



FDA Requires Strong Amputation Warning on Sedative Promethazine

Written On September 17, 2009 By [Bob Kraft](#)

As reported by the [Associated Press](#), the Food and Drug Administration is requiring manufacturers of injected promethazine, a sedative also used to treat nausea and vomiting, to put the strongest warning possible on the product because it can cause tissue damage leading to amputation. Here are excerpts from the article:

The drug, previously sold by Wyeth Pharmaceuticals Inc. under the brand name Phenergan, was at the heart of a U.S. Supreme Court case this spring that ended in a ruling that consumers harmed by a medication approved by the FDA still have the right to sue the manufacturer.

Wyeth had appealed the case up to the Supreme Court after a Vermont woman named Diana Levine, who once played the guitar and piano professionally, sued because she had to have her right arm amputated after being injected with Phenergan. Levine's lawsuit, which claimed she wasn't sufficiently warned of the risks of using Phenergan, won her a \$6.7 million jury award.

The FDA said Wednesday that makers of generic promethazine will have to put a "black box" warning at the top of the detailed package insert explaining that when the drug is administered incorrectly, it can damage skin severely, including causing gangrene.

The FDA said promethazine should be injected deep into muscle, never into an artery or under the skin and, when given intravenously, it should be done slowly and at a low concentration. That's because the drug can leach out of a vein and seriously damage surrounding tissue.

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In a 6-3 decision in March, the Supreme Court rejected Wyeth's claim that federal approval of Phenergan and its warning label should have shielded the company from lawsuits like Levine's.

Prior to that, business groups had aggressively pushed for such limits on lawsuits through the doctrine of "pre-emption" — the idea that federal regulation trumps rules that might differ from state to state.

The Supreme Court had largely agreed, ruling in the prior term that FDA approval shields medical devices from most lawsuits.