



Anapol Schwartz

ATTORNEYS AT LAW



# GADOLINIUM PSC

## GADOLINIUM LITIGATION OVERVIEW

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Barry Hill adds his mass tort reputation to Anapol Schwartz's well established national mass tort practice. Hill's more than 30 years of civil litigation experience also includes financial fraud and other complex litigation. He has handled a range of noteworthy consumer cases for the Attorney General for West Virginia.



ON MAY 23, 2007, THE FOLLOWING WAS PUBLISHED IN THE FDA NEWS:

## FDA Requests Boxed Warning for Contrast Agents Used to Improve MRI Images

"The ... FDA has asked manufacturers to include a new boxed warning on the product labeling of all gadolinium-based contrast agents which are used to enhance the quality of magnetic resonance imaging (MRI)."

... [P]atients with severe kidney insufficiency who receive gadolinium-based agents are at risk for developing a debilitating, and a potentially fatal disease known as nephrogenic systemic fibrosis (NSF) ..."

"Patients with NSF develop thickening of the skin and connective tissues that inhibits their ability to move and may result in broken bones. Other organs are at risk of thickening as well. The cause of NSF is not known and there is no consistently effective treatment of this condition."

"FDA first notified health care professionals and the public about the gadolinium-related risks for NSF in June 2006."

"...Gadolinium-based contrast agents are commonly used to improve the visibility of internal structures when patients undergo an MRI. Five gadolinium-based contrast agents have been approved for use in the United States ... Omniscan [General Electric] was the most commonly reported agent...followed by Magnevist [Bayer] and OptiMARK [Tyco Mallinckrodt /]."

## NSF IS A MAN-MADE DISEASE.

It was first diagnosed in 1997, after gadolinium-containing contrast solutions came into widespread use. At the time, scientists did not know the cause, and a variety of other names were used to describe it.

NSF is usually diagnosed by a tissue biopsy sample taken from an affected area and examined microscopically. In some diabetics and others the risks of biopsy are such that the diagnosis is made clinically and without a biopsy.

Gadolinium is a metal found in the earth's crust, and it is included in the Periodic Table of Elements. It does not exist naturally in the human body. Under ordinary circumstances of life, there is no known route of administration or acquisition of gadolinium in the body other than by injection as the radioluminescent component of contrast solutions used for enhanced MRI and MRA scans.

Gadolinium was known to be poisonous before it was formulated into contrast solutions. Scientist did not know what

would happen with free gadolinium in a person's system, but they knew it would be bad. To reduce the risk of free gadolinium, chelate chemicals were bonded to gadolinium to prevent it from being free in the body. It was known then that the longer chelated gadolinium stayed in the blood, the more the chelates would break their chemical bond with gadolinium and attach to other atoms, such as iron, in the blood to which the chelates have a stronger attraction than they do to gadolinium. This process is called transmetalation, and if it continues long enough, the result is free gadolinium.

A healthy person eliminates contrast solution within two hours or so, and transmetalation, although probably occurring during this time, does not occur to the extent where it creates a risk of free gadolinium. However, the longer the solution is in the body, the more transmetalation occurs, and this is why people with kidney failure or compromise, permanent or transient, get into trouble. It can take up to 36 hours for a renally-impaired person to clear contrast solution. This amount of time allows free gadolinium to develop and move from blood into cells.



## THERE ARE CASES WHERE PEOPLE WITH NO APPARENT KIDNEY COMPROMISE AT THE TIME OF GADOLINIUM INJECTION DEVELOPED NSF.

The means by which free gadolinium causes NSF is not clear, but a Wake Forest Medical Center study, published in the October 2007 issue of *American Journal of Dermatopathology*, suggests that gadolinium activates the enzyme TG2, which is found throughout the body. Lead author David Sayne, M.D., comments,

“Compared to the healthy subjects, there was a marked increase in TG2 in the subjects with NSF. This suggests that activation of TG2 can produce the syndrome. TG2 is expressed in virtually all tissues and may explain why the fibrosis can occur in the heart and lungs, as well as the skin.”

The plaintiffs in gadolinium litigation contend that the risk of bad consequences of free gadolinium was, or should have been, known to the manufacturers of gadolinium-containing

contrast solutions. The plaintiffs also contend that the risk of significant transmetalation that could lead to free gadolinium in renally-impaired people was known before any of the plaintiffs developed NSF and probably before the products were put into service.

The plaintiffs contend that the manufacturers had a duty to warn of these risks, which would have led to something similar to the enhanced MRI and MRA policies implemented in practically all U.S. hospitals at this point, which require an inexpensive renal function study before an enhanced scan is done, and which also require a careful risk-benefit analysis before obtaining an enhanced scan in the renally-impaired. This does not deprive the renally-impaired of the diagnostic benefit of MRI and MRA, because a scan without contrast can be done without risk, and this provides most of the same information in most instances.

### Contact a Gadolinium PSC Lawyer Free No-Obligation Consultation

Please contact us for a free no-obligation consultation. The more information that you can provide, the more helpful it will be. You are under no obligation to continue. Any information you provide will be held in the strictest of confidence.

If you have questions, please call us toll-free at **1-866-735-2792**. Thank you.

