

# MRI Contrast Agents Draw Warning

FDA Seeks Label Change

To Note Risk for Patients

With Kidney Insufficiency

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WASHINGTON -- The Food and Drug Administration said it is asking manufacturers of certain contrast agents used in patients undergoing magnetic resonance imaging, or MRI, scans to place a black-box warning on the agents' packaging.

The FDA said the warning, which would apply to five gadolinium-based contrast agents - including ones made by [General Electric](#) Co.'s health-care unit and a Bayer AG unit -- would state that patients with severe kidney insufficiency are at risk of developing a debilitating and potentially fatal disease known as nephrogenic systemic fibrosis, or NSF. A black-box warning is the FDA's strongest drug warning.

The FDA said the black-box warning would also state that patients undergoing liver transplantation, or those with chronic liver disease, are also at risk of developing NSF if they are experiencing kidney insufficiency of any severity.

Karen Riley, an FDA spokeswoman, said the agency has received 128 reports of NSF and noted that millions of Americans have been exposed to the contrast agents, making the overall risk of developing NSF very small. However, the risk of NSF for a person with severe kidney failure is about four out of 100 patients, she said.

Other contrast agents are made by [Tyco International](#) Ltd.'s Mallinckrodt unit and Bracco Diagnostics Inc., based in Princeton, N.J.

GE and Bayer HealthCare Pharmaceutical said they would comply with the FDA's request. The Medical Imaging Contrast Agent Association, which represents contrast agent makers, said all the companies would cooperate with the FDA.

The FDA said patients with NSF develop thickening of the skin, connective tissues and some organs. Fibrosis can also develop in the diaphragm, muscles in the thigh and lower abdomen, and lung vessels. NSF becomes worse over time and can cause death.

The FDA said cases of NSF so far have been seen only in patients with severe kidney impairment and there have been no reports of the problem among patients with normal kidney function or among those with mild to moderate kidney insufficiency. The patients with liver problems were included in the black-box warning because they have an increased risk of kidney problems.

Gadolinium-based contrast agents are used to improve the visibility of internal organs when patients undergo an MRI. Gadolinium is a metal that has a small magnetic field and

can provide greater contrast between normal tissue and abnormal tissue in the body on MRI scans.

Contrast agents don't necessarily have to be used for patients undergoing an MRI, the FDA said.