Breast cancer is the most common cancer diagnosis for women in the United States, excluding skin cancer; it is the second leading cause of cancer death among women in the United States (American Cancer Society [ACS], 2009). In 2009, an estimated 192,370 new cases of invasive breast cancer will be diagnosed in women and about 40,610 men and women will succumb to the disease (ACS). Many treatment options are available, including surgery, radiation, and systemic therapies such as endocrine therapy, chemotherapy, and biologic treatments (National Cancer Institute [NCI], 2008). Tremendous progress has been made in the treatment of breast cancer, but not without cost in terms of short- and long-term toxicities, one of which is cardiotoxicity from anthracyclines, taxanes, radiation, hormonal therapy, tyrosine kinase–targeting drugs, and trastuzumab (Bird & Swain, 2008; Menna, Salvatorelli, & Minotti, 2008; Viale & Yamamoto, 2008).

Trastuzumab (Herceptin®, Genentech, Inc.) is a biologic treatment originally approved by the U.S. Food and Drug Administration (FDA) in 1998 for treatment of metastatic breast cancer (FDA, 2006). Clinical trials have demonstrated a disease-free and overall survival benefit for women receiving trastuzumab in an adjuvant setting, leading to FDA approval for that indication in 2006. One of the major risks of trastuzumab is cardiotoxicity, including left ventricular (LV) cardiac dysfunction, dysrhythmias, hypertension, cardiac failure, cardiomyopathy, and death (Genentech, Inc., 2009b). The clinical challenge is to treat women to prevent or delay recurrence while sparing them the cardiotoxic effects.

Adjuvant clinical trials of trastuzumab excluded women with a history of cardiac symptoms, abnormal electrocardiographs, abnormal radiologic films, or abnormal LV ejection fraction (LVEF), as well as uncontrolled hypertension. The incidence of cardiotoxicity in such women if they are treated with trastuzumab is not known. Current recommendations for patient selection and cardiac monitoring are stated in the package insert (Genentech, Inc., 2009b) and were developed based on...