Oncology has experienced a significant increase in new drug approvals since the late 1980s. Fewer than a dozen agents were commonly employed in the treatment of patients with cancer 25 years ago. Since 2000, more than 40 new anticancer agents and cancer-related supportive care drugs have been approved for use by the U.S. Food and Drug Administration (FDA, 2007) (see Table 1). New medications may offer therapeutic benefit and improved safety profiles, leading to improved outcomes, survival, and quality of life for many patients with cancer. Approval of medications by the FDA often is a lengthy process designed to assess new agents in clinical trials for their efficacy in specific diseases and ensure that associated toxicities can be managed safely.

Although oncology nurses are well versed in the management of common toxicities (e.g., neutropenia, gastrointestinal side effects), targeted therapy agents have introduced them to new side effects, emphasizing dermatologic and other unique toxicities. However, unexpected toxicities may occur during the postapproval and postmarketing time frame with any agent. Adverse events detected during the postmarketing period for oncology drugs have included a variety of toxicities (e.g., venous thromboembolism with lenolidomide and thalidomide, psychiatric disturbances associated with interferons) (Ladewski et al., 2003). The toxicities may not have been apparent during the original controlled clinical studies because trials usually contain small sample sizes and require good organ function for eligibility, so infrequent adverse events can be difficult to detect (Trontell, 2004). For example, studies...