

FDA warns of deadly side effect with imaging drugs

September 9 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- Federal health regulators are warning doctors that a class of injectable drugs used in MRI medical imaging scans can cause a rare and sometimes fatal condition in patients with kidney disease.

The [Food and Drug Administration](#) said Thursday it is adding its strongest warning label to imaging agents that contain the chemical gadolinium, indicating they should not be used in patients with kidney problems.

"These label changes are intended to help ensure these drugs are used appropriately," the FDA said in a posting to its website. The warning language will appear in a bolded box at the top of the drugs' labels.

The agency said in a statement that use of the drugs can lead to a rare syndrome that causes hardening of the skin and tissue growth along joints, eyes and internal organs. The ailment, which is sometimes fatal, is called nephrogenic fibrosing dermopathy and has been reported in patients with weakened kidney function.

There is no known treatment for the condition, though [kidney transplant](#) appears to slow disease and even reverse it in some cases.

Known as contrast agents, the products are used to improve clarity in medical scans of the heart, liver and other [internal organs](#). The FDA has approved five such agents since 1988.

While the nephrogenic syndrome has been reported with all five drugs, the FDA said three have greater risks than the others: Bayer Healthcare's Magnevist, General Electric Healthcare's Omniscan and Covidien's Optimark.

The new FDA labels instruct physicians to screen patients for [kidney disease](#) before administering the agents. The FDA said there haven't been any reports of the syndrome in patients with normal kidney function.

There are two non-gadolinium-based imaging agents on the market, though the FDA has approved them only for liver scans.

GE Healthcare said in a statement that the FDA's labeling reinforces physician guidelines that already stress the importance of screening for patients with kidney problems.

The company said MRI [contrast agents](#) "continue to be a valuable diagnostic tool with a proven safety record for the overwhelming majority of patients to whom they are prescribed."

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