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TRANSCRIPT

Transcript Details
This is a transcript of an educational program accessible on the ReachMD network. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/FDA-Drug-Information-Updates/fda-requires-new-class-warnings-all-gadolinium-based-contrast-agents/9951/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

FDA Requires New Class Warnings for All Gadolinium-Based Contrast Agents

Welcome to the FDA Drug Safety Podcast for health care professionals from the Division of Drug Information. This is Lesley Navin, Advanced Practice Nurse.

On December 19, 2017, FDA announced that it is requiring a new class warning and other safety measures for all gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging (or MRI) concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs. Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential risks.

However, after review and consultation with the Medical Imaging Drugs Advisory Committee, we are requiring several actions to alert health care professionals and patients about gadolinium retention after an MRI using a GBCA. These include requiring a patient Medication Guide that every patient will be asked to read before receiving a GBCA. We are also requiring manufacturers of GBCAs to conduct human and animal studies to further assess the safety of these agents.

GBCAs are used with MRIs and contain gadolinium, a heavy metal. They are injected into a vein to

improve visualization of internal organs, blood vessels, and tissues during an MRI. GBCAs are mostly eliminated from the body through the kidneys, however, trace amounts of gadolinium may stay in the body long-term. Health care professionals should consider the retention characteristics of each agent when choosing a GBCA for patients who may be at higher risk for gadolinium retention, including those requiring multiple lifetime doses, pregnant women, children, and patients with inflammatory conditions.

The only known adverse health effect related to gadolinium retention is a rare condition called nephrogenic systemic fibrosis that occurs in a small subgroup of patients with pre-existing kidney failure. We have received reports of adverse events involving multiple organ systems in patients with normal kidney function. A causal association between these adverse events and gadolinium retention could not be established.

We are continuing to assess the health effects of gadolinium retention in the body and will update the public when new information becomes available.

Report side effects involving GBCAs to FDA's MedWatch program at www.fda.gov/medwatch.

A link to the full communication detailing specific information for health care professionals and a list of FDA approved GBCAs can be found at www.fda.gov/DrugSafety. If you have drug questions, you can reach us at druginfo@fda.hhs.gov.

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