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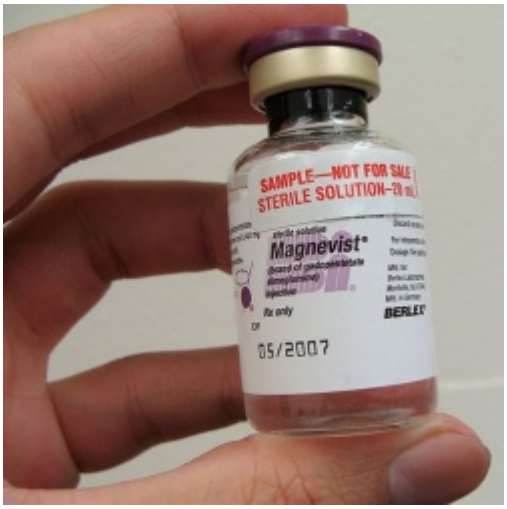
Chuck Norris, FDA and Gadolinium - Untangling The Lawsuit

By Chuck Dinerstein — November 3, 2017



Gadolinium Based Contrast Agent [1]

Chuck and Gena Norris are suing manufacturers and distributors of a contrast agent used in Magnetic Resonance Imaging (MRI) for ill effects on Gena's health. Here is the background and some of the foreground on this legal battle. MRIs use magnetic energy to visualize our bodies. In short, large magnets are turned on and off rapidly. When the magnetic is on, all of the protons in the water we contain (and we are mostly water) align; when the magnet is turned off, the protons return to their former position, and the energy they give off in returning is used to create images of our bodies. [1] In some cases, to improve the visualization of similar objects a contrast agent, in this case, based on gadolinium, is injected. For those of you who have had a CT scan, the contrast agent is in that slurpy size drink you have to finish an hour before the study. But for MRIs, the contrast agent is injected into your vein.

Gadolinium is toxic. To reduce the toxicity, gadolinium has been coated, actually linked, to another chemical to protect the body from its effects. These linking compounds (technically chelators) come in two forms, one is linear and the other more spherical. The latter covers the gadolinium more effectively than the older linear version. These compounds are referred to as Gadolinium-Based Contrast Agents (GBCAs).

GBCA has been used in MRI studies for a long time and passed the pre-marketing FDA testing. There were no apparent problems for 18 years. But in 2006 there was evidence of a new condition, nephrogenic systemic fibrosis (NSF), identified in patients with some degree of kidney failure (renal insufficiency) who when exposed to GBCA had worsening kidney failure. Identification of the problem took some time because the incidence of the problem is low and the occurrence does not impact all patients with kidney impairment. The FDA acted quickly, adding a

warning for the use of GBCA. The medical community's response was quick, screening patients before MRI for kidney impairment and these patients did not receive GBCA. Evidently, there have been no reported cases of NSF since 2009.

At the same time, there was increasing evidence that the chelating compounds were not as effective as was anticipated. A 1998 study showed 25% of the gadolinium was not recovered in patient's urine; a 2005 survey found gadolinium in some patients' bones and a 2014 study showed continued presence of gadolinium in patient's brain tissue. The hallmark study, Gadolinium in Humans: A Family of Disorders [2], was published in 2016 in the American Journal of Radiology. It describes a spectrum of conditions characterized by retention of gadolinium, from asymptomatic patients (Gadolinium Storage Condition) to symptomatic patients (Gadolinium Deposition Disease) to patients with NSF.

Gena Norris is claiming that she developed Gadolinium Deposition Disease (GDD) after undergoing three contrast-enhanced MRIs in a one week period. The Gadolinium in Humans paper from the American Journal of Radiology is included in the lawsuit filed in San Francisco [2]. Here are excerpts from the article:

- "Gadolinium deposition disease" is the name we propose for a disease process observed in subjects with normal or near normal renal function who develop persistent symptoms that arise hours to 2 months after the administration of GBCA. In these cases, no preexistent disease or subsequently developed disease of an alternate known process is present to account for the symptoms."
- "The causal relationship has not been fully established, but it is under investigation. The aforementioned MRI gadolinium-toxicity support group has reported symptoms that they considered to be consistent with the known toxic effects of gadolinium."
- "Typical clinical features include persistent headache and bone and joint pain. Patients often complain of clouded mentation that many describe as a "brain fog." More distinctive features are comparable with those observed in NSF but of lesser severity; patients often experience subcutaneous soft-tissue thickening …Tendons and ligaments in a comparable distribution may also be painful and have a thickened appearance. Patients may complain of tightness of the hands and feet,...[and] may experience excruciating pain, typically in a distal distribution, of the arms and legs …often described as feeling like sharp pins and needles, cutting, or burning."

These descriptions are consistent with Ms. Norris complaints. What is more interesting is that all of these concerns have been brought forward to a patient advocacy group, The Lighthouse Project [3], formed in 2014 by individuals who found one another in a Yahoo chat room/support group for people self-identifying with MRI-Gadolinium toxicity. I am not in a position to say whether the syndrome exists, the frequency is very low, the case reporting episodic and until recently other than identifying gadolinium persisting in scans there was no way to test for the presence of gadolinium. There are now urine tests for the presence of gadolinium that will undoubtedly assist in determining whether GDD exists and how it may be diagnosed more specifically.

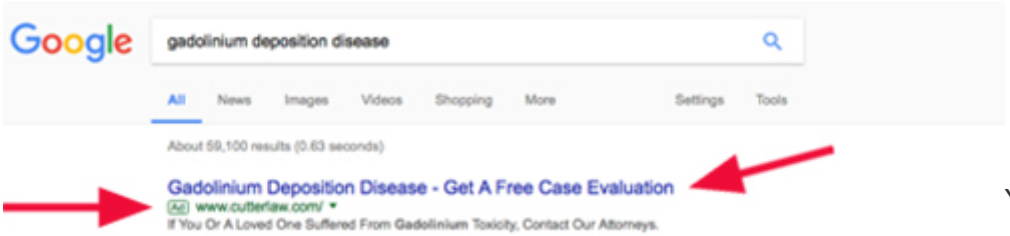
All of this information has been presented to both the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). These regulatory bodies have taken slightly different

approaches. The EMA has stopped the use [4] of GBCA protected by those linear chelating agents, that seem to do a poorer job of shielding patients from the admittedly toxic Gadolinium; they have left the use of Gadolinium protected by those macrocyclic chelators in place. The FDA merely has issued a warning [5] about the continued use of those agents. Neither agency has determined that Gadolinium results in GDD.

Ms. Norris lawsuit is currently directed at the manufacturers of GBCA with both linear and macrocyclic chelators. It is also directed at the distributors of these products. Its basis is that they should have and did know of the potential complications from the use of GBCAs and failed to warn the public. No prescribing or treating physicians are among the defendants. [2]

[1] This reminds me of Arthur C Clarke's admonition, "Any sufficiently advanced technology is indistinguishable from magic."

[2] The suit was filed by Cutter Law if you Google GDD, here is what you find.



You gotta love attorneys.

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