



THE GOLDHABER WARNINGS REPORT



VOL. I

MARCH 10, 2009

The U.S. Supreme Court ruling (Levine vs. Wyeth) has MAJOR implications for potential WARNING claims against pharmaceuticals, other health care companies and many leading manufacturers.

The U.S. Supreme Court ruling (March 5, Levine vs. Wyeth) will have major implications for the pharmaceutical industry forcing them literally to review all of their warnings and safety instructions for content, clarity and conspicuousness. The industry, unlike manufacturers of Class III medical devices (e.g., stents, defibrillators, etc.) which were preempted from warnings claims (Riegel vs. Medtronic) in a 2008 8-1 Supreme Court ruling, will now be forced to proactively review all of its drug warnings and safety instructions to make sure they are up to "best practices" for the warnings and safety communications industry. Even the medical devices industry may soon have to take a similar step because Congress is very likely to pass a law (spearheaded by Ted Kennedy) that will mandate certain warnings for Class 3 devices

and allow products liability claims against companies violating these warnings, thus negating the Supreme Court original ruling and making it likely that the court will ultimately have to resolve the inconsistencies between the two rulings. The implications go even further for ANY company which has attempted to use a preemption defense in a products liability lawsuit. The manufacturer of ANY PRODUCT will have to ensure that their warnings and safety communications meet the "best practices" of the warnings industry. The answer is very simple for any defendant confronting this issue: Conduct an immediate review/evaluation/testing program for any warnings and safety communications at potential risk for claims and costly litigation.

KEY QUESTIONS THAT MUST BE ADDRESSED IN THIS REVIEW ARE:

1. What hazard(s), risks and dangers that are known or likely to be known to us (the manufacturer) exist or are likely to exist with the use of our product(s)?
2. Who is the likely user of our products that may be hazardous, and are these hazards, risks and dangers open and obvious to the average consumer at the time of use?
3. If the hazards exist and are unknown or hidden to the user, how can we best communicate with or warn the user about these hazards, their consequences and how to eliminate or reduce the risk of exposure to these consequences?
4. If there are standards or regulations that would govern the content and/or method to warn about these hazards, what are they and how can we conform with them?

I will be providing more details about the implications of this decision and a program for evaluating warnings in the next issue of THE GOLDHABER WARNINGS REPORT. At this time, however, I would be happy to discuss (in a free consultation) a detailed warnings review program with anyone reading this newsletter or any of their relevant colleagues/contacts. Please contact me directly if you would like to set this up or if you or someone you know should get my FREE monthly newsletter exclusively devoted to warnings and safety communications issues.

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