

Cosmetic Injections Linked to Brain Damage



FDA Warns BOTOX Patients at Risk

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The [\\$212 million verdict against Allergan](#) (AGN) from a Virginia jury that found **Botox** gave a man brain damage cracks open a Pandora's Box of future potential liabilities for the company. Allergan will likely appeal, and you can assume that appeal will be aggressive because it will be a disaster for the company if a "Botox causes brain damage" meme catches on in either the media or the courts. Here's a look at Allergan's concerns:

- Although Allergan has tried to diversify, the company is still dominated by Botox, with \$1.42 billion of its sales (29 percent) coming from the botulinum toxin.
- The [verdict is the biggest](#) award a court has ever made for side effects caused by Botox.
- Allergan faces [two more suits](#) making the same claim. If they are successful, it could open the floodgates.
- The verdict highlights an issue that concerns the FDA and doctors who are critics of Botox but that has not yet received a great deal of attention in the media or medical literature: The fact that Botox can travel in the body far from the site of the injection.

- [Allergan warned doctors in Europe](#) that Botox could migrate from an injection site in 2007, but didn't give the same warning to U.S. doctors until 2009, according to the attorney who tried the case. (That's an example of a lousy but common practice across the drug business -- of giving different countries [different clinical warnings](#) for [the same drug](#).)
- Although Allergan believes its punitive damages will be capped at \$350,000, the [Virginia Supreme Court may rule](#) that caps on damages are unconstitutional.
- The plaintiff, **Douglas M. Ray**, was being treated for writer's cramp, an unapproved "off-label" condition. Allergan has previously paid [\\$600 million to settle allegations that it promoted Botox off-label](#). This case may reopen that issue.

Allergan firmly believes there is no evidence that Botox causes brain damage, and that Ray's condition was actually CADASIL, a genetic stroke syndrome. That may be true, but the worst-case scenario that Allergan faces is what happened to **Dow Corning**. In the 1990s, Corning was bankrupted by lawsuits alleging its breast implants caused a variety of illnesses even though the Institute of Medicine eventually concluded that they don't. (And yes, [Allergan makes implants too](#).)

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