



FDA ‘Black Box’ Warning for Gadolinium-Based Contrast Agents

BSGI provides a good imaging alternative to MRI for the population at risk for adverse reaction to gadolinium-based contrast agents. Due to the reported potential for adverse reaction and the FDA recommendation to limit the frequency of MRI use, institutional protocols may be subject to modification which would limit their indications for MRI. For example, an institution may adopt a protocol that indicates breast MRI for a patient with breast cancer, but may exclude the use of breast MRI for the screening of high-risk patients due to the associated risk.

The U.S. Food and Drug Administration (FDA) can require a pharmaceutical company to place a black box warning on the labeling of a prescription drug or in literature if medical studies indicate that the drug carries a significant risk of serious or life-threatening adverse effects. As this is the strongest warning that the FDA requires, BSGI can provide an excellent alternative for these patients.

The FDA warning can be found at the following link:

http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf