesity treatment drug, caused valvular heart disease. Merck was aware in 1999 that the risk of heart attacks increased with Vioxx, but it stayed on the market for five years before it was withdrawn. An estimated 88,000 Americans had a heart attack while taking Vioxx, and 38,000 of them died.

Post-marketing studies are critical in order to assess safety and efficacy on an ongoing basis and to educate the public in a timely manner to minimize harm.